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## Editorial Board



## Aim and Scope

The Journal of Business Chemistry (JoBC) focuses on current developments and insights at the intersection of management and chemistry, biotechnology or pharmacy.

The JoBC provides an international forum for researchers and practitioners in companies, research institutes, public authorities, consultancies or NGOs to present and discuss current challenges as well as potential solutions in an interdisciplinary manner. Thus, the JoBC aims to foster the dialog between science and business, to support management practice in the chemical and pharmaceutical industry and to indicate where further research from academia is needed. The JoBC offers high quality publications with academic standards, a fast publishing process and global reach. With this multidisciplinary and boundary-spanning approach, the Journal of Business Chemistry intends to become the leading journal for decision makers in the chemical and pharmaceutical industry.

## Publisher

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# Contents



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# Letter from the Editors

## VUCCA is the new VUCA world

While identifying relevant trends for the chemical industry at the start of the last issue, we were not expecting that in the following months the world would become overwhelmed by a completely new topic. Now just four months later, one cannot imagine devising a future strategy for any firm without taking the effects of the Covid-19 into account. The pandemic has added an additional element of chaos to an already volatile, uncertain, complex and ambiguous world. Similarly, in the chemical industry, the pandemic is triggering a need to approach the topics of innovation, leadership, value chains, workers and sustainability. This new situation poses so many interesting questions: what will further digitalisation in the chemical industry look like? Will we manage to maintain operations? What about the highly globalised value chains – will we try to move the supply chains back to Europe and is it at all possible? To what extent will workers' qualifications shift to eLearning? Will we value climate protection more or less than before? The articles in this issue offer valuable insights that will be highly relevant in the future.

In his article titled "Combine or combust? – Circular economy, digitalization and collaboration models for the new chemical industry 4.0" Martin Stavenhagen emphasizes the importance of new business models, new technologies and new competencies for the future development of the chemical industry, which could not be more relevant than at this time of crisis.

Secondly, Tobias Rönick et al. have developed a method to evaluate potential future innovation fields in the chemical industry. "How to evaluate the future business potential of innovation fields in the chemical industry" describes how potential innovation fields can be classified into four categories based on a set of indicators on technological, market, resource and organisational levels, taking into account the certainty of each of these parameters. The method provides a quick way to determine which projects should be progressed and which should be terminated.

In the article "Sustainability as a criterion for business models – A framework for the life science sector" Karla Gehde looked at the role of sustainability in the business models of five organisations from the e-healthcare sector. Specifically, the 20 criteria of the German Sustainability Code are discussed in a cross-case analysis of the five business models.

Tim Smolnik's article "Wealth effects of corporate spin-offs – An event study analysis of the chemical and pharmaceutical industry" discusses the positive effects of spin-off announcements on shareholder value in the chemical and pharmaceutical industries. The cumulative average abnormal return is examined in the light of impact factors such as industrial or geographical focus, parental performance, or parent and spin-off size.

Lastly, Felix Hanser et al. bring social research to a scientific laboratory in the pharmaceutical industry in their article titled "User research in pharma R&D: Contextual inquiry for the elicitation of user needs in a chemistry laboratory for analytical method development within a corporate continuous manufacturing organization". As a result, user role descriptions and a list of 96 user needs for a technician, an operations team leader and a process engineer are generated.

Please enjoy reading the second issue of the seventeenth volume of the Journal of Business Chemistry. We are grateful for all the support from authors and reviewers. If you have any comments or suggestions, please do not hesitate to contact us at magdalena.kohut@businesschemistry.org. For more updates and insights on management issues in the chemical industry, follow us on LinkedIn: www.linkedin.com/company/jobc/.

Magdalena Kohut (Executive Editor)

Bernd Winters (Executive Editor)

 

# Practitioner's Section

## Combine or combust? – Circular economy, digitalization and collaboration models for the new chemical industry 4.0

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**The chemical-pharmaceutical industry, like other industrial sectors, is facing transformative changes exemplified by 'Industry 4.0' – including digitalization, circular economy approaches, and other innovations impacting its business model. These changes also affect the relationship with its customers, and the required skills and training needs for its employees. Based on several interviews with experts conducted as part of Climate-KIC's Pioneer in Practice program, this commentary looks at emerging challenges and opportunities the chemical sector will be facing in the next decade and beyond. It also provides examples where new technologies, capacities and collaboration models have been combined into successful sustainable business models.**

### 1 Introduction: The pathway towards Chemistry 4.0

The chemical-pharmaceutical industry[1] is facing large structural changes – once again. Increasingly, it needs to adjust to the demands of the transition to Industry 4.0. This includes figuring out how to handle digitalization strategies, circular economy approaches, and new business models. But this is not the first time the sector has faced a fundamental transformation. In fact, it has already come a long way in the past 150 years.

The chemical industry's first generation or 'Chemistry 1.0' began in the mid-19th century, with increased demand spurred by the Industrial Revolution. Raw materials consisted of coal, tar, organic and animal fats and oils, which were made into products such as soap, dyes and fertilizer. From the 1950s onward, the industry's second generation – Chemistry 2.0 – focused on petrochemicals. Crude oil had become a rich source of carbon and created almost unlimited possibilities for new syntheses and molecules; also, the new technology of polymerization helped to introduce plastics and chemical fibers as everyday products. Then, beginning in the 1980s, Chemistry 3.0, or the third generation, was fueled by globalization and European (and other) market integration, as well as new production processes and technologies such as genetic engineering and biotechnology. This enabled the chemical industry to create a new and more specialized product range. Also, new business and cooperation models formed: medium-sized companies specialized and prospered, while other companies consolidated through mergers and acquisitions; international trade led to on-site production facilities ab-

[1] The term 'chemical industry' will be used subsequently for the sake of convenience.

road; chemical parks formed; and basic research at universities blended productively with applied research within the industry (Deloitte and VCI, 2017).

Since the 2010s, the chemical industry has seen the need to adapt once again. By adjusting to 'Industry 4.0', with automation and data exchange integrated into new manufacturing processes, the Internet of Things (IoT), cloud computing and 'smart' technologies, the sector needs to transform into the next generation: Chemistry 4.0 (VCI 2017). At the same time, other risks and requirements have grown in importance: sustainability risks and the climate crisis; environmental pollution and shrinking biodiversity; agriculture and food production; and the overconsumption of critical natural resources and raw materials – all of these challenges can point to the chemical industry as part of the problem, or alternatively, as part of the solution.

## 2 Research background and methodology

During Climate-KIC's Pioneer in Practice program, which is implemented in Germany by the Centre for Industry and Sustainability (ZIN) at Provadis, one of the system innovation challenges focused on the future of the chemical industry. In particular, the challenge was how to envision how the chemical industry could transform into a digital and circular economy knowledge hub in the future, and what skills future changemakers would need in order to make this Chemistry 4.0 happen. In addition to an exploratory review of literature and business cases, three expert interviews were conducted in 2018 and 2019 with lead managers, executives and academics knowledgeable about the chemical sector. The semi-structured qualitative interviews focused on five main issues: 1) challenges and megatrends for companies and the industry within the next 10 and 30 years; 2) key drivers of these trends; 3) the role of innovation and sustainability; 4) the most important future competencies for work and success in the age of Chemistry 4.0; and 5) what the future of the chemical industry will look like in 10 and 30 years.

This commentary will explore upcoming megatrends and drivers and focus on three key issues for the industry's future: circular economy; digitalization; and required competencies and training needs. It points out challenges and opportunities these transformations bring with them; and provides examples of how these changes are already being addressed in practice.

## 3 Megatrends and drivers of industry transformation

The chemical industry faces (at least) three main challenges on its path to Chemistry 4.0. First, global demand structures are shifting towards new geographical markets, specifically Asia. Second, the entry of new market players, new technologies and more specialized market needs has increased the level and intensity of competition. And third, an increasing global environmental awareness has led to a qualitative shift of societal priorities, among them sustainability, climate change, and a fundamental rethink of how to use natural resources.

Europe and North America have been experiencing stagnating growth in saturated end markets, while market demand for the chemical industry is shifting to Asia, China and India in particular. In Europe, and especially in Germany, energy and resource costs are relatively higher than in other world regions, which increases the cost of production. In addition, local environmental standards are comparatively higher in Germany and Europe, which further adds to the pressure to remain competitive. Some assets including production facilities are older in Europe, which may make them economically more feasible because of their depreciation; their investments costs have already been written off by their owners. However, this also adds to future needs for investment in aging assets and new production technologies. Huge innovation potential is slumbering in countries like China, which has a vast number of highly educated young people moving back home from their studies abroad, adding to the country's growing supply of human resource talent in the natural sciences.

One of the big transformations for Chemistry 4.0 and a key driver of change in the industry is the rise of digitalization. The new digital age offers new business opportunities, including faster and 'smarter' production processes, new employment needs, new business models, and a more efficient use of natural resources. However, new risks are emerging as well: for example, loss of employment through

robotization, higher qualification requirements for new employees, and the question of data security in a Big Data world. All of these changes are taking place in a business culture that, in Germany at least, still leaves room for innovation around new digital business models. The German chemical industry has employees with a high level of technical knowledge and a good understanding of processes. However, with new innovative market players from Asia and elsewhere on the one hand, and a more international client base on the other, the need to deepen knowledge about new digital practices, new business models, and intercultural teamwork competencies will continue to grow.

Another key driver of industry transformation is the new sense of urgency regarding sustainability and climate action, among policy makers and civil society alike. In the Paris Declaration, the world community has committed itself to reduce its greenhouse gas (GHG) emissions in order to keep global average temperatures well below 2°C, and ideally below 1.5°C compared to pre-industrial levels (UNFCCC 2015). This commitment also informs the European Commission's climate and energy targets, i.e. cutting GHG emissions by 40% (from 1990 levels) and increasing renewable energy and energy efficiency improvements to 32% and 32.5%, respectively (EU 2014; 2018). It is also the main driver of Germany's renewable energy transformation (Energiewende), which has already increased the share of renewable energy sources to 37.8% of total gross electricity consumption (UBA, 2019). Fridays for Future and other civil society organizations have regularly mobilized millions of people to take to the streets with their demands for far-reaching climate neutrality. And the chemical industry has been taking note as well: sustainable development and digitalization have been identified as two megatrends with a significant impact on Germany's chemical industry in a recent survey of 60 chemists (Keller and Bette, 2020).

## 3.1 New business models: circular economy for Chemistry 4.0

One prerequisite for the success of chemical companies and the industry as a whole is that they must understand their own business and their respective markets. However, some industry players have been realizing that they are too far removed from their end clients. This means that chemical companies increasingly feel they are too far upstream in the value chain and might even fear to be 'cut off' from their clients' business activities. The traditional business paradigm – 'produce a fantastic molecule and sell it to the market' – looks both more difficult and less relevant today. Instead, a lot of potential for innovation seems to come from a different mindset: (re)using resources, materials and (by-)products from molecules previously believed to be 'dead' or waste; and joining and supporting the end client along his or her entire value chain. These new approaches, as well as the underlying new mindset, fall into the realm of the circular economy.

Circular economy approaches focus on closing resource loops and keeping the value of materials and products as high as possible for as long as possible. They aim to design out waste and pollution; keep materials and products in use; and regenerate natural systems (EMF 2017). These concepts have gained much attention from policy makers, civil society and the business community alike, as the circular economy seems to offer a concrete strategy on how to 'do' sustainable development (EMF 2013; EC 2020). In particular, the circular economy shows how to break with the traditional linear economy and its 'take-make-use-lose' philosophy: extract resources to make a product for short-term use which is thrown away afterwards, taking all its valuable materials with it 'to the grave' or the landfill. Instead, the circular economy promises to reduce or even eliminate waste altogether. To use a simplified example, in a natural ecosystem like a forest, a leaf that falls to the ground will over time turn into nutrients for the underlying soil and its creatures. Essentially, any 'waste' will return back into the system as input or valuable 'food'. In the circular economy, this principle is exemplified by two separate material flows: one for organic substances, which will be composted; and one for non-organic materials, which are recycled separately. Ideally, both of these processes are powered exclusively by renewable energies (EMF 2017). One popular illustration of these two looping circles is the 'butterfly diagram', with its two 'wings' representing the loops for organic and non-organic materials (Figure 1).

The circular economy and its focus on resource and product (re)use and waste avoidance can help to define innovative new

business strategies (Kopel and Utikal 2019). One helpful concept for systematically exploring new ways of using resources and products is the Big Five Structural Wastes framework (Blomsma and Tennant 2020). This waste and resources grid offers five 'sets' of circular strategies by differentiating between two types of resources, i.e. particles (raw materials) and (finished/manufactured) products, and two types of waste, i.e. a lack of resource renewal and a lack of resource consumption. Subsequently, a fifth dimension is added to the grid, i.e. preventing or reducing material use altogether. Thus the five resulting sets of circular economy strategies – creating or improving specific loops – are (Figure 2):

1. Closing loop strategies like recycling or composting to use materials longer;

2. Extending loop strategies like substance cascading, downcycling or waste-to-energy in order to use materials more extensively;

3. Long-life loop strategies like maintaining, improving durability or reconditioning (e.g. repair, refurbishment, remanufacture etc.) to make products last longer;

4. Intensifying loop strategies like product cascading, alternate use, sharing and co-use to utilize products more intensively;

5. Preventive strategies like refuse, reduce, replace in order to not use more resources than necessary and prevent the use of harmful (e.g. toxic) materials.

These circular strategies have the potential to spur necessary innovation in the chemical industry. Present and future industry challenges can be addressed by utilizing circular economy principles (Deloitte and VCI 2017):

**Figure 1 Circular economy 'butterfly' diagram (source: in allusion to EMF, 2017).**

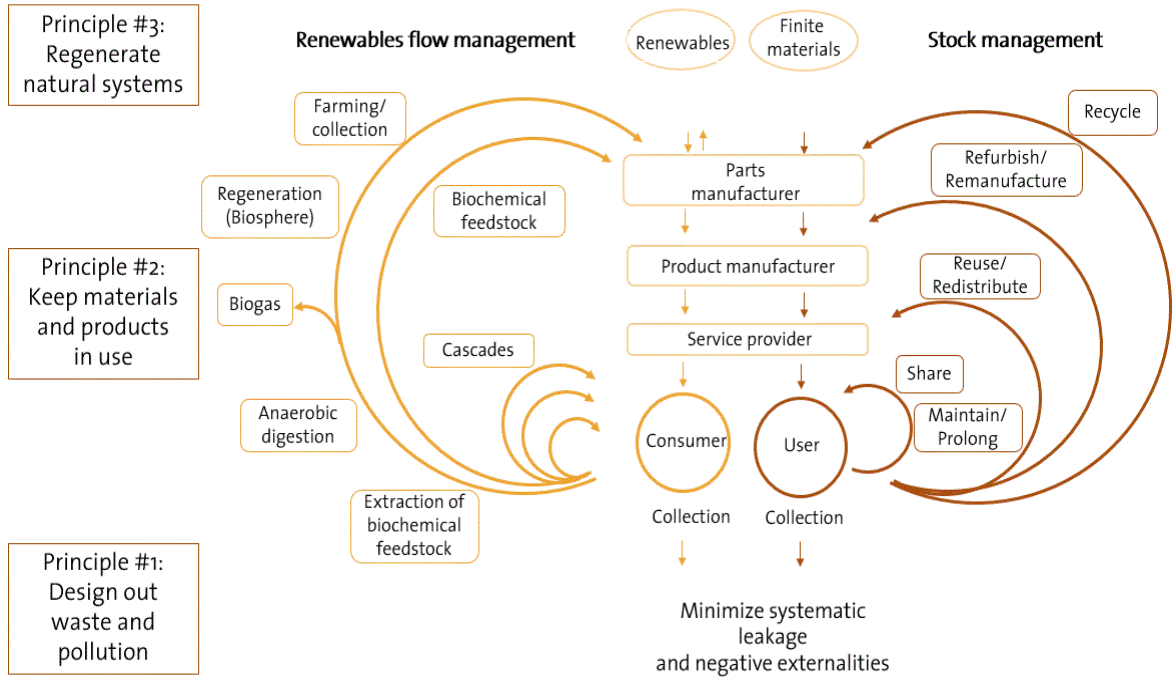
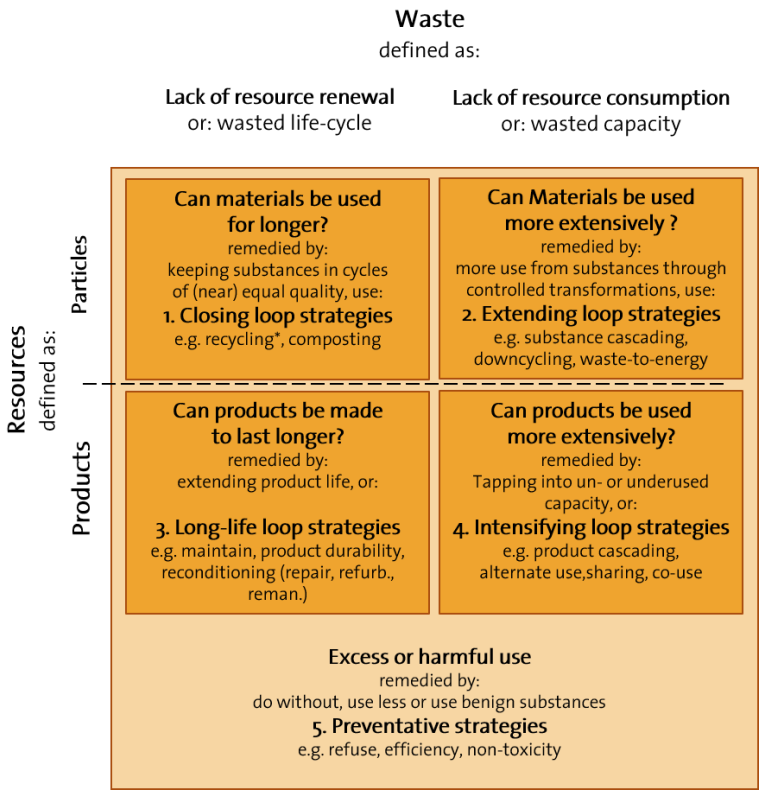


**Figure 2 The Big Five Structural Wastes framework (source: Blomsma and Tennant, 2020).**




- 'Making the most of' resources by increasing resource efficiency in all stages of the value chain (including suppliers and distributors as well as the end customer). This may entail – at the particle stage – closing loop strategies by improving and scaling recycling/composting processes; or extending loop strategies by cascading or downcycling substances, or using them for energy recovery.

- Increasing the lifetime of products and components. This may entail – at the product stage – intensifying loop strategies by reusing, sharing or cascading products; or long life loop strategies by maintaining products, increasing their durability, or reconditioning them through repair, refurbishment, remanufacturing etc.

- Reducing resource use when products are utilized. This may entail preventive loop strategies less at the manufacturing stage, but rather in designing the product to function more efficiently, e.g. making it use less energy or other resources.

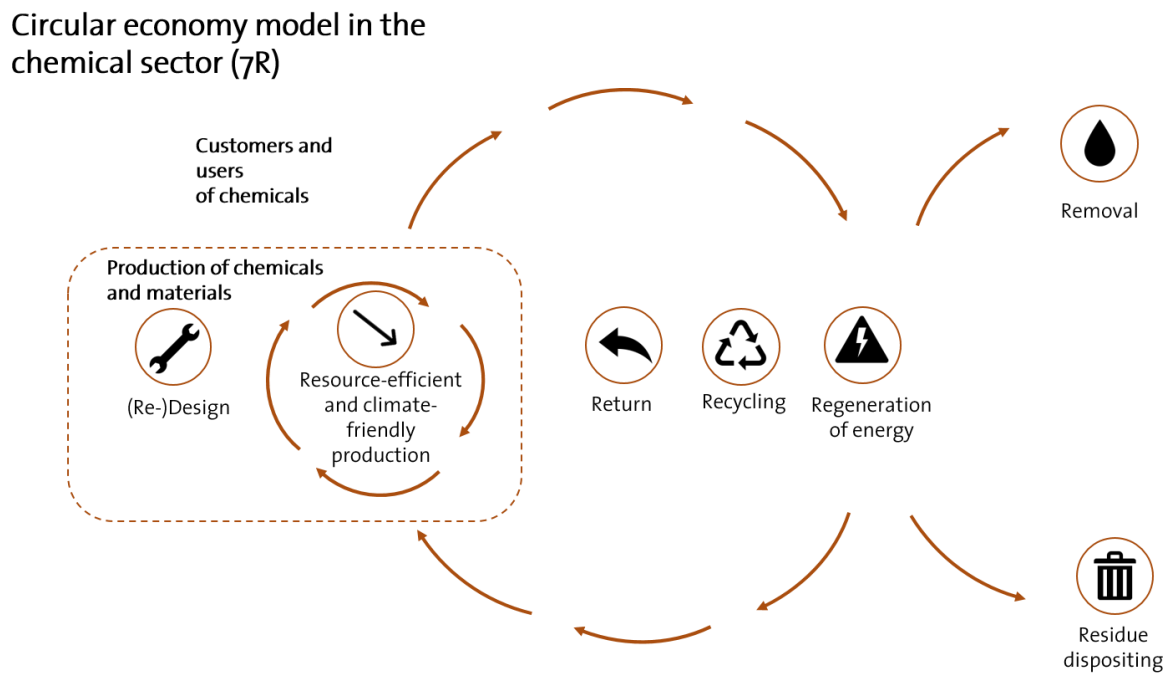
The different looping strategies can also be found in the 'seven levers' (or '7R') the chemical industry may employ going forward (Figure 3): 1) (Re-)Design (all loops); 2) Resource-efficient and climate-friendly production (all loops); 3) Return (long-life loops); 4) Recycling (closing loops); 5) Recovery of energy (intensifying loops); 6) Removal (long-life or preventive loops); and 7) Residue depositing (extending or preventing loops).

Examples: Recycling $CO_2$, reusing carbon.

Examples of practical applications of the circular economy approach – turning previous waste streams into valuable new inputs – include the (re)use of carbon dioxide ($CO_2$) as a resource. Emissions of $CO_2$ as the most prominent GHG from burning fossil fuels need to be

Figure 3 Circular economy model in the chemical industry (7R) (source: Deloitte and VCI, 2017).




curtailed drastically at a global scale. At the same time, carbon, one of the components of $CO_2$ that is usually extracted from coal, gas or crude oil, is an important building block for a vast range of chemical products, including plastics. A cooperation between RWTH Aachen University, the Max Planck Society and Covestro AG is now helping to 'close the carbon cycle' by replacing petroleum-based raw materials for chemical production with $CO_2$ (RWTH 2019). Up to 5,000 metric tons of polyol infused with carbon can be produced at Covestro's pilot plant to be processed and used as foam for mattresses, car seats or insulating materials. Another joint research project between Evonik and Siemens delves into the biologization of chemistry, a field that has a lot of potential for the chemical industry. It explores the use of electrolysis and fermentation processes to turn $CO_2$ into specialty chemicals such as butanol and hexanol, both of which are feedstocks for special plastics and food supplements (Siemens 2018). The test plant planned for 2021 would not only offer 'green chemistry' – i.e. the sustainable production of chemicals with the help of bacteria and renewable energy – but also provide multiple benefits: it would also function as an energy store, which can help stabilize the grid by responding to power fluctuations. Thus, the project also supports Germany's renewable energy transformation and energy system restructuring.

All of these innovative processes use circular strategies, i.e. closing loops strategies, by 'upcycling' $CO_2$ into valuable carbon for reuse, as well as intensifying loops, by transforming $CO_2$ from a under-utilized byproduct – basically a waste stream – into a useful resource input for a brand-new production process and value chain. Also, preventive strategies reduce natural resource inputs (e.g. petroleum) whose extraction, transport and use cause unnecessary environmental pollution, by replacing them with readily available $CO_2$. Ideally, $CO_2$ concentrations from the atmosphere are reduced by breaking them into carbon for productive products and applications, doubling as long-term carbon sinks. Finally, providing multiple benefits or different services – e.g. energy storage within a restructured electricity grid – goes

beyond the 'product level' of circular strategies. However, it shares certain attributes with intensifying loop strategies and creates more capacity from the same resources, by enabling co-use, alternate uses, and sharing services for greater functionality.

For the chemical industry, new business models must be innovative, sustainable and, of course, profitable. But innovation is difficult. In many cases, innovation 'appears' in an emergency situation that demands new and adaptive solutions. However, in situations where people already have more than they need – which arguably could be said for many parts of Europe, and Germany in particular – a certain complacency can set in, which kills the innovative spirit. Realizing the inherent need to innovate is a prerequisite for creating the necessary motivation; research and financial support are further important enablers. Also, producing a chemical 'blockbuster' has become more difficult for the industry. Customer needs – for the chemical industry and other business sectors – are becoming more diverse and more context-specific. Volume- or quantity-based business models may be replaced over time by performance-based solutions. This means innovative companies may shift from selling inputs to ensuring outcomes, including switching to product-as-a-service models – another innovative circular business strategy.

Example: Cleaning solutions as a service.

Chemical leasing is an example of a product-as-a-service model (UNIDO 2020). The traditional business model based on product volume sold defining profit is replaced by the service of 'delivering' pre-defined outcomes. This turns the business model upside down: using fewer chemical inputs would now be more profitable for the company providing the service. The amount of chemicals used is transformed from a revenue factor to what is now a cost factor for the company, thus creating incentives for innovation and increased resource efficiency.

One such innovative chemical service provider is Safechem (2020). The company offers various solvents for cleaning, industrial parts, textiles and asphalt testing applications. It also offers a host of related services: assistance and advice on safe use, quality assurance, collaboration with clients and related stakeholders (e.g. cleaning equipment manufacturers, waste managers, oil producers, local authorities, distributors and associations), and ensuring sustainable and circular solutions by decoupling the expected outcome from resource use and enhancing the performance and durability of the customer's products. The cleaning product has been replaced by a product-as-a-service business model, saving time for the customer and reducing the use of chemicals for the benefit of the environment.

## 3.2 New technologies: digitalization and Chemistry 4.0

Novel technologies and the new market opportunities they offer are often key drivers for industry change. Digitalization is one of these current megatrends. It fuels Industry 4.0 and its promise of 'smarter' solutions: smart cars, smart buildings, smart energy grids, even smart cities. However, it also raises concerns regarding data security, transparency for customers and also towards market competitors, and how to innovate beyond traditional business structures.

For the chemical industry, collecting and analyzing more data within an own company provides opportunities to optimize operations, production and business processes, and efficiency gains for increased profitability. But digital technologies also offer completely new possibilities. Large data sets regarding the actual use of products were previously not readily available for systematic analysis of, for example, customer behavior and preferences, the environmental properties of products, product usage, effectiveness and durability, etc. Digitalization enables chemical companies to integrate further into end customers' value chains and provide them with more far-reaching business solutions. These new digital opportunities for companies come in three categories (Deloitte and VCI 2017):

1. Increased transparency and digital processes: collecting and using data from processes within the company. This enables efficiency gains within largely unchanged production and business models.

2. Data-based operational models and analysis: adding external data about customers, markets and competitors to the internal process data. This enables advanced data

analysis for enhanced decision-making, efficiency and flexibility.

3. Digital business models: new value creation models that fundamentally change existing processes, products and business models. 'Digital add-ons' to existing products and services can be tailored to specific customer needs, potentially within a digital platform in collaboration with other companies.

Data collection to improve process efficiency has already been used in the chemical industry for some time, although there is still room for a higher level of automatization and the use of robotics. Nevertheless, the innovation potential here is more at an incremental scale. More disruptive change and innovation potential comes with data-based operational models. For example, predictive maintenance can minimize failure of production components and increase their durability. Connected logistics optimize inventory management and transportation of materials and products. Smart factory and virtual plant approaches employ automatization and modular production, all the way up to a complete virtualization of the entire production facility that achieves cost, quality or process improvements through real-time simulations within the 'digital twin'.

The largest reservoir for change and innovation lies in the implementation of new digital business models. This has the capacity to change companies' product portfolios, their relationship to their customers, and ultimately their own business model. One new opportunity, for example, is the 'personalization' of the chemical product desired by the end client, down to its technical properties and composition. These can be specified by the client via an interactive business-to-business (B2B) platform that is directly integrated into the customer's value chain. New business models may also include process management services for the client's production facilities that employ real-time data monitoring and long-distance maintenance. New forms of cooperation models with clients, suppliers, distributors and competitors are emerging as a result.

Example: Data platforms for digital farming.

Digital farming is one of the new market opportunities a digital business model provides for the chemical industry. In industrialized agriculture, highly automated tractors and harvesters already gather data on plant health, soil composition, harvest yields and the topography of wheat, corn, rapeseed and soy fields. This real-time data collection is supported by geographical information from satellites. It can then be correlated with historical data to more accurately assess and forecast soil quality and expected yields and to make more informed decisions on what crop to grow.

Agricultural experts from Bayer have been working on intelligently combining these different data sources into a digital management tool for farmers called an 'Agronomic Decision Engine', which would enable farmers to decide how much and what kind of pesticides to use, where on the field, and at what time (Bayer 2017). Apart from choosing what crop to sow, this data can also help to design how much irrigation is needed at what time. At the core of these enhanced forecasting and decision-making capabilities is the data platform, which bundles at least five and potentially more different sources of data: environmental data, e.g. soil properties and the exact temperature, weather information and water retention within the field; data on pathogens or other harmful factors, e.g. fungi, insects, worms, arachnids, weeds or other pests; data on plant properties, e.g. different crops' reaction to pathogens, water needs etc.; what agricultural management techniques are used, including what pesticides and what kinds of tillage the farmer uses; and, finally, a 'library' of available pesticides, their properties and effectiveness, including information about which herbicides work best at what stage of plant growth.

The potential benefits for the chemical industry and its clients are threefold. First, by analyzing and adapting to an individual locality's, field's and even field area's specific circumstances and needs, the use of chemicals can be kept to a minimum. Still, care must be taken to not overlook potentially more effective and sustainable solutions that avoid the use of chemicals in the first place, i.e. crop rotation, less intensive tillage, organic farming approaches, etc. Second, with the help of digital farming approaches, pesticide solutions can be personalized for each individual client. By creating field-specific digital maps based on available satellite, soil and topography data, any chemical product can be tailored and adjusted to specific

plant needs on (or in) the ground. The business advantage of highly tailored chemical solutions is also relevant for other sectors, for example Chemsafe's personalized cleaning products and services (see Section 3.1). Third, the customer relationship is strengthened, while the value derived from the chemical company's service is (potentially) much larger. This opens up important new business areas and opportunities for the chemical industry which go beyond the traditional business model as a chemical goods manufacturer. However, finding the right balance of data transparency, value and information sharing between the chemical company and the customer is an ongoing balancing act.

## 3.3 New competencies: collaboration and training for Chemistry 4.0

Over the decades, the chemical industry in Europe, and in Germany in particular, has benefited from a solid base of engineering know-how, linked to good higher education opportunities in the natural sciences. Process innovations have been continuously implemented. Chemical products are high-quality and reliable. However, a business innovation mentality at the system level, i.e. the readiness to leave behind old business paradigms and envision fundamentally new opportunities, seems to be less common in the industry. Some drivers for change and innovation are perhaps not as pronounced in Europe as elsewhere. The demographic changes Germany and other countries are facing have led to a shortage of skilled young people for the industry. Moreover, opportunities and changes caused by enhanced digitalization and automatization require a potentially smaller yet more highly skilled and interdisciplinary workforce. Employees for the new Chemistry 4.0 need a new skillset to enable innovation.

For people working in the chemical sector, this means a reorientation within their profession. Cross-sectoral and cross-cultural collaboration and teamwork will become more important; so will lifelong learning strategies to strengthen new skills and competencies. This will require new training and professional education formats. More fundamentally, it also involves a cultural change within chemical companies: more tolerance for experimenting and making mistakes; thinking up new ways to tackle old challenges; and integrating new technologies, capacities and business models into a more complex form of collaboration to create customer value. It also means working together with distributors, competitors and clients in new ways to provide joint services and increased value collaboratively.

However, if the chemical industry wants to integrate digitally versed innovators, start-up entrepreneurs and sustainability pioneers into its workforce, it will need to be able to attract such talent. In that case, it will compete for such experts not only with other traditional industries, but also with start-ups, creative industries and the tech sector, including the likes of Apple and Google. It may prove challenging to attract innovative 'digital natives' with an entrepreneurial background to the chemical industry. However, their new ideas will support business innovation.

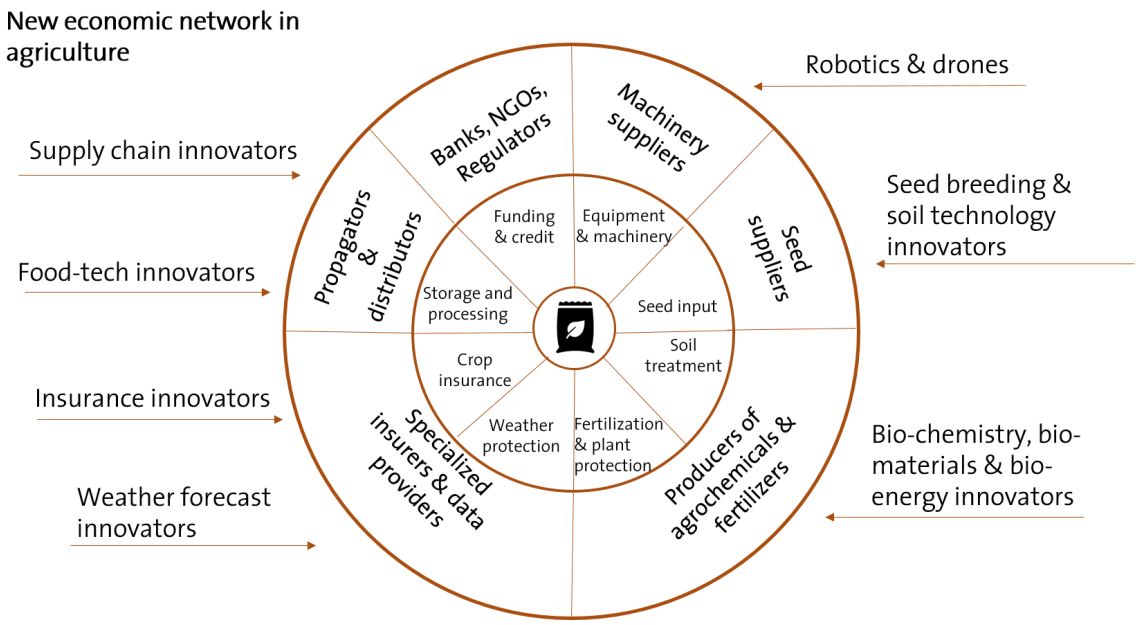
Examples: Stakeholder collaboration for digital farming and material exchange platforms.

Some of the chemical industry's new market opportunities show what complex collaboration skills are needed to design future business models with a diverse set of old and new stakeholders. The linear value chain model of business relationships – from the supplier to the chemical manufacturer on to the distributor and finally to the customer – has become more permeable and flexible. More and more often, customer and supplier relationships are realigned within an ecosystem that also includes hardware and software producers as well as companies from outside the chemical industry.

Digital farming (see section 3.2) may once again serve as an example of these new complex networks and the chemical industry's role in them (Figure 4). Established market players in the agricultural sector work even closer together. This includes various companies in the biochemistry sector, i.e. suppliers and manufacturers of seeds, fertilizers and pesticides; producers of agricultural machines; the food processing industry; logistics and transportation providers; and financial service and insurance companies. However, the further integration of digital services provides new collaboration and market entries: e.g. information providers for soil quality, field topography and satellite data; software developers for data processing and analysis applications; and hardware producers for drones, robots and sensors for real-life data

**Figure 4 New economic network for agriculture (source: Deloitte and VCI, 2017).**




collection and monitoring. Products and services are bundled by many different providers, focusing on outcomes – e.g. soil quality, plant health, harvest yield, etc. – rather than individual chemical or other inputs. The digital collaboration is essential for the business model. Current data about the soil, plants, field, weather and machines is collected and analysed. This data can then be cross-referenced with 'library data' on pests and pathogens, plant properties, agricultural techniques etc. The final step is the adjustment of the fertilization and watering process in real time for optimal results (Deloitte and VCI 2017). Altogether, this new ecosystem of interrelated producers and providers ideally helps farmers to receive more relevant information, make better decisions and grow more with less.

A different digital collaboration model for circular economy business opportunities is the Materials Marketplace (USBCSD 2020). Implemented by the United States Business Council for Sustainable Development, this regional and national platform lets companies connect and build new joint business models on the basis of sharing, recycling and reusing resources. Surplus materials, packaging or by-products from industrial or other waste streams may be offered and accepted by all members of this marketplace. Thus the traditional industrial symbiosis model is transferred into the digital space. Companies can create joint circular business strategies at the material (or particle) level: in particular, closing loops through better recycling and composting opportunities; and intensifying loops by material cascading and secondary use of by-products, downcycling and using potential waste-to-energy opportunities. Benefits for companies and the regions include: reduction of landfills (where waste would end up otherwise); additional revenue streams (by converting waste streams into valuable secondary resource inputs); cost and energy savings (for waste removal or purchasing/refining materials); new employment opportunities (e.g. in the recycling sector); new business opportunities (by creating more resources); and potentially less demand for virgin materials and less exploitation of natural resources elsewhere.

## 4 Summary: Combining circular, digital and collaborative innovation

In the coming decades, the chemical sector will continue to be an important element of society and business. No matter what changes and innovations a digital future might hold, people will still need physical products, medicines and pharmaceuticals, water, energy, and food. Commodities and basic chemicals will still be needed. Society will likely still rely on some forms of fossil fuels and hydrocarbons, although their importance will diminish in relation to renewable energy sources. However, sustainability, climate change and the ecological boundaries of resource extraction will increasingly shape future decisions and put circular economy strategies front and centre. Public pressure will increase to prevent natural resource exploitation, attempt carbon-neutrality or even carbon-negativity, and focus on adding net environmental (and social) benefit instead of minimizing harm. The 'biologization' of chemistry and the focus on natural-based solutions will likely grow, e.g. through bacteria that can dissolve certain types of plastic waste or create specific proteins. Recycling and the recovery of valuable substances is another field with enormous potential, e.g. recovering phosphates from wastewater instead of the energy-intensive and highly polluting process of extracting them from the ground. New catalytic processes – for energy production, material refinement and pollution reduction – will continue to create value and new research opportunities.

Nevertheless, the chemical industry – in Europe and in Germany in particular – will need to change in fundamental ways. Basic chemical production may shift to other regions where energy and labor costs are lower. Future relevance and market success will largely depend on companies' ability to create new business ecosystems: diverse stakeholder networks that redefine traditional supplier and customer relationships. Instead of the old linear 'supplier-manufacturer-distributor-client' processes and value chains, future business models will depend more heavily on the ability to help a client solve a particular problem, in collaboration with a diverse set of other market participants. Ideally, the chemical industry will change from a 'materials producer' to a hub within an innovation ecosystem that can steer and direct new processes for higher-value products and services.

This requires the chemical industry and its employees to adopt an innovative mindset, including a deeper understanding and application of new circular and digital business strategies. Better product and service design for increased reusability, recyclability and sharing is still a huge challenge. However, the goal must be to go beyond resource efficiency gains and related cost reductions to offer new and improved services to customers. Employees will need to engage in lifelong learning strategies and develop a culture that encourages innovation and change; this includes taking advantage of new technological opportunities. Companies need to employ ambidextrous structures that can progress in both exploitation and exploration, i.e. increase efficiency and flexibility at the same time. Innovative chemical start-ups may offer new services in collaboration with other companies via customer platforms, where physical, digital and even payment infrastructures are offered by other service providers, similar to current internet retailers. The emerging digital infrastructure will enable significant transaction cost reductions, which enable more collaboration with the customer and his specific product and service demands. For example, 'smart' chemical production process components within a company could communicate with the customer's enterprise-resource planning (ERP) system to create just the right kind of product at the right time with minimal amounts of materials and energy. These digital B2B platforms have the potential to create new forms of value-creating networks and circular ecosystems.

Companies need to figure out how to combine these new technologies, circular economy strategies, and collaboration opportunities. Only then will they be able to create sustainable business models that stay competitive in a changing market. If they don't want to go bust, they need to adapt to Chemistry 4.0, which is more collaborative, more circular, and more sustainable.

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# Research Paper
# How to evaluate the future business potential of innovation fields in the chemical industry

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Decisions about the further development or termination of innovation fields (IF) have a high relevance for companies. However, due to a lack of information in the front end of innovation (FEI) as well as missing evaluation methods and criteria, selection decisions are often based on personal "gut feeling".
By identifying 24 indicators, which have a relevant influence on the business potential of IFs, the authors present a methodology to evaluate and determine the business potential of IFs in the FEI. This potential is determined by the newly developed Innovation Field Impact Factor (IFIF) combined with a Certainty Factor and depicted in a heat map. The heat map enables the identification of strengths and weaknesses in each IF as well as a comparison of the business potential of different IFs. After developing the methodology, its viability was verified using the example of eleven IFs at a specialty chemicals company. The presented methodology is an interesting approach for companies to develop their own specific indicators for the evaluation and selection of innovation projects and IFs in the FEI.

## 1 Introduction

In order to generate successful innovations, several researchers like Cooper et al. (2004), Salomo et al. (2008) and Talke et al. (2010) suggest concentrating innovation activities in arenas or in innovation fields. "An innovation field consists of multiple, thematically related innovation projects, thus stimulating synergies among these projects" (Salomo et al., 2008). This field is an attractive market opportunity of strategic and long-term importance, linking trends and industry needs with own competences such as technologies, services and business models. The innovation projects, which exist within an innovation field (IF), are typically related by one common theme, which may be a customer need, a core competence, a technology platform, or any combination of these aspects (Salomo et al., 2008). Companies which concentrate their innovation activities in IFs may be characterized by thoughtful strategic choices concerning the focus of their innovation management (Talke et al., 2010). An IF develops out of an idea for an innovation. With an

increasing knowledge about the idea's business potential and its opportunities for application and with an advanced certainty about the innovation's future success, this idea might evolve into an innovation opportunity and an innovation concept. If the concept offers enough business potential and if it is large enough for generating several single innovation projects, it may be transformed into an IF (Figure 1).

Instead of focusing on single innovation projects, Salomo et al. (2008) and Talke et al. (2010) suggest the establishment of a whole innovation portfolio in which several resources are bundled, and innovation projects are developed simultaneously.

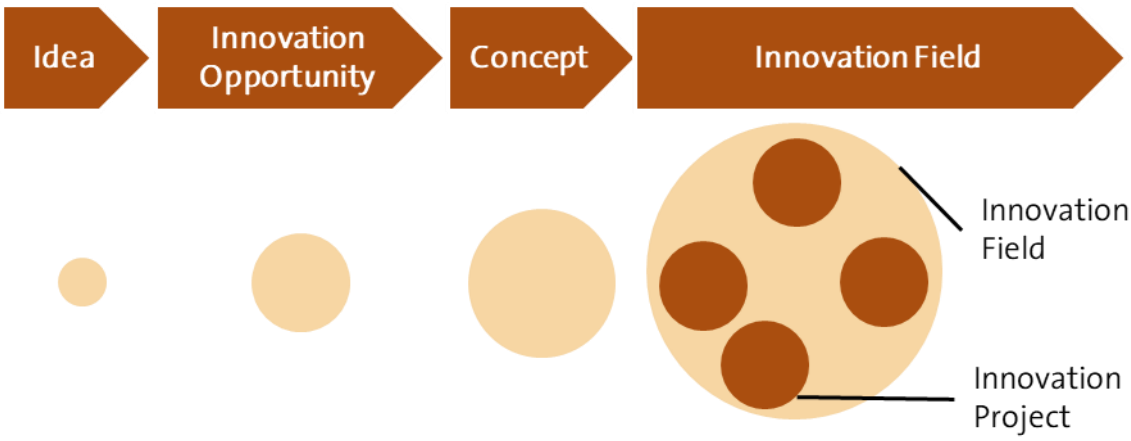
Meanwhile, various companies and their R&D departments have established a portfolio focus and a process to identify and develop new IFs. The entrepreneurial aim of new IFs is generating successful innovations to increase the organization's profitability and the success of the company in the long term. Martinsuo and Poskela (2011) and Kock et al. (2015) demonstrated in their research that the utilization of decision criteria may be beneficial for achieving future business potential and increases the probability of success in the early stages of the innovation process.

However, not all IFs turn out to be successful and due to the large amounts of spent resources, the failure of an already developed IF and its innovations may be severe. For this reason, the business potential of intended IFs and their probability of success should be evaluated and analyzed early in the innovation process in order to avoid spending too many resources such as time and money on potentially unsuccessful IFs.

Although the relevance and the advantages of focusing and developing innovations within IFs have been described and emphasized (Salomo et al., 2008), literature on the research and on the selection of IFs has been neglected. Consequently, there is no methodology available which evaluates and analyzes new IFs.

It is the authors' aim to identify criteria and to develop a methodology to evaluate the business potential of IFs in the specialty chemicals industry at the beginning of the innovation process in the front end of innovation (FEI). The methodology's purpose is a quick and simple evaluation of the IF's business potential after

**Figure 1 Different stages from an idea to an innovation field (own representation).**



the collection of relevant information during idea generation.

This paper is structured as follows: In the next section, a literature review presents the most important research about innovation management and decision-making. The following chapters outline the methods which have been used for the identification of the criteria evaluating the business potential of IFs and the weighting methods which were applied for the weighting of the identified criteria. In the fourth section, the identified business potential evaluation criteria and their weighting factors are demonstrated. In addition, the newly developed Innovation Field Impact Factor (IFIF), the heat map as well as the methodology's application on the evaluation of eleven intended IFs are shown in this chapter. This article ends with a summary and an outlook.

## 2 Literature Review

This section gives an overview about the Fuzzy Front End (FFE), innovation portfolio management as well as selection and decision making methods used in innovation management.

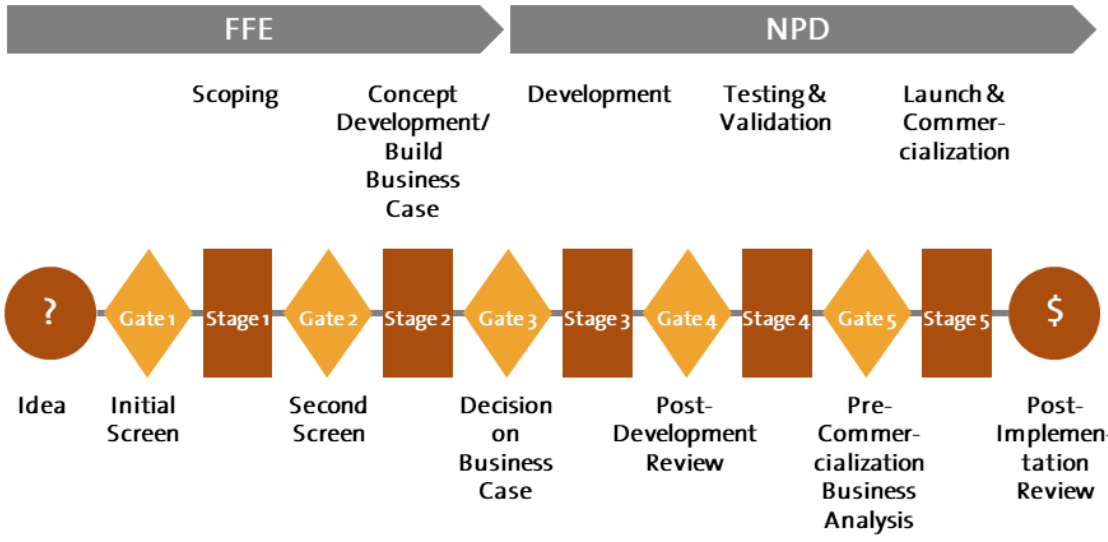
### 2.1 Fuzzy Front End

Every innovation originates out of a stimulus and an idea for an innovation. If this idea or stimulus seems to be successful and worth for further analysis, it is further developed in the innovation process.

The first phase of the innovation process (Figure 2), in which a stimulus and an idea for an innovation is created, is called the front end of innovation (FEI). The FEI is often referred to as the Fuzzy Front End (FFE) (Montoya-Weiss and O'Driscoll, 2000; Koen et al., 2001) due to its chaotic, undefined and unstructured activities and processes. Kim and Wilemon (2002) define the front end as "the period when an opportunity is first considered and when an idea is judged ready for development". Koen et al. (2001) describe the FFE as the mysterious portion of the innovation process. Therefore, the FFE is of very high interest in the literature and many researchers have worked and concentrated on the processes within the FFE.

In contrast to the more chaotic FFE, the new product development (NPD) process, which follows after the FFE in the innovation process, is highly structured and organized. The processes

Figure 2 Innovation Process/Stage-Gate-Process (in allusion to Edgett, 2015).



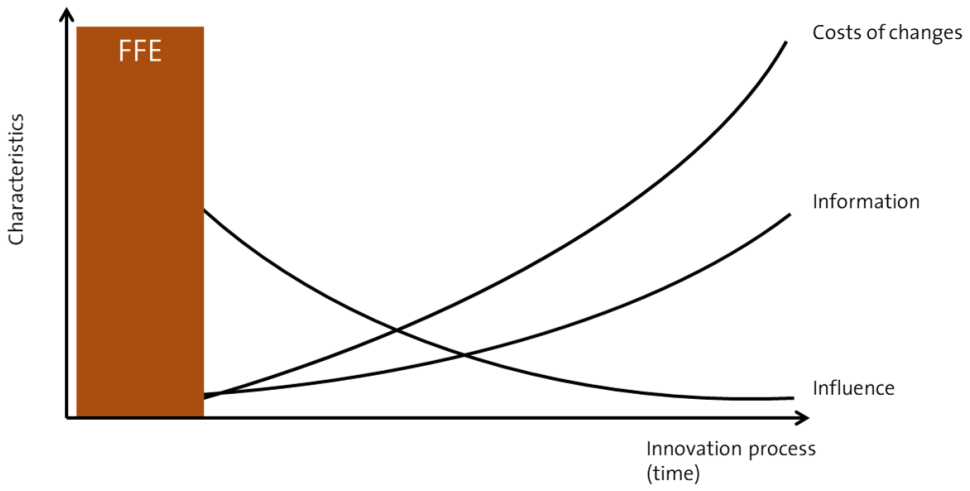
and activities in the NPD are strictly based and orientated on goals and milestones which have been determined in the business plan. The achievement of these goals is controlled at the gates with the help of an increasing number of criteria which need to be achieved prior to the transfer into the next stage (Cooper, 1990; Edgett, 2015; Herstatt et al., 2004).

The FFE is recognized as a driver for successful product innovation and future business success (Khurana and Rosenthal, 1998; Verworn, 2009). It is considered to be the first phase of the innovation process and covers the stages from idea generation until its approval for development, funding and the launch of a new product development project or its termination. In this phase first ideas are generated, developed and evaluated, opportunities are identified, potential concepts are developed and formulated, products are defined and also first plans for further potential development projects are initiated (Khurana and Rosenthal, 1998).

Figure 3 shows typical characteristics of the innovation process. In the FFE, there are many opportunities for the development. On the one hand, the degree of freedom for the design and the influence on information and on the cost structure is very high. On the other hand, the amount of information concerning the new product or service, is usually low compared to the following phases of the innovation process (Herstatt and Verworn, 2004). Especially, the level of uncertainty concerning the innovation's market and technology is high (Herstatt and Verworn, 2004). Due to the lack of information, symbolizing the main limiting factor in the FFE (Herstatt and Verworn, 2004), decisions in the FFE are often just made on the basis of the managers' "gut feeling" which is based on subjective evaluation and therefore is not conducive to a comparative analysis (Montoya-Weiss and O'Driscoll, 2000).

The costs for processes in the FFE are quite low compared to the following phases, but a high amount of costs for the further development of the innovation and its design are already determined in this early phase of the innovation process. Thus, it is worth to invest more money, time, intelligence and resources in the early stages of the innovation process to avoid having spent money on innovations which turn out to be unsuccessful in the later phases of the innovation process (Reid and de

**Figure 3 Influence, cost of changes, and information during the innovation process (source: Herstatt and Verworn, 2004).**



Brentani, 2004; Verworn et al., 2008).

Since future products, services, quality and costs are already defined in the FFE, it has a key role in the innovation process. The decisions and processes executed in the FFE may have an enormous impact on the subsequent innovation process and the innovation itself and determine to a great extent which projects will be executed and continued. For this reason, the company's success largely depends on the success of the innovation activities and processes in the FFE.

By developing a method to evaluate the future business potential of IFs, it is the approach of this research to bring visibility to the FFE and to make decisions taken in the FFE more objective, transparent and comparable so that decisions taken in the FFE do not need to be taken just on the basis of "gut feeling". Such a methodology is even supported by Kock et al. (2015) who suggest the introduction of formal processes in order to evaluate and select innovation ideas and concepts which might evolve to successful innovations and services.

## 2.2 Portfolio Management

In order to be successful, it is essential for companies to define an innovation strategy with a portfolio perspective on the ideation phase instead of developing several independent innovation projects (Kester et al., 2011; Kester et al., 2014; Kock and Gemünden, 2016). Companies need to continuously generate, develop and maintain a sufficient amount of high-quality and promising ideas and concepts to obtain a well-balanced portfolio of potential innovations. This portfolio may capture the portfolio value, leverage synergies and reduce risks at the portfolio level (Kock et al., 2015). These ideas and concepts should be strictly evaluated, selected and prioritized (Kock et al., 2015; Martinsuo and Poskela, 2011). The selection of ideas and concepts is of special importance and interest, since the companies' resources for the development of new innovations are usually scarce, and only the most promising ideas may be further supported (Heising, 2012; Kock et al., 2015). For this reason, a strict evaluation and selection system of the ideas and concepts, which might offer the highest potential for success, must be developed to select the most promising ones out of the large pool of ideas generated in the ideation phase (Martinsuo and Poskela, 2011). Therefore, a systematic portfolio management is needed for the early stages of idea generation and concept development in order to ensure that only appropriate and promising opportunities for further development are selected and supported (Meifort, 2016). Kock et al. (2015) state that a portfolio perspective and the formalized evaluation and selection of ideas and concepts are beneficial for the company's front-end success. The right management of front-end activities within the portfolio management has a huge impact and relevance for the performance of subsequent phases in the innovation process. The successful management of activities in the FFE might lead to innovation portfolio success and successful innovation projects and IFs (Kock et al., 2015; Verworn, 2009).

Portfolio Management may be divided into two subtypes which need to be clearly distinguished from each other: Innovation Portfolio Management (IPM), also including Ideation Portfolio Management, and Project Portfolio Management (PPM).

Ideation portfolio management concentrates on the formulation and the development of a portfolio strategy and the selection of promising concepts in the FFE which might evolve into successful innovation projects (Mathews, 2010). Ideation portfolio management is a central process for turning the corporate strategy into action and is defined as dynamic decision-making process in which innovation concepts and projects are constantly evaluated, updated and selected, and resources are allocated to them (Cooper et al., 1999; Meifort, 2016). IPM needs to provide a fast, unbiased decision-making process, in which the

concepts with the highest business potential among the large pool of ideas that may originate in the ideation are quickly identified (Mathews, 2011). The management of an innovation portfolio is quite complex, since the uncertainty in the early stages of the innovation process concerning the ideas and concepts is very high (Mathews, 2011; O'Connor and Ayers, 2005; Paulson et al., 2007).

A systematic portfolio management is needed for the early stages of idea generation and concept development in order to ensure that only appropriate and promising opportunities and concepts for further development are selected and supported. If the selections and decisions are performed properly and if the ideation portfolio is well integrated into the subsequent PPM, the support and funding of the selected projects may be increased and projects may be implemented faster (Heising, 2012). Thereby, the probability that supported projects may lead to successful innovations is increased (Say et al., 2003). IPM should emphasize the focus on ideas and concepts in the phases of the FFE as well as the integration of these projects into the company's innovation portfolio.

In contrast to the IPM, PPM is focused on managing and delivering projects in the NPD and is managed in a linear process (Cooper et al., 2000; Mathews, 2011). PPM deals with the coordination, and control of multiple projects pursuing the same strategic goals and competing for the same resources (Martinsuo, 2013). Companies have adopted several frameworks such as the utilization of project evaluation and decision criteria, project evaluation and control routines and other means to formalize their PPM and to improve product success rates (Hunt et al., 2008; Martinsuo, 2013). Managers use these methods to prioritize the different projects for achieving strategic benefits (Cooper et al., 1997).

## 2.3 Decision Making and Idea Selection

Due to scarce resources and the possible failure of innovations, an innovation portfolio management is required in order to strictly evaluate and select the most promising opportunities and concepts. Thus, besides the requirement for an efficient and effective portfolio management for the evaluation and selection of innovation concepts in the FFE, a reliable decision-making mechanism is needed for the transparent and effective evaluation of innovation ideas and concepts. Several researchers suggest the introduction of formal processes to evaluate and select innovation ideas for increasing the probability of success in the FFE (Carbonell-Foulquié et al., 2004; Hart et al., 2003; Martinsuo and Poskela, 2011). In addition, the usage of certain criteria might offer a high benefit for achieving future business potential (Martinsuo and Poskela, 2011). A well-managed innovation portfolio may increase the amount and quality of new innovation concepts which can be turned into innovation projects and IFs. According to Mathews (2011), criteria for decision-making should be uniform, broadly-comparable, objective and verifiable, independent, sufficient for effective decision-making and quantitative to allow the calculation of additional value metrics in order to ensure a transparent selection and decision process.

The quality of decision-making in innovation portfolio management is of high importance since the way decisions are made determines whether the right opportunities and concepts are chosen and whether the portfolio is in alignment with the strategy (Kock and Gemünden, 2016).

Since the 1950's, innovation research has shown several different methods and multiple sets of criteria and indicators for the evaluation of innovation projects – yet only in the New Product Development (NPD) phase of the innovation process.[1] Widespread and established criteria are e.g. the amount of patents, patent citations, patent family classes, publications,

the possible amount of applications or the estimated market size. Up to this point, no criteria have been developed to evaluate concepts and innovation opportunities in the FFE.

## 3 Methodology for identification and weighting of criteria

In this chapter, the process to identify relevant criteria for the evaluation of the IFs' business potential is shown. Furthermore, the methodology for weighting these criteria is demonstrated.

### 3.1 Qualitative expert interviews

For the development of a methodology to evaluate the future business potential of IFs, a set of criteria needed to be identified at first. In order to identify suitable and relevant evaluation criteria, qualitative expert interviews have been conducted. In the description of their method to identify a set of criteria for weighting proposed projects, Henriksen and Traynor (1999) state that the most correct set of criteria is the one the majority of stakeholders finds most accurate and comfortable and which captures the relevance of the company's innovation and R&D goals. Hagedoorn and Cloodt (2003) suggest to use several criteria for the evaluation of innovation opportunities, too. Instead of assuming the 'correctness' of a single indicator, the utilization of multiple criteria in an evaluation system allows the measurement of the innovation opportunity's innovative performance in a more complex and informative approach (Hagedoorn and Cloodt, 2003).

The criteria, which determine the business potential of IFs in the chemical industry, were derived from expert interviews. In this study, 35 experts have been selected from a group of innovation managers, all working in lower and middle management positions in a specialty chemicals company.

By asking the innovation managers for their opinion on the indicators, the set of criteria might be very accurate and might capture the organization's goals and its innovation strategy (Henriksen and Traynor, 1999).

The expert interviews were conducted as systematic, semi-structured expert interviews, in which the experts were regarded as advisers telling a large amount of process and technical knowledge voluntarily to the interviewer (Qu and Dumay, 2011). This interview format enables interviewees to provide responses in their own terms and in the way that they think and use language (Qu and Dumay, 2011). In order to structure the research field's topic and the interviews themselves, a guideline with a set of pre-defined questions was prepared prior to the interviews. This guideline was utilized to lead through the conversations (Bogner et al., 2014). All experts were asked the same questions and the managers were enabled to answer freely without any restrictions and thus, enabling the interviews to become open, trustful conversations (Qu and Dumay, 2011).

### 3.2 Quantitative questionnaire survey

#### 3.2.1 Weighting Method

The relevance and the importance of the different indicators mentioned during the expert interviews might differ. Therefore, the mentioned indicators were weighted in order to reflect the preferences of the organization (Henriksen and Traynor, 1999). The distribution of the weights may be used to develop and generate a balanced portfolio of multiple innovation projects that possess the favored and preferred characteristics (Henriksen and Traynor, 1999).

Weighting and determination of the weighting factors was executed with the help

[1] The authors refer to the methods developed by Davis et al. (2001), Dodgson and Hinze (2000), Henrikson and Traynor (1999), Mathews (2011), Paulson et al. (2007) and Say et al. (2003).

of a survey. Project and innovation managers from the company's strategic innovation unit as well as the interview partners served as respondents. By asking several innovation and product managers, on the one hand, the management is given the possibility to influence the outcome of the methodology and, on the other hand, the acceptance of the developed methodology may be increased (Henriksen and Traynor, 1999).

In the literature, several methodologies to weigh different criteria and to solve multiple criteria decision making (MCDM) are available. These selection methods may vary from unstructured question lists (Cooper et al., 2002), structured scoring models (Henriksen and Traynor, 1999) and anchored scales (Davis et al. 2001), to analytic hierarchy processes (Calantone et al., 1999), simple additive weighting (Afshari et al., 2010) and to mathematical models such as the Conjoint-Analysis (Martinsuo and Poskela, 2011).

In this study, the scoring method described by Henriksen and Traynor (1999) was selected for utilization in order to weight the indicators and clusters which have been identified for the evaluation of the business potential of IFs.

Scoring methods are widely used to weight different attributes and clusters. These methods are simple, flexible and yet quantitative. They are most often used for the evaluation of R&D projects since they are less time-consuming and require less resources than the other above-mentioned methods. With the help of the scoring method, also non-quantitative criteria may be evaluated by the usage of a constructed ordinal scale for the question responses in the selection process. In addition, the criteria may be customized and selected by the organization in accordance with its strategy and its preferences which shall be emphasized (Henriksen and Traynor, 1999).

One common approach for scoring methods is to rate and evaluate potential projects against a set of criteria (Henriksen and Traynor, 1999). The criteria's importance is evaluated with the help of an algorithm. By using such an algorithm, the potential projects will receive their final score and may be ranked. Thereby, decisions regarding scarce resources may be facilitated and project managers may evaluate and compare different promising and potential projects or IFs (Henriksen and Traynor, 1999).

### 3.2.2 Questionnaire design

The mentioned indicators from the expert interviews were summarized in four clusters after the interviews' analysis (see Chapter 4.1). In the survey, the respondents were asked to distribute 100 points per cluster among the cluster's indicators with regard to their importance and relevance. The clusters' relevance for the evaluation of the IF's future business potential was weighted, too. By the distribution of 100 points among the indicators and clusters in order to weight their relevance for the evaluation of the business potential, the authors followed the weighting technique used by Davis et al. (2001).

The survey was sent to 84 employees from a specialty chemicals company which currently work or have worked within the innovation department. The survey was active for three weeks and a reminder was sent after two weeks. However, unfortunately, the survey was only completed by 45 employees, resulting in a response rate of 54 %. Since the survey was conducted in June, the start of the vacation time and thus, a bad timing as some employees were either very busy or already on vacation could be a reason for the low internal response rate.

## 4 Results and Discussion

In this section, the identified criteria and clusters determining the business potential of IFs and their relevance are presented. The equation for the calculation of the Innovation Field Impact Factor (IFIF) is deduced and the heat

map, in which the business potential is classified, is depicted. In addition, the applicability of the methodology is demonstrated in eleven innovation opportunities.

## 4.1 Identified criteria

In total, the 35 expert interviews yielded in 337 indicators which have been reduced to 76 single indicators after doublets were eliminated.

These indicators were carefully analyzed, categorized and summarized into four clusters: Technology, Market, Resources and Organization. The categorization into these four clusters is also advised and suggested by researchers and is beneficial for the future business potential of the promising innovations which will defend the company's competitiveness (Calantone et al., 1999; Carbonell-Foulquié et al., 2004; Englund and Graham, 1999; Hart et al., 2003; Martinsuo and Poskela, 2011; Montoya-Weiss and O'Driscoll, 2000). According to Martinsuo and Poskela (2011), Hart et al. (2003) and Carbonell-Foulquié et al. (2004) it is important to evaluate innovations in the FEI on the basis of several different criteria. Furthermore, these authors demonstrated in their research that the technical feasibility, market criteria, the market size and the strategic fit are very important for future business potential and are the most frequently used criteria in the FFE (Carbonell-Foulquié et al., 2004; Hart et al., 2003; Martinsuo and Poskela, 2011). The reason for the high relevance of technical and market criteria is that market and technical conditions are the main uncertainties in product innovation (Kleinschmidt and Cooper, 1991; Martinsuo and Poskela, 2011).

Obviously, not all of these indicators could have been considered and implemented in the final methodology, since its purpose is a quick and simple application after the collection of information about the intended IF during idea generation. Thus, the amount of indicators, which need to be determined and investigated, was reduced to meet the methodology's purpose.

After screening and evaluation of the 76 indicators, 24 were considered to be relevant for the utilization. A list of these relevant indicators is shown in Table 1.

Due to the fact that the interviews have been conducted in a specialty chemicals company, the indicators summarized in the cluster Organization are clearly focused on the specialty chemicals company. However, all 24 indicators build up a strong basis for the determination and evaluation of the business potential. The identified indicators may be worth to consider for practitioners dealing with IFs – especially in the specialty chemicals and chemicals industry, but also in other industries and branches.

## 4.2 Determination of weighting factors

In the survey, the cluster Market was weighted from the respondents as the most relevant cluster (0.35). In the view of the respondents, the second most important cluster is Technology (0.26) followed by Resources (0.21) and Organization (0.18). As a result, one may notice that in the view of the respondents, all clusters are important and relevant for the business potential of IFs and that there is no strongly dominating cluster. Nevertheless the respondents have a market-orientated focus.

In addition, in the survey, the respondents also had to weigh the indicators of the four clusters. The indicators "Amount of markets in which the technology may be applied" (Technology), "Addressable market size" and "Expected compound annual market growth rate in the next five years" (Market), "Competences within the specialty chemicals company and the alignment level" (Resources) and "Fit to the Segment- and/or Department-Strategy" (Organization) were considered as most important. The results of this survey may be found in Tables 2 and 3.

**Table 1 24 selected indicators for the evaluation of IFs business potential, divided into four clusters (own representation).**

| Cluster | Indicator |
|---|---|
| **Technology** | Amount and growth of scientific publications in last five and ten years |
| | Amount and growth of patents in last five and ten years |
| | Technology Readiness Level |
| | Stage of Gartner Hype Cycle |
| | Technical hurdles |
| | Effort for development |
| | Grade of novelty |
| | Amount of start-ups and spin-offs |
| | Amount of different markets in which the technology may be applied |
| **Market** | Addressable market size |
| | Expected compound annual market growth rate in the next five years |
| | The company's role in the market |
| | Competition in the market |
| | Legal regulations |
| | Time-to-Market |
| **Resources** | Competences within the company |
| | External competences |
| | Potential for activities in several segments and departments |
| | Alignment level |
| **Organization** | Fit to segment- and/or department-strategy |
| | Link to the company's growth fields |
| | Link to the strategic innovation unit's innovation fields |
| | Fit to specialty chemicals |
| | Initiatives outside growth fields and innovation fields |

**Table 2 Weighting factors of the four clusters, determined in the survey (own representation).**

| Cluster | Weighting Factor | Size of Weighting Factor |
|---|---|---|
| **Technology** | t | 0.26 |
| **Market** | m | 0.35 |
| **Resources** | r | 0.21 |
| **Organization** | o | 0.18 |

**Table 3 Weighting factors of the 24 indicators, determined in the survey (own representation).**

| Cluster | Indicator | Weighting Factor | Size of Weighting Factor |
|---|---|---|---|
| **Technology** | Amount and growth of scientific publications in last five and ten years | $a_1$ | 0.09 |
| | Amount and growth of patents in last five and ten years | $a_2$ | 0.14 |
| | Technology Readiness Level | $a_3$ | 0.12 |
| | Stage of Gartner Hype Cycle | $a_4$ | 0.03 |
| | Technical hurdles | $a_5$ | 0.12 |
| | Effort for development | $a_6$ | 0.11 |
| | Grade of novelty | $a_7$ | 0.11 |
| | Amount of start-ups and spin-offs | $a_8$ | 0.11 |
| | Amount of different markets in which the technology may be applied | $a_9$ | 0.17 |
| **Market** | Addressable market size | $b_1$ | 0.25 |
| | Expected compound annual market growth rate in the next five years | $b_2$ | 0.21 |
| | The company's role in the market | $b_3$ | 0.16 |
| | Competition in the market | $b_4$ | 0.15 |
| | Legal regulations | $b_5$ | 0.10 |
| | Time-to-Market | $b_6$ | 0.14 |
| **Resources** | Competences within the company | $c_1$ | 0.32 |
| | External competences | $c_2$ | 0.17 |
| | Potential for activities in several segments and departments | $c_3$ | 0.21 |
| | Alignment level | $c_4$ | 0.30 |
| **Organization** | Fit to segment- and/or department-strategy | $d_1$ | 0.32 |
| | Link to the company's growth fields | $d_2$ | 0.25 |
| | Link to the strategic innovation unit's innovation fields | $d_3$ | 0.10 |
| | Fit to specialty chemicals | $d_4$ | 0.23 |
| | Initiatives outside growth Ffelds and innovation fields | $d_5$ | 0.10 |

Since the amount of the survey's respondents is below 50 (only 45 respondents), the results of the survey are statistically not representative and need to be regarded with caution. In addition, it needs to be considered that the survey was only sent to employees working in Germany and for this reason, the results from the survey must not inevitably represent the opinion of the whole company. Essentially, it needs to be emphasized that the data and the results of the survey only represent the views and the opinions of a group of innovation managers.

Nevertheless, the data enable interesting insights into the opinions and views of the innovation managers working at the specialty chemicals company. Therefore, these data were utilized for the development of the methodology to evaluate the future business potential of IFs.

## 4.3 Innovation Field Impact Factor

After the execution of the survey, in which the identified indicators and clusters have been weighted, the final score for the evaluation of the future business potential of IFs can be calculated. This score is called Innovation Field Impact Factor (IFIF). The calculation of the IFIF follows the following formula:

$$IFIF = T^t * M^m * R^r * O^o \quad (4.1)$$

The values T, M, R and O are the individual Impact Factors of the clusters Technology (T), Market (M), Resources (R) and Organization (O). The exponents t, m, r and o are the weighting factors of the four clusters, which have been determined in the survey.

The IFIF is a factor, which has not been published so far in the literature and which has been created, developed and introduced in this research. This factor is a core factor of this evaluation methodology, by which the objective business potential of future innovation fields is determined on the basis of 24 indicators summarized in four clusters.

In order to determine the Impact Factors of the four clusters Technology, Market, Resources and Organization (T, M, R, O), the methodology and the algorithm from Henriksen and Traynor (1999) are applied. These algorithms may be found in the equations 4.2 to 4.5.

$$T = \frac{1}{4} * ({T_1}^{a_1} * {T_2}^{a_2} * {T_3}^{a_3} * {T_4}^{a_4} * {T_5}^{a_5} * {T_6}^{a_6} * {T_7}^{a_7} * {T_8}^{a_8} * {T_9}^{a_9} - 1) = \frac{1}{4} * ((\prod {T_k}^{a_k}) - 1) \quad (4.2)$$

$$M = \frac{1}{4} ({M_1}^{b_1} * {M_2}^{b_2} * {M_3}^{b_3} * {M_4}^{b_4} * {M_5}^{b_5} * {M_6}^{b_6} - 1) = \frac{1}{4} * ((\prod {M_k}^{b_k}) - 1) \quad (4.3)$$

$$R = \frac{1}{4} * ((\sqrt{R_1 * R_2})^{c_{12}} * {R_3}^{c_3} * {R_4}^{c_4} * {R_5}^{c_5} - 1) \quad (4.4)$$

$$O = \frac{1}{4} * \left({O_1}^{d_1} * {O_2}^{d_2} * {O_3}^{d_3} * {O_4}^{d_4} * {O_5}^{d_5} - 1\right) = \frac{1}{4} * ((\prod {O_k}^{d_k}) - 1) \quad (4.5)$$

When completing the methodology after having executed the initial research about the potential IF, the project manager will need to specify and select values, numbers and estimations in order to answer the questions which are linked to the 24 identified indicators. Depending on the answer given to the specific indicator, a value from a Likert-Scale ranging from 1 to 5 will be assigned to the given answer: Answers with a favoring estimation will get the value 5, weak ones will receive the value 1. The numbers from the Likert-Scale of the indicators in the cluster Technology are the values $T_n$. The values $a_n$ symbolize the weighting factors of the individual indicators from the cluster Technology, which have also been determined in the survey. In the other clusters Market (M), Resources (R) and Organization (O), the indicators are evaluated and named accordingly ($M_n$, $R_n$, $O_n$). Each value of the indicator is then exponentiated with its weighting factor ($a_n$, $b_n$, $c_n$, $d_n$).

Since the indicator "Competences within the company" in the cluster Resources contains two questions, which need to be answered and

which were not weighted separately, the formula from Henriksen and Traynor (1999) was adjusted for the calculation of the impact factor of the cluster Resources. The final value of the indicator "Competences within the company" is calculated by extracting the square root of the product of both values which need to be answered for this indicator. It was decided, not to calculate the average mean, since extracting the square root has the advantage that small values are more emphasized and thus, have a higher influence on the result in comparison to the average mean. For the calculation of the Resources Impact Factor, the square root is also exponentiated with the weighting factor of the indicator "Competencies within the company".

The final IFIF results from multiplying the respective impact factors of the four clusters, which are exponentiated by their individual weighting factors (equation 4.1).

## 4.4 Certainty Factor

As already outlined in chapter 2.2, the FFE is characterized by a high amount of uncertainty regarding the available information. Thus, the information, which is needed to complete the evaluation methodology, may also be neither available nor completely uncertain. Due to the limited amount of available information and the high uncertainty, decisions in the front end are still to a high extent based on the decision maker's "gut feeling". Even, if the required information was available, it may be uncertain and decision makers or project managers may not trust this information. Thus, the "gut feeling" may still have an important role.

In order to take into account the high uncertainty about available information, a Certainty Factor (CF) was implemented in the methodology. On the one hand, it should symbolize the uncertainty concerning the gathered and analyzed information about the potential IF and on the other hand, this factor is used to display the "gut feeling" of the project manager working on the IF.

The average CF of the potential IF is based on the individual certainty factors of the four clusters and is calculated according to equation 4.6:

$$CF_{IF} = \frac{{CF_T}^t * {CF_M}^m * {CF_R}^r * {CF_O}^o}{100} \qquad (4.6)$$

In this formula the weighting factors, and thus the relevance of the clusters, are considered, too.

The formula for the determination of the CF was developed by the utilization and adjustment of the formula for calculating the IFIF (4.1). In the formula determining the CF, the weighting factors, and thus the relevance of the clusters, should be considered, too. Therefore, the clusters' certainty factors were exponentiated with the determined weighting factors. The certainty factors for the individual clusters are not determined in an objective process. The values ranging from 0 (high uncertainty) to 1 (low uncertainty) are estimated by the innovation manager on the basis of the certainty about the analyzed information and his own "gut feeling".

Hence, the Certainty Factor of the potential IF offers the possibility to include a personal, subjective opinion by considering the personal view and the "gut feeling" in the structured process of the determination of the IF's business potential.

## 4.5 Innovation Field Heat Map

In order to simplify the analysis of the future business potential, the final business potential is visualized in a heat map. In the following, the design and the methodology's application on eleven intended IFs is demonstrated.

### 4.5.1 Design

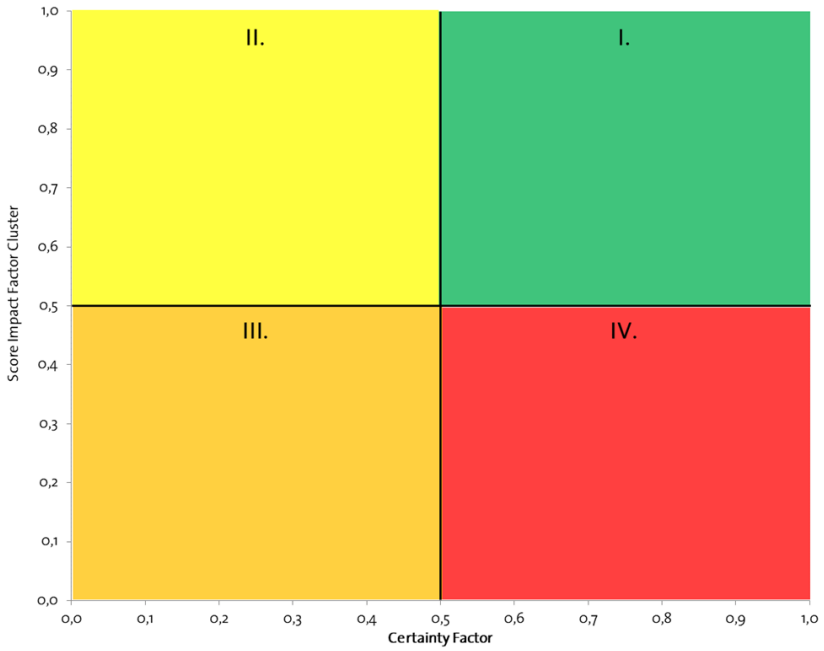
Within this research, two factors which affect the business potential have been developed: The IFIF and the CF. The Innovation Field Impact Factor (IFIF) describes the researched information and thus the potential of an IF from an objective perspective. The Certainty Factor (CF) includes a subjective view about the IF. Since both factors are completely independent, it does not make sense to combine both factors in one value or score. Thus, for the determination of the IF's business potential and for the useful visualization of the IFIF and the CF, both factors are represented in a heat map (Figure 4).

On the heat map's X-axis, the Certainty Factor (CF) from equation 4.6 is plotted. The values for the CF may range from 0 (completely uncertain) to 1 (very certain). The value of the IFIF (equation 4.1) is marked on the Y-axis. The value of the IFIF may also range from 0 (low potential) to 1 (high potential). The heat map may be used for two purposes:

First, after the methodology has been completed for one specific intended IF, the business potential of each cluster of the innovation opportunity may be depicted in the heat map. Thereby, clusters offering high or low business potentials may be identified and differentiated. Moreover, out of the clusters' business potentials, the average business potential of the intended IF may be calculated.

Second, by the evaluation of many different innovation opportunities and by the determination of the average business potential of those opportunities, these innovation opportunities may be compared according to their business potential. By directly comparing the business potential of different innovation opportunities in the heat map in the FFE, this evaluation methodology suggests which innovation op-

**Figure 4 Heat map template: Visualization Score Impact Factor Cluster vs. Certainty Factor (CF) (own representation).**



portunities might be worth to develop at first. Hereby, the evaluation methodology may support innovation managers in decision-making.

The heat map is divided into four quadrants: Quadrant I (upper right corner), which is depicted in a green color, is most promising. Clusters and innovation opportunities which are classified in this corner seem to offer a high business potential since they have a high impact factor (higher than 0.5) and in addition, the project manager is certain about the collected information (certainty factor higher than 0.5). Thus, potential IFs which are located in this corner should be considered for further development and support since they may lead to successful innovations.

Clusters and innovation opportunities which are classified in quadrant II (upper left corner) are characterized by a high impact factor, but also a low certainty. At the first glance, these clusters and innovation opportunities seem to offer a high business potential, but further research is required to confirm the first estimation.

Quadrant III (lower left corner) shows the business potential of clusters and innovation opportunities which received a small impact factor. But still, this value is very uncertain according to the responsible project manager. The cluster or innovation opportunity remains a "question mark", since the impact factor may increase with an increasing amount about the information's certainty and the business potential may even develop towards the quadrant I. Further research is needed for increasing the amount of certainty in order to see in which direction the business potential of the cluster or the innovation opportunity might develop and if a further development seems to be promising.

Clusters and innovation opportunities which are depicted in quadrant IV (lower right corner) only offer a small business potential. The impact factor is low and the project manager is reasonably certain about the values. Thus, this cluster or innovation opportunity is not promising and may include weaknesses. Therefore, this innovation opportunity should be terminated since it only offers small business potential, according to the IFIF and the manager's estimation about the certainty.

The four quadrants are separated from each other at an impact factor and a certainty factor of 0.5. The separation of the quadrants at these values is a guideline and 0.5 was selected as a reference value. If the heat map shall be applied in other branches and industries or for other models, the value where the quadrants are separated from each other, might be adjusted.

It needs to be emphasized that the developed methodology described above is just an evaluation methodology. It is only suitable for the evaluation of the business potential of clusters and potential IFs. The results depicted in the heat map may only give a first indication about the business potential. Thus, the heat map and the indicated business potentials may only be considered as an advice and support for the project managers. The methodology is not a selection methodology and no potential IF should be selected or terminated on the single basis of the heat map. Even innovation opportunities in the green area may be terminated just as the ones in the red area may be further supported if the project manager decides in this way.

Nevertheless, the visualization of the business potentials in the heat map might be helpful for practitioners and may be a valuable contribution to the literature since it shows a simple and quick methodology to evaluate the business potential of IFs.

## 4.5.2 Application

After the completion of the developed methodology, its suitability and applicability was tested and determined. For this reason, innovation managers from the company's strategic innovation unit determined the business

potential for innovation opportunities which have already been executed or which were just executed at the time during this research. In total, eleven innovation opportunities were evaluated and classified. The results and the values for the opportunities' evaluation may be found in Table 4.

With the help of the methodology, two purposes may be realized: On the one hand, the business potential of the different clusters of one innovation opportunity may be displayed in the Innovation Field heat map. The Innovation Field Heat Map, generated for the innovation opportunity 11 based on the estimation of the project manager, may be found in Figure 5. This innovation opportunity has an IFIF of 0.53 and a CF of 0.75. Thus, the innovation opportunity is classified in the first quadrant of the heat map, symbolizing an advanced business potential. In the heat map, which was generated for this opportunity, the clusters Resources and Organization are very strong and have a high business potential. In contrast, the clusters Market and especially Technology show less business potential and may contain some weaknesses.

After the opportunity's evaluation, the clusters Technology and Market were further analyzed. However, the opportunity's weaknesses and uncertainties were not considered as such remarkable that the further development of the innovation opportunity would have needed to be terminated. The innovation manager was aware of the weaknesses and thus, the innovation opportunity had been transformed into an IF.

On the other hand, the average business potentials of multiple innovation opportunities may be calculated. These average business potentials may be displayed and compared in another heat map to evaluate which innovation opportunity might be worth for further development or which one should be prioritized. The results and the classification of the IFs are depicted in Figure 6.

The business potential of the analyzed innovation opportunities is depicted in different colors: black, grey and white. The innovation opportunities colored in black have been evaluated and analyzed in the FFE during the research. The innovation opportunity 11 has now been transformed into a real IF, the innovation

**Table 4 Overview of evaluated innovation opportunities (own representation).**

| Innovation Opportunity | Score IFIF | Certainty Factor | Current Stage in the Innovation Process |
|---|---|---|---|
| Innovation opportunity 1 | 0.42 | 0.78 | FFE |
| Innovation opportunity 2 | 0.34 | 0.65 | Innovation Project at another department |
| Innovation opportunity 3 | 0.50 | 0.85 | FFE |
| Innovation opportunity 4 | 0.67 | 0.56 | FFE |
| Innovation opportunity 5 | 0.54 | 0.81 | FFE |
| Innovation opportunity 6 | 0.43 | 0.67 | Innovation Project |
| Innovation opportunity 7 | 0.47 | 0.74 | Terminated |
| Innovation opportunity 8 | 0.61 | 0.69 | FFE |
| Innovation opportunity 9 | 0.33 | 0.80 | FFE |
| Innovation opportunity 10 | 0.47 | 0.45 | FFE |
| Innovation opportunity 11 | 0.53 | 0.75 | Innovation Field |

**Figure 5 Innovation Field Heat Map of innovation opportunity 11: Visualization Score Cluster Impact Factors vs. Certainty Factors (own representation).**

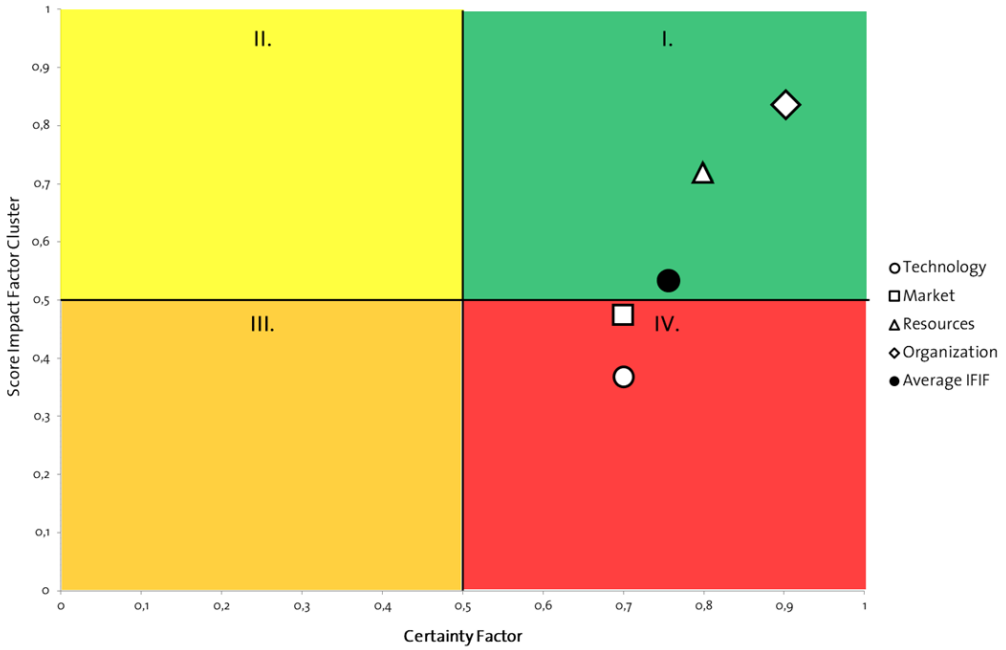
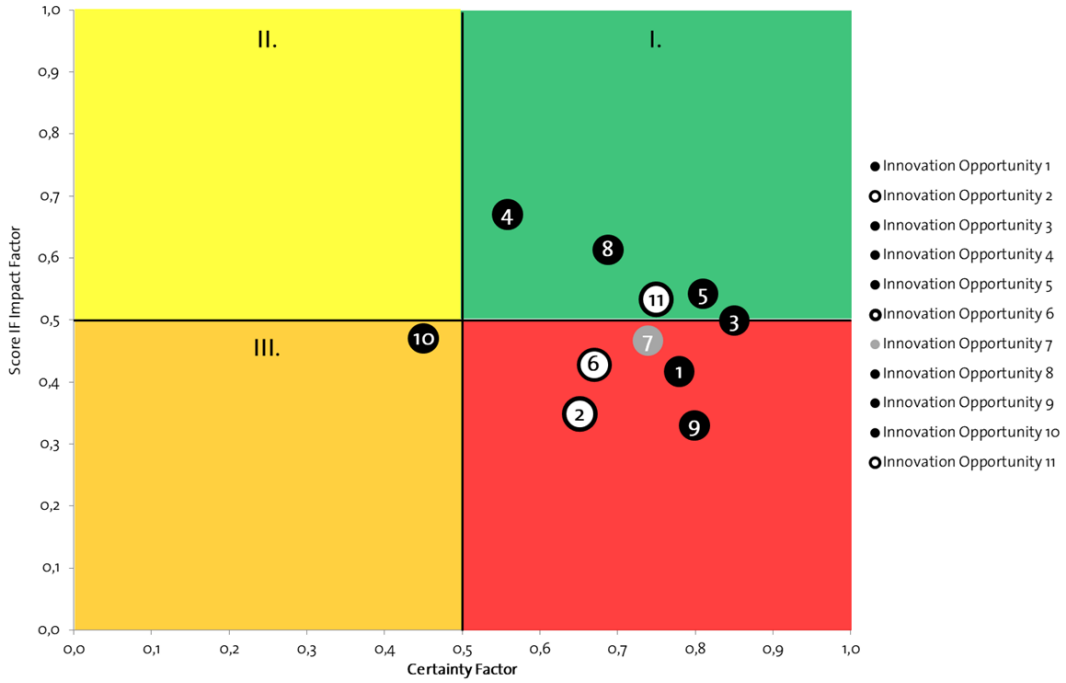



**Figure 6 Comparison of the business potential of eleven executed innovation opportunities: Visualization IFIF vs. CF (own representation).**



opportunity 6 has been transformed into an innovation project and the innovation opportunity 2 has been handed over to the segment. Thus, these opportunities are colored white. The innovation opportunity 7 (grey) has been terminated due to weak market opportunities and a low potential for applications.

It is obvious, that the innovation opportunities 3, 4, 5, 8 and 11 are displayed in the green area (first quadrant of the heat map) which means that they might have a higher business potential and are promising candidates for further development in order to generate and develop successful innovations. Five other innovation opportunities (1, 2, 6, 7 and 9) are classified in the fourth quadrant (red area) signaling only less business potential. The innovation opportunity 10 which is classified in quadrant III, is a "question mark" and thus requires much further analysis before it may be transformed into an IF.

Having applied the methodology to examples from a specialty chemicals company, it becomes clear that there are several innovation opportunities which are classified in the first quadrant and therefore, have enough business potential to be transformed into an IF. The innovation opportunities which are treated and analyzed in the company's strategic innovation unit mostly contain an IFIF between 0.3 and 0.7 and a CF of 0.5 to 0.9 (except innovation opportunity 10). Thus, it can be concluded that after few weeks of research, the uncertainty regarding the opportunities' information may be reduced but not completely eliminated, so that the opportunities' CF is higher than 0.5. As the IFIF of the analyzed innovation opportunities is higher than 0.3, it may be assumed that the opportunities which are developed in the strategic innovation unit contain an advanced level of business potential.

From the results and the classifications of the analyzed innovation opportunities in the heat map, several final conclusions may be drawn:

The business potential of several evaluated innovation opportunities is classified in the green area (Quadrant I). These opportunities may be candidates for further development and transformation into IFs since, as they offer a high business potential.

Innovation opportunities classified in the yellow field (Quadrant II) show less business potential as there is a high uncertainty regarding the good results of the IFIF. In addition, opportunities which are depicted in the orange area (Quadrant III) show less business potential at a first glance, since the IFIF is lower and there is a higher level of uncertainty. But since it is the task of a strategic innovation unit to develop innovations with a higher disruptive potential focusing on new markets and technologies and including a higher level of risk, one might argue that IFs classified in these quadrants are those, which the innovation unit should focus on and should further support. If IFs develop more towards the first quadrant, they might be ready for transfer to other departments or to the operational segments.

When taking decisions about the further proceeding of the innovation opportunities which are classified in the red area (Quadrant IV), these opportunities and especially their weaknesses should be carefully evaluated. Still, if these opportunities might be selected for further development, the introduction of critical assumptions and milestones, which need to be eliminated at first in the next stage of the innovation process, might be reasonable. Critical assumptions are those aspects of an innovation opportunity or a project which are most critical and uncertain. If those assumptions are wrong, the project has a high risk to fail. Therefore, it is the task of the innovation manager to identify critical requirements and thus, determine critical assumptions which need to be verified prior to further development and further spending of resources. If the innovation opportunity is transferred to the next stage of the innovation process, these assumptions must be verified at first, before the field is further investigated. The critical assumptions for

this opportunity may be derived from the 24 identified indicators. Thereby, effectivity may be increased and resources might be saved, since innovation managers will at first focus on the execution of the uncertainties and the solution of the critical assumptions.

The results of the evaluation of the already executed innovation opportunities once again reveal that the developed methodology is only designed for evaluation, not for selection: As the examples of the innovation opportunities 2 and 6 reveal, opportunities which are classified in the Quadrant IV. (red area) may not automatically be terminated. Although the opportunities in this quadrant may contain weaknesses and do not seem to have large business potential at first glance, they may still be worth for further development or the transformation into an innovation project or an IF after careful analyzation. Therefore, the methodology may not be taken for final selections. The innovation opportunity 2, only showing less business potential was considered to be relevant by an organizational department, and thus, directly handed over to the department. In addition, the innovation opportunity 6 was transformed into an innovation project as the opportunity was considered to be worth for further development despite its weaknesses.

These examples clearly demonstrate that the intention of this methodology is a simple and quick evaluation of an innovation opportunity's business potential after a short analysis.

The methodology is not suitable for the final selection of innovation opportunities. Moreover, the methodology is not able to forecast the profitability and the success of the innovation field.

However, it might seem peculiar that no innovation opportunity is classified in the top right corner showing a certainty factor of more than 0.9 and at the same time an impact factor that is close to one. Even the innovation opportunities which have been selected for further development do not reach such values and are classified close to the border of the first and fourth quadrant (green vs. red) or even in the red area.

There may be two interpretations for this phenomenon: On the one hand, after a few weeks of research, there remains a high amount of uncertainty concerning the further development of the innovation opportunity as it is still part of the FFE. Thus, the innovation managers made realistic and responsible estimations concerning the innovation opportunities and showed that after the first screening, uncertainty may not be completely eliminated. For this reason, it is very unlikely to achieve certainty factors higher than 0.9.

On the other hand, when looking at the 24 indicators which need to be completed for the determination of the IFIF, it seems virtually impossible to reach a high value for all indicators. Every innovation opportunity shows weaknesses or medium values for some indicators. Therefore, it is quite hard to find innovation opportunities which receive an IFIF close to one. Consequently, an innovation opportunity which is classified in the very upper right corner may be an ideal state offering a very high business potential. An explanation for this assumption might be that the opportunities and IFs classified in the top right corner could be characterized as rather incremental, since the level of certainty as well as the IFIF are high. As abovementioned, the analyzed innovation opportunities which have been developed and processed in the strategic innovation unit have an IFIF of 0.3 to 0.7 and a CF higher than 0.4 but not exceeding 0.9. Since it is the unit's goal to focus and develop more disruptive innovations and IFs, it might be assumed that disruptive innovations and innovation opportunities might have an IFIF between 0.3 and 0.7 and a CF higher than 0.4 and not exceeding 0.9. Thus, the analyzed innovation opportunities due to rather being disruptive than incremental did not reach high CFs exceeding 0.9 and also no IFIF close to 1. Consequently, when having a look at the results of the methodology's application, promis-

ing incremental opportunities might be classified in the top right corner of the heat map, whereas the more disruptive innovation opportunities might contain a lower IFIF and even a lower CF.

The developed methodology may be utilized for two purposes: First of all, by the classification of the business potential of the innovation opportunity's clusters, weak and strong clusters may be identified. Thereby, the innovation manager may get an indication which clusters need to be focused and especially developed before the opportunity can be transferred to the next stage of the innovation process. Hence, the methodology offers the possibility to speed up the innovation process, since project managers may directly concentrate on the investigation of weak clusters and improve or verify their values. By the execution of iterative cycles and the early focus on the investigation of weak clusters, the methodology offers the application of agile methods in the early stages of the innovation process. The utilization of an agile approach in the management of innovations and projects offers an increased flexibility and speed to the innovation process in order to adapt to changes in the innovation's environment (Kester et al., 2011; Meyer and Marion, 2010). Companies which use an agile framework may improve the effectivity of their predevelopment and innovation activities (Gonzalez, 2014). Thus, this methodology may lead to iterative processes, which may accelerate the development of IFs, reduce the uncertainties concerned with IFs and develop more effective innovations and IFs.

Secondly, by calculating the innovation opportunity's average business potential, the innovation manager gets the possibility to compare the analyzed innovation opportunity to other innovation opportunities. Thereby, the methodology may support the innovation manager in the decision which opportunity might be worth for further development and which potential IF should be selected for further support and development at first.

This comparison of different innovation opportunities is very important and useful and might be valuable to departments or groups with scarce resources. By classifying and comparing several innovation opportunities, the opportunity with the highest business potential might be identified and thus, should be further developed. The most promising innovation opportunity can be selected for further development within the innovation process, due to its high potential to generate new successful innovations. The other opportunities are put on hold and will only be further developed if there are further resources available.

## 5 Conclusion

In this chapter, results of the practical application of the evaluation tools are summarized. Ideas for future research which might be based on this methodology are given in the outlook.

### 5.1 Summary

In the course of this research, a methodology was developed and applied which enables a quick pre-screening as well as analysis and evaluation of the business potential of potential IFs after only few weeks of research about related topics and literature. Criteria and indicators, which determine the future business potential of IFs were identified in expert interviews. The interviews resulted in 24 individual, relevant indicators, which build a strong basis for the determination of the business potential of IFs in the chemical industry. These indicators were summarized in the four clusters Technology, Market, Resources and Organization.

The importance and the relevance of the indicators' and clusters' individual influence on the evaluation of the innovation opportunity's and IF's business potential were determined in a survey. In the view of the respondents, the market was weighted to be the most important cluster. The addressable market size, the inter-

nal competences, the alignment level and the fit to the segment- or department-strategy were weighted as most relevant indicators.

The business potential of innovation opportunities and IFs may be estimated and evaluated on the basis of objective criteria which are summarized in the Innovation Field Impact Factor (IFIF) and on the basis of the subjective Certainty Factor (CF).

The visualization of the business potential was realized in a heat map. With the help of this visualization, it is possible to identify the business potential of both, the four clusters and the complete innovation opportunity. In addition, it allows a comparison of several intended IFs to select the most promising IF. Evaluation, analysis and classification of certain innovation opportunities within the heat map may give an indication of the opportunity's business potential and thereby, may support innovation managers in their decision-making.

The developed method was applied by evaluating the business potential of eleven executed and completed innovation opportunities. With the help of the methodology, it was possible to identify weak and strong clusters within the innovation opportunities and to compare the opportunities' business potential.

Thereby, it became obvious that the developed methodology may only give an indication about the business potential of possible future IFs. It is another basis for decision-making using information on technology, market, required resources, the organization and the analyst's certainty. The methodology is only a decision guidance and should not be seen as standalone solution for final go- or stop-decisions.

This research shows that the developed methodology for the evaluation of IFs is a valuable tool for practitioners innovating in IFs, not only within the chemical industry.

## 5.2 Outlook

The methodology and the criteria utilized for the evaluation of the business potential of IFs offer the possibility for further investigation and analyses. Besides adjustments in the utilization of the demonstrated methodology, future research might investigate the long-term impact and the consequences, the utilization of the methodology within the strategic innovation unit might offer. It would be interesting to analyze and evaluate the methodology's influence and the impact on the innovation portfolio. How might the utilization of the evaluation lead to changes within the unit's innovation portfolio? Which impact might this have for the specialty chemicals company as a whole organization? Does the demonstrated methodology symbolize a competitive advantage for the specialty chemicals company? Following these ideas concerning the methodology's impact, in case of a successful utilization of the methodology, a comparison of the company's innovation portfolio and the innovation portfolios of other (specialty) chemical(s) companies might be the core of future research. Future studies might identify if the investigated specialty chemicals company becomes more successful in the development of IFs and commercialization of innovations by using the new evaluation methodology.

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## Appendix

**Table A1 Interview guidline (own representation).**

| Number | Questions |
|---|---|
| 1 | **Introduction**<br>a) Welcome, presentation of interviewer<br>b) Explanation of confidentality, secrecy, recording of the interview and data's anonymization |
| 2 | Presentation of the interview partner<br>Name:<br>Position:<br>Duration of company affiliation:<br>Final degree: |
| 3 | a) Presentation of the research structure<br>b) Explanation of the research purpose and research goals |
| 4 | **Entry of the interview**<br>a) What was your first innovation project? What was this project about?<br>b) Why was this innovation project selected? Which reasons have led to the selection of this innovation project?<br>c) Which additional criteria have led to the innovation project's selection? |
| 5 | a) Which indicators and factors determine, describe and influence an innovation field?<br>b) Why do the mentioned indicators determine and describe an innovation field? |
| 6 | a) Which indicators and factors have the largest influence on an innovation field?<br>b) In your view, are there any differences among the indicators regarding the influence on an innovation field? |
| 7 | a) How may the mentioned indicators and factors be evaluated, estimated and quantified?<br>b) How may the business potential of a whole innovation field be estimated and quantified? |
| 8 | **End of the interview**<br>■ Questions of the interview partner<br>■ Explanation of further procedure<br>■ Further interview partners?<br>■ Acknowledgement and adoption |

 

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# Research Paper

## Sustainability as a criterion for business models – A framework for the life science sector

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The research discourse on sustainability and on business models can be described as diverse in approaches and understanding of subject areas. The value-oriented business model and the twenty criteria of the German Sustainability Code represent a sample which is used for this research to examine and compare the sustainability of business models in practice. In addition, the relation between digital transformation and sustainability is considered. For this purpose, influences from theory and practice are included in order to further support the combination of these two concepts. With a qualitative document analysis, the selected business model cases are reviewed for their sustainability and finally characterized with the help of established hypotheses. It can be stated that sustainability aspects are potentially present in business models in the health care sector, but that there are clear deficits in the development and strategic anchoring. A first proposal for a solution is presented in the form of a framework.

## 1 Introduction

The life science industry and especially the health sector has gained major interest over the last years. Its increasing interest in digital solutions for treatments and healing methods and the promotion of solutions for these approaches is strongly evolving. Still, the sector is highly regulated by several laws such as the law for secure digital communication and healthcare applications, also known as the e-health law (Federal Ministry of Health, 2019). This law benefits the distribution of the IT-infrastructure and therefore helps to promote the network and digitalization. The new digital-care law is especially favorable to digital health applications. These applications are supposed to especially improve the care of insured people (German Parliament, 2019). The digital care law should help to include more health applications in the service catalogue of the statutory health insurances. Data-driven healthcare is becoming more important, digital transformation and platforms define new business models in the sector. Even though the healthcare sector is not as advanced as other industries in the field of business model innovation in Germany, it is even more important to be as dynamic as possible to adapt the constantly changing needs (Granig and Lingenhel, 2016). For this purpose, Granig and Lingenhel (2016) have designed a model: 1. analyze trends, 2. generate ideas, 3. create/innovate business model, 4. pilot project, 5. implement business model, 6. evaluate results. With this approach, business models in the health sector can be improved and adapted. Their intention is to start with trend recogni-

tion and thus to be able to generate a fast implementation, to determine their own strengths and weaknesses and to then derive the individual idea and the resulting market position.

Regarding Ahrend (2016), not much research has been done concerning business models in the health sector combined with sustainability as criteria. Thus, the present article aims to expand the research discourse on sustainable business models. It does so by developing theory- and practice-oriented hypotheses and providing the research field a model design in the context of the health care and life science industry. With increasing economization, changes in patient care and the corresponding interest in interpreting these changes in terms of patient well-being, Ahrend (2016) sees the niche of this emerging market.

The importance of digital transformation owing to constantly changing needs and therefore the growing market of digital health start-ups was already detected twenty years ago (Deluca and Enmark, 2000). The ecosystem which developed around these mostly digital start-ups is marked by investors and support such as the Flying Health Incubator GmbH. As an incubator in the health sector it has gained major responsibility for its value creation. Due to this importance it was chosen as one of the case-studies in this article and will be examined later. Another organization to be named with a global program for digital health start-ups is G4A, formally known as Grants4Apps and founded in 2013. By now, the accelerator of the chemical and pharmaceutical group Bayer no longer only supports the funding of app projects in digital health. It provides a whole program for entrepreneurs in the digital health sector including office space, start-up financing, mentoring and also Venture Design as a young business unit (G4A Bayer, 2020).

There will be a gain in knowledge especially at the organizational level for the management of health therapy facilities among others, as well as for organizations working at the intersection with the health sector, for organizations and associations in the health sector and other actors in the industry. Business models can be explicitly set up, compared and, if necessary, ideas for improvements can be extracted. On an individual level, the topic is of interest for those in health education, for therapists and physicians who are already practicing. Furthermore, it is useful for those actors, who are about to start their own business, are developing business models in the health sector and are looking for investors.

This article discusses the question of *what business models in the health sector look like, how they might be characterized and why it is worthwhile to compare them in terms of sustainability*. The objective is to expand the existing business model research discourse in combination with corporate sustainability research by reviewing both literature and business cases to develop it further. The proposal of this article is an extended value-based business model approach for the life science sector on the basis of analyzed sustainability criteria to integrate economic, environmental and social concerns into a holistic business model view.

## 2 Sustainability and business models in life science – A review

### 2.1 Sustainability

The concept of sustainability is treated as the main guiding principle in this article. The established hypotheses for comparing the business models are based on the idea of sustainability and are developed from this theoretical construct. Hence, sustainability is understood as a strategic corporate task, which means that the implementation of a concept is the responsibility of corporate management (Kanning, 2008).

The underlying definition of sustainable development is based on the Brundtland Report - Our Common Future - which was published

under the leadership of the Norwegian Prime Minister Gro Harlem Brundtland. It states that development is about meeting the needs of the present without depriving future generations of the possibility of satisfying their needs (WCED,1987).

The German Council for Sustainable Development (RNE) was first appointed by the German government in April 2001, to improve social communication and to provide consulting. It defines sustainability as the fact that environmental, social and economic criteria must be taken into account in equal measure, and that it is everybody's duty to leave an intact ecological, social and economic system for future generations (RNE, 2010). Hauff (2014) for instance sees the goal of sustainable development in the permanent fulfilment of basic human needs, taking into account the capacity of the natural environment, by which he specifically mentions the social and environmental components.

This article is based on the classic three-pillar model of sustainable development, which was first formulated in 1997 by the European Union. According to this principle, the social, environmental and economic approaches are equally pursued and related to sustainability (IHK Nürnberg, 2015). The balance of the three dimensions are seen in the understanding of strong sustainability (Kanning, 2013). Strong sustainability means that none of the types of capital may fall, but individually rise - they are therefore not substitutable as in weak sustainability (Hauff,2014).

The three dimensions are composed of Economy, Culture and Social, which stand on the foundation of Natural Resources / Climate. This dependency implies that each of them must remain intact (Stahlmann, 2008; Corsten and Roth, 2012).

Sustainability criteria refer to criteria that describe, characterize and promote the nature of sustainability. The concept to be applied should be based on objectives for the improvement of the sustainable corporate management (Ahrend, 2016). For this reason, the criteria of the German Sustainability Code (DNK) of the RNE (2016) are chosen and used as the analytical framework to examine the business models. It consists of the four areas of strategy, process management, environment and society which are assessed with a total of twenty criteria (Table 1). In concrete terms, this approach is

**Table 1 Sustainability criteria matrix (in allusion to RNE, 2016).**

| Strategy | Process Management | Environment | Society |
|---|---|---|---|
| 1. Strategic analysis and measures | 5. Responsibility | 11. Use of natural resources | 14. Employee rights |
| 2. Materiality | 6. Rules & processes | 12. Resource management | 15. Equal opportunities |
| 3. Objectives | 7. Control | 13. Climate relevant emission | 16. Training |
| 4. Depth of the value chain | 8. Incentive systems | | 17. Human rights |
| | 9. Stakeholder participation | | 18. Community |
| | 10. Innovation and product management | | 19. Political influence |
| | | | 20. Law & directive-compliant behaviour |

particularly useful for small and medium-sized organizations with a need of EU reporting and as a control instrument for sustainable management.

Strategy (RNE, 2016):

- The first criterion - *strategic analysis and measures* - is used to show what opportunities and risks are based on the main activities and in relation to sustainable development and under what standards this is done. Concrete measures can be listed here as well as the possibility of integration into the value creation process.
- *Materiality* expresses the influence which different aspects of sustainability have on business activities, the strategic consideration and how the core business affects the environment and society.
- The criterion of *objectives* describes how the company has set qualitative and quantitative sustainability objectives and the extent to which these are measurable and verifiable. This is only possible if the time of target achievement is clearly defined.
- *The depth of the value chain* is a criterion for demonstrating the significance of sustainability aspects for value creation and how profoundly they permeate the process.

Process management (RNE, 2016):

- *Responsibility* as a criterion sees accountability in corporate management, enabling direct intervention in decisive strategic measures.
- *Rules and processes* are used to present and implement sustainability strategies in business operations.
- The *control* criterion discloses management indicators that help to plan and control sustainability. Consistency, reliability and comparability are relevant factors here.
- *Incentive systems* are used to determine how the rewards of employees and employers are oriented towards the achievement of sustainability goals and long-term value creation.
- *Stakeholder participation* describes the identification of stakeholders, their involvement in the sustainability process and the resulting frequency and form of communication.
- The *criteria innovation and product management* provide information on the extent to which organizations use innovations to reduce their own resource consumption and that of their stakeholders.

Environment (RNE, 2016):

- The *use of natural resources* describes the extent to which they are used and the resulting emissions.
- *Resource management* explains the objectives in terms of resource efficiency, the use of renewable energies, increasing raw material productivity and reducing the use of ecosystem services.
- *Climate-relevant emissions* are listed again separately and describe the concrete reference to greenhouse gas emissions and the planned targets for reducing these.

Society (RNE, 2016):

- *Employee rights* disclose which recognized standards are pursued in the company in this regard and how the participation of employees in sustainability issues is supported.
- Equal opportunities show how diversity, occupational health and safety, immigration, appropriate wages and work-life balance are respected.
- *Training* outlines what the company is doing to promote the employability of all employees in the light of demographic change.
- *Human rights* are intended to prevent problems in the form of forced and child labor and exploitation of any other kind, and to describe what the company is doing about

it.

- The *community* criterion aims to show what measures the organization takes to make a contribution in the regions with the most important business activities.
- *Political influence* on decisions and developments in the form of membership fees, lobby lists, donations to political parties and other actions in this area should be disclosed.
- Finally, the *law and directive-compliant behavior* is considered in order to show which measures exist to prevent illegal behavior and, in the event of it being detected and sanctioned.

Due to the visualization, sustainability performances can be made transparent and comparable in order to assess how organizations anchor sustainability in their core business. With the Sustainability Code as a voluntary instrument on behalf of the Federal Government, RNE intends to give new impulses to the concept of sustainability in business and society. Furthermore, there is the possibility of a declaration of conformity for organizational communication and adaptations to different industry sectors. A DNK database is available for this purpose, in which, among other things, the declaration of compliance with the twenty criteria must be filled in. This reporting obligation, which has been in force since 2017, is covered equally and is in conformity with the law, and is legitimized by the EU Commission as a corresponding instrument (RNE, 2017).

## 2.2 The business model approach

Osterwalder et al. (2005) define business models as a conceptual tool supporting the business logic of an organization. It contains several elements, the relationship between these elements and to external actors as well as different concepts. The challenge is to display the simplified descriptions and representations of the concepts and relationships, what value is presented to the customers under which circumstances and with what financial consequences. Accordingly, it is a conceptual tool for demonstrating any constructs, subjects and processes that represent the business intention of an organization. Further definitions declare the presentation of several aspects of the resource transformation just like the relations with other market participants (Becker and Ulrich, 2013), as well as the representation of the central logic and strategic decisions to create and capture both social and economic values within a value network (Dahan et al. 2010). Demil and Lecoq (2010) describe it as the articulation between the different business areas and the way the organization creates sustainable value.

Furthermore, the delimitation between strategy and business models needs clarification. Osterwalder (2004) perceives strategy as being translated and implemented into the business model. Becker and Ulrich (2013) see strategies as dynamic and action-oriented, while business models are static (structure-like) or can be understood as dynamic (structuring). Hence, Bieger and Reinhold (2011) as well as Lüdeke-Freund (2017) position the business model between the strategic and operational level. It intends that the group of values and value mechanisms are established from strategic success positions. The objective of a business model in sustainable terms is the long-term nature in social, economic and ecological aspects (Ahrend, 2016). Therefore, the conceptualization of Bieger and Reinhold (2011) the value-based business model is used here as the conceptual foundation (Figure 1). The holistic and generic nature of this business model and its elements is particularly suitable for comparing different organizations.

Their approach provides a six-step model which is based on the creation of monetary and non-monetary value not only for the organization itself, but its stakeholders. It is dynamic and includes elements of business development and change. The individual business mod-

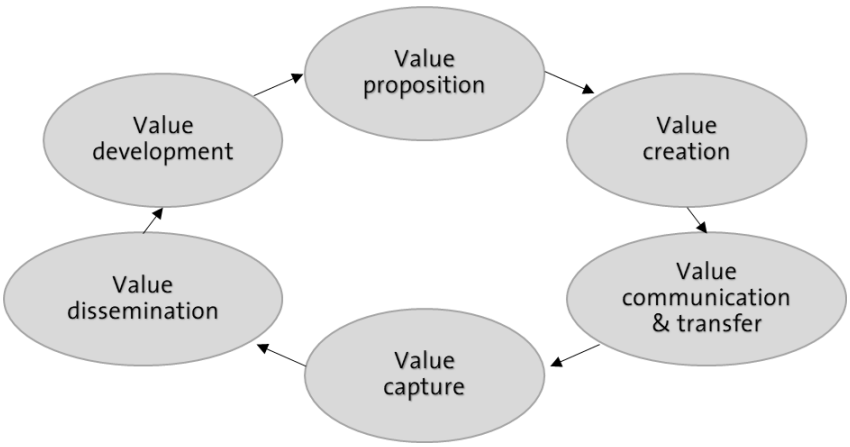
 

el elements interact within a business model architecture, whereas sustainability is understood here as the continued existence of the company and is also measured within it. To ensure the longevity of the organization, the following elements serve in synergetic cooperation:

- Value proposition - contains the organization's offer in the form of a value proposition for the customer.
- Value creation - shows how value is created through resource combinations of both internal and external capabilities in a value network.
- Value communication and transfer - communicate the transfer of the created values to the customer, the form and the way
- Value capture - shows how the value created is returned to the company in the form of revenues.
- Value dissemination - regulates the distribution of values and revenues within the organization and stakeholders.
- Value development - describes the continuous qualitative and quantitative improving value creation from an evolutionary and revolutionary perspective.

Another approach to be considered in this context is that of "sustainable entrepreneurs" according to Morris, et al. (2005). In this approach, the need for sustainability in business models is specifically identified and included accordingly. Since ultimately the question of sustainability as a criterion in business models is fundamental to this work, this model is presented here. The underlying understanding of business models is based on the assumption that they provide a compact summary of the decision variables of a company, which are reflected in the anchoring corporate strategy, architecture and economics and, in combination, ensuring sustainable competitiveness (Morris et al., 2005). They identify the difficulty in standardizing business models that generalized models are often too bold, while they still meet the individual needs of the organization. Accordingly, they propose an approach that serves different levels of strategic decision-making - "foundation", "proprietary" and "rules" (Morris et al., 2005). In the following the levels are understood as foundation, individual nature or characteristic, and rules where each

**Figure 1 Value-based business model (in allusion to Bieger and Reinhold, 2011).**



contains six basic decision areas (Table 2):

- At the foundation level basic decisions are made regarding the basic activities of an organization, which are supported by the following questions: 1) How does the organization create value? (supply factors) 2) For whom does the organization create value? (market factors) 3) What is the competence source? (skills) 4) How can the organization compete for a position? (competitive strategy) 5) How does the organization earn its money? (Economic factors) 6) What are the time, size and ambitions in the field of technology?
- In comparison to the first level, the sustainable approach is formed on the second level in such a way that this level emphasizes the specific unique selling propositions of an organization and thus represents the level that is more difficult to imitate for competitors.
- The third level represents the operational rules, which ultimately bundles the preceding two elements into instructions for action and represents them in strategic management decisions (Morris et al., 2005). "Sustainability requires that model components demonstrate consistency" (Morris et al., 2005), which means that the individual components of a business model have to last, and there must be no contradictions between the individual core activities, both internally and externally.

An interconnection can be drawn, among others, to the sixth element of the value-based approach, in which development is differentiated into quantitative growth, evolutionary adaptation, and which also takes the view that on the external level, a change in the environment implies a change in the organization, while internally the individual components are mutually dependent (Bieger and Reinhold, 2011; Morris et al., 2005).

The entire concept of Morris et al. (2005) serves as a framework for entrepreneurs at the time of foundation to formulate core elements and intentions, to achieve consistency between the individual elements and to create individual attributes for sustainable competitiveness. For this reason this model in combination with the value-based approach of Bieger and Reinhold (2011) is considered the foundation for the

**Table 2 Sustainable entrepreneurs - model (in allusion to Morris et al., 2005).**

| LEVEL | DECISION AREAS |
|---|---|
| Foundation | 1. How does the organization create value? (supply factors)<br>2. For whom does the organization create value? (market factors) |
| Individual character | 3. What is the competence source? (skills)<br>4. How can the organization compete for a position? (competitive strategy)<br>5. How does the organization earn its money? (Economic factors) |
| Rules | 6. What are the time, size and ambitions in the field of technology? |

analysis of business models.

## 2.3 The research discourse on business models and corporate sustainability

Regarding the research discourse between developing business models and corporate sustainability, Lüdeke-Freund (2017) presents the relevant topics such as corporate sustainability and sustainable business models for corporate competitiveness and the fulfilment of strategic goals, such as ecologically and socially responsible action (Lüdeke-Freund, 2017; Lüdeke-Freund, 2009; Lüdeke-Freund et al., 2016). Building on the understanding of Schaltegger et al. (2016), Lüdeke-Freund (2017) understands sustainable business models as a value-creating concept for interest groups. It initially does not further damage the three dimensions of the understanding of sustainability - ecological, social and economic. If necessary it even regenerates them and thereby represents an "ideally designed and implemented value creation logic" (Lüdeke-Freund, 2017). Sustainable entrepreneurs achieve their business goals with the help of business cases for sustainability. They are dedicated to the conditional economic success and at the same time have positive effects on environment and society. For the corresponding design, Lüdeke-Freund (2017) distinguishes between three different phases as a preliminary consideration based on Wunder (2013): business model analysis, business model innovation and business model implementation. The business model analysis contains the success and strategy potential; the business model innovation the sustainability potential; and the business model implementation contains the introduction of new value creation logics oriented towards sustainability dimensions. With regard to sustainability, Lüdeke-Freund (2017) continues to distinguish between "success through and success with sustainability". While success through sustainability stands for using core businesses of the company to introduce sustainable conditions, success with sustainability appeals to short-termism and temporarily seizes market opportunities. He also sees the integrative creation of sustainable values, ecological, social and financial as relevant in the sense of entrepreneurial action.

Kandolf (2016) describes how start-ups develop a sustainable business model. He understands sustainability of business models as longevity on the market. It is therefore particularly interesting for start-ups and founders, where the survival and subsequent maturation of an idea is first of all important. Therefore, he relies on the business model canvas approach of Osterwalder and Pigneur (2011) with its nine elements, and recommends to include it in a three -step approach. Step one involves working out the nine elements to make the idea concrete. Step two is the systematic development phase, in which strategic instruments are used to verify correctness and the business model approach becomes more concrete. The process in this stage contains corresponding tools such as industry structure analysis, customer profiling, revenue models and the marketing mix. The results are then transferred to the business model canvas again and tested in a test phase. Step three incorporates the corresponding changes resulting from the feedback into the business model and the result according to plan is a validated business model (Kandolf, 2016). It is clearly evident here that the term sustainability in the three-dimensional understanding plays a rather subordinate role and is ultimately purely responsible for the successful introduction of a new business model to the market.

Broman and Robèrt (2017) have designed an approach in a framework model, "the FSSD has been designed to promote a thorough understanding of both the full scope of the sustainability challenge and the related opportunities". The question why business models are important for sustainability is the research question of Bocken et al. (2014).

Thus, Ahrend (2016) sees few viable ap-

proaches and therefore suggests further research in the discourse on corporate sustainability. This is again why this article emphasizes the relation between corporate sustainability and business models and proposes a framework to the research question presented above.

## 2.4 Methodology

For this purpose, a qualitative empirical document analysis is conducted. Five different cases from the health sector are considered as objects of investigation and evaluated in form of a case study analysis according to the understanding of Yin (2003). The selection has to be as heterogeneous as possible with regard to the service concept and as homogeneous as possible with regard to the number of employees in order to ensure comparability. The organizations selected for the case studies due to their accessibility are Sonormed GmbH, Medlanes GmbH, Flying Health Incubator GmbH, DockCheck Medical Services GmbH and In good Health. The data sources used were primary and secondary online accessible data. It most concretely reflects the business models of the individual cases and thus contribute to the explanation of the phenomenon investigated. By using secondary sources and incorporating current company data, a detailed view of the respective business models and thus the empirical data basis for this work is achieved. The explorative procedure aims to generate hypotheses and assumptions for further research. Subsequently, after each individual case study, a cross-case analysis according to Yin (2003) is done. It is used to establish a comparison across the case studies in order to achieve a final conclusion regarding the research question. The supporting hypotheses are developed on the basis of the case studies presented. Incorporating the theoretical findings previously elaborated, the theses themselves can already be regarded as findings. The evaluation method according to Habermas (1973), as an emancipatory cognitive interest, is aimed at further developing the theoretical level while the technical interest is based on generating a model on this level.

Thus, in addition to answering the research question, the aim is also to draw a graphic conclusion from the entire collected and analyzed document data. The conclusion is a model design that meets the sustainability criteria from the German-speaking area and is specifically applicable to the health care system.

### 2.4.1 Analysis matrix

The value-based business model approach of Bieger and Reinhold (2011) serves in the following to picture the five business cases. Table A1 in the Appendix shows the matrix which is used in order to ensure a coherent presentation. The column "Element" I) - VI) shows the business model elements according to Bieger and Reinhold (2011), while the row "Level" a) - c) shows the levels introduced according to Morris et al. (2005). It serves the different levels of strategic decision-making and ensures greater individuality in presentation. The overlaps between the respective elements have already been described and thus legitimize this mix of the two business models.

The *value proposition* is subdivided into A) service and B) customer groups and can be further broken down. Product, product system, assortment, service, integration of the service, integrated project management, emotional profile and customer experience as far as the data material permits this classification (Belz, 1997). Furthermore, the *value creation* is divided into A) resources and B) capabilities; the *value communication and transfer* as presentation consists of A) communication and B) transmission of performance; the *value capture* - of A) customer values and B) company values; the *value dissemination* of A) direct and B) indirect stakeholders in the organization; the *value development* presents the development of the value creation under given and new circumstances. In the business model matrix, each

element of the organizations under review is described on the basis of the available data. On the base of these five matrixes the cross-case analysis is conducted due to the link of both analysis matrixes: the business model and the criteria of sustainability matrix (Table A2 in the Appendix).

### 2.4.2 Hypotheses

The formulation of hypotheses is carried out in order to support the analysis of the so far scarcely researched field of business models from the health care industry with regard to the sustainability criteria established by the RNE. The working hypotheses, as consistent and unproven assumptions, should serve in this case for the knowledge gain of new observations to modify and improve them. In the qualitative procedure, the hypotheses serve to generate new knowledge and thus contribute to the research discourse (Gläser and Laudel, 2010). The individual hypotheses are developed on the basis of the theory elaborated, the state of research and the sustainability criteria established.

Hypothesis 1: Business models with a sustainable character in the health sector are determined by the strategic orientation of the organization.

Hypothesis 2: Business models from the health sector, which are based on the materiality of sustainability, describe in their value creation concept processes that are decisive for social well-being.

Hypothesis 3: Business models from the e-health sector have the potential to be highly competitive in the healthcare market due to the developing trends.

Hypothesis 4: Sustainably declared business models from the health sector can satisfy people's basic health needs in the best possible way and, conversely, secure their own competitiveness.

Hypothesis 5: Through stakeholder participation, the aspects of sustainability relevant to business models can be pursued and disseminated even more comprehensively and widely.

The following section deals with the implementation of the established constructs, analysis matrixes and hypotheses in relation to the empirical data. Therefore, a diminished overview of the case studies is given.

## 3 The comparison of the case-studies

### 3.1 The business models

Case 1:

The Sonormed GmbH (as in 2017) is a medical technology company with their main product Tinnitracks. It is considered as a partially digital treatment (Mey, 2016). Accordingly, this also forms the core of the business model and is the core product in the system. The foundation lies within the e-health sector with the IT-Audio-Health technology app, which is a medical device in the field of digital audiology for tinnitus therapy. The value proposition is shown with the Tinnitracks App, the Tinnimatch App and the Specialist Finder, which accompanies therapy videos and the cooperation with Sennheiser and their headphones in combination with the app. The creation of value through the combination of resources is evident in the business process: 1. diagnosis 2. frequency determination 3. creation of user account 4. addition of the app 5. editing of music (5.1 Optional: purchase of headphones) 6. therapy 7. accompanying videos 8. physician consultation 9. submission of incurred therapy costs to participating health insurance companies. In addition, the application process of the app, which forms the core of the business model, is also listed. The selected channels for value communication and transfer of the service to the customer are web-based channels as well as other communication media. Contact with the target group takes place via user accounts, while for the network, potential doctors can also contact via telephone and e-mail. The val-

ue capture shows that the sale of the product serves as the main source of revenue, and that the financing services of the various funding agencies can also be seen as indirect revenue. The actual dissemination of value takes place in the course of the fact that donor partners receive a high proportion of presentations on the website, thus ensuring continued participation by these stakeholders. The dissemination of the created value does not allow any further conclusions. In this case, the last element of the business model is the value development. It indicates a development that shows the involvement of specialists in the form of ENT physicians as well as a change on the technological level in the way it is used as a form of therapy.

Case 2:

The business model of Medlanes GmbH (as in 2017) consists of the product app medlanes at its core. This app can be used to book home visits, ask questions to doctors, manage one's own medical file and share it with the attending doctor, and, if necessary, to call up and clarify the medical history and any further questions that may arise. With their business model they describe the field of activity of the digital organization of the doctor-patient relationship (Mey, 2016). The managing director and co-founder have laid the foundation in digital business, the e-health sector with a medical product in the form of an online medical platform. The individual value proposition is determined by free access to general practitioners and specialists through online appointment scheduling and the corresponding subsequent home visit by the doctor. The performance of the business model itself is extended by the sending of medication if necessary and a follow-up treatment in the form of a digital meeting. Thanks to an extensive network of doctors, the app now provides its services in 25 cities in Germany. Furthermore, mainly private health insurance companies are involved. To what extent the benefit is refunded to the company in the form of revenue is not evident from the available data. The financing by at least two investors allows an initially guaranteed cash flow. Medlanes creates the intangible value in the form of trust and identification with its verification as a member of the Federal Association for Internet Medicine. The continuous technical development is already determined by the digital environment. On the level of individual character, Medlanes has already made the transition from Berlin to other cities in Germany. Furthermore, the general conditions, the medical legal text, has led them to abandon the originally planned purely digital treatment and to introduce home visits by doctors.

Case 3:

The third case describes the Flying Health Incubator GmbH (as in 2017) as an incubator for healthcare entrepreneurs. They support and accompany start-ups with product and service ideas for digital diagnosis and therapy applications during their foundation and market launch. Flying Health provides the program for start-ups with the objective of a successful market entry. They distinguish between the value creation concept for early- and late-stage start-ups. Further distinction is made between the potential partners who support Flying Health and the start-ups who need support and expertise on a conceptual level. The focus is always on the medical benefit for the patient as an indirect stakeholder group and customers, such as start-ups as the immediate stakeholders. In this way, the value dissemination of the business model is distributed to the stakeholders, whereby the return is negotiated through an individually determined level of participation. The value communication and transfer are not predominantly web-based, but there is rather direct contact in the form of laboratories primarily for the transfer of services for start-ups. In conclusion, it should be noted that this business model is to be understood as a supportive business model in the health care sector, the individual nature of value capture and the dissemination of value remain unclear.

Nevertheless, the core of the business model lies in the digital health sector, the further development and improvement of the existing health care system is equally focused on partners and start-ups.

Case 4:

The core of this business model of DocCheck Medical Services GmbH (as in 2017) is the B2B online platform for medical professionals throughout Europe. It is equipped with different services and focuses on e-marketing, customer relationship management and online market research. This business model follows a business-to-business orientation. The foundation of this business model lies in the e-health sector and serves as an online platform for doctors, pharmacists and medical professionals to exchange information. The individual nature of this element is characterized by the diverse services offered by the platform for a specific customer group. A total of ten different services are offered, including the possibility to ask colleagues (Ask), access to news, short reports, blogs, a medical lexicon, scripts and lectures, certified advanced training (CME) and access to information channels. For each service provided, a DocCheck employee is introduced virally who acts as a contact person and can be contacted via personal e-mail. A pure web-based communication and exchange of propositions as well as access via a user account is guaranteed. There are no external partnerships or alliances identifiable, as the corporate network of the DocCheck AG is already large. The users form their own network as well as the internal number of employees is significantly higher than in the other cases. In return, it is recognizable that access to the community is distributed to third parties in the form of pharmaceutical companies and publishers and that the product system is completed by online advertising, market research, studies and paid content.

Case 5:

The business model of the In good Health academy (as in 2017) is presented as a value proposition. It is located in the e-health sector and is dedicated to direct health care in the form of nutritional advice, ayurvedic teaching and yoga philosophy in individual coaching's, via webinars and online-coaching. According to Ahrend (2016), it is firstly a personal health service, which is intended to work directly with patients, and secondly a non-personal health service, if the services are available online, for example. Thus, it is a hybrid model. The individual characteristic of the performance of this model lies in the courses and the combination of webinars, online yoga training and nutrition coaching as well as the individual development of concepts for yoga studios. The online portal "In good Health Academy" represents the core resource. Together with the qualifications of Dr. med. Scharfenberg it forms the individual nature of the value creation concept. A high proportion is due to external partnerships, which Dr. Scharfenberger uses as a freelance lecturer in institutions to offer and provide her services in the form of workshops, further training, courses and retreats. Web-based media is primarily used as a communication tool and to transfer while a group of customers also experiences direct face-to-face contact. The value development concept is pronounced in the Ayurveda Online Teachings via the Academy, i.e. digitalization is recognized and used as a progressive business field. It is evident that this business model with its fields of activity is the most distant from the traditional healthcare market and has entered the new market niche, the second healthcare market. Well-being and health are the core elements, but the skills and the corresponding offer in this model are based on one persona.

## 3.2 The cross-case analysis

First, it can be stated that the criteria 1. strategic analysis and measures, 2. materiality, 3. objectives and 4. depth of the value chain cannot be identified as obvious aspects of sustain-

ability in any of the five cases examined. The main criteria of the strategy, which can be expressed primarily at the level of value proposition, but also by all other elements of the business model, are not clearly defined in terms of sustainability aspects. Nevertheless, if one considers the business models and their foundation, all cases are rooted in the e-health sector. This fact combines the two components digitization and health, which are to be understood as important sustainable topics. On the one hand, digitization means the preservation of natural resources. The fact that users usually access services from their homes means that $CO_2$ emissions are not necessarily increased further.

Another component of digitization is the decline in the use of paper as a natural resource. In the second case, for example, an anamnesis and follow-up treatment is carried out via the app. The online courses in the fifth case also mean that no course scripts have to be printed out, as they are available digitally. The consideration of some ecological components is thus initially guaranteed for all business models. In the form of treatment and care management, the doctor-patient relationship, indirect prevention and healing, and the well-being and fitness aspect, various components of the health market are served. Accordingly, these have the ambition of having a long-term impact on the health of society. The support for start-ups in order to be able to intervene sustainably in these components is both economic and a decision for the development of the health care for the society. An online platform for actors in the health care system only works when the intention to network and to share ideas is strikingly the same and when it is supported by the thought of ultimately being able to help other people and profit economically from it. Also, the last business model contributes to one's own well-being and that of others through its service and ultimately ensures that long-term health is cultivated. These aspects can be derived as the main objectives of the sustainability concept in the e-health sector for strategic orientation.

The criteria regarding process management can also be regarded as very homogeneous in comparison. In all cases, responsibility is assigned to the management, which is understood in the business model as a resource, since knowledge is accumulated here and carried top-down through the company. Based on the given resources, appropriate skills can be developed. The handling of rules and processes cannot be presented due to the lack of an internal view of all five business models. In the form of guidelines, information boards and other media up to working groups, the design of this criterion for the topic of sustainability can take shape. For the business model, this would be particularly important with regard to rules for suppliers, partners and financiers.

The criteria on innovation and product management must be linked to element VI), the value development, in all considered cases. It can be seen that through constant development and improvement, the e-health concept contributes to the fact that innovation is a permanent task, also due to the rapid technological innovations. In this context, sustainability is ensured in a general sense by the health orientation and in an economic sense.

The environmental criteria relating to the use of natural resources, resource management and climate-relevant emissions are again applied equally to the value creation concept for all five case studies. Above all, the consumption of natural resources is at least not increased by the digital aspect; there is a lack of insight into resource management and climate-relevant emissions.

In the case of the society criteria, no valid statement can be made about labor rights, human rights and political influence. In the fourth case, a statement on equal opportunities can only be made in the form of addressing future employees. The atmospheric working environment with an open culture is used to ensure a steady flow of new knowledge, manpower and

corresponding skills. As a training criterion, the DNA Career Laboratory is used to ensure the importance of the qualification of its own employees. Furthermore, case five can be mentioned in the sense of the qualification of the performance creation process, in which yoga teachers receive further training.

Finally, the law and directive-compliant behavior is mentioned, which is only followed by case two in the sense of the fulfilment of the standards of the Federal Association for Internet Medicine. In the third case it can be assumed, as one of the managing directors is a member of the board of directors of this association. However, only assumptions and no concrete statements can be made.

In summary, it can be said that a very homogeneous picture of business models in terms of sustainability has emerged. The prerequisites in the strategic sense are met in all the cases examined, the obvious integration of the sustainability aspects considered as important in each case must then follow. This is done on an internal company level by defining sustainability goals, thinking through and checking the integration of the entire value creation process and then implementing it.

## 4 Discussion

It can be stated that the business models described in the e-health sector are, due to the nature of the industry, first of all per se socially sustainable and positioned in favor of sustainable development, which benefits society on the one hand and in return also the competitiveness of the company.

The four criteria of the DNK's strategy show that all cases have the potential to further develop explicit sustainability strategies owing to the combination of digitalization and health. In addition, the services and products are aimed at maintaining health, which can be claimed to be fundamentally sustainable for society. A special market niche then makes up the individual company concept. Partnerships and financing are decisive for the competitiveness and thus the longevity of the organization. Furthermore, both personal and non-personal health services also work as perspectives.

In process management, the observation of rules and processes as well as their control is difficult and would have to be reassessed by a different perspective. The role of partners and alliances has proved to be important and essential in all cases. It should be further emphasized as an element in combination with the health sector's own sustainability strategies. For example, in the sense of core partnerships, which are crucial to the business process.

The strategy and its responsibility should be highlighted as the most essential aspect. If sustainability is anchored in the strategy, then it is also reflected in the business model. If the business model is viewed as a blueprint (Osterwalder et al., 2005), it can function as a simplified representation and communication medium for sustainability, and must be integrated into it by means of specific criteria. In this way it can be shown how a conceptual model can be created from the corporate strategies.

### 4.1 The new approach

Ahrend's (2016) research regarding sustainable business models is now used to be combined with the gained knowledge from the case studies to propose a sustainable business model approach for the life science sector (Table 3). It follows the business model canvas approach (Osterwalder and Pigneur, 2011), takes the value -based approach (Bieger and Reinhold, 2011) into account and serves as an exemplary concept in the development of new business models.

The own presentation of the understanding of sustainability in the health sector and the social objectives that should be pursued are: long-term, holistic, patient well-being, health, quality of life, mandatory health care, reduction of threats and risks to human health.

**Table 3 Sustainable business model matrix for the health sector (own representation).**

| Business model elements | Sustainability components |
|---|---|
| 1. Key activities | 1. Trend analysis, definition of objectives, level, use |
| 1.1 Field of action | - Contributions to environmental protection |
| 1.2 Target group | - Low resource consumption, digitalization |
| | - Responsibilities, corporate management and strategy |
| | 1.1 Create long-term social and health benefits |
| | 1.2 Improve ecological footprint of the customer |
| 2. Key partners | - Alliances with health insurance companies and doctors |
| | - Investors and supporters |
| 3. Key resources | - Technical equipment |
| | - Experience and skills |
| 4. Customer relations and channels | - Quality seal, e.g. Federal Association for Internet Medicine |
| | - Building trust through communication and accessibility |
| | - Digitization |
| 5. Development and innovation | - Innovation circle |
| | - Trend development |
| | - Prizes and honourings |
| 6. Revenues, costs and dissemination | - Sustainable value creation |
| | - Revenue models and sources of income |
| | - Research and development costs |
| | - Participation in achieved sustainability goals |
| 7. Employees | - Qualifications |
| | - Employee rights |
| | - Standards |
| | - Trainings |
| | - Incentive systems |
| 8. Society, laws and directives | - Social engagement, human rights |
| | - Consideration of current political situations |
| | - Verbalization of internal rules, processes and control |
| | - Sustainability standards (DIN ISO 26000) |

The model and the sustainability criteria in the health sector should be based on it in order to ensure a holistic approach and to use sustainability criteria in a meaningful way. The own competitiveness as an economic component is relevant to assure the fulfilment of social objectives. Furthermore, the ecological component in the form of resource protection must be taken into account in every process and the management must ensure that this component has the highest priority in its relations with all stakeholders.

Whether describing or developing a business model, it is important that the individual elements of the business model are specified (Ahrend, 2016).

The identified important elements for a business model in the healthcare sector consist of the elements 1.-8. in Table 3. The corporate strategy is synchronized with the strategies of sustainability and how this is understood in the company. The strategies of sustainability are represented by the explicitly formulated components, as expressed in the second column of Table 3. In each element of the business model, the proposed corresponding aspects of sustainability must be taken into account and corporate management must consider the extent to which its own organization emphasizes various aspects and may neglect or even add others, depending on the given priorities. The process model presented by Granig and Lingenhel (2016) can serve as a template for developing one' s own business model. Figure A1 [cf. Appendix] shows the findings of Table 3 in a compromised form and might be used for first drafts.

## 5 Conclusion

The following mentioned hypotheses and their explanations represent a summary of the results of this article. They can also be used to serve as a reference understanding for further research in this discourse.

H1: *Business models with a sustainable character in the health sector are determined by the strategic orientation of the organization.*

The strategic orientation and thus the basic decisions for the further development of the business model determine whether there is a strategy for sustainability or not. Starting with the Executive Board as the responsible person for implementing the subject, the components and criteria are then distributed and applied to the various elements and levels of the business model (see additionally Lüdeke-Freund, 2017).

H2: *Business models from the health sector, which are based on the materiality of sustainability, describe in their value creation concept processes that are decisive for social well-being.*

Due to the general orientation of the companies, their fields of activity and their value proposition, the objective can be determined by mapping the entrepreneurial action. In each of the cases, the combination of resources and skills is designed to strengthen and increase social well-being through the help of therapy, support for doctor-patient communication, support for the development of therapy and prevention products, a medical platform and health coaching.

H3: *Business models from the e-health sector have the potential to be highly competitive in the healthcare market due to the developing trends.*

As a result of social developments and the constant evolution of technology and technical standards it can be said that there is a high potential. Due to the ever-increasing awareness of environmental protection in the course of the ongoing climate debate, the growth of the e-health sector has demonstrated that the potential in this segment has not yet been fully exploited. In particular start-ups with their dynamism and competitive intensity can exploit their potential for the healthcare market even further here.

H4: *Sustainably declared business models from the health sector can satisfy people's basic health needs in the best possible way and, conversely, secure their own competitiveness.*

The connection with regard to social and economic dimensions and the connection of the balance of interests is fulfilled by the business models in the health sector described. The necessary measurement to show the actual share of sustainability in this fact is missing due to the chosen research strategy and the limitation of the possible measurement concepts. Nevertheless, it can be said that social sustainability in the health sector is taken into account above all and that there is a corresponding relationship.

H5: *Through stakeholder participation, the aspects of sustainability relevant to business models can be pursued and disseminated even more comprehensively and widely.*

The size, the number of employees and the economic efficiency of the organization are decisive. Here, manpower is defined and accordingly the workload, which has a decisive influence on corporate activity. The intervals at which offers, products or services can be expected and how comprehensive these can be also depend on the number of employees. In the cases considered, this means that small organizations in particular have many cooperation's and partnerships externally, which naturally also spreads the influence of sustainability. Through the network, a larger circle of indirect stakeholder groups also experience the relevant aspects, provided that these are consciously lived as rules, anchored in the strategy.

## 6 Limitations and further research

There are limitations regarding the chosen model and theory. Yin (2003) uses the four criteria of internal and external validity, reliability and objectivity for the evaluation of qualitative case studies. Regarding objectivity, this is permanently given by the external company view in form of a mere document analysis. Hence, reliability is partly proven as the consideration of the different business cases under the given theoretical approaches in the same investigation steps should lead to the same results. The internal validity is ensured by the establishment of the hypotheses, the presentation of the relationships in the cross-case analysis and the final consolidation in a separate presentation that documents the consolidation of the observed events. The generalizability of the research results in relation to the entire health care sector and thus an external validity is more difficult to confirm due to the limitations of the model and the theory. The value orientation of the value-based business model approach leads to a certain homogeneity in the case studies due to its economic orientation. For a valid external validity, further empirical analysis material needs to be collected in order to ensure meaningful and generalizable findings under a greater heterogeneity. Nevertheless, the general bias of this methodology is enormous. In this article especially the researcher or observer bias is worth mentioning since there were no other instances involved in the writing process but the supervisor. For this, it is important to constantly confront prejudices with the gathered data to avoid subjectivity. Further, the criteria model of the DNK was originally designed to serve as an information and communication instrument for internal reporting within the company. The criteria model could be investigated in further research within organizations to confirm the suitability of the criteria. Therefore, Interviews with the corporate management and responsible persons from the strategic management are suggested for further research. In the theoretical construct of strong sustainability it has been shown that there was no relevance for the component of culture for this research in life science and therefore replacing the dimension with the element "health" could be considered. A further research approach could also be the classification of start-ups after their fields of action and the

comparison of each field and the belonging business models regarding sustainability to gain a wider understanding of the industry.

The potential in the healthcare sector is enormous. This specific, dynamic and fast-growing field of research has given rise to a further approach for the design of business models in the health sector. The e-health sector and the e-business typologies provide a decisive outlook on the opportunities that this sector contains. Further research projects can be taken up for this purpose.

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# Appendix

Table A1 Business model matrix (own representation).

| Level | a) Foundation | b) Individual character | c) Rules | No. |
|---|---|---|---|---|
| Element | | | | |
| I) Value proposition – divided in A) services and B) customer groups (product, product system, assortment, service, integration of the service, integrated project management, emotional profile and customer experience | | | | |
| II) Value creation – integration of A) resources and B) capabilities | | | | |
| III) Value communication and transfer as presentation - consists of A) communication and B) transmission of performance | | | | |
| IV) Value capture - A) customer values and B) company values | | | | |
| V) Value dissemination - of A) direct and B) indirect stakeholders in the organisation | | | | |
| VI) Value development - the development of the value creation | | | | |

Figure A1 Sustainable business model draft (own representation).

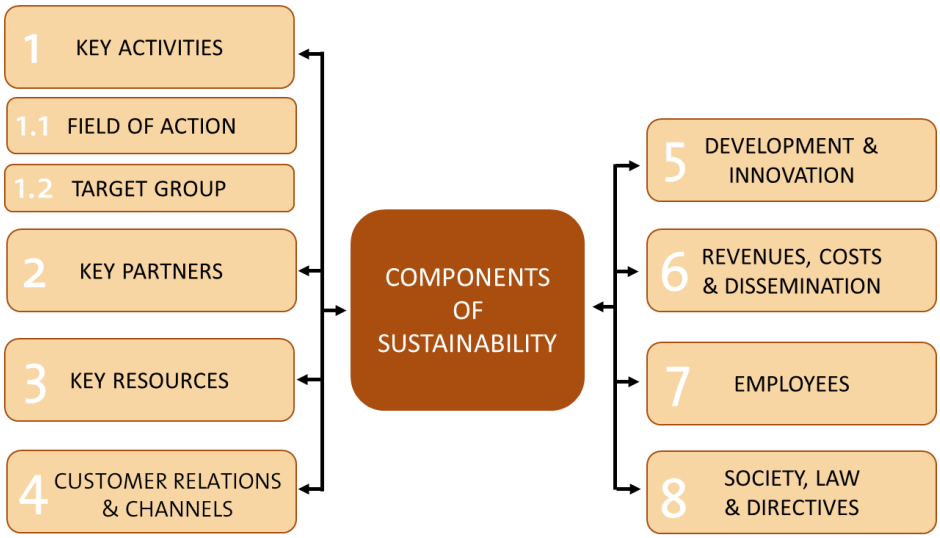


 

**Table A2 Cross-case analysis matrix (own representation).**

| Criteria of the German Sustainability Code | | Sonormed GmbH | Medlanes GmbH | Flying Health Incubator GmbH | DocCheck Medical Services GmbH | In good Health |
|---|---|---|---|---|---|---|
| Strategy | **1. Strategic analysis and measures** | I-VI), a-b) key activities: no explicit reference | I-VI), a-b) key activities: no explicit reference | I-VI), a-b) key activities: no explicit reference | I-VI), a-b) key activities: no explicit reference | I-VI), a-b) key activities: no explicit reference |
| | **2. Materiality** | I, II a-b) no specific reference identifiable | I, II a-b) no specific reference identifiable | I, II a-b) no specific reference identifiable | I, II a-b) no specific reference identifiable | I, II a-b) no specific reference identifiable |
| | **3. Objectives** | I-VI a-b) no explicit objectives are declared | I-VI a-b) no explicit objectives are declared | I-VI a-b) no explicit objectives are declared | I-VI a-b) no explicit objectives are declared | I-VI a-b) no explicit objectives are declared |
| | **4. Depth of the value chain** | II b) internal and external value creation | II b) internal and external value creation | II b) value creation in terms of start-up support / Incubator | I, II b) online services | I, II b) online services / face-to-face |
| Process management | **5. Responsibility** | II b) with the three managing directors | II b) with both managing directors | II b) with both managing directors | II b) no explicit reference | II b) treating and executing doctor |
| | **6. Rules and processes** | c) no internal view accessible | c) no internal view accessible | c) no internal view accessible | c) no internal view accessible | c) no internal view accessible |
| | **7. Control** | no internal view accessible | no internal view accessible | no internal view accessible | no internal view accessible | no internal view accessible |
| | **8. Incentive systems** | V) no explicit reference | V) no explicit reference | V) no explicit reference | V) no explicit reference | V) no explicit reference |
| | **9. Stakeholder participation** | V) no explicit reference | V) no explicit reference | II), V) no explicit reference | II), V) no explicit reference | II), V) yoga studios |
| | **10. Innovation- and product management** | I) VI) development concept in the technological sense | I) VI) continuous technical development | I), VI) continuous technical development | I), VI) continuous technical development | I), VI) first online training |
| Environment | **11. Use of natural resources** | II) preferably none | II) if possible none | II) little | II) little | II) little |
| | **12. Resource management** | II) no explicit reference | II) no explicit reference | II) not recognizable | II) no explicit reference | II) no explicit reference |
| | **13. Climate relevant emission** | II) no explicit reference | II) no explicit reference | II) no explicit reference | II) no explicit reference | II) no explicit reference |
| Society | **14. Employee rights** | no explicit reference | no explicit reference | no explicit reference | no explicit reference | no explicit reference |
| | **15. Equal rights** | no explicit reference | no explicit reference | VI) no explicit reference | VI) DNA Career laboratory | VI b) no explicit reference |
| | **16. Training** | no explicit reference | no explicit reference | VI) no explicit reference | VI) DNA Career laboratory, I b) CME | I b) external |
| | **17. Human rights** | no explicit reference | no explicit reference | no explicit reference | no explicit reference | no explicit reference |
| | **18. Community** | II b) partnerships and alliances | II, VI b) partnerships and alliances in 24 cities in Germany | II b) partnerships with 9 industrial organizations | I b), VI b) job market, DNA Career laboratory | I b), VI b) partnerships |
| | **19. Political influence** | no explicit reference | no explicit reference | no explicit reference | no explicit reference | no explicit reference |
| | **20. Law & directive-compliant behaviour** | II b) partnerships and alliances | V b) member of the Federal Association for Internet Medicine | II) board of directors of the Federal Association for Internet Medicine | V) no explicit reference | no explicit reference |

 

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# Research Paper

## Wealth effects of corporate spin-offs – An event study analysis of the chemical and pharmaceutical industry

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The present article studies wealth effects of global spin-off announcements of the chemical and pharmaceutical industry that were announced between January 2001 and October 2019. The cumulative average abnormal return over the 3-day event window is 3.91%. This result is significant at the 0.1%-level. Moreover, varying the event-window and utilizing a second statistical approach strongly supports these findings by yielding similar results at a 0.2% significance level which is rare for the event study methodology. This study strongly corroborates the hypothesis that wealth effects associated with spin-off announcements are very strong in the chemical and pharmaceutical industry.

## 1 Introduction

It has been widely proven in literature that spin-offs and spin-off announcements cause an increase of the shareholder value (see, e.g. Veld and Veld-Merkoulova, 2009; Veld and Veld-Merkoulova, 2004). The positive effects of spin-off announcements have been proven by several event studies focusing on the analysis of abnormal stock returns. Thus, different researchers who mainly focused on the US market provided evidence that, on average, the announcement of a spin-off causes significantly positive abnormal returns (Rosenfeld, 1984). Nevertheless, a small number of studies analysing the European market (Sudarsanam et al.,1996; Veld and Veld-Merkoulova, 2004) show similar results. Thus, much more research is required to validate these results. However, some studies have proven that the height of wealth effects defined as abnormal stock price reactions varies among several industries based on the circumstance that the effect of diversification on performance is not homogeneous across industries (Santalo and Becerra, 2008; Vollmar, 2014). These findings, the large number of spin-off announcements in the chemical and pharmaceutical industry and the high degree of diversification, give reason to separately investigate spin-off announcements of the chemical and pharmaceutical industry. Therefore, the present article sheds light on the spin-off-based wealth effects within the chemical and pharmaceutical industry.

Spin-offs are defined as pro-rata distribution of the shares of a firm's subsidiary to the shareholders of the parent company (Veld and Veld-Merkoulova, 2004). Moreover, spin-offs are legally and economically independent companies (Ernst et al., 2005). Over the last decades diverse spin-off definitions arose in literature. Table 1 provides an overview of these definitions.

The definition spin-off can be reduced to the following five deliverables (Smolnik, 2020).

 

1. Divestment of a subsidiary:
   Separation of subsidiary/corporate division.
2. Legal and economic independence:
   Spin-off is an independent legal entity and affects own market performance.
3. Continuance of parent company:
   After creating a spin-off, the parent company has to persist.
4. Pro-rata distribution of shares:
   The shares are distributed pro-rata to the shareholders of the parent company.
5. Absence of cash transactions:
   Divestment of assets without cash transactions.

**Table 1 Overview of spin-off definitions (own representation).**

| Researcher | Spin-off definition |
|---|---|
| Hite and Owers (1983) | *"Spin-offs are by their very nature the mirror image of mergers. [...]. A spin-off, by contrast, results in the creation of an independent firm with a corresponding reduction in the asset base of the divestor. The assets divested may be transferred to a newly organized and incorporated firm whose shares are distributed to the original shareholders of the divestor firm. Alternatively, the divestor may transfer the stock of an incorporated subsidiary to its shareholders. In either case, the distribution of the unit's shares is on a pro-rata basis to the original stockholders."* |
| Miles and Rosenfeld (1983) | *"A spin-off occurs when a company distributes all of the common shares it owns in a controlled subsidiary to its existing shareholders, thereby creating a separate public company."* |
| Schipper and Smith (1986) | *"In a spin-off, distinct equity claims of a wholly-owned subsidiary are distributed (pro-rata) to the consolidated entity's shareholders and begin to trade in public equity markets."* |
| Krishnaswami and Subramaniam (1999) | *"A corporate spin-off is one of several ways in which a firm may divest a division and improve its focus. A spin-off is a pro-rata distribution of the shares of a firm's subsidiary to the shareholders of the firm. There is neither a dilution of equity nor a transfer of ownership from the current shareholders. After the distribution, the operations and management of the subsidiary are separated from those of the parent. Spin-offs constitute a unique mode of divesting assets since they involve no cash transactions."* |
| Gertner et al. (2002) | *"In a spin-off, the parent company establishes one of its divisions as a new publicly traded company and distributes the shares of this company to the parent's existing shareholders. It is almost always structured as a tax-free transaction with no cash flow implications to the parent, spin-off, or shareholders."* |
| Veld and Veld-Merkoulova (2004) | *"A spin-off is a pro-rata distribution of the shares of a firm's subsidiary to the shareholders of the company. No cash transaction takes place. After the spin-off, the shareholders of the parent company hold shares in both the parent company and the subsidiary."* |

 

As previously mentioned, wealth effects of spin-off announcements have been mainly analyzed in the US. These analyses have shown that spin-off announcements result in cumulative abnormal returns of up to 5.56% (Rosenfeld, 1984). Thus, the highly positive abnormal returns represent the shareholder's expectation of future benefits which are based on the spin-off announcement. Additionally, some studies of spin-off announcements in the European market exist which are in line with the findings of the US market analyses (Sudarsanam et al., 1996). Table 2 gives an impression as to how spin-off announcements affect the shareholder-value by displaying the results of several event studies (for a more comprehensive list of event studies on the wealth effects of spin-off announcements (Smolnik, 2020). Event studies usually analyse short-term wealth effects for several reasons.

The main reason focuses on the increasing influence of automated trading systems. Nowadays a majority of stock market transactions is based on automated trading systems and therefore most shares are sold within a two-day time window (Huang, et al., 2019).

**Table 2 Overview of the wealth effects of spin-off announcements based on the event study methodology. (source: Smolnik (2020); Veld and Veld-Merkoulova (2009); Vollmar (2014).)**

| Researcher | Country | Research period | Observations | Event window | CAAR [%] |
|---|---|---|---|---|---|
| Schipper and Smith (1983) | US | 1963–1981 | 93 | [-1;0] | 2.84*** |
| Hite and Owers (1983) | US | 1963–1981 | 123 | [-1;0] | 3.30*** |
| Miles and Rosenfeld (1983) | US | 1963–1980 | 55 | [0;1] | 3.34*** |
| Rosenfeld (1984) | US | 1963–1981 | 35 | [-1;0] | 5.56*** |
| Kudla and McInish (1988) | US | 1972-1981 | 39 | [-7;0] | 3.3* |
| Ball et al. (1993) | US | 1968–1990 | 39 | [-1;0] | 2.55[n.r.] |
| Slovin et al. (1995) | US | 1980–1991 | 37 | [0;1] | 1.32** |
| Chemmanur and Paeglis (2000) | US | 1991-1998 | 19 | [-5;5] | 2.70[n.s.] |
| Bühler (2000) | Europe | 1989-1999 | 42 | [-1;1] | 2.60*** |
| Alli et al. (2001) | US | 1984-1994 | 47 | [-1;1] | -1.05[n.s.] |
| Schauten et al. (2001) | UK | 1989–1996 | 23 | [-1;1] | 2.13[n.r.] |
| Kirchmaier (2003) | Europe | 1989–1999 | 48 | [-1;1] | 3.07*** |
| Bühner (2004) | Europe | 1991-2001 | 39 | [-1;1] | 2.27*** |
| Sin and Ariff (2006) | Malaysia | 1986–2002 | 85 | [-1;1] | 1.80* |

Notes: This table presents the cumulative average abnormal stock returns around the announcement dates of spin-offs.
[n.s.] Not significant for this event window; [n.r.] Significance level is not reported for this event window;
***Significance at the 1% level; **Significance at the 5% level; *Significance at the 10% level.

 

Thus, a large number of factors that can probably explain the wealth effects of spin-off announcements have been identified. Extensive empirical research has shown that an increase in diversification results in equities that are traded at a discount (Mansi and Reeb, 2002). Separating from a corporate division is the simplest way to decrease a company's diversity and therefore avoid the diversification discount. Consequently, spinning-off a division with the aim to narrow the industrial focus could culminate in positive stock price reactions. Daley, Mehrotra, and Sivakumar (1997), Desai and Jain (1999) and Krishnaswami and Subramaniam (1999) analyzed this relationship and found that abnormal returns for firms that want to increase their industrial focus by spinning-off a division are significantly higher than for spin-offs which are not executed to narrow the industrial focus.

A second factor focuses on the improvement of the geographical focus. Thus, spinning-off a division abroad increases the company's geographical focus. However, researchers advance two antithetic views. While some researchers hypothesize a positive correlation between improving the geographical focus and abnormal returns, other researchers opine that narrowing the geographical focus by spinning-off a division negatively affects the abnormal returns (Bodnar, Tang, and Weintrop, 1997; Veld and Veld-Merkoulova, 2004). The positive effects should be based on the reduction of complexity and the decrease of risks, whereas the hypothesised negative effect should be rooted in the reduction of economies of scale, disadvantages with the competitors and the signal that the firm is not willing to expand (Bodnar et al., 1997; Boer et al., 2002; Hitt, et al., 1997). Until now the effect of narrowing the geographical focus on the abnormal returns is not enlightened because empirical results are as ambiguous as the hypotheses. Rüdisüli (2005) and Veld and Veld-Merkoulova (2004) could not prove a significantly positive relationship.

Furthermore, the hypotheses about the effect of the performance of the parent company on the abnormal returns are also diverse. One argumentation line contends that a positive market reaction follows the announcement of a spin-off, if there is a negative performance trend before the announcement. Thus Villalonga (2003) claims:

*"Considered together with the findings about diversification, the findings about refocusing seem to indicate that, when firms are outperformed by their competitors, any change in their current strategy is welcome by the stock market".*

For this reason, announcing to spin-off a division, while facing a negative performance trend, should cause positive stock price reactions. However, the second hypothesis claims that the market perceives a spin-off announcement from firms with negative performance trends as "cry for help" in an unwinnable situation (Bartsch and Börner, 2007). So far no empirical study has proven significantly positive correlations between performance indicators and abnormal returns (Bartsch and Börner, 2007; Vollmar, 2014).

Additionally, the size of the spin-off and the parent company is found to cause larger wealth effects (Slovin et al., 1995). Veld and Veld-Merkoulova (2009) states that "This result is in line with intuition, since the impact of spinning-off a large division can be expected to be bigger than the spin-off of a relatively small division". Moreover, the positive relationship could be based on the fact that larger companies and larger spin-offs create more attention because higher returns are expected. This effect is amplified by the fact that the equities of larger companies are traded more intensively.

Finally, the parent company's industrial sector could have an influence on the abnormal returns. Merely a few researchers analyzed the relationship between the industrial sector and the stock price reactions. Ostrowski (2008) and Stienemann (2003) could not identify dependencies of abnormal returns on the parent company's industrial sector. However, it was found that that the effect of diversification on performance is not homogeneous across different industries (Santalo and Becerra, 2008). This applies especially for the chemical and pharmaceutical industry which show a high complexity and degree of diversification (Hill and Hansen, 1991). This circumstance could be based on the unique characteristics of this industry which has been claimed as one of the most important sectors of the European economy (Chapman and Edmond, 2000). This industrial sector has been the most central focus of mergers and acquisitions activity since the 1980s which tend to be similar for the EU and the US market (Chapman and Edmond, 2000;

 

Walter, 1993). Simultaneously, over the last decades chemical and pharmaceutical firms raised prominence as target for investors and private equity firms based on its fragmented industry holding high opportunities and threats in terms of high stock price reactions (Bee and Chelliah, 2013). These findings can be directly transferred to the topic of spin-offs. Since general attractiveness and promising de-/investment strategy of the chemical and pharmaceutical industry has already been shown, spin-off announcements are expected to yield larger abnormal returns.

Nevertheless, more reasons exist as to why spinning-off a division is considered as trend-setting management tool. One of the most important characteristics of the chemical and pharmaceutical industry is "that it gave rise to many and diverse technologies which aimed at different markets, so that there are several sectors to be followed [...]" (Achilladelis, Schwarzkopf, and Cines, 1990). Thus, chemical and pharmaceutical industry is highly connected to other industries and therefore has a huge influence on several industrial sectors. This industry represents a high complexity due to a high durability in numerous industrial classification schemes. Simultaneously, it undergoes a high demand for changing products and processes driven by ever-decreasing product lifecycles (Festel, 2014). Therefore, global competitiveness rises and the divestment of non-core businesses to narrow the industrial focus and to concentrate management activities in addition to financial resources on focus areas is becoming an imperative (Dewdney and Smith, 1998). Especially the increasing shareholder pressure demanding steady maximization of the gross-margin by optimizing the diversification strategy with the aim to ensure corporate growth causes the necessity of creating sophisticated spin-offs (Carnahan et al., 2010). However, previous empirical results merely give first evidence but serve as a starting point for further investigation of the wealth effects within the chemical and pharmaceutical industry.

In this paper spin-offs of the chemical and pharmaceutical industry are studied to amplify and substantiate the insights on wealth effects as a result of spin-off announcements. The number of spin-offs steadily increases from 1995 onward and the number of spin-off announcements before 1995 is small (Veld and Veld-Merkoulova, 2004). Since data availability until 2001 is rare, the period from January 2001 to October 2019 is investigated within the present study. Choosing this time period additionally ensures the timeliness and relevance of the present study. Thus, the findings can serve as guideline to decide whether and at which moment chemical and pharmaceutical companies should be included in present stock portfolios.

## 2 Hypotheses

Based on the variables that are described in section 1 the following hypotheses are deduced. All these hypotheses are derived from either spin-off or divestiture literature. Thus, there is already existing evidence that these factors could hypothetically affect the abnormal return's height.

Hypothesis 1: The cumulative average abnormal return in consequence of spin-off announcements in the chemical and pharmaceutical industry equals zero.

Hypothesis 2: The abnormal return is independent of the year of the spin-off announcement.

Hypothesis 3: Improving the industrial focus by spinning off company divisions which do not apply for the core business, has no impact on the CAAR.

Hypothesis 4: Increasing the geographical focus by spinning-off company divisions abroad, has no effect on the CAAR.

Hypothesis 5: A correlation between the parent company's performance before the spin-off announcement and the CAAR height exists.

Hypothesis 6: A correlation between the parent company's size before the spin-off announcement and the CAAR height exists.

Hypothesis 7: No correlation between the spin-off's size and the CAAR height exists.

## 3 Data description and methodology

### 3.1 Data description

The present study comprises a sample of spin-off announcements of the chemical and pharmaceutical industry. Thus, a spin-off of the chemical and pharmaceutical industry is defined as spin-off in which a company of the chemical and pharmaceutical industry separates

 

from a specific division. The spin-off can be registered either in the same or in a different industrial sector. All spin-off announcements of the chemical and pharmaceutical industry are investigated irrespective of the operating country.

The sample contains all spin-off announcements from January 2001 to October 2019. The spin-off announcements are obtained from the Thomson Reuters Database, whereas exact announcement dates are derived from the investor relations of the respective parent company, since announcement dates in several databases are not accurate. Therefore, it is advised against using the exact dates from any database. It should better be assessed by the ad-hoc press releases of the respective companies which are published on the investor relations news. Data on stock prices, total assets, revenue, key performance indicators (KPI) and market indices are obtained from the Thomson Reuters Fundamentals Database. The market index chosen is the MSCI International World Price Index owing to its broad coverage of emerging markets (Neukirch, 2008). Classification of the industrial sector is based on the Global Industry Classification Standard (GICS®). GICS® codes are also derived from the Thomson Reuters database. The primary sample comprises 285 spin-off announcements of the chemical and pharmaceutical industry. However, a number of spin-off announcements had to be eliminated from the primary sample. Table 3 reports the reduction of the primary sample. First of all, the Databases sometimes list spin-off announcements several times. Therefore, double records have been identified and eliminated from the sample. Additionally, announcements where confounding events contaminate the event of interest were eliminated to ensure that stock price reactions are solely based on the spin-off announcement. The third reason why events

**Table 3 Reduction of the primary sample comprising spin-off announcements of the chemical and pharmaceutical industry. (source: in allusion to Vollmar, 2014).**

| Selection criterion | Definition | Adaption | Left |
|---|---|---|---|
| Total | - | | 285 |
| Double records | Events are stated multiple times are excluded from the sample. | -51 | 234 |
| No confounding events | If another event contaminates the spin-off announcements event window, the element is excluded from the sample. | -12 | 222 |
| Definition conform | The demerger needs to be conformed to the requirements of divestment of a subsidiary; legal and economic independence; continuance of parent company; pro-rata distribution of shares and absence of cash transactions. | -27 | 195 |
| Detectability of announcement date | The announcement date is the day on which the information is primary published. Since, most announcement days of any database show great differences in comparison to the real ad-hoc announcement, data are doublechecked with the company's investor relations data. If the day cannot be defined exactly, the element is excluded from the sample. | -110 | 85 |
| Availability of stock prices | Stock prices are obtained from the *Thomson Reuters* database. If no information is available, the element is excluded from the sample. | -49 | **36** |

 

are removed from the primary sample is that in some cases the spin-off did not conform the definition.

Moreover, spin-off announcements are excluded from the primary sample if the exact announcement date could not be identified, or no stock-price information are available for the parent company. The final sample contains 36 spin-off announcements of the chemical and pharmaceutical industry.

The final sample shows a large representation of spin-off announcements in the United States (US) with 18 observations (50%) which is based on two reasons. On the one hand, the US generally shows the highest number of spin-off announcements over all industries. On the other hand, the availability of stock price information and the detectability of the exact announcement date is more accurate in comparison to Eastern Europe and Asian regions (cf. Thomson Reuters Database). Moreover, Finland and the Netherlands are represented with three observations (8.5%), whereas Switzerland, Germany and Norway comprise two observations (6%) respectively. Out of these 36 spin-off announcements, six (17%) were announced in 2015 and five (14%) were announced in 2018 and 2019 respectively. A steady increase of spin-off announcements over the last two decades can be recorded and therefore the rising trend of spin-offs as strategic management and divestment tool (Wan, et al., 2011) can be proven.

## 3.2 Proxies

All variables that are utilized in the present study are related to the hypotheses listed in section 2.

Industrial focus

Narrowing the industrial focus is measured by using a dummy variable. The variable counts 1 if the GICS® code of the spin-off varies from the GICS® code of the parent company. The variable is 0 if both have the same GICS® code. The GICS® code is used because all observed companies trying to improve industrial focus spin-off a division that acts also in the chemical and pharmaceutical industry but in a subcategory. The GICS® code enables to detect these changes in industrial focus.

Geographical focus

An increase of the geographical focus can be measured by introducing a dummy variable. This variable is 1 if the headquarter of the spin-off is domiciled in a foreign country. The variable values 0 if the parent company's headquarter and the spin-off's headquarter are in the same country.

Size of parent company and spin-off

The size of the parent company has been measured by utilizing two variables. These two variables comprise the total assets and the revenue of the preceding account period before the spin-off announcement. Both variables are obtained from the Thomson Reuters Fundamentals.

Performance of parent company

The performance of the parent company is measured by two variables. The first variable is the Return on Assets (RoA) which has been widely proven as strong performance indicator (Selling and Stickney, 1989). The RoA is obtained from Thomson Reuters Fundamentals. The second variable is the change in RoA (the two preceding periods are taken as basis). This variable allows to monitor the current performance of the parent company right before the spin-off announcement.

## 3.3 Methodology

The wealth effects of spin-off announcements are measured using an event study methodology in the style of Hite and Owers (1983) and Miles and Rosenfeld (1983). Some adaptions and extensions are implemented in order to improve statistical power, validity and therefore explanatory power. However, the general calculation remains the same. The abnormal returns that represent market response to specific information measure all changes in shareholder value induced by the observed event (Fama et al., 1969). The abnormal return (AR) is the difference between the actual return (R) and the expected return (ER) based on the regression model (Campbell et al., 1997). Subsequently, the ARs of all of the days in the event window are cumulated and divided by the number of event days to calculate the cumulative abnormal return (CAR). Since most event studies analyse samples of more than one sample element, the cumulative average abnormal return (CAAR) is calculated by dividing the sum of all CARs by the number of sample

 

elements. Since the sample covers a wide time frame with expansive and recessive market phases and also comprises a huge variety of companies, the actual return on average over the investigated event window equals zero.

$$CAR(t_1, t_2) = \sum_{t=t_1}^{t_2} AR_{i,t} \quad (1)$$

$$CAAR(t_1, t_2) = \frac{1}{n} \sum_{i=1}^{n} CAR(t_1, t_2) \quad (2)$$

$$AR_{i,t} = R_{i,t} - ER_{i,t} \quad (3)$$

Statistical model

In comparison to most event studies on wealth effects of spin-off announcements the present study consults the results of two separate statistical models in order to validate the findings. Thus, results of the market model and the market adjusted model are considered. The market model introduced by Sharpe (1963) is the most prominent statistical model for event studies. This statistical approach assumes a linear correlation between the company's return and the return of the market portfolio. In order to calculate the regression parameters an estimation window which does not overlap with the event window needs to be defined (Strong, 1992). In addition to the market model, the market adjusted model is utilized to verify the results of the market model and to improve the explanatory power of the present study. The market adjusted model postulates that the expected returns of the sample elements equal the returns of the market model (Campbell et al., 1997). For this reason, the necessity of defining an estimation window can be avoided. Both models on its own already demonstrably show a high statistical power (Brown and Warner, 1985; MacKinlay, 1997; Strong, 1992) but considering the results of both models increases the validity of the present findings.

Estimation window

Contrary to Hite and Owers (1983) which used a 200-day estimation window, within the present study a 250-day estimation window is defined as basis for the calculation of the regression parameters for the market model. The decision of adapting the estimation window for the market model is based on empirical results which demonstrate that a 250-day estimation window ensures stable model parameters and therefore the conduction of an appropriate regression analysis (MacKinlay, 1997). Thus, the regression parameters can be seen as market and risk adjusted (Brown and Warner, 1980).

Event window

The present work aims to provide for all contingencies by covering a wide range of event windows. These contingencies comprise the incorporation of information leaks about the event and deferred market reactions regarding the observed event (Acquisti, Friedman, Telang, and Alessandro Acquisto, 2006). Therefore, the event windows of [0], [-1;0], [0;1] and [-1;1] are used in this study.

Statistical/Significance tests

In contrast to most event studies, within this work two significance tests are conducted. Since Harrington and Shrider (2007) proved that merely about 5% of all event studies contain tests that are robust to cross-sectional variation, results of a parametric and a non-parametric test are compared. The parametric test is the Cross-sectional test and the non-parametric test is the Wilcoxon signed rank test. The Cross-sectional test is conducted as described in, e.g. Boehmer, Masumeci, and Poulsen, 1991, whereas the Wilcoxon signed rank test is applied to the present data sample as described in, e.g. Wilcoxon (1945) and Wilcoxon (1947). Blair and Higgins (1980) demonstrated that the Wilcoxon signed rank test perfectly complements parametric tests, such as the Cross-sectional test. Thus, conducting both significance tests and comparing the results strengthens the explanatory power of the present event study findings.

Moreover, the significance of the impact factors presented within section 1, are tested by a multiple linear regression analysis and the WELCH-test. Multiple linear regression analysis is a well-proven and commonly used tool for assessing the impact of several factors on the dependent variable (Myers and Myers, 1990). In this case the dependent variable is the abnormal return. However, the WELCH-test methodology is used because of its well-founded results for samples with a high variance heterogeneity (Tomarken and Serlin, 1986) and is conducted as described in, e.g. Welch (1947).

 

# 4 Results

## 4.1 Wealth effects

Table 4 summarises the event study results for the whole sample of spin-off announcements of the chemical and pharmaceutical industry. The results show a cumulative average abnormal return of 3.91% for the event window from day -1 to day 1 within the market model. This result is significant at the 0.1%-level. These findings are proven by the market adjusted model which shows a cumulative average abnormal return of 3.62% for the same event-window which is also significant at the 0.1%-level. The abnormal returns for the other event windows are also significantly positive at the 0.1%-level.

This is a strong factor proving the validity of the present study, since many event studies can merely show one significant result for one single event window (Rosenfeld, 1984). However, these results are also confirmed by the non-parametric Wilcoxon signed rank test displaying a significance level of 2% for all event windows. Therefore, the present findings can be considered valid and hypothesis 1 can be declined.

**Table 4 Cumulative average abnormal returns of spin-off announcements of the chemical and pharmaceutical industry from January 2001 to October 2019 (own representation).**

| **Panel 1: Market model** N=36 | Event window | | | |
|---|---|---|---|---|
| | [0] | [0;1] | [-1;0] | [-1;1] |
| **CAAR** | **2.99%** | **3.70%** | **3.20%** | **3.91%** |
| Median CAR | 2.03% | 2.76% | 3.16% | 3.08% |
| Cross-sectional test(t-value) | 4.55*** | 4.53*** | 4.10*** | 4.35*** |
| Wilcoxon signed rank test (z-value) | 3.08** | 3.03** | 2.70* | 2.97** |
| Min. | -3.12% | -4.10% | -5.33% | -6.82% |
| Max. | 13.35% | 18.94% | 15.20% | 18.84% |
| Percentage positive | 86.11% | 83.33% | 75.00% | 86.11% |
| **Panel 2: Market adjusted model** N=36 | Event window | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] |
| **CAAR** | **2.95%** | **3.54%** | **3.03%** | **3.62%** |
| Median CAR | 1.92% | 2.35% | 2.50% | 2.49% |
| Cross-sectional test(t-value) | 4.43*** | 4.28*** | 3.80*** | 3.94*** |
| Wilcoxon signed rank test (z-value) | 2.94** | 2.92** | 2.66* | 2.91** |
| Min. | -4.53% | -6.61% | -7.54% | -9.62% |
| Max. | 13.31% | 18.39% | 13.57% | 18.64% |
| Percentage positive | 77.78% | 83.33% | 77.78% | 83.33% |

Cumulative average abnormal returns (CAARs) for the whole sample of chemical and pharmaceutical industry from January 2000 to October 2019. Spin-off announcements are derived from the Thomson Reuters Database, whereas exact dates are identified from the investor relation homepage of the respective company. Abnormal returns are based on both market model and market adjusted model to validate the results. The market model comprises a 250-day estimation window. Significance of the results is tested by a cross-sectional test (parametric) and Wilcoxon signed rank test (non-parametric). The null-hypothesis for the significance tests is $H_0$: $CAAR_{t(1)-t(2)} = 0$. Asterisks indicate significance at the 2% (*), 1% (**) and 0.2% (***) level.

 

Finding 1: *Spin-off announcements of the chemical and pharmaceutical industry can be associated with significantly positive abnormal returns.*

The present findings are in line with the previous results for the European and American market.

Furthermore, the first tendencies showing that especially the chemical and pharmaceutical industry shows high abnormal returns for spin-off announcements are supported by the present findings. In comparison to the abnormal returns calculated over all industries (c.f. Table 2), the chemical and pharmaceutical industry yields higher abnormal returns with merely one exception (Rosenfeld, 1984). Therefore, it can be assumed that spin-off announcements of the chemical and pharmaceutical industry raise higher expectations in terms of future stock price performance in comparison to other industries. This circumstance could be due to the characteristics of the chemical and pharmaceutical industry. These characteristics comprise the facts that the chemical and pharmaceutical industry is one the most prominent in America and Europe, that this special industry has many other industries to be followed and that this industry is already of major interest as target for investors and private equity firms (Bee and Chelliah, 2013; Chapman and Edmond, 2000). This favoured position mainly based on the high opportunities in terms of higher-than-average returns (Scherer, 1993), draws interest of many investors. These promising opportunities are accompanied by high threats (Bee and Chelliah, 2013) which are often neglected given the potential of high market returns. However, in the case of spin-off announcements, the likelihood of surpassing returns for an investor is high when relying on the chemical and pharmaceutical industry. These findings are strongly in line with the topic of mergers and acquisitions, since this industrial sector has been the most central focus of mergers and acquisitions activity from the 1980s on and therefore offers the same surpassing opportunities (Chapman and Edmond, 2000; Walter, 1993). Nevertheless, further research is needed to detect the reasons why especially spin-off announcements in the chemical and pharmaceutical industry cause higher investor expectations. Although the present study provides first evidence on the effects of several impact factors by using multiple linear regression analysis and the WELCH-test, more research is required to, e.g. investigate the relationship of the different factors affecting the abnormal return‘s height.

Since it has already been shown that spin-off announcements of chemical and pharmaceutical companies cause significantly positive cumulative average abnormal returns and the present study comprise 50% US spin-off announcements, it can be assumed that abnormal returns are independent of the country of spin-off announcement. For this reason, the present study does not contain an analysis on the influence of the country of the parent company.

Positive cumulative average abnormal returns are found for every year in which minimum two spin-off announcements of the chemical and pharmaceutical industry took place. This is highly in line with the previous findings on the US and European market (Vollmar, 2014).

Finding 2: *The abnormal return‘s height is independent from the year of spin-off announcement.*

Several years are excluded from the analysis owing to a lack of observations. Additionally, some years do not show significant positive results which could be based on the fact that many years contain merely two spin-off announcements which decreases the statistical power of the test. This circumstance cannot be avoided when focusing on solely one industry because the number of observations is consequently smaller. Table 5 displays the abnormal returns for the years of the observations period separately. However, abnormal returns of up to 8.39% in 2016 and 6.74% in 2019 for the event window from day -1 to day 1 which is significant at the 5%-level support the general findings of high stock price reactions of chemical and pharmaceutical companies (Scherer, 1993).

 

**Table 5 Cumulative average abnormal returns of spin-off announcements of the chemical and pharmaceutical industry for specific years (own representation).**

| Panel 1: 2002 N=2 | Event window | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Market model | | | | Market adjusted model | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] | [0] | [0;1] | [-1;0] | [-1;1] |
| CAAR | 6.09% | 3.81% | 6.07% | 3.78% | 6.66% | 5.11% | 6.23% | 4.68% |
| **Panel 2: 2004 N=2** | **Event window** | | | | | | | |
| | Market model | | | | Market adjusted model | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] | [0] | [0;1] | [-1;0] | [-1;1] |
| CAAR | 1.44% | 0.65% | 1.80% | 1.02% | 1.36% | 0.78% | 1.35% | 0.77% |
| **Panel 3: 2005 N=2** | **Event window** | | | | | | | |
| | Market model | | | | Market adjusted model | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] | [0] | [0;1] | [-1;0] | [-1;1] |
| CAAR | 3.84% | 3.30% | 3.29% | 2.75% | 4.02% | 3.49% | 3.43% | 2.90% |
| **Panel 4: 2012 N=2** | **Event window** | | | | | | | |
| | Market model | | | | Market adjusted model | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] | [0] | [0;1] | [-1;0] | [-1;1] |
| CAAR | 0.14% | 0.94% | -0.22% | 0.57% | 0.23% | 1.49% | -0.28% | 0.98% |
| **Panel 5: 2013 N=3** | **Event window** | | | | | | | |
| | Market model | | | | Market adjusted model | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] | [0] | [0;1] | [-1;0] | [-1;1] |
| CAAR | -0.14% | 3.81% | -1.00% | 2.94% | 0.09% | 4.22% | -0.79% | 3.35% |
| **Panel 6: 2015 N=7** | **Event window** | | | | | | | |
| | Market model | | | | Market adjusted model | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] | [0] | [0;1] | [-1;0] | [-1;1] |
| CAAR | 3.87% | 3.02% | 3.94% | 3.09% | 4.27% | 3.42% | 4.32% | 3.47% |
| **Panel 7: 2016 N=3** | **Event window** | | | | | | | |
| | Market model | | | | Market adjusted model | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] | [0] | [0;1] | [-1;0] | [-1;1] |
| CAAR | 5.14% | 7.29% | 6.24% | 8.39% | 5.31% | 7.10% | 6.00% | 7.78% |
| **Panel 8: 2018 N=5** | **Event window** | | | | | | | |
| | Market model | | | | Market adjusted model | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] | [0] | [0;1] | [-1;0] | [-1;1] |
| CAAR | 1.76% | 1.59% | 0.83% | 0.64% | 1.21% | 0.68% | 0.18% | -0.34% |

 

**Table 5 continued**

| Panel 9: 2019 N=5 | Event window | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Market model | | | | Market adjusted model | | | |
| | [0] | [0;1] | [-1;0] | [-1;1] | [0] | [0;1] | [-1;0] | [-1;1] |
| **CAAR** | **2.67%** | **5.81%** | **3.59%** | **6.74%** | **2.11%** | **4.89%** | **3.25%** | **6.04%** |

Cumulative average abnormal returns (CAARs) for each year of the sample of chemical and pharmaceutical spin-off announcements from January 2001 to October 2019. Spin-off announcements are derived from the Thomson Reuters Database, whereas exact dates are identified from the investor relation homepage of the respective company. Abnormal returns are based on both market model and market adjusted model to validate the results. The market model comprises a 250-day estimation window. Significance of the results is tested by a cross-sectional significance test (2008). Years 2013 and 2016 their low sample size.

These high returns which can be expected from spin-off announcements persuade investors to take the initiative risk and buy shares of chemical and pharmaceutical firms that want to spin-off a specific division. In consideration of the fact that maximum 22.5% of the chemical and pharmaceutical spin-off announcements (c.f. Table 4) for the event window comprising day 0 yield negative abnormal returns the risk of loss can be considered small. The fact that nearly all cumulative average abnormal returns are positive highly corroborates the conclusion based on the results of the whole sample. Thus, the conclusion contains the recommendation for investors to evaluate the possibility of integrating spin-off announcing company's stocks into current stock portfolios and investment funds. In order to validate and support this conclusion a long-term event study on the sustained effects of these companies is required.

## 4.2 Impact factors

In Table 6 the event study results are presented for companies which try to improve either the industrial focus or the geographical focus by spinning-off a specific division. In panel 1 the cumulative average abnormal returns for companies that want to increase the industrial focus by separating from a division and for firms that do not want to increase the industrial focus are compared. It is shown that 18 firms pursue the goal to increase the industrial focus by spinning-off a division that works in another market. In contrast 18 companies do not intend to narrow their industrial focus in an analogous manner. Nevertheless, it should not be withheld that all 18 focus-increasing companies spin-off a division that are registered in a subcategory of the chemical and pharmaceutical industry. The GICS® code enables to detect these differences, since it also incorporates information on the sub-industrial registration of companies.

Since all focus-increasing companies solely announce spin-offs that will be registered in cognate industrial sectors, the focus-increasing effect is small. Therefore, the perception of an improvement of the industrial focus is weaker when a pharmaceutical company separates from a biotechnological company in comparison to a mining company that spins-off a real estate agency.

This is probably the main reason, why no significant differences between focus-increasing and non-focus increasing companies can be identified. The cumulative average abnormal returns of both sub-samples are very similar and thus the marginal differences that value from -0.73% to 0.64% are not significant. Consequently, hypothesis 3 can be rejected, as the aim of improving the industrial focus has no significant effect on the abnormal returns.

 

**Table 6 Comparison of cumulative average abnormal returns of companies that try to improve the geographical/industrial focus with non-focus increasing companies (own representation).**

| Panel 1: Industrial focus | Market model | | | | Market adjusted model | | | |
|---|---|---|---|---|---|---|---|---|
| **Event window** | CAAR ind. foc. [0] N=18 | CAAR ind. foc. [1] N=18 | CAAR difference | t-value | CAAR ind. foc. [0] N=18 | CAAR ind. foc. [1] N=18 | CAAR difference | t-value |
| [0;1] | 4.06% | 3.33% | -0.73% | -0.45 | 3.67% | 3.42% | -0.25% | -0.15 |
| [-1;0] | 3.37% | 3.03% | -0.35% | -0.22 | 2.78% | 3.28% | 0.50% | 0.32 |
| [-1;1] | 4.16% | 3.66% | -0.50% | -0.28 | 3.30% | 3.94% | 0.64% | 0.35 |
| **Panel 2: Geographical focus** | **Market model** | | | | **Market adjusted model** | | | |
| **Event window** | CAAR geo. foc. [0] N=32 | CAAR geo. foc. [1] N=4 | CAAR difference | t-value | CAAR geo. foc. [0] N=32 | CAAR geo. foc. [1] N=4 | CAAR difference | t-value |
| [0] | 2.90% | 3.71% | 0.81% | 0.56 | 2.88% | 3.51% | 0.63% | 0.42 |
| [0;1] | 3.68% | 2.91% | -0.78% | -0.45 | 3.56% | 3.21% | -0.35% | -0.17 |
| [-1;0] | 3.21% | 1.84% | -1.37% | -0.92 | 2.89% | 2.60% | -0.29% | -0.17 |
| [-1;1] | 4.00% | 3.80% | -0.20% | -0.09 | 2.86% | 3.93% | 1.07% | 0.51 |

CAAR [0] and CAAR [1] corresponds to narrowing [1] or not narrowing [0] the focus of the respective factor. Spin-off announcements are derived from the Thomson Reuters Database, whereas exact dates are identified from the investor relation homepage of the respective company. Abnormal returns are based on both market model and market adjusted model to validate the results. The market model comprises a 250-day estimation window. Significance of the results is tested by a WELCH-test. Thus, t-values show the results of the WELCH-test. Industrial classification is based on the (GICS®). Asterisks indicate significance at the 5% (*), 2.5% (**) and 1% (***) level.

Finding 3: *Aiming to improve the industrial focus by separating from a specific division has no significant effect on the abnormal return's height.*

Thus, it can be hypothesized that the higher the difference of the spin-off's industrial sector to the core business of the parent company, the more positive is the shareholders' response to a spin-off announcement. This hypothesis is in line with the findings of Daley et al., (1997), Desai and Jain (1999) and Krishnaswami and Subramaniam, (1999) who identified positive effects of the aim to improve the industrial sector by analysing solely the main industrial sectors according to the SIC code.

In panel 2 of Table 6 the abnormal returns of firms that increase their geographical focus by spinning off a company abroad and companies that do not want to narrow their industrial focus are compared. The geographical focus-increasing subsample comprises 32 spin-off announcements, whereas the non-increasing subsample merely contains 4 observations. However, the sub-sample of focus-increasing companies is associated with a mean cumulative average abnormal return of 3.06% over all event-windows and the non-focus increasing subsample exhibits a mean cumulative average

 

abnormal return of 3.45% averaged over all event windows based on the market model. The market adjusted model shows similar results, as the mean cumulative average abnormal return is 3.05% for the companies that aim to increase the geographical focus and 3.31% for the firms that do not want to narrow the geographical focus. Therefore, hypothesis 4 can be seen corroborated.

Finding 4: *The aim to improve the geographical focus by spinning-off a foreign subsidiary has no significant effect on the abnormal return's height.*

These findings are in line with the results of Rüdisüli (2005) and Veld and Veld-Merkoulova (2004), who also could not find significant effects of changing the geographical focus on the abnormal returns. This could be based on the fact that the negative effects outweigh the positive effects. On the one hand, trying to increase the geographical focus creates the impression that the parent company is not willing to take initiative risks and expand to foreign markets (Bodnar et al., 1997; Boer et al., 2002). This behaviour represents a conservative corporate strategy, which is often associated with a decelerated company growth and constant but lower stock price amplitudes. On the other hand, by increasing the geographical focus risks can be minimized, complexity can be controlled and the cross-subsidization of company divisions abroad can be avoided (Hitt et al., 1997).

Table 7 presents the results of the regression analysis of factors that could potentially affect the abnormal returns. Unfortunately, some variables are only available for a limited number of observations of the sample. Especially, the variable spin-off size shows a lack of data. Therefore, merely 23 observations are incorporated into the regression analysis. The reason for this circumstance is that this variable is only available if the spin-off is already completed and spin-off size is deposited in the Thomson Reuters Database.

The first regression analysis presented in panel 1 and 2 of Table 7 shows that the parent company's performance has no significant regression coefficient, neither associated with the independent performance, which was measured by incorporating the RoA nor associated with the relativized performance analyzed by the change in RoA. The regression coefficient values nearly zero and is very similar for the market model and the market adjusted model. Hypothesis 5 therefore needs to be rejected.

Finding 5: *The parent company's performance previous to the spin-off announcement has no effect on the abnormal return's height.*

Similar to the factor of narrowing the geographical focus it can be assumed that negative and positive effects that accompany with the parent company's performance equalise each other.

The positive effects that are based on capital markets rewarding the corporate strategy adaption of weak performing firms in terms of announcing to spin-off a division (Villalonga, 2003), is countervailed by the perception of spin-off announcements as "cry for help" in an unwinnable situation of these firms (Bartsch and Börner, 2007). These findings are congruent with the previous results of Bartsch and Börner (2007) and Vollmar (2014). To date there is no evidence showing that a significant relationship between the parent company's performance and the abnormal returns exists. However, it again needs to be mentioned that all these studies have analyzed all industrial sectors, whereas the present study focuses solely on the chemical and pharmaceutical industry, which is already an industry with high margins and special characteristics, which are mentioned in section 1. This result again constitutes the necessity for further analysis of impact factors besides the regression analysis.

In panel 3 and 4 of Table 7 the influence of the parent company's size on the height of the abnormal returns is demonstrated. Similar to the regression analyses in the first two panels, the regression coefficient is not significant. This result is proven by both statistical models and over all event windows. For both variables the regression coefficients are nearly equal zero. This applies to both statistical models as well as for all event windows. Consequently, hypothesis 6 is rejected.

 

**Table 7 Regression analyses of impact factors for spin-off announcements (own representation).**

**Panel 1: Parent company's performance RoA% (N=33)**

| | Market model | | | | | Market adjusted model | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Event window** | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ |
| [0] | 0.0332 | -0.0002 | -0.18 | 0.0021 | -0.0291 | 0.0357 | -0.0004 | -0.35 | 0.0070 | -0.0240 |
| [0;1] | 0.0361 | 0.0000 | -0.02 | 0.0000 | -0.0312 | 0.0397 | -0.0003 | -0.20 | 0.0030 | -0.0282 |
| [-1;0] | 0.0352 | -0.0001 | -0.04 | 0.0001 | -0.0311 | 0.0367 | -0.0003 | -0.22 | 0.0026 | -0.0286 |
| [-1;1] | 0.0381 | 0.0001 | 0.06 | 0.0004 | -0.0308 | 0.0406 | -0.0002 | -0.12 | 0.0011 | -0.0301 |

**Panel 2: Parent company's performance RoA change in % (N=33)**

| | Market model | | | | | Market adjusted model | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Event window** | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ |
| [0] | 0.0442 | -0.0008 | -0.69 | 0.0400 | 0.0100 | 0.0444 | -0.0009 | -0.78 | 0.0419 | 0.0120 |
| [0;1] | 0.0624 | -0.0016 | -1.11 | 0.0918 | 0.0634 | 0.0639 | -0.0017 | -1.15 | 0.0103 | -0.0206 |
| [-1;0] | 0.0435 | -0.0005 | -0.37 | 0.0120 | -0.0189 | 0.0458 | -0.0008 | -0.58 | 0.0249 | -0.0056 |
| [-1;1] | 0.0615 | -0.0013 | -0.82 | 0.0486 | 0.0189 | 0.0652 | -0.0016 | -0.98 | 0.0773 | 0.0485 |

**Panel 3: Parent company's size (revenue) (N=35)**

| | Market model | | | | | Market adjusted model | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Event window** | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ |
| [0] | 0.0206 | 0.0005 | 0.44 | 0.0169 | -0.0120 | 0.0166 | 0.0007 | 0.61 | 0.0317 | 0.0032 |
| [0;1] | 0.0484 | -0.0006 | -0.43 | 0.0164 | -0.0125 | 0.0420 | -0.0004 | -0.28 | 0.0051 | -0.0242 |
| [-1;0] | 0.0259 | 0.0004 | 0.30 | 0.0072 | -0.0220 | 0.0228 | 0.0005 | 0.37 | 0.0092 | -0.0199 |
| [-1;1] | 0.0537 | -0.0007 | -0.46 | 0.0196 | -0.0092 | 0.0482 | -0.0006 | -0.38 | 0.0124 | -0.0166 |

**Panel 4: Parent company's size (total assets) (N=35)**

| | Market model | | | | | Market adjusted model | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Event window** | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ |
| [0] | 0.0206 | 0.0005 | 0.45 | 0.0169 | -0.0120 | 0.0166 | 0.0007 | 0.61 | 0.0317 | 0.0032 |
| [0;1] | 0.0484 | -0.0006 | -0.44 | 0.0164 | -0.0125 | 0.0420 | -0.0004 | -0.28 | 0.0051 | -0.0242 |
| [-1;0] | 0.0259 | 0.0004 | 0.31 | 0.0072 | -0.0220 | 0.0228 | -0.0005 | -0.37 | 0.0092 | -0.0199 |
| [-1;1] | 0.0537 | -0.0007 | -0.47 | 0.0196 | -0.0092 | 0.0482 | -0.0006 | -0.39 | 0.0124 | -0.0166 |

 

**Table 7 continued**

**Panel 5: Spin-off size (total assets) (N=23)**

| | Market model | | | | | Market adjusted model | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Event window** | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ | Abs. term | Reg. coeff. | t-value | $R^2$ | corr. $R^2$ |
| [0] | 0.0282 | 0.0003 | 0.25 | 0.0028 | -0.0284 | 0.0247 | 0.0006 | 0.50 | 0.0076 | -0.0234 |
| [0;1] | 0.0458 | -0.0011 | -0.74 | 0.0212 | -0.0094 | 0.0397 | -0.0008 | -0.52 | 0.0083 | -0.0227 |
| [-1;0] | 0.0330 | 0.0004 | 0.30 | 0.0029 | -0.0283 | 0.0285 | 0.0005 | 0.36 | 0.0048 | -0.0263 |
| [-1;1] | 0.0507 | -0.0011 | -0.67 | 0.0162 | -0.0145 | 0.0434 | -0.0008 | -0.47 | 0.0087 | -0.0223 |

**Parent company's performance** is based on the RoA and the change in RoA of the last quartal in comparison to the RoA of the same quartal of the previous year. The correlation between the **parent company's size** and the CAAR has been analyzed by incorporating the two variables of revenue and total assets (annual report of the year before spin-off announcement). **Spin-off** size has been evaluated by utilizing the determinant of total assets (first annual report after completed spin-off). Data on revenue and total assets is derived from the Thomson Reuters Database. The **t-value** is based on the t-test of the respective regression coefficient. **$R^2$** correspond to the coefficient of determination, whereas **corr. $R^2$** is the corrected coefficient of determination. Asterisks indicate significance at the 10% (*), 5% (**) and 1% (***) level.

Finding 6: *The parent company's size previous to the spin-off announcement has no effect on the abnormal return's height.*

While the present findings support the results of Ostrowski (2008) and Vollmar (2014), the findings of Slovin et al. (1995) cannot be proven. Reasons why larger firms could yield higher abnormal returns are rare. The most prominent reason comprises the fact that larger companies gain more prominence and their shares are traded more intensively. This effect can be relativized nowadays because the ongoing development of information technology for trading and the continuous improvement of the required data lake, enable equity trading which is independent of the company's prominence (Vanstone and Finnie, 2009). Additionally, most shares traded on international stock exchanges come from automated trading systems (Huang et al., 2019).

In panel 5 regression parameters for the correlation between spin-off size and abnormal returns are presented. No significance for the regression parameters can be shown. This applies to all event windows and the two statistical models. Similar to the previous regression analysis the regression coefficient nearly equals zero. Therefore, hypothesis 7 cannot be proven.

Finding 7: *The previous size of the spun-off subsidiary has no effect on the abnormal return's height.*

However, it needs to be considered that a long observation period is analyzed. For this reason, several changes in the market environment are incorporated and therefore the likelihood of cross-correlations between the impact factors increases. The present analysis investigates each factor separately, whereas more research on the relationship between these factors is needed in order to provide more precise information as to how impact factor combinations could affect the abnormal returns. Especially for long observation periods the effects of these factors could compensate each other.

## 5 Summary and conclusion

The present study analyses the wealth effects in consequence of global spin-off announcements in the chemical and pharmaceutical industry. This work provides evidence that wealth effects of spin-off announcements vary across different industrial sectors. Therefore, the wealth effects are measured by event study analysis of spin-offs that were announced between January 2001 and October 2019.

The cumulative average abnormal return is significantly positive for all event windows and

 

for both statistical models. The cumulative average abnormal return fluctuates between 3.91% for the three-day event window (market model) and 2.95% for the one-day event window (market adjusted model). In comparison to event study analysis incorporating all industrial sectors (c.f. Table 2) the present findings on chemical and pharmaceutical spin-off announcements provide evidence that wealth effects are higher for this industry which is probably linked to the high degree of diversification of chemical and pharmaceutical companies. All results are minimum significant at the 2.5%-level, whereas actually most abnormal returns are significant at the 0.1%-level which is rare for the event study methodology. It has to be mentioned that market model and market adjusted model strongly corroborate each other and that the cumulative average abnormal returns are invariably significantly positive. Moreover, the Cross-sectional test and the Wilcoxon signed rank test yield similar results with merely small deviations. These findings prove the statistical and explanatory power of the present study.

The present study also proves via multiple regression analysis that the cumulative abnormal returns are independent of the individual factors of parent company's performance, parent company's size and spin-off size. The first two factors are cross-checked by utilizing two variables for each factor. The results are the same for each variable. The findings on the parent company's performance and the parent company's size are in line with previous results of the European and American market. Indeed, in contrast to previous findings the present analysis shows no significantly positive correlation between the spin-off size and the abnormal returns. This could be based on the fact that this study comprises a long observation period and therefore the likelihood of cross-correlations increases. It should not be withheld that the multiple regression analysis is not able to detect these cross-correlation and much more research is required to prove whether these impact factors affect the abnormal returns in combination.

Finally, the present article provides substantiated evidence on the outstanding wealth effects in consequence of spin-off announcements in the chemical and pharmaceutical industry. The findings of the present study give reason for investors and companies to prove either the integration of shares of these companies into present stock portfolio or to scrutinise how spinning-off a specific division could be beneficial for the current corporate strategy.

## 6 Limitations and outlook

A limitation of the present study is based on the low number of observations, which is due to the investigation of spin-off announcements from one single industrial sector. Nevertheless, there are no options to increase the sample size, since increasing the observed event-window to the years before 2000 is not possible because data availability for these years is very limited. The sample size is comparable to previous studies on this topic, which conducted a cross-industry study and the highly significant results prove that already an analysis with a sample size of 36 can provide reasonable evidence for the special position of the chemical and pharmaceutical industry. Another limitation is the small event-window of the analysis, which is not useable to prove sustained wealth effects of spin-off announcements. This would require a separate study since a different analysis approach needs to be applied. However, it has been shown that the majority of stock transactions is based on automatic systems and therefore the average time a stockholder owns a share values less than two days (Huang et al., 2019). Consequently, the short-term wealth effects are more relevant for shareholders and investors.

Previous research on spin-offs focuses mainly on the short-term stock price effects in the US. Therefore, much more research is required to investigate specific industries as well as other economic areas beside the US market. Furthermore, researchers should also analyse the advantages and disadvantages for the other two participants of a spin-off transaction, namely the mother company and the spin-off itself.

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# Research Paper

## User research in pharma R&D: Contextual inquiry for the elicitation of user needs in a chemistry laboratory for analytical method development within a corporate continuous manufacturing organization

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Laboratories in the pharmaceutical industry see an ongoing transition towards continuous manufacturing by means of tighter integration of novel and existing technologies and, thus, the introduction of new work methodologies. However, technological studies focusing novel manufacturing methodologies usually do not address social aspects, while social sciences studies on the other hand rarely address scientific and industrial aspects of manufacturing processes and therein involved personnel. Hence, the scientific literature lacks systematic analyses of human and social factors in such continuous manufacturing environments. Therefore, the study provides a literature review of social research of scientific laboratories and lab work. Then, ethnographic field research is conducted in a laboratory for continuous manufacturing. One by one a team of six lab workers are observed and interviewed during a typical day shift (N=6). All sessions are recorded on video (4h 47mins) and transcribed to enable a qualitative content analysis. The overall work environment of a research and development chemistry laboratory of a big multinational pharma company is described including the general laboratory workflow. Finally, a list of 96 user needs as well as user role descriptions of the participating lab workers are generated. One key finding of the study is that the work culture in this lab follows a mode of constant debate trying to contain knowledge transfer in teams top-down as well as bottom-up, e.g. during experimenting with hardware setups trying not to compromise the chemical recipe following a research hypothesis. In this regard, digitization efforts like introducing electronic lab notebooks should prioritize to promote and support communication and collaboration over features and technological enhancements. Specifically, learning can be considered a shared responsibility to promote a common work process knowledge that is needed to successfully act and react in the context of continuously changing experiment setups and team compilations. Based on these results, the authors highlight the importance of holistic upfront user research to uncover underlying human and social factors as determinants for the success of socio-technical systems. All in all, with this study the authors provide a data set, which may serve as a foundation for future research and development projects in similar, industrial research working conditions, following a human-centered design approach.

# 1 Introduction

Social research addressing the pharmaceutical industry or the life sciences is usually focused on high-level critical debates about political regulation, consumption and consumerism, customer expectations and broader innovations (Williams et al., 2008), while social studies that address scientific and industrial aspects of manufacturing processes and the therein involved people are rare. This assertion is true for processes in corporate research-and-development (R&D) in industrial research (Darrouzet et al., 2009; Jordan and Lambert, 2009) and it is especially true for R&D in the pharmaceutical industry and the life sciences industry. Typically, such R&D organizations are focused on the creation of intellectual property (IP) as the output of all activities. Some pharmaceutical researchers argue that this strict focus is the root of the "culture of secrecy" and a cause for the massive duplication of effort. Further, these researchers argue for the adoption of open science approaches allowing organizations to experiment with new forms of collaboration (Bountra et al., 2017). This is also what makes this study unique, because social field research in many cases still lacks recognition of management and business stakeholders. As a result, social scientists, ethnographers and user researchers in industry often find their efforts devalued, neglected, or not realized by stakeholders (Amirebrahimi, 2015).

In this spirit of innovation by means of openness and transparency this study aims to encourage a more deliberate discussion about laboratory processes. Specifically, these strict R&D processes center around highly regulated laboratory workplaces, which are common place in any pharmaceutical or life sciences organization (Osakwe, 2016).

However, there is a lack of research that offers insights into how these corporate labs are run, how people actually work there, what these people require to work efficiently, and what they might need in the future to enhance their current workflows.

Now, this study aims to shed light on the field of corporate laboratory work by investigating the work performed in a research laboratory for continuous manufacturing of a big, multinational pharma company.

## 1.1 Background: Working in pharma R&D

The pharmaceutical industry includes the manufacture, extraction, processing, purification, and packaging of chemical materials to be used as medications for humans or animals (World Bank Group, 1998; Konstantinos et al., 2011). Following Konstantinos and colleagues (2011), pharmaceutical manufacturing can be separated into two main phases: (a) the production of the active ingredient or drug (primary processing, or manufacture) and (b) the secondary processing, the conversion of the active drugs into products suitable for administration.

According to the European Federation of Pharmaceutical Industries (EFPIA), turning a newly synthesized active substance into a marketable medicinal product takes an average of 12-13 years. However, only three in ten of these products will produce revenues that more than cover their research and development costs (EFIPIA 2010; Konstantinos et al., 2011). In addition, the pharmaceutical manufacturing industry produces therapeutic substance (human and veterinary medicines, drugs, and related products) in an increasingly concentrated set of mostly transnational company and subcontracting facilities. The sector has five broad areas of activity: (a) research and development, (b) manufacturing, (c) sales and marketing, (d) distribution, and (e) administration (Konstantinos et al., 2011).

For the manufacturing of pharmaceutical products many facilities have multi product capability and the equipment may in some cases be the same as are operating personnel. Thus, in the same workplace different raw materials are used, different processes are executed, and different waste streams are generated (Gad, 2008; Konstantinos et al., 2011). These facilities are considered highly maintained environment wherein equipment must be cleaned, to avoid cross-contamination. This involves water, steam, detergents, as well as organic solvents.

Today, many steps are automated in these processes, with examples of employee tasks including: (a) weighing and dispensing solids and liquids (using pumps or pouring), (b) charging and discharging solids and liquids from containers and process equipment, (c) manual materials handling, (d) equipment

maintenance and repair, and (e) watching controls and processes (Konstantinos et al., 2011).

Furthermore, as Konstantinos and colleagues (2011) summarize, the employees working in these environments of a manufacturing facility may be exposed to all kinds of influences like noise, heat, and humidity. Also, surfaces can be hot and slippery, while some surfaces and floors may be covered with dust from the process. Moreover, employees may be exposed to hazards like moving machinery parts and pressurized pipes and vessels, and some work is done in confined spaces or with high-energy sources. In extreme circumstances involving large quantities of highly charged powder particles explosive atmospheres can exist, for example, solvents can burn or explode, especially in organic synthesis. To cover all these work-related risks, general manufacturing practice and other quality control rules set by regulatory agencies, customers, and pharmaceutical organizations cover a number of these processes and the equipment used. Health and safety laws as well as good manufacturing practices (GMP) guidelines apply to all of them (Konstantinos et al., 2011).

Overall, the pharmaceutical industry relies on highly-regulated work processes on the one hand, while it relies on constant discovery of new recipes for drugs in R&D that may have great impact on the health of consumers on the other hand. The main goal of the laboratory is to gain a fundamental understanding of chemical synthesis through workflows of mechanistic and statistical analysis, ultimately leading to increased knowledge of not just one process, but of common schemes.

## 1.2 Current developments: From batch to continuous manufacturing

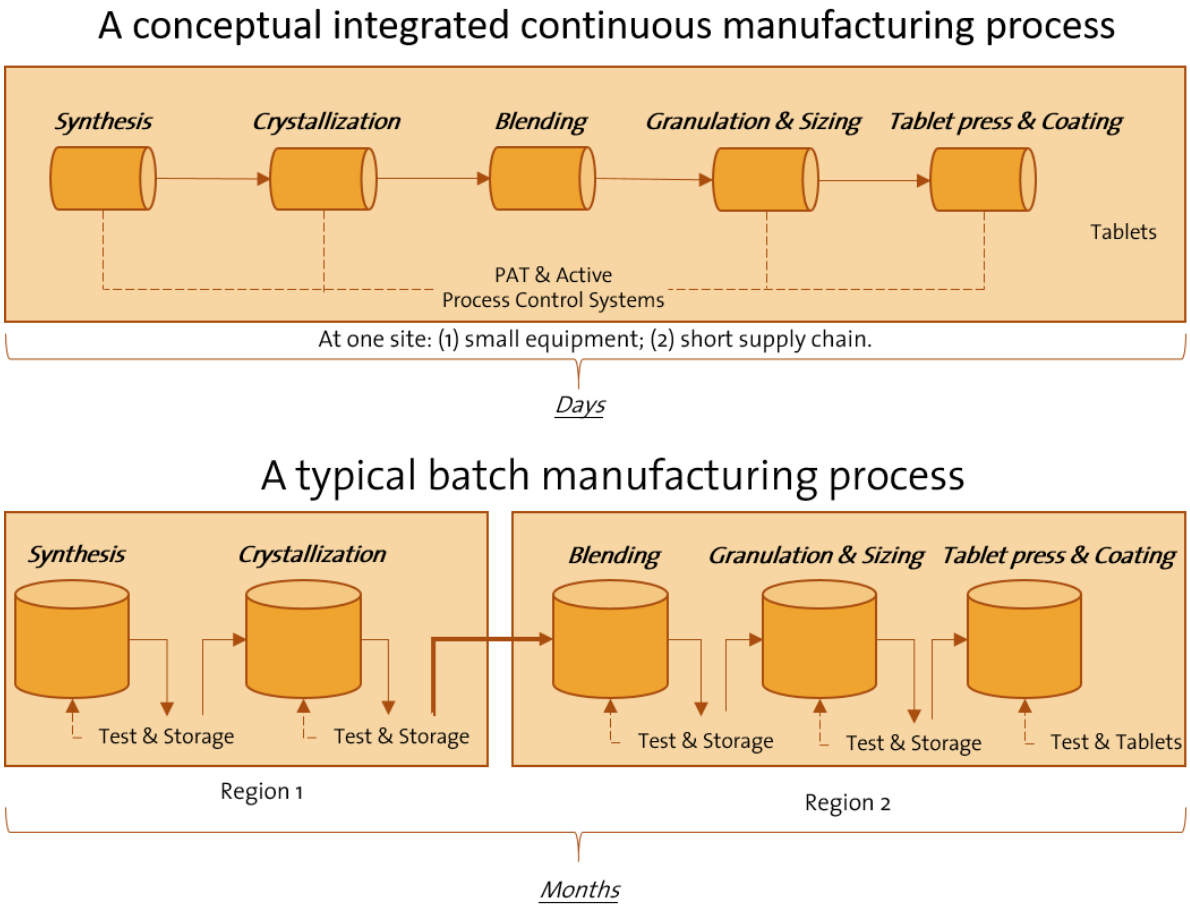
For several decades, pharmaceuticals have been produced using a method known as 'batch manufacturing', a multi-step, lengthy process that involves the use of ungainly, large-scale equipment (see Figure 1). Recently, advances in manufacturing technology have encouraged the pharmaceutical industry to move from this traditional way of manufacturing to a faster, more efficient process known as 'continuous manufacturing' (FDA, 2004; Lee et al., 2015). Some authors even argue that the lack of agility, flexibility, and robustness in the pharmaceutical manufacturing sector poses a potential public health threat as failures within manufacturing facilities that result in poor product quality can lead to drug shortages (Throckmorton, 2014; Myerson et al., 2015; Lee et al., 2015). In this regard, the Food and Drug Administration (FDA) considers continuous manufacturing the innovation that has great potential to improve the aforementioned level of agility, flexibility, and robustness in the manufacturing of pharmaceuticals (Lee et al, 2015).

In continuous manufacturing pharmaceuticals are moved nonstop within the same facility, which eliminates hold times between steps. Substances are fed through an assembly line of fully integrated components, which saves time, can reduce the likelihood for human error, and lab managers can respond more easily to market changes.

However, continuous manufacturing requires a different experimental approach. The impact of the equipment used within drug development has a large impact of the industrialization approach, which requires far greater understanding of the impacts of the equipment on the synthesis of substances. Specifically, certain equipment does not scale, especially those used in early screening, such as microfluidics. Therefore, a complete understanding of the characteristics of the equipment is needed to ensure that the processes are well understood to realize commercial requirements. Done right, the coupling of mechanistic process understanding along with equipment models allows the development process to move rapidly from different scales of operation, without the need for extended development operations. To ensure that the required process data is captured to support the mechanistic model generation, standard platforms are needed to provide consistent data. These platforms have a high level of automated control, data capture and data processing. In this regard, debates about standards of workflows, process models and data handling are still ongoing, e.g. in international consortiums like the Allotrope Foundation (see Figure 2). While continuous manufacturing is a general methodology, the investigation of a laboratory for so-called 'analytical method development' following this methodology builds the center of this study. Therefore, this study aims to investigate the people and their work in pharmaceutical research and development laboratories for continuous manufacturing.

**Figure 1 A conceptual fully integrated continuous manufacturing process versus a typical batch manufacturing process for tablets (source: Lee et al., 2015).**




## 1.3 Literature review

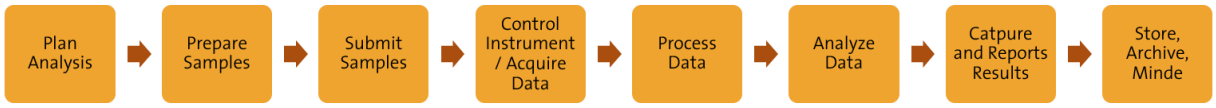
In order to research people working in pharmaceutical research and development laboratories for continuous manufacturing a literature review is conducted. Its goal is to review current literature that studies cultural, social and psychological factors in laboratory work. The review applies the following two major literature categories: Academic Social Sciences literature originating in anthropology, sociology, and general psychology; and Applied Sciences Literature originating in (a) education and instructional psychology, (b) human factors, and (c) user experience design.

Academic Social Sciences Literature about Lab Work

The academic social science studies of scientific laboratories go back to the 1970s and is called 'Science and Technology Studies' (STS). Typically, the main aim of laboratory studies in STS addresses broader concerns of epistemology of science and technology demonstrating the local accomplishment and social construction of scientific knowledge (Harrington, 2013; Sormani, 2014; Stephens and Lewis, 2017; Friberg, 2017). The research perspective in these studies is committed to the interactionist tradition of ethnographic work that focuses on the interactive practice and detailed observation of how scientific work is accomplished through social interaction (Atkinson et al., 2008; Atkinson, 2015; Stephens and Lewis, 2017). Other approaches to laboratory studies are rooted in

**Figure 2 General Workflow Process in Analytical Chemistry (source: Allotrope Foundation, 2018).**




sociology which treated scientific practice as a strange and alien culture (Latour and Woolgar, 1986). This is in contrast to other research focusing on understanding the scientific work from the individual perspective of the scientists (Knorr, 1977). But all authors utilized the detailed ethnographic observation of day-to-day work to document how normal scientific knowledge is accomplished (Knorr, 1977; Latour and Woolgar, 1986; Lynch, 1985; Traweek, 1988). Somehow connected to this research are organizational studies investigating the every-day life, skills, knowledge, identities, and attitudes of technicians as a general working type (Barley, 1996; Barley et al., 2016).

Another body of laboratory ethnography specifically investigates scientific laboratories as spatial arrangements and work environments for the social construction of knowledge. This research also borrows from social research of architecture design (Gieryn, 2002). Here, the laboratories are treated as special work spaces focusing on rhythms of day-to-day work, movements, materials, transitions, boundaries, and barriers as labs come in different shapes and sizes. Some are large and spacious, others small and confined, some are busy and heavily populated, others quiet and conspicuous by the absence of workers (Stephens and Lewis, 2017). Many labs are gated communities, others are linked closely to hospitals and clinics. Some are distant from highly populated regions e.g., the UK Stem Cell Bank (Stephens et al., 2008), and some are transient spaces that pop-up as "portable packages" (Lewis et al., 2014; Stephens and Lewis, 2017). In this regard, some authors argue for a radical redesign of scientific space speculating that new life science buildings following these redesigns are designed not only to intentionally produce intense social action between scientists but are also built to reflect the state and status of bioscientific innovation (Thrift, 2006). Other researchers argue for shifting focus of STS studies towards the private sector (Penders et al., 2009).

Applied Sciences Literature

The body of research coming from applied sciences, industries, and corporations aims to investigate and optimize the work experience for employees (e.g., training and ergonomics), workflows, technical processes, management, and businesses.

Education and Instructional Psychology

One branch of research coming from the disciplines of education and instructional psychology discusses current challenges like lifelong learning on the job or mental stress in knowledge work (Boreham and Morgan, 2004; Fischer, 2005; Grundgeiger et al., 2017; Bahl and Dietzen, 2019). Here, some research is focused on learning at work in general (Maclean et al., 2009; Fischer et al., 2004) as well as learning and teaching in specific domains of work (Boreham et al., 2002; Fischer, 2005). Some studies include learning in laboratory work environments with respect to the generation and appropriation of 'work process knowledge' of chemical laboratory assistants in particular (Talanquer, 2006; Fischer and Röben, 2002a; Fischer and Röben, 1997; Storz et al., 1997; Kruse, 1986). Following Boreham (2002) the concept of 'work process knowledge' goes back to Kruse (1986) who originally defined the term as 'labour process knowledge', meaning:

- an expanded understanding of work roles in parts of the organization other than the employee's own;
- an awareness of the interdependency of the activities in different departments, including characteristics of the system as a whole, such as the flow of work through the organization, both upstream and downstream of the worker's own station; and
- participation in a workplace culture which provides a service to colleagues in support of a high quality of service to the actual customer.

The concept of work process knowledge was developed to define the knowledge that workers, whether hotel employees, machinists or laboratory assistants, need in order to cope with more organic and knowledge-creating working environments. Developing work process knowledge helped them to adjust to more flexible processes (Boreham and Fischer, 2009; Fischer and Boreham, 2004).

However, only a few studies investigate learning processes inside scientific laboratories of companies (Torz and Eichhorn, 2001; Röben et al., 1998). Mariani (2002) as an exception conducts an in-depth investigation of the R&D practices of a major Italian chemical company that has been in existence for 40 years and employs about 1000 people. The study is focused on investigating the claimed competitive advantage of this company by looking into team work and the respective work process knowledge of individual team members, while including organizational factors of short-term contracts for learning and group dynamics. In this study the site management of the company is convinced that innovation and especially the invention of new products are a function of the number of tests and experiments that are run. Research processes, in contrast to production processes, have very uncertain outcomes and it can be very difficult to make a rational selection of trials. Hereby, one comment stands out pointing towards the special circumstances and social dynamic of laboratory teamwork:

"*When the R&D project is planned, managers of the different customer areas and researchers are asked their 'wish list' of activities. They always say that they need a research centre that is three times bigger. But when the R&D starts, we find that the eighty percent of the new ideas originate from everyday activities on the basis of local insights. (Excerpt from an interview with the person responsible for Planning and Control)*" (Mariani, 2002)

The employees of the chemical company argue for flexibility of workflows within a strict ruleset of controls for scientific discovery and safety regulations. Therefore, Mariani (2002) concludes that successful R&D depends critically on two preconditions: The capacity to perform a large number of experiments and the capacity to rapidly modify or adjust production programs so that, whenever a line of research produces promising results, processes in the plant focus on producing the chemical in question. Interestingly, the call for flexibility and increased rate of experimentation over regulations to foster scientific discovery is also demonstrated by changes in attitudes towards confidentiality. During the evolution of this chemical company's laboratory work culture the employee's focus shifted from covering all site installations with opaque steel shielding to get rid of everything that slows down the whole process, including expenditure for hiding their work. Employees summarized this shift in philosophy by stating that if they are first, it would not matter who might copy them. Regarding the organization of the company's lab work both the pilot plants and the laboratories started to operate on a 24-hour cycle in order to maximize the rate of experimentation. Also, on the basis of a very small increase in personnel, activity in the pilot plants was increased from one experiment per month at the beginning of the 1980s to the present rate of two per week. And by introducing a continuous work cycle, the output of the laboratories was increased from two or three tests per day to 20 to 25 per day.

These intense boundaries for teamwork seem to be especially effective in the pilot plants of the company. Work in these pilot plants consists mainly of running investigations to discover new products and develop new production technologies. As Mariani (2002) observes, this work is managed by two types of teams, one performing on a technical level and one on an operational level. The technical teams are responsible for setting up and mo-

difying the program in each pilot plant. They consist of three people with different responsibilities:

- a plant manager who takes responsibility for the overall functioning of the plant (this role was created in the early 1970s),
- a process engineer, responsible for designing the test which is to be run (this role was created in the mid 1980's),
- a technologist responsible for the technology needed to perform the test (this role was created in 1990). Its rationale is that, to adjust activities as a function of progressively emerging findings, it is critical that the technological configuration of the scaled down chemical installations can be altered very rapidly.

In order to investigate the lab work in teams of such chemical companies it is important to be aware of technical constraints in contrast to the adaptability of chemical formulas. For example, while the time required by the investigation itself might be fixed, the time needed for installation set up could be shortened as a function of team efficiency (Mariani, 2002). In this regard, team members of this chemical company's operational team rotate between roles to secure efficient teamwork even if one team member drops out. This way the lab team is flexible enough to react on changing circumstances. In addition, this kind of rotation exists for technical employees, too. Before a new employee, such as an area technologist, becomes fully operational, he or she is asked to work for a period in the operational teams as an ordinary team member. As Mariani (2002) concludes, this eliminates the familiar problem of engineers and researchers who are very knowledgeable theoretically, but whose knowledge of plant structure and organization is almost nil. Within both teams, therefore, everybody comes to know everybody else's job and to compensate each other's lack of experience. In this way, the different phases of the work process become well known to all members of the team, making it possible to develop a common language that allows a tight coupling of activities. Beyond this idea of sharing work process knowledge to ensure efficiency, having experts to teach their work to novices can be regarded as very positive alone (Mariani, 2002). It represents a step back to the tradition of apprenticeship that has been undermined by industrial change or as one experienced lab worker commented during the study (Mariani, 2002):

*"It also . . . increases our professionalism. For example, if we did not have to teach some of our plant schemes to newcomers, we would not look at those schemes for four-to-five months. In this way, we have got to continuously refresh our knowledge in order to be able to transmit it. (Excerpt from an interview with a skilled worker)"*

However, the informative corporate study of Mariani (2002) does not offer concrete descriptions of the actual lab work (workflows) nor does it offer insights into the specific needs of lab workers (user needs) to work in a team and to perform respective everyday tasks. So far it can be noted that laboratory workers possess a specific kind of work process knowledge that is quite different from academic knowledge of chemistry and that dynamic team work in some laboratories has high demands of situational adaptability. Nevertheless, their work is similar to work in any scientific lab: Variations are introduced in existing substances by a (synthetic) chemist, which are subjected to standardized tests to determine their chemical properties.

Now, complementary to Mariani (2002), Fischer and Röben (2002a) investigate the actual work of laboratory assistants inside analytic laboratories. Analytic laboratories are involved in both the development of new drug substances eventually becoming medicines and the translation of the chemical reaction from the laboratory standard to the production standard. For example, such labs are responsible for determining the structure, purity, and content of substances produced by means of synthetic chemists. They develop the first procedure for ascertaining the identity, purity, and content of screening substances. Also, these laboratories offer advice with regard to possible ways of synthesizing substances. In addition, standard operating procedures for determining the identity, purity, and contents of the byproducts of these syntheses are elaborated and stability tests, in particular, are carried out. Regarding the work environment and workflows, the authors investigate the organizational structure of labs. They postulate that the fundamental

principle of the organization of a chemical laboratory is the established division of labor between a chemist and a laboratory assistant, wherein, traditionally the latter is considered the former's helper (Fischer and Röben, 2001).

Specifically, in the companies the authors surveyed, the employees of the laboratory work in teams mostly made up of one chemist and several laboratory assistants. These teams work on one or more analytical procedures while the number of people working in a team depends on the amount of work needed for the analytical methods used, and also on the complexity of these methods (Fischer and Röben, 2002a; Röben, 2002b). Furthermore, the authors describe the different responsibilities of scientists (e.g. chemists or pharmacists) and assistants. Work of scientists is based on their scientific knowledge about the structures, reactions and properties of chemical substances (Schmauderer, 1973). Sometimes scientists are acting as heads of a laboratory and manage teams which usually consist of two to five laboratory employees. More often scientists are taking charge of research projects, which includes that they discuss and collaboratively decide what is to be measured, in what form and with which methods (Fischer and Röben, 2002a; 2002b). This academic laboratory staff is occupied with planning and carrying out analysis as well as evaluating and controlling validity of results.

The work of laboratory assistants on the other hand is focused on determining the quality and the quantity of substances (Ciommer, 1996; Fischer and Röben, 2002a). While a chemical analysis in its entirety goes through the stages of taking samples, preparing samples, analysis and evaluation, the job of laboratory assistants consists mainly of the preparation of samples and then the process of taking measurements (Mohler, 1970). Generally speaking, they work in the context of the work of scientists, that is, cleaning components and the lab environment, maintenance, calibration, quality control, buying equipment, taking samples, or providing and documenting measurements at the end of an analysis. Of course, this assisting work is critical to the quality of the measurement, which is – in most cases – done automatically by computer-controlled instruments (Fischer and Röben, 2002a). But this does not relieve the lab assistant's work, because the representativeness of samples must not be compromised by any treatment carried out before the computer-controlled measurement. Thus, meeting these conditions requires working closely to the instructions and regulations, which represent the context of the analysis. The authors stress the fact that, for example, scientific procedures given for an analysis might specify that a sample should be crushed with a pestle and mortar, dissolved in a solution and then filtered. But these procedures do not say anything about the method of filtering, which is not a trivial issue. Therefore, it is argued again that laboratory assistants need a kind of work process knowledge to successfully interpret and follow laboratory instructions (Fischer and Röben, 2002a). Here, the authors rely on two psychological constructs: Context awareness and context comprehension. The authors describe work process knowledge as a construct that connects the requirements of a task with the company-specific conditions under which a task is to be carried out (Boreham et al., 2002). Such knowledge is acquired from the experience gained by working in a specific work environment. This is important, because it is often the case that for example an instruction refers to a five minutes treatment of a sample, while practical experience tells that this treatment might require eight minutes with a particular device. Another example are process drawings or specifications, which are usually made by someone other than the assistant worker who uses it. Here, the lab assistant needs to learn and understand the specifications before he or she uses it in the work process. This insight then follows the argument that if a laboratory assistant lacks the relevant scientific understanding, it is not possible to develop adequate work process knowledge (Fischer and Röben, 2002a). Successful lab work relies on subject matter expertise, practical expertise as much as it relies on the actual work community and the division of labor. Therefore, like Mariani (2002) the authors conclude that it seems to be very important that lab assistants are able to make mistakes within the rule set of strict organizational regulations, in order to educate themselves in a pragmatic learning-by-doing manner within a scientific laboratory environment to progressively combine their practical knowledge with the feedback and scientific knowledge of their colleagues (Fischer and Röben, 2002a).

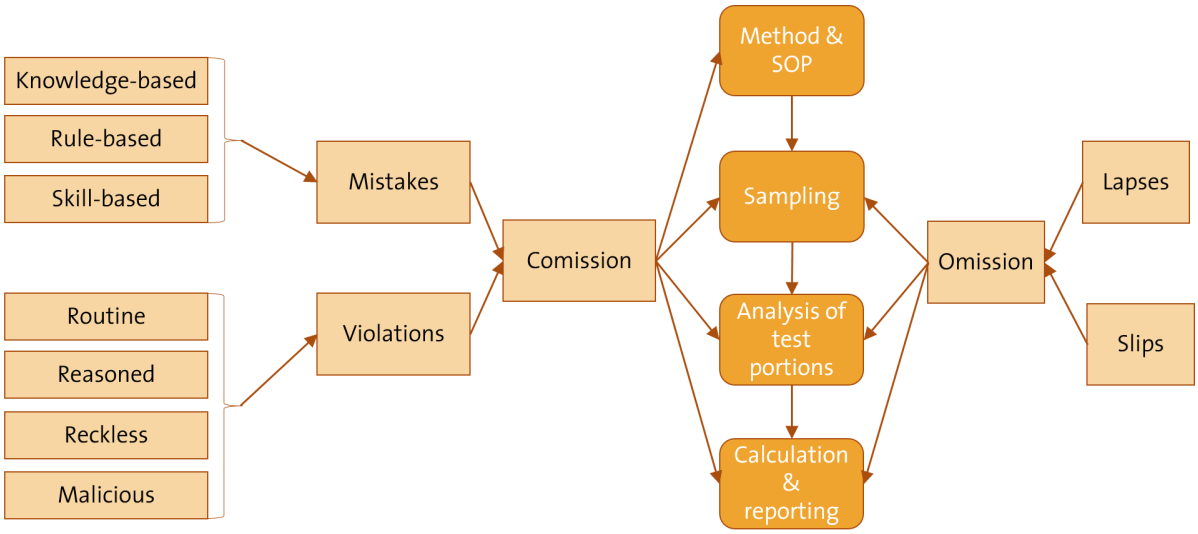
 

Human Factors Literature

In contrast to this body of applied research about scientific laboratories focusing on education, training and instructional psychology, there is another prominent field of applied research focusing on optimizing work processes. The Human Factors and Ergonomics (HFE) studies conducted on scientific research laboratories as a work domain are minimal (Jones, 2005; Jones and Nemeth, 2004). This is probably because historically HFE as a discipline has emphasized naturalistic studies of real-life "in the wild", in order to contextualize laboratory-based experimental results (Kant and Burns, 2016). Besides the interdisciplinary nature of HFE that as a discipline proposes a holistic view regarding product strategy, field research, requirements engineering, and usability engineering (Privitera, 2019), another general theme in HFE research is the strong focus on human error (see Figure 3; e.g. false identification of a component) in contrast to equipment error (e.g. insufficient sample or a broken container), and safety issues (e.g. individual attitude damage or hygiene regulations). This is also true for HFE studies about laboratory work environments (Ala and Bagot, 1994; Bonini et al., 2002; Hockey, 2005; Ross, 2008; Haile and Hussen, 2012; Kuselman et al., 2013; Perry, 2018). Here, HFE researchers try to transfer their experience and knowledge from work on medical devices, military systems, and aviation safety systems (e.g. Endsley and Robertson, 1996) to the lab work (Konstantinos et al., 2011).

Nevertheless, it is argued that HFE research could provide sustainable mechanisms to support innovation at a "grassroots-level"; i.e., from "bottom-up" (Kant and Burns, 2016). Another limiting aspect of these initial HFE studies is the fact that they typically aim to study laboratory processes exclusively addressing scientific laboratory work within government research facilities or universities. Access to corporate research facilities seems to be an issue. However, in this regard the study of Konstantinos et al. (2011) can be highlighted as a resourceful source of insights. The study is focused on Human Factors, that is, any factor that affects human performance and increases the probability of errors in the workplace. Theoretically, the authors base their work on a model created to represent the human factors in aviation maintenance. This model was named Safety Training for the Aircraft Maintenance Industry. The study of Konstantinos and colleagues (2011) contains a literature review of legislation surrounding the manufacturing process of pharmaceuticals (Good Manufacturing Practice, GMP; Occupational Safety and Health, OSH), so as to reveal if human factors were in-

**Figure 3 Steps in measurement process and types of human errors (source: Kuselman et al., 2013).**



corporated in the various laws, directives or guidelines produced by the legislative bodies. Secondly, the authors conducted research at a large commercial biopharmaceutical manufacturing facility and a small pharmaceutical manufacturer.

Overall, the results of their literature review show that the compliance with the legislation regarding the GMP regulations are the main requirement for pharmaceutical production. This does not directly emphasize the human factors aspect. On the other hand, the authors conclude that the researched OSH legislation gives more attention to human factors, although indirectly, and could be used as guidance towards effective organizational planning that incorporates more of these aspects.

Here, the authors conclude that if an organization uses both GMP and OSH legislation to their full effect, it will provide the foundations for a safe, dynamic working environment that has as the production of safe pharmaceutical products of high quality as main priority, but also respects the individual needs and abilities of the worker. Thus, the likelihood for errors produced from human factors will be reduced and their effect on manufacturing minimized. Furthermore, the authors mention the future trends in pharmaceutical manufacturing and in industry as a whole, that reinforce the need of a stronger utilization of human factors aspects, as many issues of concern can be avoided or their effect minimized (Konstantinos et al., 2011).

In addition to the literature review, the authors conducted observations in the field (what they call "walk-arounds") to identify cognitive demands, physical demands, verbal communication requirements, non-verbal communication requirements (e.g. paperwork), interaction with automation and equipment, potential human errors, potential machine errors, potential human-machine interaction error, and general workload issues. Also, they conducted informal one hour interviews to investigate responsibilities, priorities, rules, staff, working hours, sources of pressures and constraints, and workarounds. In addition, the authors conducted a survey to gather perceptions, opinions and further comments regarding factors that influence human performance and endanger worker safety, reliability, and pose a risk to the product. The survey was made available at large scale to employees at all levels and all departments.

The final results contain an overview of "skills/competencies required" in the daily work of the study participants, which represent "factors that can lead to errors/events in BPM" from the authors Human Factors perspective. For example:

(a) Task-related skills include "Preserving attention to detail", "set up and clean processes", "responding to time/operational/production pressures";
(b) Individual-related skills include "Physical, cognitive capabilities and limitations on job performance (dealing with fatigue, interruptions, distractions, complacency, etc.)", "identifying the preconditions/precursors for errors", "Patience: resistance to rushing; maintaining vigilance", "Professionalism: sense of ownership in task/process/product-outcome";
(c) Team-related skills include "Teamwork (benefits, challenges)", "Danger of diffusion of responsibility", "Communication (effective, frequent, different types of, as a function of level, of time of day, limitations of)", "Hand-over/ shift changes: ensuring situation awareness/ common operational picture quality support needed on shifts, transfer of responsibility, planning activities near hand-over";
(d) Organization-related skills including "Management of unscheduled-tasks", "Monitoring (without losing focus)", "Cross training (advantages, disadvantages)", "Introduction of new technologies/equipment", or "Time-Management" for example (Konstantinos et al., 2011).

In addition, the survey results contain several issues regarding risks for human error. Specifically, as far as task factors are concerned, the primary human factors-related issues that employees generally agree are potentially error -inducing and threaten safety: (a) Time Pressure, (b) Distractions, and (c) Interruptions. Furthermore, "Unclear procedures" was reported as an issue that appeared to specifically concern employees, perhaps due to a large range of activities which require detailed procedures. Konstantinos and colleagues (2011) see a trend for employees to believe that the human factors issues ranking high on the list of concerns are also those for which employees are not well-equipped or trained to effectively address them. Regarding individual factors, the respectively same issues seemed to concern

employees: "Stress," "Fatigue," and "Personal problems". The authors mention that some employees reported that they had some type of training on how to handle fatigue, while all respondents appear to believe that "Stress" is an issue for which they require more assistance in dealing with. In addition, survey participants from the larger facility placed emphasis on the issues of "Lack of motivation" and "Personal problems" (Konstantinos et al., 2011). On the other hand, both team and organizational factors appeared to generate more consensus regarding their potential to induce errors. Half of the listed team and organizational issues generated agreement that they are potentially error-inducing, compared to only a third of the listed task-related issues and individual issues. Within team factors, specifically, the issue that appeared to concern all participants the most were unclear roles and responsibilities. Another issue the study showed was a general unwillingness to ask for help from colleagues. All in all, the top-issue from all target groups and facilities indicated not having been trained on how to deal with this lack of communication among team members. Lastly, within Organizational factors, respondents from different facilities responded differently about issues that may lead to errors. At the smaller facility respondents selected: (a) Lack of effective response from Supervisors and Management regarding reported safety issues, while respondents from the larger facility selected, (b) Insufficient workforce, (c) Inadequate tools and equipment, (d) Poor documentation as issues which may lead to error. In terms of knowing how to handle issues, the interesting finding has to do with the larger facility response, which highlights the need for training regarding a clear leadership structure (Konstantinos et al., 2011). All in all, the study from Konstantinos and colleagues (2011) follows the tradition of HFE research focusing on the specification of human errors in specific situations, while concrete workflows and observations are not described in detail.

User-Experience Design Literature

Following, the literature coming from User Experience Research is discussed (UXR; formerly called User Research or Usability Engineering). UXR is another field of disciplines that is in relationship with Human Factors and Ergonomics. But, while HFE is rooted in occupational and engineering psychology (Badke-Schaub et al., 2008), the quite younger discipline of User Experience Research goes back to the human-centered design methodologies co-developed by psychological researchers and design practitioners within the fields of Human-Computer Interaction (Stuart et al., 1983; Norman, 1988; Preece et al., 2007; Grudin, 2017) and Product Design (Holtzblatt and Beyer, 2017) hereby the authors include the fields of industrial design, media design, user interface design, graphics design, and visual design). Although there are a lot of studies of industrial environments and systems (Lee et al., 2017; Jakl et al., 2018; Aromaa et al., 2018; Karim and Tretten, 2014; Terzic et al., 2009) and some exclusively focus on user research to explore user needs (Palviainen and Leskinen, 2006; Sørensen et al., 2008), technology adoption (Singh, 2019) or evaluation of user acceptance (Gavish et al., 2015), there seems to be not one study regarding the user needs within scientific laboratory work environments.

Conclusion and Research Question

Social research addressing the pharmaceutical industry or the life sciences is usually focused on high-level critical debates about political regulation, consumption and consumerism, customer expectations and broader innovations (Williams et al., 2008), while social studies that address scientific and industrial aspects of manufacturing processes and the therein involved people are rare. This assertion is true for processes in corporate R&D in industrial manufacturing (Darrouzet et al., 2009; Jordan and Lambert, 2009) and it is especially true for R&D in the pharmaceutical industry and the life sciences industry.

Currently, social research of laboratory work lacks systematization from an interdisciplinary point of view. Studies aiming for an academic audience of social scientists have a diverse and broad set of topics and are very specific in their theoretical perspective, e.g. investigating the spatial arrangements of laboratories. The Applied Sciences literature on the contrary seems to have a limited set of topics that share general themes of process optimization and efficiency, e.g. focusing on identifying the potential for human error in general laboratory workflows. Another aspect is the clear lack of studies on lab work coming from the human-centered design community, although comparable studies investigating work inside of other indust-

ries seem promising, especially in view of hedonic qualities of actual working experience (see: User Experience Design). However, many studies of human-centered design are performed privately as part of contract work and may not be published respectively.

In sum, the current literature either explores fundamental themes like the social construction of scientific knowledge or identifies and discusses specific human factors in an explanatory way trying to understand cause and effect of errors and respective risks in manufacturing. While individual studies are exploring processes of learning and knowledge sharing of teams working in laboratories, they do not explicitly describe the actual workflows, tasks, responsibilities, expectations and respective needs of people.

In addition, there seems to be a general selection bias in the actual access to laboratory facilities that limits the scope of investigation, e.g. while the study of work in public labs of universities seems to be convenient, only a few publications address the work in corporate laboratories.

Therefore, the current literature not only lacks descriptive, exploratory research on people working in pharmaceutical research and development laboratories in general, but also lacks research on people working in corporate continuous manufacturing laboratories. Concluding, the authors aim to close this gap by addressing the following research question in this research article:

RQ: How do people work in corporate pharmaceutical research and development laboratories for continuous manufacturing, what are their respective needs, and how can these needs be met?

## 2 Methodology

### 2.1 Contextual inquiry and content analysis

The nature of organizations as emergent open systems, subsisting through on-going interactions of the individuals who act within them, means that it is necessary to 'view them as human activity systems' (Checkland and Poulter, 2006). In this regard, people often fail to manage organizational change and innovation, because they are not able to articulate and describe the current as-is situation of processes, workflows, habits, and people's attitudes in place.

Therefore, methodologies like requirements engineering, ethnography, as well as user research and user needs analysis as the rather technology-oriented social research methodologies, aim to describe and clarify these as-is situations to derive meaning and offer insights for optimization and management. The explorative nature of the qualitative research methodology offers opportunities to explore contextual dependencies, both for individuals and in groups, and to question assumptions that are taken for granted (Bednar and Welch, 2014). This study follows a qualitative user research methodology to explore workflows and derive user needs of people working in a research lab. While user requirements refer to potential system qualities that need to be met for some kind of user satisfaction, User needs refer both to the difference between users' goals and the present condition, which is manifested by user problems and possibilities, and the context of use, which includes the characteristics of the intended use reflecting a users' present tasks and environment (Lindgaard et al. 2006; Kujala et al., 2001). User needs also imply that researchers focus on the underlying needs of participants and try to infer these broader needs on the basis of what participants are saying during interviews. Thereby, the researcher deliberately separates the interviewee's wishes (sometimes called "user wants"; Yi, 2018; Hartson and Pyla, 2019).

In order to build an understanding of how work in a modern pharma R&D laboratory is conducted and what the individuals working in this environment actually need to perform tasks and reach their goals, participating observations with live interviews are conducted.

This applied research method is also known as Contextual Inquiry, which originates in ethnographic research traditions coming from anthropology (Plowman, 2003; Stanton et al., 2013; Ladner, 2014). In addition, a master-apprentice approach is applied in which the researcher takes on the role of an apprentice treating the interviewee as an expert in the current situation and tasks at hand (Downey et al., 2015). From a practitioner's point of view, such a Contextual Inquiry can be considered an extremely well-prepared customer visit, site visit, or field visit (Goodman et al., 2012) to gather insights of users within the context of use.

The core of contextual inquiry is to conduct focused observation and having a conversation while a user is performing a task of interest. This includes gathering artifacts, taking field notes, while at the same time conversing with the user in an informal manner. This requires the researcher to be adequately prepared, travel to the workplace, follow the appropriate requirements for access, gain approvals for recording, and bring along all the necessary equipment. Having a plan to collect reliable data is necessary, especially in pharma laboratories, where schedules are quite busy and at times uninterruptible (Privitera, 2015; Werner and Kirsten, 2003). Analysis of contextual inquiries explore users' experiences, aspirations, sense-making processes, and surface their tacit understandings of contextual dependencies in the context of their 'problem space' (Bednar and Welch, 2014; Privitera, 2015).

In the following sections the results of a contextual inquiry in a selected R&D chemistry laboratory focused on continuous manufacturing are presented. Thereby, the authors aim to describe the as-is situation and dependencies of actual lab work including the elicitation of user need. These insights shall build a body of knowledge to identify challenges and design implications for chemistry laboratory workplaces. Laboratory staff is interviewed during their daily work in the chemistry lab with a focus on workflows and used tools. Additionally, videos are recorded to optimize the workflow analysis process, resulting in four hours and 47 minutes (287 mins) of video documentation. On this data basis, transcripts of the interviews are created containing key images of the video recordings to set up an 'authentic' set of qualitative data (Ladner, 2014). Then an in-detail content analysis is conducted, which is an extensive, transparent, stepwise interpretation process applied to the qualitative data gathered (Mayring 2000). Here, a researcher sorts the text snippets of transcripts into groups and assigns codes, e.g. values, roles, goals, tasks, mental model, behaviors, pain points, or mistakes (Goodman et al., 2012).

## 2.2 Sample

As the literature review illustrates, gaining access to corporate research facilities for conducting social research cannot be taken for granted. In addition, the goal of this study is to study not only people in a special research facility for continuous manufacturing, but people working within a big pharma company. Therefore, recruiting lab managers for this study is a challenge. While the recruitment process included lab managers from several of the world's biggest pharmaceutical companies, only one company was interested to cooperate for the study investigating human factors for continuous manufacturing. In addition, the scope of the cooperation for this study was limited to conduct research in one laboratory. Also, the access to the laboratory was limited to one day, which corresponds to participating in one day shift of lab work in this laboratory.

All in all, five in-depth participating interviews are conducted in situ during one day shift and one 70 minutes expert interview with the respective lab manager to cover the bigger picture of the current organizational setup of the lab and its possible future direction. In detail, the set of participants contains a team leader for a group of technicians (called 'Operations Team Lead'), who reported eight months of experience in this laboratory, one Continuous Processing Engineer (called 'Engineer') with one year of experience in this lab, and three Continuous Processing Technicians (called 'Technicians') with many years of experience.

# 3 Findings

Regarding the question, how people work - and what they need to do so - in corporate pharmaceutical research and development laboratories for continuous manufacturing, the findings from the qualitative content analysis are summarized and presented in four steps. First, the laboratory setup is explained. Second, general observations are summarized describing the organizational setup. Third, the observed workflow for analytical method development is described. Fourth, responsibilities, needed information, and needed intercommunion and advocacy regarding the job roles of study participants are summarized. Finally, a summary of initially 96 elicited user needs (see appendix) is presented in four overarching categories of people's needs during lab work.

## 3.1 Laboratory setup

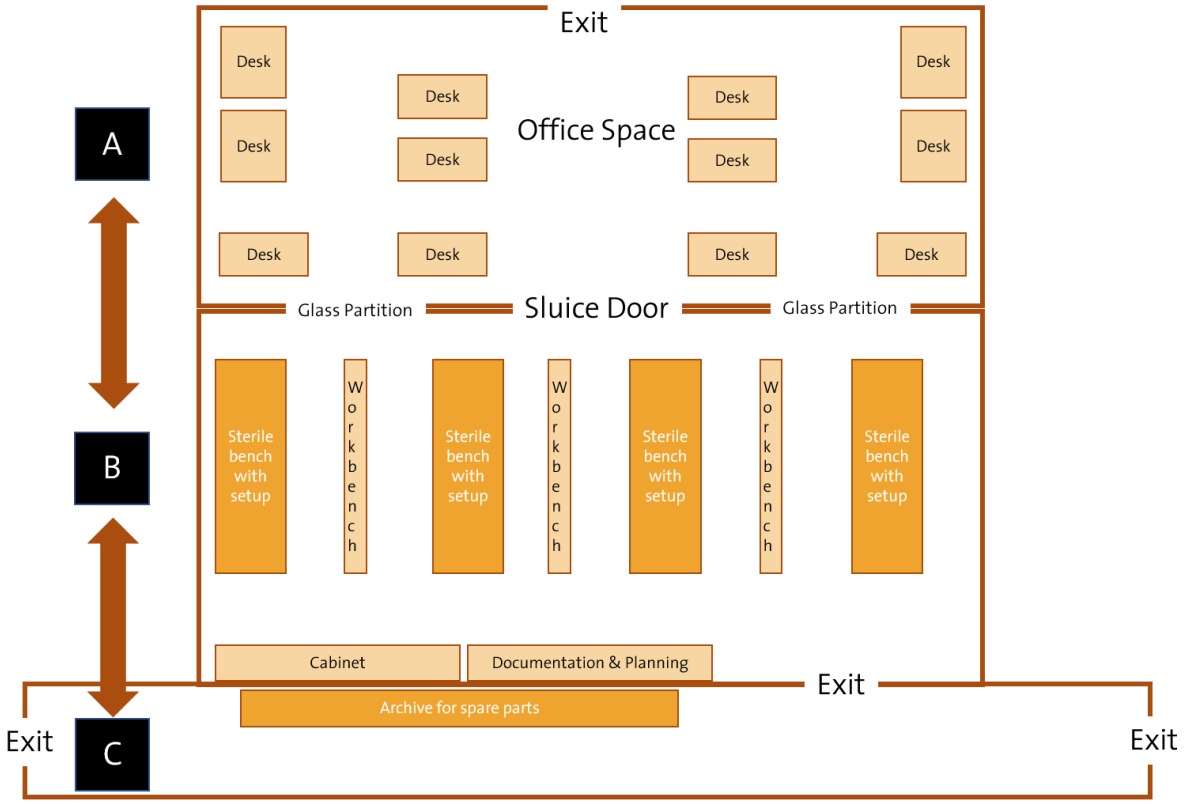
In order to understand the activities involved in working in a laboratory focusing on continuous manufacturing, the first step requires highlighting the layout of the equipment besides the processes of teamwork and communication, hardware and automation setup, and maintenance, as well as testing and data analysis. In the following section a rough scheme of the laboratory floor plan is presented, which does not include the actual setup of additional sinks beside sterile work benches or safety related equipment that is mandatory in such research facilities. Overall, the laboratory space can be divided in three main regions A, B, and C (see Figure 4).

Section A constitutes the office space where responsible scientists (chemists, pharmacists, engineers) meet, plan, analyze data, and manage their research projects that are conducted in the laboratory next door. This area is connected to the overall office space of the building.

The section B represents the actual research laboratory where chemical experiments are set up in big sterile work benches to test chemical recipes in different scale, ranging from very small, microscopic experiment setups in the beginning to medium sized setups occupying the complete space of a big sterile work bench in the end of a test series before a possible hand over to other departments responsible to scaling the setup to big production plants. Here the chemistry is tested using pressure controllers and computer software for recording data. The workflows deal with chemicals as well as specialized equipment. Some equipment and chemicals are stored in a cabinet directly located inside the laboratory.

But most of the equipment is placed in the hallway outside the laboratory, in section C, in a manner that separates the hardware archive while providing adequate safety. This hallway is

**Figure 4 Schematic building plan of the laboratory investigated in this study (own representation).**



connected to the suppliers input areas and other laboratories. Along with the above setup, safety is a key concern in the laboratory. Technicians and scientists working in the laboratory have to undergo mandatory safety training. Everyone entering the laboratory uses glasses, gloves and laboratory coats to ensure precaution during work hours. As mentioned above there are additional sinks and eyewash stations as well as steps outlined about what is to be done in case of an emergency. There are also emergency contact numbers and a phone available in the laboratory. All employees involved take the utmost care during the setup as well as during the testing process. Typically, there are considerable safety risks involved in this work. All handling of dangerous chemicals is done under the sterile work benches which contain a ventilated fume hood.

## 3.2 General observations

The overall goal of the investigated R&D chemistry lab is the continuous design and evaluation of chemical recipes for drug development on a small scale. Validated recipes are then scaled to a bigger development setup until they fit the needed outcome on the one hand and regulatory norms on the other hand. Usually, several recipes on diverse scale levels are tested side by side in one lab environment. The recipes are tested with specific setups under controlled conditions in fume cupboards. As sterile work benches have glass doors a lab worker can easily have a look at the current hardware, which is the experiment setup for testing a chemical recipe. The desks of the lab manager and responsible chemists are visibly placed in the glass office right next to the sterile experiment laboratory. This spatial setup enables ad hoc discussions between the operation teams, chemists, and lab management.

In the beginning of a shift, the team of engineers and lab technicians takes a look at the current project plan to clarify the current situation the last shift team ceased to work and in what condition the respective experiment setup is right now. Besides these daily check-in and check-out meetings, the operations teams meet with the chemists that are assigned to their project on a regular basis.

In general, the team differentiates three overall workflow phases: (1) Inventory Management, (2) Setup, and (3) Risk Management. First, technicians take a look at the current state of the hardware setup they are assigned to. They walk up to the sterile work bench they are assigned to, visually inspect the experiment setup and read the process diagram poster that is attached onto the front of a sterile workbench. The process diagram posters are prepared by the assigned chemist. The technicians look for planned changes to the experiment setup and then check for additional hardware components that are needed to rearrange the setup accordingly. Hardware components are stored in a separated inventory. Technicians then collect the needed components and iteratively change the setup according to the process diagram. During their lab work they are always in correspondence with the overall team and the assigned chemist or their lab manager to clarify information or discuss issues like e.g. how to document a specific abnormality or which component could be used alternatively in order to optimize the overall experiment setup. In general, everyone involved is required to document any changes they make, abnormalities as well as incidents they observe. Therefore, the lab management provide printout documentation templates called “proforma” on a regular basis. These printouts cover specific sub-processes like cleaning a specific part of an experiment setup and are stored in a specific cabinet inside the lab.

In addition, general paper lab notebooks are used for overall documentation, which are covered in red color. These lab notebooks are then placed upon the work benches opposite to the sterile work benches.

Besides these assets of pen and paper documentation there are several laptops and desktop computers installed on top of every line of work benches to provide access to company internal IT systems. These IT systems include for example: An Electronic Lab Notebook, Electronic Ordering Systems, and Equipment Booking Systems.

Currently problems occur at the intersection of several ongoing processes, that is, the synchronization of research design, management of employees, concrete project planning and resource management. This also includes the supply of expensive resources and equipment over long periods of time. Momentarily a central problem in the laboratory is the finding of specific equipment. This is especially difficult because equipment is shared amongst the

different teams and there can be long time elapses during projects, e.g. it is possible that there are two years between the first and second use of a component part. Thus, the corresponding need for a systematically processed storage system and dynamic scheduling tools becomes stronger.

## 3.3 Workflow for analytical method development

In analytical method development people are looking to build appropriate testing platforms that are able to meet the needs of the process as well as provide a platform for consistent operation and data processing. The process starts off with a hypothesis of the mechanism for the chemical transformation. This results in a number of potential experimental designs that can be used to test this. An experimental design is always assessed against the equipment capabilities. There is a library of modelled equipment that is available to be used to create the test conditions needed to explore the mechanistic hypothesis of how a chemical recipe might be applied technically. Here, the equipment is matched against the proposed experimental requirements and the operational recipe developed. Modular automation is used to apply standard automation controls to the assembled platform. All aspects of the platform configuration are captured in the design process to ensure that full context information of the experimental design is documented.

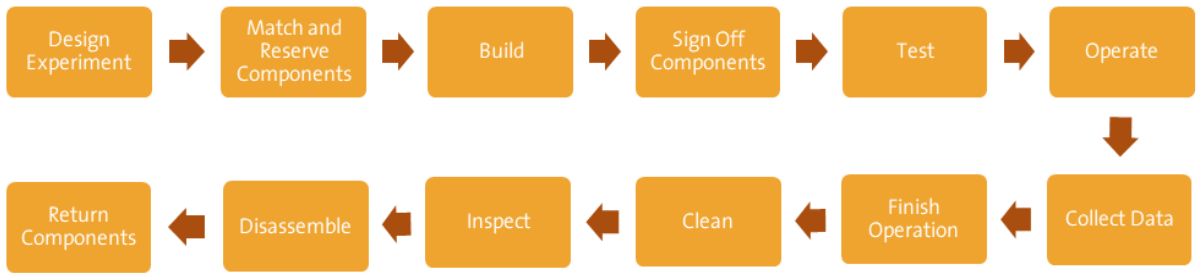
These details include all factors that could impact the repeatability of the experimentation, which in flow includes all aspects of the wetted flow path, such as interconnecting pipework geometry, ambient conditions, equipment baseline characteristics. All the experimental design is held electronically in an electronic lab notebook, with appropriate experimentation context to allow for indexing.

Once built and tested (baseline standards) the platform will run a number of transient and steady state experiments to allow for efficient data collection with minimal material utilization. Operation of the platform, although automated, still relies on human oversight, and this is carried out through a number of dashboards that support both experimental and operation aspects.

Each experiment is monitored and data analyzed as close to real time as possible - dependent on the complexity of the model - to ensure that experimental requirements are met before moving to the next run. Where experimental data is not in line with the hypothesis, the operator is informed as a user response is required to move the process forward.

At the end of an experimental run, the system is automatically cleaned and inline sensors determine the end of the cleaning cycle. During the cleaning cycle the equipment performance is again baselined to determine any impacts from experimental processing. Then follows cleaning and an inspection is carried out, which is then followed by disassembly (further inspections at this time), and any observations made to the experimental procedure is documented. Components are then returned to stores and the electronic equipment tracking system is updated. The workflow comprises the following steps in the given order (see Figure 5):

**Figure 5 Workflow for analytical method development in the investigated pharma laboratory (own representation).**



(1) Design Experiment: Initially, experiments are being designed by scientists based on previously conducted experiments or prior knowledge. The outcome of this step are recipes and instrumentations, which are filed in some repository supporting versioning. The design phase includes an intensive negotiation between scientific and technical staff that aims to obtain an implementable experiment design. Specifically, a joined risk analysis is conducted and documented, which is not covered in the above figure.
(2) Match and Reserve: Components Given a recipe and instrumentation plan, requirements imposed by both are matched against specific physical components represented in a component inventory database. The outcome of this step is a bill of materials accounting for specific components that have been reserved for experimentation and that need to be collected. The reservation status of components is updated accordingly. If matching fails, experiments need to be redesigned or rescheduled. This step usually also includes collecting of components. Here, technicians search and collect components from physical inventories based on the bill of materials, which is embedded into a record containing all information relevant to the experiment. If component can actually be found, their status is updated accordingly. If components cannot be found because they are either not available or obviously broken, other components have to be found in another match -and-reserve components step.
(3) Build: Technicians assemble the experiment based on the mod-prep record. If components turn out to be incompatible, technicians have to go back and repeat the match-and-reserve components step.
(4) Sign-off Components: After successful build-up of the experiments, all utilized components are signed-off in the component inventory database and, thus, made unavailable and locked for further use. The usage status of components is updated accordingly.
(5) Test Experiment: Instrumentations are required to be tested prior to ordinary operation. In case this step fails, technicians have to revert to the match-and-reserve components step in order to remedy failures. Testing involves running a system with proxy solvents as well as with the target agents.
(6) Operate: Successfully tested experiment instrumentations can be operated. Data obtained during operation is stored in locally or remotely in respective data silos (databases). Operation of experiments is conducted according to a manual called Process Guide.
(7) Collect Data: Experiments that have been run successfully for the desired amount of time require the collection of data that is not automatically transmitted to back-end data storage.
(8) Finish Operation: Technicians shut down experiment operation.
(9) Clean Components: After experimentation, equipment must be cleaned superficially by technicians. The cleaning state is adapted accordingly.
(10) Inspect: Technicians inspect components after cleaning of experimental setups in order to check their functionality. Component's functional statuses are updated accordingly.
(11) Disassemble: Technicians disassemble the experimentation setup and prepare individual components for their return to storage.
(12) Return Components: Individual components are returned to the component inventory and their usage status is updated accordingly.

## 3.4 User roles

This section contains results that summarize (a) responsibilities (see table 1), (b) needed information (see table 2), and (c) needed intercommunion and advocacy (see table 2) regarding the job roles of study participants. The authors consider this kind of job role descriptions a foundation for the creation of people's role profiles that may help other researchers, designers, software developers, engineers, and manufacturers to initially specify and discuss the user requirements of respective workflows, lab instruments, and lab software. Such summarizing role descriptions are considered highly important in human-centered design methodology, because they offer a set of information clarifying which type of user might need what information in which situation. Therefore, these role descriptions are referred to as 'user roles', sometimes also called 'user profiles' or 'personas'.

**Table 1 Responsibilities of participants sorted by job role (own representation).**

| | Technicians | Operations Team Leader | Process Engineer |
|---|---|---|---|
| **Responsibilities** | Setup of experiments; Maintenance of experiments set-up; Maintenance of equipment; Focus on flexibility for trial and error as continuous iteration | Keep the workflows of the lab running; Organize team meetings; Set organizational priorities / managing demands; Keep track of and maintain documentation offline (lab notebooks, workflow proformas, notes) and online (intranet wiki/platform, Tracking-Spreadsheet); Optimizing overall lab workflow (e.g. working on automation of equipment tracking with barcodes), Broadcast key information for experiment set-ups; Relate and share shift plans, lab status overview, project status, and template status for lab management; Coordinate skills of technicians to tasks; Check for training demand of team members; Broadcasting important information (e.g. safety issues); Broadcasting the different work requirements and rules between GMP and Non-GMP. | Discuss experiment process theory and proof feasibility of experiments; Relate information of operating conditions (e.g. temperature), challenges with operation limits, to operation capacities of the system (heat and cold); Write specification sheets for materials; Check suitability of equipment (e.g. limits listed in manufacturer manuals); Keep track of current stock spares and ordering of new equipment; Maintain and share templates for process diagrams; Plan processes and draw process diagrams; Maintain process diagrams at the place of respective setups; Discuss setup solutions; Keep track of special equipment (e.g. reactors, pressure sensors and temperature sensors); Maintain settings of special equipment (e.g. pressure reliefs); Documentation |

## 3.5 User needs elicitation

Another result of the conducted content analysis is an extensive list of 96 elicited user needs referring to things, information, knowledge, or communication the observed and interviewed participants need in their work environment to perform tasks and reach their respective goals. The complete list can be found in in the appendix. It contains redundancies as different users share the same tools and lab space and report similar things respectively. Therefore, it represents the complex mesh of everyday lab work that needs to be considered when discussing lab management, lab processes, workflow optimization, or the potential development of hardware and software for chemistry laboratories. But for reasons of readability presenting the complete list would be beyond the scope of this paper. However, the authors consider the following summary to be sufficient for understanding the main user needs and their interdependencies that occur in the flow of the studied lab work.

Therefore, the complete list is considered 'first-order' content regarding user needs interpretation. 'First-order' user need statements refer to concrete tasks, goals, or concepts like "checking pressure values". The complete list is broadly grouped by the mentioned job roles (scientist, lab technician, operations team leader, engineer) and - where possible - by application context (design, setup, communication, documentation), while the actual user need statements all follow a consistent syntax containing (a) which job role a user has (b) what a user needs (c) as well as a contextual reason why a user needs it.

On this basis, summarizing categories or clusters of user needs are generated resulting in two further levels of interpretation and respective coding: 'Second-order' concepts that generalize the first-order statements, and a final 'third-order' level, here called 'aggregate dimensions', which represents the most general interpretation of groups of statements across job roles. The following section highlights some examples for this qualitative data analysis and stepwise interpretation process.

**Table 2 Needed intercommunion and information of participants sorted by job role (own representation).**

| | Technicians | Operations Team Leader | Process Engineer |
|---|---|---|---|
| **Needed intercommunion & advocacy** | Receives initial process definition briefing; Receives ad hoc advice from every team member at any time in person and via online platform (wiki); Receives top-down advocacy before reserving components (e.g. due to cleaning); External support advocacy for facility operations (e.g. restarting operation system, earthing of setups); Receives ad hoc top-down direction for changing priorities; Offers bottom-up suggestions for optimization and workarounds | Requests information for documentation, management, and planning; Resource planning in discussion with scientists; Offers proformas & templates for workflows | Offer notes and instructions at the location of an experiment setup (e.g. need for cleaning of components); Offer preparation and instructions for the team of the following lab shift |
| **Needed information** | Planning for projects, shifts and job rotations; Picture of process definition for setup; Changes in process definition, Required equipment and setup parts; Technical interfaces of a setup ("Inlets" and "Outlets" as connectors); Consistency of language, codes and symbols; Current setup performance status (by visual inspection and by instrument data); Current performance status of especially error-prone equipment (e.g. pumps); Equipment location (e.g. archive); Equipment status (e.g. ready to use); Equipment history (e.g. last time of cleaning, last user, project number); Equipment manufacturer manuals; Equipment exchangeability/ compatibility (compensating for missing components); Equipment capabilities and weaknesses (official and actual); Equipment mail ordering periods; Rules for processes and equipment documentation (e.g. cleaning record), Rules for changing processes including documentation templates; Current team setup (who) and responsibilities (what and when); Summary of the last shift event history including respective directions (day shift and night shift) | Current status of everything in the lab (maintenance status, equipment status, time plans etc.); Overview of requests and respective priorities (input via email, notes, whiteboard, in-person); Equipment location (e.g. archive); Equipment status (e.g. ready to use); Setup categorization (GMP or Non-GMP) | Operating conditions; Flow rate; Volume of materials; Suitable equipment; Equipment location (e.g. archive); Equipment status (e.g. ready to use); Equipment history (e.g. last time of cleaning, last user, project number); Equipment manufacturer manuals; Equipment exchangeability/ compatibility (compensating for missing components); Equipment capabilities and weaknesses (official and actual); Equipment mail ordering periods; Serial numbers of equipment and materials; Maximum pressure of a pump compared to a system's pressure including flow rate; Material risks/hazards about chemicals; Material and solvent compatibility (e.g. max. and min. pressure, temperature rating) |

General Need for Information

The observations and interviews from the contextual inquiry show a "general need for information". This category contains user need items that reference needed types of information (see examples in Figure 6).

General Need for Efficient Collaboration

Another overarching category that contains multiple user need statements is named "general need for efficient collaboration". Here, user need items that address the need for efficient communication, documentation, and active information sharing are summarized (see examples in Figure 7).

General Need for Control

The third category that contains multiple user need statements is called "general need for control". This category addresses user need items regarding preparation or being prepared, reassurance or control checks, as well as authentication or responsibility checks (see examples in Figure 8).

General Need for Flexibility

The last summarizing category is called "general need for flexibility". Here, user need items that address issues regarding frustration tolerance and openness to cope with constant changes as well as iterations during the lab experimentation are collected (see examples in Figure 9).

**Figure 6 Illustration of coding (aggregation) of user needs into overarching category "need for information" (own representation).**

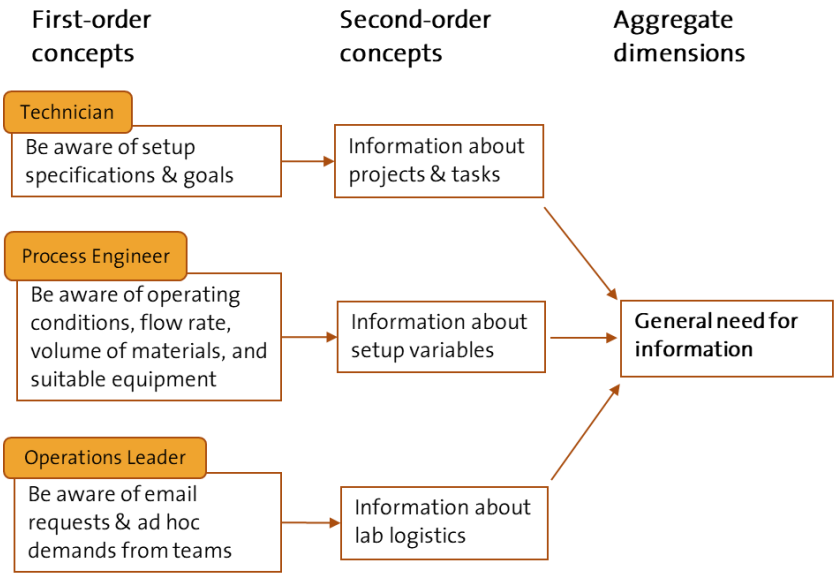


**Figure 7 Illustration of coding (aggregation) of user needs into overarching category "need for efficient collaboration"." (own representation).**

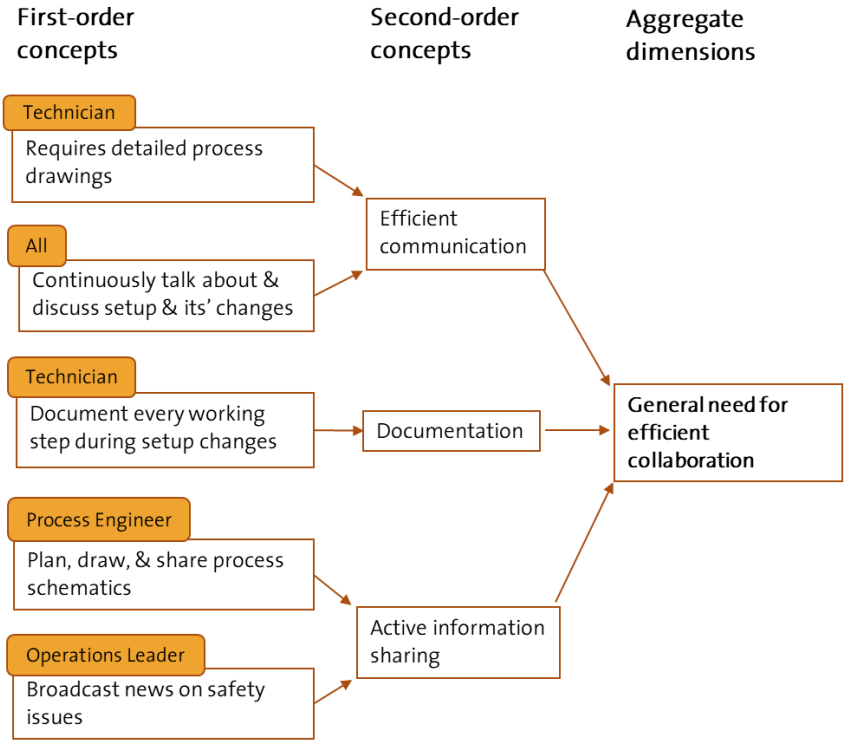



**Figure 8 Illustration of coding (aggregation) of user needs into overarching category "need for control". (own representation).**

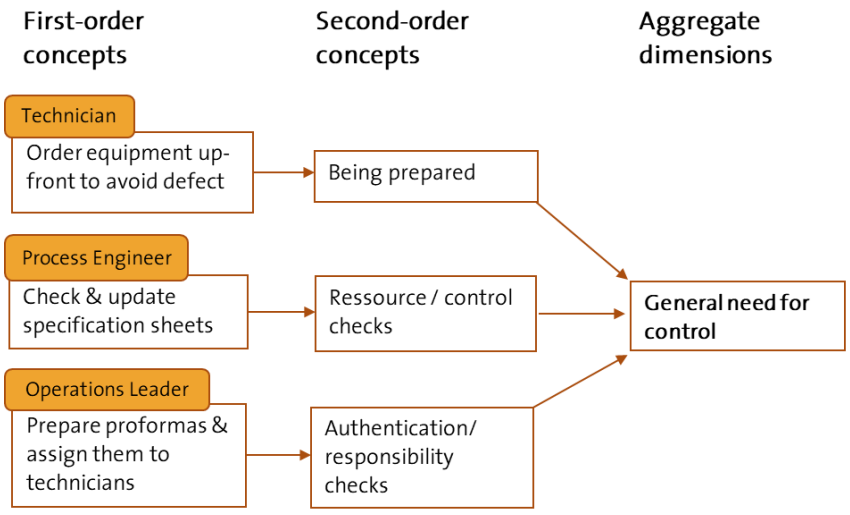
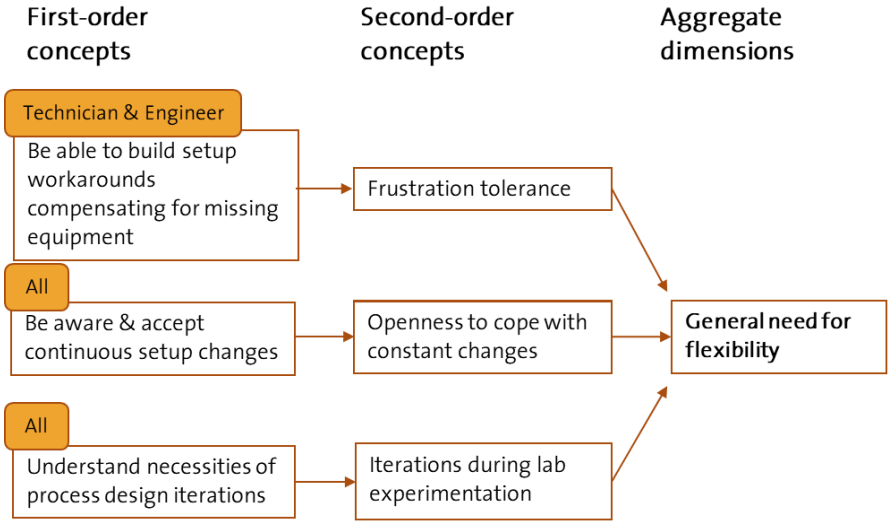


**Figure 9: Illustration of coding (aggregation) of user needs into overarching category "need for flexibility". (own representation).**




## 4 Discussion

Employees working in pharmaceutical R&D for drug discovery and manufacturing preparation face diverse challenges in all aspects of everyday laboratory work. Against this background, this study addresses the question of how people work in corporate pharmaceutical research and development laboratories for continuous manufacturing, what their needs are, and how these needs could be met.

The results of the current qualitative study show their extensive and diverse set of interrelated (user) needs from their employee's point of view. Typically, these needs are supposed to be supported by e.g. rule sets like good manufacturing practice (GMP), safety regulations, and trainings. Looking at the literature, the importance of these 'human factors' has been emphasized.

For example, while Konstantinos and colleagues (2011) on the one hand mention future trends in pharmaceutical manufacturing and in industrial manufacturing as a whole, which reinforce the need of a stronger utilization of human factors aspects, as many issues of concern can be avoided or their effect minimized. On the other hand, their results show that compliance with the legislation regarding GMP regulations still seems to be the main requirement for pharmaceutical production, while human factors are not explicitly emphasized.

However, in the context of the results of this study these traditional rule sets and top-down management activities do not support all aspects of the employee's experience. Overall, aspects of team culture and communication seem to be as important as these traditional approaches for safety and risk management.

Therefore, based on the results of this study several implications are discussed as general findings.

Finding 1: *Digitization efforts should prioritize communication and collaboration over features.*

The results of this study also show that the lab workers struggle with the currently not consistent digitization efforts regarding documentation and organization of materials, solvents, and setup components. Digital tools like an Electronic Lab Notebook (ELN) or Wiki as knowledge base are already in place in this research laboratory, but are used to a less degree, because they either do have technical limitations or are limited in provided features – so they do provide some benefits, however, are not comprehensively deployed and thereby do not fit the user needs for constant and consistent communication during collaboration identified in the inquiry. Therefore, the support of effective collaboration is identified as a major challenge for the digitization of lab work, that is the continuous transition between both the analog and the digital world. For example, there is no consistent electronic documentation system in

place and just specific workflows take advantage of specific features of such tools. So, on the one hand it is still common practice to use paper-based lab notebooks. On the other hand, there are a lot of ELNs available on the market. This, however, seems to be common practice in the majority of laboratories and evidence suggests that whilst scientists willingly make use of generic software for note taking and documentation, spreadsheets, general office software, as well as special scientific software to aid their work, current ELNs are lacking the required functionality to meet the needs of the researchers (Kanza et al., 2017). For example, most of available ELNs offer basic cloud-based text functionality like Microsoft Word while many of them fail to offer basic not to mention convenient capabilities of data sharing features. Based on this study's results it is argued that such tools like ELNs should offer data and knowledge sharing as a main feature next to documentation for teams working in research laboratories. Data sharing thereby includes features like transparent versioning of documents and visualization of data wherever possible in order to enable respective knowledge sharing and collaboration. Goal should be to not simply replace existing solutions, e.g. replacing Microsoft Word or Excel by a process development tool not just for the features or to digitize an analogue process, but more so if the latter is enabling better collaboration by fostering the right organizational climate that persuades people to create, reveal, share and use knowledge (Davenport et al., 1998; O'Dell and Grayson, 1998; Mariani, 2002).

Here, again, the fact can be highlighted that in the development of new lab workflows or refinement of current workflows there are process plans and instrumentation blueprints that are communicated as diagrams, while the collaboration happening with these diagrams is not yet digitized consistently. But this exactly might be one issue to enable better communication and thereby avoid mistakes and workflow errors. In this regard, the current investigation shows challenges in communication, e.g. by means of ad-hoc documentation with printouts and lab notebooks in correspondence with partially available digital documentation and knowledge sharing possibilities. For example, one technical solution addressing this finding may be to include interconnected large display covering live data, which could replace the mentioned paper-based setup diagrams that are currently pinned on the front of sterile work benches. Thereby, research laboratories might benefit from the logistics of so-called 'control rooms' (Lischke et al., 2018).

Finding 2: *Learning is considered a shared responsibility to foster an agile work culture for efficient in-team knowledge management*.

In order for the lab team to collaborate efficiently there needs to be constant dialogue of team members fostering knowledge sharing and thereby collaborative learning. This finding relates to the general best practices in software engineering that follow a lean project management approach called 'agile' (Cardozo et al., 2010). Agile is a project management system where so-called 'sprints' or iterations are utilized to complete allocated tasks and assignments. Sprints or iterations are short spans of time, usually two weeks, where a team meets up and discusses the cycle of a project. In these meetings, tasks are assigned according to a proper timeline. Also, team work plays a significant role in the success of a project and there are frequent interactions between the client and the developers. Although there seems to be a common understanding, that agile development methods conflict with the generally accepted software development methods within the pharmaceutical industry (Hajou et al., 2014), it can be argued that the scientific lab work in the investigated pharmaceutical R&D laboratory shares some key dynamics to agile team work, following an overall mindset of adapting to change including trial and error for successful and constantly evolving collaboration. One key aspect of agile methodology is constant communication or focusing on relationships to foster team work and knowledge sharing. This finding is supported by the results from Mariani (2002) who describes the working culture in a very successful research laboratory in a way that resembles the ideal type of agile development methodology (Beck et al., 2001). In addition, some application-oriented publications argue that agile methodology is showing itself a promising way of working and moving beyond software development projects and soon will find its place in other industries like pharmaceuticals (Alaedini et al., 2014).

Overall, the results of this study suggest to lean more towards theories of human factors and education in lab management to foster this

kind of sociocultural, organizational way of learning. For example, Boreham and Morgan (2004) propose a sociocultural model which identifies 'dialogue' as the fundamental process by which organizations learn, and relational practices as the social structure which embeds the dialogue and makes it sustainable in a potentially conflictual environment. They define a pedagogy of organizational learning in terms of participation that builds on relationships between employees in addition to the traditional focus on autonomy of individuals. This argument is also supported by Konstantinos and colleagues (2011) who state that lab workers need to interact as to form social networks, interactions and teams that can facilitate group identification and lead to more smooth coordination and collective action, while the parameter of auditing can be an issue among the workers and again prohibit the teamwork (Hutchinson and Zain, 2009). In addition, these authors generalize such issues stating that in many organizations, a major cultural shift is required to change employee attitudes and behavior so that they willingly and consistently share their knowledge and insights and thus help management and control process. Another study supporting this argument showed that in order to be successful in pharmaceutical R&D teams depend on the capacity to perform a large number of experiments and the capacity to rapidly modify or adjust production programs (Mariani, 2002). Here, the call for flexibility, continuous learning and teaching of team members, coupled with an increased rate of experimentation challenging strict regulations including confidentiality is especially interesting.

Finding 3: *Incorporating user research practices is important to uncover underlying social systems as determinants for the success of socio-technological systems.*

One goal of this in-depth exploratory user study is to foster fundamental and interdisciplinary debates about the design and implementation of applications based on novel hardware and software products in laboratory environments. Such debates are considered very important since the conceptualizations of managers, engineers, developers, and designers are often based on initial hypotheses concerning the collaborative relationship between their technological product and the potential end-users, while these collaborative relationships are often neither made explicit nor are these assumed relationships verified in the field (Sharit, 2006). Furthermore, the conduct of validation and verification studies during product development and after product release is usually limited to the technical side of implementations, thus results may be informative but hardly about a combined view of social and technical aspects. On the other hand, the potential to succeed or to fail of a system, once it has been brought to the field, is strongly determined by the adaptation of both social and technical aspects (Dekker, 2005). In this regard, the reward structure of organizations usually emphasizes on rapid completion of projects and the insulation of engineers to give less consideration to factors related to ease of operation and even safety (Perrow, 1983). Here, the results of this study show the interdependencies between all individual employees working in the lab, their need and constant effort to initiate and maintain an efficient mode of communication and collaboration as a foundation for the technical side of chemical research and recipe development.

The most striking yet straightforward example for this interdependency of responsibilities and respective communication routines is found in the collaboration around the already mentioned process design drawings. Here, a scientist creates and proposes a process drawing which follows his current experimental hypothesis in order to discuss the technical feasibility of a respective process setup in the lab. The process engineers and technicians on the other hand rely on this process drawing in order to understand what they are supposed to do next, while also anticipating the broader research idea of the scientist. In theory, this collaboration seems like a top-down approach of research design and management, but the results show that it is rather a constant debate or iterative collaboration for setup refinement to find technical solutions as a team, which need to be feasible yet do not compromise the scientific hypothesis. Surprisingly, interview partners also mentioned that technicians sometimes have more in-depth knowledge about equipment and instrumentations than their highly skilled scientist and engineering colleagues. One interview partner even mentioned that occasionally scientists first ask technicians to propose a setup instrumentation to iterate

on a recipe experiment or that a recipe and its experimentation setup is changed, because of a proposed technical solution from a technician. Thereby, it can be concluded that the scientists include bottom-up experimentation in their research rationale. This statement also supports the finding regarding work culture in this lab to follow a mode of constant debate that tries to contain knowledge transfer in teams top-down as well as bottom-up.

In the end, the importance for lab management to identify and clarify such aspects regarding the flow of information for effective knowledge sharing in teams working in such fast-paced and everchanging work environments can be inferred. Hence, team leaders or lab managers should know and communicate which team members need to know what information in what kind of form and when in which point in time from whom to what effect. This finding goes along with the research regarding the theoretical construct of 'work process knowledge' from Fischer and Röben (2002a), which highlights a special type of shared knowledge that team members working in organizations need to develop and continuously expand in order to anticipate the organizational requirements and the needs of their colleagues. Thereby, it can be concluded that it could be helpful and might become important for pharmaceutical companies in the future to incorporate such kind of user research or human-centered design practices to uncover such underlying individual needs and social interdependencies as determinants for the success of the socio-technological system that is the chemistry laboratory for research and development.

Generally speaking, it is suggested to research and analyze cultural and social aspects of workflows in special environments like laboratories before designing and developing digital solutions on the road to paperless work (Thimbleby, 2019). In addition, it is argued to respect and include bottom-up processes of collaboration that are based on experiential knowledge. Here, the increased cost of repetition (trial and error), e.g. by failed measurement, has to be balanced against the contribution to the development of individual competence and quality assurance within an organization (Fischer and Röben, 2002a).

This 'cultural approach' to lab knowledge management could also help organizations to specify opportunities and benefits regarding the adoption of new tools and solutions, which is often a challenge, because the benefits of outdated yet established tools and solutions usually predominate the adoption costs of new tools and solutions that, however, may offer more benefits in the long run (Rogers, 2003; Wang et al., 2010). For example, Schmitt (2019) investigates the challenges regarding the adoption of B2B electronic marketplaces in the chemical industry and argues for a top-down approval approach for introducing new solutions through managers, because on the one hand operative individuals in general show the tendency to stick to familiar processes and on the other hand there is often a lack of incentives for employees to take up the challenge of new digital solutions bottom-up. However, as mentioned above, decision making for such top-down introduction of new solutions could be informed by bottom-up processes of cultural analysis and knowledge management.

This is considered highly important, because beyond the study of lab work, these circumstances would appear to shift the attribution of user errors from engineers, developers, and designers to management in the development of laboratory hardware and software products. Following Reason (1990) and Sharit (2006), such organizational 'management errors' represent types of latent errors that are responsible for creating preconditions of user errors in the end. Finally, this misaligned error attribution problem created by poor engineering, development, design, or management policies traditionally have been duped on training departments to compensate for these problems (Sharit, 2006). Respectively, it is argued that one major deficiency in these development processes may be the hubris of decision makers underestimating the human factors in their planning, as well as the inability of employees and management to appreciate human fallibility by failing to take into account relevant information. Overall, the step of developing a Human Factors Engineering strategy or User Experience strategy or Human-Centered Design strategy is either not completed or it is accomplished by non-human factors personnel, which can lead to poor results (Privitera, 2019). In this regard, Privitera (2019, p. 28) explicitly argues:

"The reasons for this are varied; however anecdotal evidence suggests that manufacturers often believe only a minimum of Human Factors input is required based upon what they

believe to be the agency requirements. Manufacturers then provide a rationalization that doing more is not necessary because they, in fact, "know their users". In instances where manufacturers lack Human Factors analysis procedure, they may rely on hearsay without an optimized or documented approach. This becomes problematic in developing the required Human Factors submission documentation for agency review. Lastly, personnel without additional education in Human Factors may not ask the right questions necessary to determine appropriate human factors strategies required to optimize the device interface. Thus, developing a Human Factors strategy at the onset of a device program assures that all User Needs are met and that the manufacturer has a firm commitment to quality from the user's viewpoint."

Therefore, the notion of Ulbrich and Aggarwal (2019) is supported that companies will need "translators-specialists" – the aforementioned user researchers or human factors engineers – who are able to understand the functionality desired by e.g. lab workers and translate it into technical requirements that can be understood and processed by the IT staff. In this spirit, this exact concern is given serious consideration in human-centered design practices (Nielsen, 1995; Sharit, 2006; ISO/IEC 13407) and this study represents a source of insight for user needs in the context of laboratory workflows in general.

Limitations of this study

Nevertheless, the aforementioned results and findings need to be reflected in context of the methodological limitations of this study. These limitations include a lack of prior research studies on the specific topic of lab work in continuous manufacturing labs of big pharmaceutical companies.

Further research might also apply mixed-methods research designs combining not only observation and interviews, but also surveys or longitudinal data collection approaches like diary methods for continuous experience sampling. In addition, reliability of qualitative data is always an issue due to the methods for data collection relying on self-report data only. Here, it needs to be clarified that this study represents a first step in exploring the field of corporate lab work in continuous manufacturing and that more research is needed to generate more reliable data and respective insights. However, the most prominent limitation is the small sample size due to limited access to pharmaceutical companies as well as people working in these companies. Here, different modes and contract models of collaboration for co-innovation could be explored to get more access to corporate research facilities (Schneiderman, 2016), e.g. by supporting and fostering open innovation initiatives (Hunter and Stephens, 2010; Bianchi et al., 2011; Schuhmacher et al, 2013) between social researchers and corporations.

## 5 Conclusion

Scientists, engineers, and lab workers developing chemical solutions in big pharmaceutical companies construct, engineer, monitor, and manage complex processes. Staff members have to follow strict regulations while making system-relevant and sometimes safety-critical decisions. Thereby they are supported by a large amount of information in form of lab notebooks, drawings, or diverse format templates for documenting specific processes and incidents. This study provides an in-depth view into common work practices and aims to identify challenges for workflows, processes, decisions, and actions in a chemistry research laboratory for analytical method development in continuous manufacturing.

The findings show what people in this laboratory need to work together and communicate effectively. On top, in comparison to current psychological and social studies in the field of laboratory work, e.g. from the human factors community, the results show that there is a fundamental difference in research design focusing on human needs instead of human error. Thereby, the study follows the paradigm of positive psychology (Seligman and Czikzentmihalyi, 2000) instead of a paradigm of economic and mechanistic efficiency or technical functionality that typically considerers humans as a source of risk and technical errors, hence, the traditional goal of such research initiatives is to optimize the human-machine system (sometimes even called 'co-operation') for reducing the potential for human error. For example, in comparison to these studies which offer the overall identification and listing of risk factors like "stress" or "time pressure", this current study investigates and identifies the constitutional employee needs as user needs in situ that

lead to such psychological and social phenomena. Hereby, this study is in line with the overall goal of human-centered design including the user-research-led product development practice of user experience design, which are both fundamentally focused on human needs and their relationship towards environments, systems, applications, and products. By providing an extensive list of 96 user needs (see appendix) and detailed descriptions of user roles this study aims to encourage a debate about human-centered design in pharmaceutical manufacturing.

Finally, the findings support the notion of Ulbrich and Aggarwal (2019) that it is vital for chemical companies to incorporate employees in transformation processes, e.g. when implementing cloud and analytics solutions that are centered on the users, who are in this case scientists, engineers and lab technicians. In this regard, the study aims to fill a gap in discussions around enabling future laboratory processes. Here, typically project stakeholders are not able to describe the current as-is situation of processes, workflows, habits, and people's attitudes in place, which is why the authors hope that this study also contributes to the overall discourse of change management and innovation in laboratory environments.

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# Appendix

## Complete list of elicited user needs:

### Scientist:

(1) A scientist in this laboratory needs to proof his thinking around a concrete set of chemistry. Therefore, he needs to produce an understanding of the process, that is, about the reaction time and the mixing characteristics of the equipment. With these data a scientist in this laboratory needs to build a model to be able to scale that in correlation to bigger setups for mass production.

### Continuous Processing Technician (Technician):

Design Phase

(2) A technician in this laboratory needs a diagram of the setup in order to understand what a scientist wants to do.

(3) A technician in this laboratory needs to interpret process design drawings in order to be able to start building the setup

(4) A technician in this laboratory needs to identify changed parts of the setup diagram (in his proforma) in order to account for the newest version of the setup.

(5) A technician in this laboratory needs to read and understand the process design/drawing in order to know which parts he has to find for the setup.

(6) A technician in this laboratory needs to know the “Inlets” and “Outlets” of a setup in order to know how special components are connected to the other parts of the setup.

(7) A technician in this laboratory needs to get as much information about the setup as possible from different people in order to understand their goals.

(8) A technician in this laboratory needs to get specific information on layers and details of setup diagram in order to avoid iterations.

(9) A Technician in this laboratory needs to be able to understand the necessities of process design iterations in order to avoid knowledge gaps and frustration.

(10) A Technician in this laboratory needs more detailed and standardized process diagram containing consistent symbols in order to be more efficient.

Setup Phase

(11) A technician in this laboratory needs to visually control the setup flow in order to get a first impression of its status.

(12) A technician in this laboratory needs to be aware and constantly control setup equipment for errors, especially pumps, in order to be able to change and thereby dispose the defective equipment.

(13) A technician in this laboratory needs to flush pumps with solvents in order to clean setup parts.

(14) A technician in this laboratory needs to be able to put a component aside for further cleaning when it is not clean and should be able to take a new (clean) component instead in order to continue a setup.

(15) A technician in this laboratory needs to identify errors on the operation system gathering data on the setup.

(16) A technician in this laboratory needs to be able to build setups in iteration in order to coordinate/compensate missing equipment.

(17) A Technician in this laboratory needs to do (besides visual check, a pressure check) a flow rate check with equipment in order to assess if the pumps are delivering what their status claims to be able to deliver.

(18) A Technician in this laboratory needs to be able to work on basis of the process diagram without thinking of alternative setup possibilities including special components.

 

(19) A Technician in this laboratory needs to be able to work with a sorted and fully equipped (all in one) toolbox in order to be able work "out of the box" spontaneously.

(20) A Technician in this laboratory needs to be reassured about working rules for each component, with or without serial number, in order to know how to document/log them.

(21) A Technician in this laboratory needs to be able to help himself in terms of training, that is, getting specific manufacturer manuals on the spot.

(22) A Technician in this laboratory needs to analyse the setup step by step with his boss or a chemist before he is allowed to run the setup.

(23) A Technician in this laboratory needs to have an equipment-recipe attached to the process design/drawing in order be more efficient.

(24) A Technician in this laboratory needs to be aware of component capabilities and weaknesses that can unfold during instalment of different components (e.g. the pressure or tension of a screw that is fixing a tube that might lead to a leak).

Communication

(25) A technician in this laboratory needs to communicate to colleagues in order to seek and get advice or to find the right equipment.

(26) A technician in this laboratory needs to be able to talk to a chemist engineer in order to start the cleaning of components.

(27) A technician in this laboratory needs to order a specialist (e.g. from IT or facility management) to restart and fix the operation system in order to keep the process running.

(28) A technician in this laboratory needs to react spontaneously to demands of scientists who are present in the lab and adapt his plans or priorities.

(29) A technician in this laboratory needs to discuss original setup designs/drawings/plans at the very beginning in order to get a clear understanding of the goals.

(30) A technician in this laboratory needs to be able to commit suggestions for setup changes or adaptations in order to start a discussion with a scientist (e.g. about how the setup might be more efficient).

(31) A technician in this laboratory needs to be aware of the intranet team-sites in order look up suggestions from colleagues and share his own experiences with specific equipment or setups.

(32) A Technician in this laboratory needs to communicate with his colleagues to share knowledge about current status of a setup and what is to do next.

(33) A Technician in this laboratory needs to know the current status of project setups, who is working right now, who will be working in the next shift (am-shift & pm-shift) and when who will be on vacation.

(34) A Technician in this laboratory needs to anticipate support by colleagues in order to know how to wrap up his shift or how to leave a setup (turn off or leave it running).

(35) A Technician in this laboratory needs to be able to place orders for equipment sooner in order to avoid the lack of equipment.

(36) A Technician in this laboratory needs to be able to share his current point of view of a part of the setup in order to get 'hands-on' feedback or advice from a colleague.

(37) A Technician in this laboratory needs to be reassured about his role in order to manage expectations regarding rotation of team members and responsibilities.

Documentation

(38) A technician in this laboratory needs to get a proforma to be able to focus on the required

 

setup specifications.

(39) A technician in this laboratory needs to know where specific parts of equipment are right now in order to collect them to be able to start the setup process.

(40) A technician in this laboratory needs to document every adaptation of the setup diagram in the Proforma.

(41) A technician in this laboratory needs to be aware that there might be a lot of changes to the setup and the Proforma in order to optimize the process that is to be developed.

(42) A technician in this laboratory needs to understand protocols for lab notebooks and discuss them with an engineer.

(43) A technician in this laboratory needs to visually inspect components and take them apart while documenting their status for cleaning.

(44) A technician in this laboratory needs to fill out a cleaning record that is a protocol within the lab notebook that requires him to sign of single tasks, in order to be accountable for the cleaning of components.

(45) A technician in this laboratory needs to know in which condition a component is before he is allowed to use it.

(46) A technician in this laboratory needs to sign things correctly in the lab notebook, that is, starting on the actual protocol and ending on the page of the lab notebook that contains the actual protocol.

(47) A technician in this laboratory needs to be aware of several projects, their status and current tasks.

(48) A technician in this laboratory needs to gather and document all information regarding his current tasks in order to hand it over to colleagues during the handover of a shift.

**Operations Team Leader:**

(49) An Operations Team Leader in this laboratory needs to organize and manage the storage and maintenance of materials and equipment in order to keep the workflow of the lab running.

(50) An Operations Team Leader in this laboratory needs to prioritize many different requests.

(51) An Operations Team Leader in this laboratory needs to maintain the lab's intranet teamsite in order to track tasks and equipment, e.g. in combination with Proformas.

(52) An Operations Team Leader in this laboratory needs to document equipment status, that is, where they are in use at the moment, their current status as material and where it is stored.

(53) An Operations Team Leader in this laboratory needs to combine information from lab notebooks and Proformas in order to keep track of equipment.

(54) An Operations Team Leader in this laboratory needs to manage single requests, that is, assigning equipment to the request by checking its status (e.g. via tracking-list or spreadsheet).

(55) An Operations Team Leader in this laboratory needs to think about ways to track equipment with barcodes.

(56) An Operations Team Leader in this laboratory needs to talk to scientists in order to discuss the organization of resources for new ideas and significant setup changes.

(57) An Operations Team Leader in this laboratory needs to prepare Proformas and assign them to technicians.

(58) An Operations Team Leader in this laboratory needs to relate changes of shifts, the overview and current status information for each project and the current status of individual Proformas.

 

(59) An Operations Team Leader in this laboratory needs to know if the setup is GMP or Not-GMP and identify relevant implications.

(60) An Operations Team Leader in this laboratory needs to be able to standardize resource management in order to plan and structure the expectations of team members.

(61) An Operations Team Leader in this laboratory needs to be able to set requests 'on hold/halt' in order to avoid excessive demands by gathering more information and discussing challenges.

(62) An Operations Team Leader in this laboratory needs to organize requests in coordination between email and demands that are broadcasted between team members and in the lab, that is, e.g. on a whiteboard.

(63) An Operations Team Leader in this laboratory needs to coordinate the skills of technicians to tasks and further discuss demands for training.

(64) An Operations Team Leader in this laboratory needs to be able to broadcast specific information for safety issues, e.g. prior experiences or highlight hazards working with a specific component.

(65) An Operations Team Leader in this laboratory needs to broadcast the following key information for setups: What equipment, what capabilities for the materials of construction (e.g. stainless steel), where is it going, what are the goals to aim for with this setup.

(66) An Operations Team Leader in this laboratory needs to be able to manage/coordinate initial meetings including technicians in order to enable an ongoing knowledge transfer between science and know-how.

(67) An Operations Team Leader in this laboratory needs to be able to highlight and coordinate differences between the workstyles of GMP and NON-GMP.

**Continuous Processing Engineer (Engineer):**

(68) An engineer in this laboratory needs to be able to proof the feasibility of experiments.

(69) An engineer in this laboratory needs to be able to work and easily switch between the office work place and the laboratory in order to discuss process theory and feasibility.

(70) An engineer in this laboratory needs to be aware of operating conditions, flow rate and volume of materials on the one side and suitable equipment on the other side.

(71) An engineer in this laboratory needs to write specification sheets for materials.

(72) An engineer in this laboratory needs to be able to check the suitability of equipment by reading manufacturer manuals and so-called 'specification sheets' which contains basic information of materials and limits.

(73) An engineer in this laboratory needs to check the Team-Sites/Spreadsheets to see which equipment is available.

(74) An engineer in this laboratory needs shared templates for process drawings.

(75) An engineer in this laboratory needs to plan and draw process schematics on his office-PC and share these schematics with technicians at the place of the setup.

(76) An engineer in this laboratory needs to be able to use small-scale experiment setups for simulation in order to brainstorm and discuss possible setup solutions.

(77) An engineer in this laboratory needs to know which special components are ready for setup and if not, what they need to become ready for use (e.g. pressure sensors and temperature sensors require an interface with a control and data logging system.

(78) An engineer in this laboratory needs to know and document the status of each component before using it, that is, the history of it including dates of use, project/experiment

 

number, name of the person who has signet out, specific logging codes for the component.

(79) An engineer in this laboratory needs to document smaller changes and adaptations in the lab notebook ("logging") using references via logging codes (shortcuts) and specific serial numbers for specific components like pumps that are enlisted in the lab notebook.

(80) An engineer in this laboratory needs to document events in detail during experiments or cleaning.

(81) An engineer in this laboratory needs to be able to simplify documentation habits, especially in order to document group meetings.

(82) An engineer in this laboratory needs to know risks/hazards about chemicals as well as compatibility data of the equipment (high temperatures & pressures) in order to get an idea about the process assessment.

(83) An engineer in this laboratory needs to get a rough idea of what has to happen/to be done in what order to document processes.

(84) An engineer in this laboratory needs to be able to place short notes/instructions on the setup in order to highlight simple tasks, e.g. cleaning of a component.

(85) An engineer in this laboratory needs to be able to communicate instructions for the evening shifts in order to prepare things for the next morning.

(86) An engineer in this laboratory needs to know the weak spots of a setup, that is, what is the limiting bit of equipment and be able to focus on the 'delivery system' and the 'reactor'.

(87) An engineer in this laboratory needs to identify a component by serial number in order to discriminate between logged equipment and consumable materials.

(88) An engineer in this laboratory needs to know about the current stock spares and who is involved in the ordering of new equipment.

(89) An engineer in this laboratory needs to be sure about the documentation and specific storage of components.

(90) An engineer in this laboratory needs to know the last person responsible for a component of equipment.

(91) An engineer in this laboratory needs to know compatibility of solvents, max. and min. pressure and temperature rating for equipment in order to build a setup for experimentation.

(92) An engineer in this laboratory needs to know the last settings of components, e.g. of pressure reliefs, and how to change the settings the right way (and when it was tested).

(93) An engineer in this laboratory needs to decide on which reactor to use, inlet-points and their class as well as the outlet-points in order to start modelling a small-scale simulation setup with the based on a rough idea for a process.

(94) An engineer in this laboratory needs to combine the information of operation conditions (temperatures), what and where to operate, problems with operation limits, operation capacities of the system (heat & cold), needed speed of mixer-components.

(95) An engineer in this laboratory needs to know the maximum pressure of the pump compared to the system pressure, also considering flow rate.

(96) An engineer in this laboratory needs to be able to find the person to talk to in order to gather information about new components.

 

## Interview guideline for contextual inquiry in continuous manufacturing lab

Introduction / Instruction

The goal of this document is to guide you through the data gathering process during user interviews on site. Overall, we aim to cover and understand the sense making processes of people during work within a specific work place that comes with a specific culture, including respective individual and social practices in place (e.g. habits, routines, and rules).

The guideline document structure follows a successive logic, beginning with easy to answer questions for rapport to warm-up or break the ice for having a relaxed and authentic discussion. Interviewees shall know and understand that this is not a test, that we are just curious outsiders trying to understand the way they think and work.

The overall structure is as follows:

1. Introduction / Instruction
2. Participant & his goals ("Me as a person & employee")
3. Working in a team („Me and the others in the team")
4. Tasks („What I do & my tools")
5. General workflow („What I usually do, in which order and why")
6. Current workflow (Introduction to work place)
7. Closing the interview

 

**Table A1 Interview guideline for contextual inquiry in continuous manufacturing lab (own representation).**

Project/Topic: _____ Date: ____.____._____

Participant: _____ Time: _____ until _____o'clock

| No. | Check column, if topic was mentioned | Introduction / Instruction | |
|---|---|---|---|
| | | Summarize the reason for being here again & clarify the overall process and next steps | |
| | | | |
| **Participant & his goals ("Me as a person & employee")** | | | |
| | | Who are you and what is your job and your tasks here? | |
| | | Since when do you work here? | |
| | | What kind of education and training did you receive? | |
| | | Who do you work with? | |
| | | What do you like most about your work? | |
| | | What is your first step? | |
| | | What do you not like at all about your work? | |
| | | Is there anything you wish you could just skip? | |
| | | Is there anything you tend to postpone? | |
| (short notes/keywords) | | | |
| **Working in a team („Me and the others in the team")** | | | |
| | | How do you share your tasks within the team? | |
| | | Who decides what? | |
| | | Who is taking responsibility, if something goes wrong? | |
| | | Do you have an example maybe? | |
| | | What are the goals of your team? | |
| | | What is your role for achieving these goals? | |
| | | What do you consider as most important here? | |
| | | What do you need for your work in this team? | |
| | | What helps you make decisions in your work? | |
| | | How does a great work day or workflow look like? How looks a bad day or run in comparison? | |
| | | Which activities currently waste your time? | |
| (short notes/keywords) | | | |

 

Table A1 continued

| | | | |
|---|---|---|---|
| **Tasks („What I do & my tools“)** | | | |
| | | What do you do most often? | |
| | | What or which parts do you use most often? | |
| | | What do you like about it? Any favourits? | |
| | | How do you help yourself when problems occur? | |
| | | Which abbreviations or short cuts do you use? | |
| (short notes/keywords) | | | |
| **General workflow („What I usually do in which order and why”)** | | | |
| | | What did you do first today when starting to work? What are your first steps? | |
| | | How often do you do these activities? | |
| | | What do you do in addition or not that often, from time to time? Weekly or monthly? | |
| | | How does a typical day in your work life look like? Please describe! | |
| | | What would be an extraordinary event or exceptional circumstances in your work? | |
| (short notes/keywords) | | | |
| **Current workflow** (Introduction to work place)<br>**(Think-aloud during demonstration: „What do I do exactly, when, how, where, and why?”** | | | |
| | | Why are you doing this right now? Why do you need to do that? | |
| | | How often do you do this? | |
| | | When is it necessary to do this task? What pushes you to do this in the first place? Where is the task coming from? | |
| | | What needs to be done before you can do this task? | |
| | | What task follows on this task? What depends on this working step? | |
| | | Are there special or especially difficult tasks/activities? | |
| | | What happens, if something goes wrong there? | |
| | | How do you usually deal with such a situation? | |
| (check audio recording, if possible - short notes/keywords) | | | |
| **Closing the interview** | | | |
| | | Did we forget something that is important for you or your job? | |
| | | Or is there something else on your mind you want to share? | |
| | | | |

 

## Submission guidelines

Manuscripts may be submitted for consideration as research papers, papers for the practitioner's section or as commentaries.

All submitted manuscripts should contain original research not previously published and not under consideration for publication elsewhere. Papers may come from any country but must be written in American English.

## Initial Submission

Authors are required to submit manuscripts via e-mail (submit@businesschemistry.org). Please prepare the text in Microsoft Word or rtf-format. When submitting a manuscript, please include the following information:

- Information about the authors (affiliation, postal address, e-mail address)
- Tables and graphics separately in jpg-format (high quality), Microsoft Excel or Powerpoint.

Additionally, please stick to the formal requirements presented below, especially concerning citations and graphics. Manuscripts disregarding the guidelines may be returned for revision prior to any reviewing activity.

## Organization of the manuscript

Manuscripts can be arranged in the following order:

- Title, author(s), and complete name(s) of institution(s), corresponding author's e-mail address
- Abstract
- Introduction
- Methods
- Results
- Discussion
- References

These guidelines are, however, flexible, especially for case studies. To structure your manuscript, please try to restrict yourself to a maximum of three levels of headlines.

### References and footnotes

The authors are fully responsible for the accuracy of the references. Citations in the text contain only authors' names and date of publication [e.g. (Leker, 2001), (Bröring and Leker, 2006) or (Bröring et al., 2006) when three or more authors]. Full references have to be included at the end of the paper in alphabetical order. For more information on the reference style, please visit www.businesschemistry.org.

### Tables and figures

Tables must have titles and sufficient empirical detail in a legend immediately following the title to be understandable without reference to the text. Each column in a table must have a heading, and abbreviations, when necessary, should be defined in the legend. Please number the tables. Figures should have titles and explanatory legends containing sufficient detail to make the figure easily understood. Appropriately sized numbers, letters, and symbols should be used. The abscissa and ordinate should be clearly labeled with appropriately sized type.

## Revision

Revise text in Microsoft Word. Revise graphics at publication quality resolution. You may submit the revised manuscript as a single Microsoft Word document. Please send the revised manuscript via e-mail to the Editor who contacted you. You will need:

- Your submission number
- A cover letter with information for the Executive Editor and responses to raised concerns
- The revised manuscript.

## Publication

The Executive Editor responsible for your submission might ask you to change the format of your files in order to publish it. If the manuscript does not fulfill the formal requirements, the paper might be denied publication.

## Comments

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**Thank you for your contribution!**

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