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Letter from the Editor

Spotlight on: Process Innovation Management

After 2011 represented another record year for the chemical industry, a significant lower growth is expected for the next few months. In particular, the high US government debt level as well as the still ongoing debt crisis in Europe are both leading to a concerned macroeconomic sentiment. As a consequence, companies of the chemical industry are very reserved in spending cash. Although this is not considered as a strong crisis within the chemical industry, cost savings or the resulting increase of margins, for instance, are playing a decisive part in the competition. One possibility to achieve such a performance improvement is the optimization of business or production processes.

In this context, we are proud to introduce a new section within the Journal of Business Chemistry: Process Innovation Management. In addition to product innovations, process innovations play a crucial role in guaranteeing the long-term success of a company. Therefore, we are glad to welcome Prof. Dr. Thomas Lager as new member of the editorial board. As an affiliated professor at the Centre for Innovation, Technology and Entrepreneurship at the Grenoble École de Management in France, he will provide the Journal of Business Chemistry with the most interesting and newest insights in his field of research. In the current issue, he discusses the startup of new plants and process technology in the process industries. A special emphasis is placed on the previously scarce treated aspect of an efficient organization and different organization models.

In our second research article “The founding angels investment model – case studies from the field of nanotechnology” Gunter Festel and Jan Kratzer present a model to overcome the gap between academic research and the commercialization of research results. Within this model, early stage investors found start-up companies together with appropriate research partners to conduct research and later to commercialize the results. The implementation of the model in the United States, for instance in the area of nanotechnology, illustrates its successful application. The authors base their data on literature research as well as on interviews with 35 nanotechnology experts.

In the first of our two practitioner’s section articles “Standardized cost estimation for new technologies (SCENT) – methodology and tool”, an opportunity to prepare preliminary economic estimates of the total production costs related to manufacturing in the process industries is introduced by the authors Stanil Y. Ereev and Martin K. Patel. The underlying methodology uses the factorial approach, whereas the cost objects are estimated with the help of factors and percentages on the basis of the purchased equipment cost. The presented approach contains the main advantage that it can be based on a limited amount of data making it particularly suitable for new emerging technologies.

The question of an effective outsourcing strategy for toxicological studies in the chemical industry is answered by Katja Hempel, Sandra Zumstein, Michael Graef, Hennicke Kamp, Bennard van Ravenzwaay in our last practitioner’s contribution. The work has been developed at the BASF SE’s Experimental Toxicology and Ecology Unit with the aim of promoting a faster reaction to the testing demand, driven by the European Community Regulation REACH (Registration, Evaluation, Authorization and restriction of Chemicals). The increasing necessity of Toxicology Unit’s outsourcing activities leads to the following goals: on the one hand the optimizing of the selection and management process of Contract Research Organizations and on the other hand the development of a performance measurement system in form of a balanced scorecard.

Now, please enjoy reading the first issue of the ninth volume of the Journal of Business Chemistry. We would like to thank all authors and reviewers who have contributed to this new issue. If you have any comments or suggestions, please do not hesitate to send us an email at: contact@businesschemistry.org.
Research Paper
Startup of new plants and process technology in the process industries: organizing for an extreme event

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In the startup of new process plants or in the introduction of new process technology, even minor installation work can cause plant downtime. On the other hand, the increased income from compressing time schedules for the introduction of new process technology or launching of associated new products on the market surely offers an incentive for securing efficient startups, which is the purpose of this study. A review of publications in the area of startup of process plants shows that organizational issues are scarcely discussed. A new conceptual framework has therefore been developed for organizing startups and the modelling of alternative startup organization structures. Four types of organizational models have been depicted, derived from information from the literature survey and the author’s own first-hand experience of startups. They include a “fully integrated” type of organizational model for startups together with a profiling of startup contexts. How to organize a startup is, however, only one aspect that will determine the outcome of a project, and other influencing factors ought to be further explored. The framework must be tested and validated in real-life startup situations and in further empirical research. The information from the literature survey, the alternative types of startup organizational models and determinants can already be deployed by firms in the Process Industries, triggering discussion and providing guidelines in their selection of preferred startup organization.

1 Introduction - preparing for an extreme event

The Process Industries, including many different sectors like minerals and metals, pulp and paper, food and beverages, chemicals and petrochemicals and pharmaceuticals, constitute a large part of all manufacturing industry. To err a little on the conservative side, one can say that about 30 percent of the most R&D-intensive firms worldwide belong to the Process Industries (Lager, 2010 p.23). In the startup of new process plants or in the introduction of new or improved process technology in existing plants, even minor installations or modifications can cause disruption of the process and/or plant downtime. Such disturbances not only result in loss of production volume but often seriously affect product quality from the production unit. Calculations of the cost of process disturbances or unnecessary downtime associated with startup stumbles often give frightening results (Leitch, 2004a). On the other hand, the increased income from compressing the overall project time schedules by excellence in introducing new process technology and/or launching of associated new products on the market surely also offers a strong incentive for securing smooth and efficient startups.

1.1 What is the problem?

Some experience from startups in the Steel Industry can serve as an important introduction to the problems of practical implementation of process technology. Experience from introduction
of partly new, novel and untested technology and from startups of large-scale steelmaking projects between 1995 and 2000 was generally dismal (Bagsarian, 2001). Figure 1 shows that none of the plants had reached design capacity within one year, and only one after two years.

These slow startups were mainly attributable to investment in new and untried process technology and other managerial and organizational issues.

Companies that expected startups to last months were still trying to get the mills working smoothly years after the first heat. The more new technologies a mill installed, the longer the startup took. … Some mills also had the wrong people in place. Despite the millions of dollars companies spend on the most modern systems, new furnaces, casters and rolling mills, putting the right people in charge of starting up a new mill is paramount (Tom Bagsarian, 2001).

The experiences reported by Bagsarian are unfortunately not solitary events! In a fairly old but interesting study of 24 steel industry process startups the duration, as measured by the amount of time required to achieve steady-state productivity, varied from 2 to 42 months (Baloff, 1966). Comparable durations were also found in the glass, paper and electrical products industries. In a large case study covering 41 process plants in the area of extraction of base metals, including flotation plants, leaching plants and smelters, the poor startup performance for many of these plant installations was scary (McNulty, 1998). The organizational aspects of those startups were not discussed explicitly, but it was hinted that for the group of low-performing projects, hands-on training of the workforce was lacking, supervisory staff were inexperienced, and technical support during commissioning and startup was inadequate.

A smooth startup is however of interest not only to firms in the Process Industries, but also to equipment suppliers, contractors, consultants and suppliers of raw materials and reagents. Successful introduction of their technology and startup at a customer’s plant is of an importance second to none (Lager and Frishammar, 2010).

Startup of plants in the Process Industries may have interesting similarities with startup of plants in other kinds of manufacturing industry, but there are also many differences. The most important difference is probably that process plants often have continuous (or semi-
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Continuous) material flows which make them not only difficult to start up but also difficult to shut down and restart, e.g. blast furnace operations. From the outset the need for 24-hour shift operation, sometimes also combined with complex physical or chemical reactions of a phase transformation character (e.g. petrochemical crackers, boilers in the forest industry), often makes a startup in the Process Industries an extreme event.

Startups of new process technology and production plants in the Process Industries are consequently very important corporate activities which unfortunately are often discussed simply in terms of “plant commissioning” (Horsley, 2002), and such general guidelines for startups are many (Gans, 1976, Gans et al., 1983). Startup performance in a wider context is only sparingly discussed in the literature, which could tempt the author to draw the conclusion that success depends solely on following such proper startup procedures. However, referring to the previous presentation, experience tells that there are many other factors that influence the outcome of startups. In such a typical engineering startup context, however, the fact is sometimes overlooked that startup is very much about people interacting with technology! Because of that, organizational aspects of startups do not always get the attention they deserve in firms; sometimes, indeed, they are almost entirely neglected. The purpose of this research was thus, focusing on the organizational issues of startups, to develop a theoretical platform for further empirical research.

1.2 Research approach

In the light of this introduction, the following research question was formulated and has consequently also guided the development of the new conceptual framework:

RQ1. In a “work process perspective”, what alternative types of organizational structures can be outlined, and which potential determinants can be identified for their selection in startup of process plants and new technology in the Process Industries?

A literature search was initially conducted with a view to establishing a theoretical knowledge base. Since this indicated that this topic has not been very well researched recently, the author, using his own first-hand personal knowledge of startups, began to develop a conceptual framework for alternative types of startup organizations. The input was based on the author’s own practical experience of starting up base-metal plants and a large iron-ore production plant in West Africa, and additional information from a handful of experienced startup leaders in the author’s personal network.

This approach is in line with Doty and Glick (1994).

“Organizational typologies have proved to be a popular approach for thinking about organizational structures and strategies. Authors developing typologies, however, have been criticised for developing simplistic classification systems instead of theories. Contrary to this criticism, we argue that typologies meet the criteria of a theory”.

The author’s own startup experience gave him a status of not only researcher but informant, inputting first-hand knowledge of startups in the Process Industries into this study (Yin, 1994 p.84). Such a research approach also resembles “innovation action research”, not because of the aspect of implementing research results, but as action research in a conceptualisation of his own hands-on startup experience (Kaplan, 1998). This is also a recommended research approach when theory is nascent or intermediate (Edmondson and McManus, 2007).

“Before collecting extensive quantitative data, the researcher wants to be confident that the key hypotheses are sensible and likely to be supported. This requires extensive conceptual work to develop the ideas carefully, obtaining considerable feedback from others, and refining the predictions before data collection.”

This article is “started up” with an identification of contextual determinants for startups. Afterwards a formal startup work process has been outlined as a processual perspective on startup activities. Using this template, four alternative structural organizational models are afterwards developed, followed by a final review of the startup more relational teambuilding activities. Managerial implications are put forward and suggestions for further research are presented.
2 Organizing for startups – the development of a conceptual framework

Organizational matters are usually high on firms’ agendas for achieving good performance. The traditional functional or departmental organization is still most common for production, sales and marketing, and R&D in many sectors of the Process Industries, but is sometimes complemented with cross-functional work processes and networks (Bergfors and Lager, 2011, Mintzberg, 1999). A matrix organization is nowadays still also a fairly common solution that captures the best features of functional and project organizations. Lean production focuses on more efficient resource utilization and eliminating factors that do not create value for the end user (Liker and Meier, 2006). In a similar vein, a “lean startup organization” concept could be defined and utilized as deploying better functioning organizational solutions and work processes for startup, aiming at the creation of more value for the firm for less input of startup resources.

In this context one should not overlook the installation and startup of even minor equipment integrated in large plants because, regardless of size, there is always a potential of major process and production disruption. Consequently, when things do not go according to plan, which is often the case during startup, this may influence not only the internal and external production environments, but customer satisfaction with delivered products. Regrettably, in preparations for the plant startup, the importance of the process and product dimensions are sometimes neglected because of too much focus on the engineering dimensions and commissioning. That is to say, and it is argued, that the final outcome and related success in startups is not the successful plant commissioning as such, but the delivery of products (within or above set specifications) from a well-functioning production process (delivering design product volumes at target production cost).

2.1 Profiling the startup situation – a contextual perspective

Depending on different project characteristics, one could imagine that alternative organizational solutions are more or less functional for startups. That is to say, a small project introducing well proven technology probably requires a different startup organization compared to a startup of a large new production plant using new technology and producing new kinds of products?

Identification of potential contextual determinants

In the selection of a startup organization there are a number of possible determinants that could be considered for the guidance of such a selection. One is the novelty dimension of the selected process technology (Bagsarian, 2001, Leenders and Henderson, 1980). One tool in the discussion of technology newness is the “S-curve” concept (Foster, 1986). For further discussion on the newness of process technology see for example (Tushman and Anderson, 1986, Utterback and Abernathy, 1975). The newness of technology was also singled out by Agarwal as one of the most important factors to consider in startups in the Process Industries (Agarwal et al., 1984, Agarwal and Katrat, 1979). Apart from the newness of technology, a number of other potential determinants are also presented in the following.

Newness of process technology

For categorization of the newness of process technology, the dimensions from a process matrix developed by Lager (2002) were selected, where newness is considered in the two dimensions of “newness to the world” and “newness to the firm”.

Newness of process technology to the world

The degree of newness of a process technology to the world can sometimes be related to whether the process can be patented, but since new processes are sometimes not patented but kept secret, the newness can also be estimated by how well it is described in professional publications.

- **Low**: The process technology is well known and proven (can often be purchased).
- **Medium**: The process technology is a significant improvement on previously known technology (incremental process technology development).
- **High**: The process technology is completely new and highly innovative (breakthrough or radical technology development).
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Newness of process technology to the firm

There are several possible ways to define the degree of newness of a process technology to a firm, but before a firm starts a process development project, one of the most important considerations is how easily the process technology can be implemented in the company’s production system.

- **Low**: The process technology can be implemented and used in existing process plants.
- **Medium**: The process technology requires significant plant modifications or additional equipment.
- **High**: The process technology requires a completely new process plant or production unit.

Newness of product(s)

In a study by Booz Allen & Hamilton and further presented and used by Cooper, the newness of products is positioned in a product matrix of which the following scales for the two dimensions have been derived (Booz Allen & Hamilton, 1982, Cooper, 1993).

Newness of product to the world

- **Low**: Minor product improvement.
- **Medium**: Major product improvement.
- **High**: Completely new product that may create a new market.

Newness of product to the firm

- **Low**: Existing type of product within an existing product line.
- **Medium**: New product within existing product line.
- **High**: New product and a new product line.

Complexity of technology

The survey of project management literature provided an important aspect that well suited the classification of the startup context. The system scope dimension proposed by Shenhar & Dvir provided an important missing link (1996). Their original trichotomy has been modified to suit the Process Industry startup context better:

- **Low**: Only one process unit operation.
- **Medium**: A process system including a number of unit operations,
- **High**: A super-system of process systems (large production plant).

Size of installation or process plant

The size of the process installation could also influence the selection of the most appropriate organizational solution. A small installation may thus only require a more ad hoc organization compared to a startup of a very large production plant. Nevertheless, even small startups integrated in a very large production environment may cause serious problems if not prepared and executed well, as has been pointed out in the previous presentation. The following classification is only tentative, and each firm should develop its own scale.

- **Small**: < €100 000
- **Medium**: €100 000 – 100 000 000
- **Large**: > €100 000 000

Supplementary project specific determinant(s)?

For each new installation there may be some project specific aspects that ought to be considered in the selection of a startup organization. Such determinant(s) can naturally be included as well.

Profiling the startup context

In Table 1 the selected potential determinants have been put together and used in a characterization of the startup context. The importance of each determinant can thus first of all be estimated for each project and afterwards the position of the project on each determinant can be made. The resulting “snake plot” can afterwards be used in further discussions related to the selection of an appropriate startup organization.

The results from a profiling of the startup context and the analysis of the contextual situation bring us further to the issue of how startups are carried out; a processual perspective related to a startup work process.

2.2 Outlining a formal startup work process – a processual perspective

There is nowadays general agreement that the development and use of more formal work processes can often facilitate repeatable industrial activities of different kinds. It is often claimed that carefully crafted and continually improved innovation work processes, like a
product development work process, are useful tools not only for improved efficiency but also for improved organizational learning (Cooper, 2008). In the framework of such work processes, technology transfer has long been recognized as a weak area (Holden and Konishi, 1996, Leonard-Barton and Sinha, 1993, Levin, 1993). This is a noteworthy fact since successful startups in many instances often rely on efficient technology transfers. In a study of success factors for process development (Lager and Hörte, 2002), the importance of technology transfer was also recognized and “using the results from process innovation” received by far the highest ranking points in that study. A review of late publications in the area of project management literature indicates, however, that focus nowadays is more on the issue of reduction in project cycle time (Hastak et al., 2007, Hastak et al., 2008) rather than on startup organization as such. For further reading about work processes see for example (Hammer, 2007, Malone et al., 2003, Margherita et al., 2007). It has already been pointed out by Leitch (2004a) that an integrated work process and upfront planning for the startup are recommended actions.

Innovation in the Process Industries, be it product or process innovation, will in its final stage often involve modifications of existing production equipment, new process installations or even the erection of a complete new production plant. The product development work process starts with ideation and development and finishes with the launch of the product on the market outside the company (Cooper, 2008). In a similar vein, the process development work process also starts with ideation and development and finishes with the startup of the new process technology, but then inside the company, see Figure 2.

A startup of new process technology in a production plant environment can thus be looked upon as an analogy to a product launch on the market in product innovation. In the development and implementation of new (and older) process technology, it is thus essential in a work process perspective to secure that startup will not be the weakest link in the long chain of activities and cause project disturbances or even failures.

In a work process perspective, startups could be considered as a sub-work process of the total “construction and erection work process” in which the “startup work process” must be well

<table>
<thead>
<tr>
<th>Contextual startup determinants</th>
<th>Importance of determinants to the project (low =1; high = 5)</th>
<th>Project Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newness of process technology to the world</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Newness of process technology to the firm</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Newness of the product to the world</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Newness of product to the firm</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Complexity of technology</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Size of installation of process plant</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>Supplementary project specific determinant(s)?</td>
<td>Low</td>
<td>Medium</td>
</tr>
</tbody>
</table>

* The profile for a startup has tentatively been illustrated. For the characterization of each determinant a round symbol (three point ordinal scale) connected by a “snake plot” has been used. For the importance rating of each determinant, a five point ordinal scale is suggested.
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2.3 Clarifying organizational responsibilities and interfaces – a structural perspective

The startup of new process plants and new process technology, if not carried out entirely within the production organization, is an activity where two different forms of organization meet – where a project organization, normally in charge of such an installation, transfers responsibility for the plant or new installation to an operational line organization. Organizational interfaces often have a tendency to create problems, and the issue of successful startup is thus not solely within the domain of project management but also most certainly within the even larger context of operations management and sometimes also innovation.
**Figure 3 An outline of the “startup work process”**

- **Project start & “kick-off”** (Prestudies, design & construction not included in the figure)
  - Commissioning without material (Pre-commissioning)
  - Commissioning with material
  - Final adjustments, fine tuning of the process and test on completion
  - Project closure “kick-out”

- **Pre-startup activities**
  - Start up point of time (Operations started on a shift-basis)

- **Start up space of time**

*The three sub-phases included in the startup work process are (1) commissioning without material; pre-commissioning, (2) commissioning with material, and (3) final adjustments and fine tuning of the process and test on completion.

**Figure 4 Organizational model No 1**

- **The production organization (production)**
  - The production organization is fully embedded in the production organization (design, construction, start-up)

- **Pre-startup activities**
  - Start up point of time (Operations started on a shift-basis)

- **Start up space of time**

- **Post-startup activities**

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management.

As pointed out, problems often occur in handovers and in organizational interfaces, and this interface is no exception. Sometimes one imagines that management is hoping that startup is just a matter of “pressing the button”, after which everything will run smoothly from the word go and that there is consequently no need for any special arrangements. Referring to the previous presentation, nothing could be more wrong, since startup is and always will be an extreme event which consequently demands well adapted organizational solutions. Referring to the previous section, experience suggests however that the organization of startups is not given proper attention in connection with investments in new products, process technology or in new production plants.

Modelling alternative startup organizations

The need for a separate project management organization before startup is often well recognised, and the consecutive takeover by a production line organization is only natural, but how to manage and organize the “fuzzy-in-between” startup phase?

Organizational model No 1: Production organization fully responsible from “kick-off” to “kick-out”.

The model presented in Figure 4 is most likely feasible only in smaller installations under a limited frame of time, and even then it cannot be done without the assistance of subcontractor/supply chain specialists. One can expect an easy and fast handover after startup with a minimum of paperwork. Nevertheless, this model may possibly also be used successfully even in fairly large installations of well proven technology, if additional project and other expert resources are sub-contracted (Frazier et al., 1996). However, it is not often that a line organization has the necessary resources to manage a large investment project, and there is consequently a certain risk for project mismanagement with this model.

Organizational model No 2A: Project organization is responsible until startup and project handover; production organization is responsible for startup.

A presumably fairly common organizational solution, presented in Figure 5, is a handover from the project organization to the line organization when the pre-commissioning is finished and when it is time to “press the start button” and run the process on a continuous shift basis with material (Bodnaruk, 1996). Such handovers sometimes work, but are often a source of startup problems. Commissioning with material invokes the production organization’s permit-to-work system when systems “go hot”.

If the line production organization has not been involved in the design and commissioning, its people are often not familiar with the new equipment, and the startup may run into problems. At the same time the project organization sometimes has a tendency to disappear too soon after pre-commissioning is finished. The situation has been well described as: “They leave us with an unfinished plant; the voice of production. Production will never let us go and wants us to stay forever; the voice of the project (Eriksson, 2008).”

Organizational model No 2B: Project organization is responsible during startup; project handover when the plant is operating well.

This organizational alternative, presented in Figure 6, relies fully on the project organization during startup, which allows the project manager to assume the role of startup leader. The project organization will then be in charge of plant operation during pre-commissioning, commissioning and subsequent final adjustments and tests on completion. When the plant is operating smoothly, it is handed over to production. The solution of letting the project organization remain in charge during startup is sometimes complicated because of union or other organizational problems with the “ownership” of equipment. In one alternative, plant operators are recruited by the production organization but are “borrowed” during startup by the project organization; in another alternative the project contractor uses his own crew. This is a model often used in some “turnkey” installations. The project usually has some production organization “implants” who can check that their specifications have been complied with. If not, this model may end up in tears. Experience of this model was not very encouraging for IPSCO, and in their lawsuit against Mannesmann it is stated (Bagarian, 2001): “Not only was the completion of the project delayed for an extraordinary and wholly unanticipated amount of time, but neither the
Figure 5 Organizational model No 2A

Project start & “kick-off” (Prestudies, design & construction not included in the figure)

The project organization (design, construction)

Commissioning without material (Pre-commissioning)

Commissioning with material

Final adjustments, fine tuning of the process and test on completion

Project closure “kick-out”

Pre-startup activities

Start up point of time (Operations started on a shift-basis)

Commissioning without material (Pre-commissioning)

Commissioning with material

Final adjustments, fine tuning of the process and test on completion

Project closure “kick-out”

Post-startup activities

Start up space of time

Figure 6 Organizational model No 2B

Project start & “kick-off” (Prestudies, design & construction not included in the figure)

The project organization (design, construction & start up)

Commissioning without material (Pre-commissioning)

Commissioning with material

Final adjustments, fine tuning of the process and test on completion

Project closure “kick-out”

Pre-startup activities

Start up point of time (Operations started on a shift-basis)

Production takeover of production plant and operation

Post-startup activities

Start up space of time
"facility components, nor the plant in general, has the quality, fitness for purpose, productivity, and performance as represented, warranted, and guaranteed."

Organizational model No 3: An intermediate, fully integrated type of startup organization (project together with production) is formed to assume responsibility from pre-commissioning without material until the plant is operating well.

A study of the transfer of new biotechnological processes from research and development to manufacturing also highlights the importance of a more closely integrated technology transfer team with membership from development, manufacturing, engineering, quality and validation (Gerson and Himes, 1998). In this model, Figure 7, the two organizational structures, project organization and production organization, are supplemented by a very distinct and formal intermediate startup organization (Lager, 2010 p.256). From the start of pre-commissioning activities, and naturally in preparations long before startup, the intermediate organization takes full responsibility for all startup activities. In such a merger of the project organization and future production organization, the startup leader is fully in charge of an exceptionally strong and well-integrated organization. It is often reinforced with internal and external resources, and there should be no mistake about who is in charge. The team is gradually mobilised before and during pre-commissioning, and at full strength when commissioning with material starts. This startup organization then stays in operational control until the plant is running smoothly. It may take a few days, weeks or even a few months (hopefully not years). When agreed performance criteria have been met, the production organization takes over operation of the plant. After the plant has been in operation for some time and the list of outstanding construction items has been seen to, the production organization finally and formally takes over the production plant from the project.

3 Building a startup organization – a relational perspective

Regardless of whether the production organization or the project organization is fully responsible for a startup situation, or whether handover takes place in the middle, or whether a fully integrated organization is created, a startup team must always be mobilised for this event. In the planning and preparation for startups, the importance of completing a risk analysis before plant commissioning is stressed by Cagno & al. (2002), but one should not conclude that complete risk avoidance is the proper route to follow. When new technology is introduced, preparations before startup can, however, considerably reduce associated risks.

3.1 Pre-startup and post-startup activities

One can recognize, in a work process perspective, that many issues must be addressed well before startup (Leitch, 2004b), e.g. pre-studies and mechanical completion. On the other hand some must be addressed just before the startup, while some must be addressed during or even after startup. In collaboration between equipment manufacturers and process firms over the life cycle and installation of process equipment, Lager & Frishammar (2010) have recognized the importance of such collaboration well in advance of startup:

The collaborative solutions and selected organizational structures and mechanisms must not only be adapted to the situation but also facilitate management of the technology transfer between the equipment supplier and the process firm. ... It is therefore important that both parties agree at a relatively early stage of the procurement phase on how the equipment is to be put on stream.

Good planning before a startup is thus extremely important and has been reported as a success factor of the highest rank (Callow, 1991, Meier, 1982, Leitch, 2004b).

This also emphasizes the fact that success in startups is also related in many cases to decisions already taken during the pre-studies of an installation. The startup leader and startup organization are thus not always to blame if things go wrong; the fault may also be traceable to management decisions which have failed to allow sufficient resources (time and training) for rehearsing the startup of this type of process. Other factors may influence startup performance, and taking new plants, production processes, minor unit operations or even a single item of equipment on stream is not only a production and financial risk, but an activity that is also a safety-critical endeavour (Agarwal et al., 1984). The importance of post-startup activities is seldom touched upon in the literature. This too, however, is an area that
should deserve more attention; the conclusion from the startup of Temple-Inlands' Paper Mill No. 5 was that they managed the planning and startup well, but they could have done better on post-startup activities (Ferguson, 1995). There may thus be many factors influencing the success and performance of startups. Referring to the quotation from Bargsarian, one factor to consider is how to select and set up a proper startup team.

3.2 Building a startup organization

Preparations before startup like recruitment and training of people, mobilisation of external resources, preparing for efficient communication before and during startup, and selecting a proper startup team are issues that ought to have high priority when successful startups are desired. It is thus not the knowledge of individuals in the firm that counts, but knowledge shared and executed as a joint effort that is the hallmark of a professional and successful startup organization. As such, excellence in startup is a good example of successful corporate organizational learning (Nonaka and Takeuchi, 1995). The importance of building a resourceful startup organization that is well prepared to handle the extreme environment associated with startups appears paramount. The published literature relating to startup organizational issues is however surprisingly scarce, and the issue is only sparsely discussed in some publications (Bodnaruk, 1996, Bowdoin K.A, 2001, Mueller et al., 2002, Powell, 1999).

**Selecting the startup leader(s)**

Choosing the chief operating engineer (startup leader) is claimed to be 90% of the successful approach to good startup, since he will be faced with the overall planning for the startup, as well as the day-to-day decisions (Gans, 1976). In the discussion of the roles of the process development group and manufacturing in biopharmaceutical process startup (Goochee, 2002), the importance of selecting startup leaders is stressed. The recommendation there is to select process development and plant startup leaders nine months prior to startup. The importance of giving new management "ownership" of the facility is often stressed, and it is considered a grave mistake to transfer a manager to the startup and then move him to another facility (Bargsarian, 2001). As leader of the technology transfer team, Gerson (Gerson
and Himes, 1998) points out that the project transfer champion is required to take a proactive role. It must also be crystal clear what responsibilities the leader(s) should have during startup, to whom they should report and their availability during startup. Because of the need for quick decisions and action during this period, shift-working startup leaders are sometimes preferred. If the project manager for pre-studies, design and plant erection can later assume responsibility for being the startup leader and afterwards become the plant superintendent, that is often a good organizational solution to be pursued.

Assembling the startup crew

Referring to the quotation at the beginning of the first section, securing the availability of an experienced startup crew is crucial. Forming a startup team well in advance, including mill engineering staff, consulting engineers and chemical suppliers who were able to develop working relations in a low-stress environment prior to startup, was a success factor for the Rainy River plant startup (Frazier et al., 1996). The importance of securing a team including manufacturing, process development, engineering, facilities, quality control and quality assurance is stressed by Goochee (2002), and that the need for individual talent is at least matched by the need for team harmony. It is often also recommended to organise a problem-solving task force (Agarwal et al., 1984), sometimes called a “flying squad”, of very experienced personnel on standby to be used when major problems are encountered during a startup.

Training before startup

Training of plant operators, maintenance crews and supervisors is naturally of the utmost importance, but it is also vital to map in advance the kind of training the organization needs for each specific project. Apart from many different kinds of startup training, it is necessary that the operators also gain a conceptual understanding of the new process, so that unexpected problems can be quickly assessed and appropriate responses made (Agarwal et al., 1984). Another matter is how the training should be organised. Traditional classroom training with engineering professionals doing slide presentations does not always work well alone, but may provide the foundation for other associated activities outside the classroom. There are a number of alternative training approaches, the main difference being whether the training takes place on the job or in a classroom in a different environment outside the plant (Agarwal et al., 1984). The opportunity to involve equipment and raw material (reagent) suppliers in these activities should not be overlooked, and the use of dynamic simulation for training is another approach that is gaining stronger and stronger importance (Frazier et al., 1996, Rutherford and Persard, 2003).

In summary

Since the startup leaders’ qualifications and personalities to a large extent will influence the climate during startup, it is recommended to begin all activities by such an recruitment. Because a startup is often an extreme event, it is recommended that both a startup leader and an assistant startup leader initially are recruited. They can, depending on the startup context, either share this responsibility each on a 12-hour shift basis or if the startup period is extended, relieve each other on a weekly or on a monthly bases. The startup leaders are afterwards to select the organization for the startup and, depending on the startup context, build a more or less resourceful team. Experience thus tells that it is not good enough to use the normal number of shift operators and supervisors, but that a “doubling” of operators and supervisors on shift is recommended using resources from the previously mentioned different kinds of organizations. After the structural organization has been set up, the training can be planned and scheduled in accordance with project goals and needs. A proper mix of classroom and on the job training is here strongly recommended when the startup team can begin to establish good personal relations and collaborations.

4 Discussions and two theoretical propositions

In the literature review on plant startups in the Process Industries one finds many important early publications around the seventies and eighties that are certainly still of interest not only to scholars researching this topic but also to industry professionals involved in startups. Interest in the topic seems, however, to have declined during the past two decades, possibly because of a stronger interest in emerging new industry sectors and a stronger focus on non-process industries. This is a rather unfortunate state of affairs, because the Process Industries
constitute a large part of all manufacturing industry, and startup of new plants and process technology is nowadays an important part of corporate activities, especially in the further exploitation of natural resources. The influence on startup performance of pre-startup and post-startup activities – pre-studies, technology selection, training, process improvements after startup, etc. – has however only been touched upon in this article. Because of that, a retrospective literature survey of startups has already been initiated, where general aspects of startups will be structured and presented in more detail in a forthcoming article.

In the light of the problem description in section one, the results from the literature survey and the development of the framework two theoretical propositions are put forward:

**Proposition 1:** In the startup of new process technology or process plants in the Process Industries, the selection of the most appropriate startup organization is one success factor for achieving good startup performance.

**Proposition 2:** The newness of process technology, newness of products, the complexity of installation and size of the project are important determinants in the selection of appropriate startup organizations in the Process Industries.

5 Managerial implications and further research

The presented information from the literature survey and the alternative types of startup organizational models can already be deployed by firms in the Process Industries in their discussions and their selection of alternative startup organizations. It is first of all strongly recommended that firms initially should profile each startup context in order to build a solid platform for the selection of a proper startup organization. For smaller, not too complex projects using proven process technology the production organization may be the preferred organizational choice. On the other hand, the fully integrated startup model is recommended for large complex startups of new technology. In such an instance the startup organization should be a total mobilisation of all necessary and available resources within and outside the firm. It is not difficult to demobilise such resources if the startup runs very smoothly, but on the other hand, it is very difficult to mobilise more resources during startup if and when problems occur. The alternative use of the other two “in-between organizations” with either a handover before commissioning with materials, or a handover after commissioning with materials and fine tuning, must be carefully considered because of the previously presented bad startup experiences sometimes related to those organizational settings. Finally, smooth implementation and startup of new or improved process technology or complete production plants is “money in the bank” for any firm in the Process Industries.

In further empirical research it is important to recognise the difference between descriptive and prescriptive research results. That is to say, visiting companies in different sectors of the Process Industries to enquire about what type of startup organizational model they are currently using does not necessarily give prescriptive answers, since the model they are now using may be, more or less, dysfunctional. A more fruitful approach may be to employ this framework for a classification of different kinds of startup contexts and to further enquire which of the different types of organizational model (or suggested alternative models) they believe would provide them with the best startup result and overall success. If such an inquiry were instead deployed in a larger survey, including many different sectors of the Process Industries, a statistical analysis of different sectorial behaviour could be an interesting outcome. Another alternative research approach could be to make in-depth interviews in some selected firms supplying equipment to the Process Industries. Their frequent experience with startup of new installations could then give interesting new perspectives and opportunities for learning. If a firm is testing the fully integrated startup model in a real startup situation, it could naturally be a rewarding exercise to follow such a startup in the form of a single case study. Such a research approach would then also have attributes related to “action research” methodology.

6 Conclusions

When new technology is introduced in the Process Industries, it is first of all important in a pre-startup perspective to ensure that such technology is properly tested in advance in pilot plants or in demonstration plants and that that design solutions are professional and robust. Nevertheless, despite following proper procedures, implementation and startup of new
technology will always be an extreme event associated with a degree of uncertainty. It is noteworthy that past experience of startups does not make very pleasant reading, and the reasons for startup delays and stumbles appear to be many and varied. Reviewing publications in the area of startup of process plants and new technology is strangely enough revealing, in that managerial and organizational issues are scarcely discussed at any depth.

As a consequence of this, four types of startup organizations have first of all been depicted, relying on the fragmented information in those publications and on the author’s own personal startup experience. A number of potential determinants for a better definition of the startup context have also been developed. The conceptual framework gives some initial insight and a platform for further empirical research, but can already be deployed by firms in the Process Industries in their discussions of alternative startup organizations. Finally, it is argued that organizational aspects should be more in focus in the planning of startups, and selecting and building a proper startup organization as such could be one important success factor in getting new plants and process technology on stream in a more efficient manner.

7 Acknowledgements

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References


Research Paper

The founding angels investment model - case studies from the field of nanotechnology

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The gap between academic research and the commercialization of research result can be overcome with the founding angels investment model where very early stage investors found start-up companies together with appropriate research partners to conduct research and later, alone or together with industrial partners, commercialize the results. The engagement of founding angels is compensated not monetarily but through an equity share of the new company. This business model is already being implemented in the United States with some interesting examples in the area of nanotechnology. This article analyses approach and investment strategy as well as defines a best practice process of founding angels as early stage technology investment model applying an exploratory multiple case analysis. The empirical data are based on literature research with a focus on document analysis and interviews with 35 nanotechnology experts.

Introduction

Nanotechnology is a broad term that refers to anything engineered down to the nanometer scale. It provides the ability to isolate and manipulate single atoms, which behave much differently than clustered atoms. This change in behaviour is due to an increased relative surface area, producing more chemical reactivity, and the dominance of quantum effects, altering the material’s optical, magnetic and electrical properties. The aim is to unlock capabilities in materials by manipulating them at the atomic level. Building at the nanometer scale allows scientists and engineers to design specific magnetic, thermal, and strength properties into products. Nanotechnology is expected to play a key role in the 21st century with large market potentials in numerous applications.

Companies such as 3M have been leading the change, citing nanotechnology as a primary driver for future revenue and technology growth. 3M has been working on nanomaterials since 1985 when it started using nanostructures in its film coatings. 3M is now expanding into developing biomedical sensors, new metal matrix composites, strong adhesives and advanced protective coatings. Chemical companies such as BASF, Bayer, DSM, DuPont, GE, Honeywell, Mitsubishi and Rohm and Haas have also begun to invest heavily in nanotechnology. These firms are developing, for example, scratch resistant polymers, super insulating wire coatings or batteries with longer shelf life. HP, IBM, Lucent and Motorola have turned to nanotechnology for the next breakthroughs in semiconductor manufacturing. These companies have also invested in developing super capacity data drives and nano emissive displays.

Governments worldwide are recognizing the importance and potential of nanotechnology (Roco, 2005) and the number of patents is continuously growing, led by the United States (US) and Europe (Chen et al., 2008).

But a gap can be identified between academic research and the commercialization of research results, which represents a serious barrier for innovation. This gap can be overcome with the founding angels investment model where very early stage investors proactively found start-up companies together with appropriate research partners to conduct research and later, alone or together with industrial partners, commercialize
the results.

This paper discusses early stage technology investments in the area of nanotechnology by founding angels.

In the first part we analyse a typical innovation process in nanotechnology and the role of start-up companies taking carbon nanotubes (CNTs) as an example. Then we show case examples of professionals using the founding angels investment model in the area of nanotechnology. Based on the investigation of the innovation process and the case examples we then analyse the founding angels investment model, define a best practice investment process and discuss the investment strategy.

Literature review

Importance of start-up companies

In many cases of innovation processes a technology transfer gap exists between academic research and the commercialization of the results to realise industrial applications. This gap can be closed through start-ups as they facilitate the transfer of research results into products. Therefore, they are important for innovation and an accelerator of economic growth, especially in high-tech areas like nanotechnology, targeting markets with high growth potentials (Roberts, 1991; Heirman and Clarysse, 2004; Stam et al., 2009). The importance of start-ups is also seen by universities (Shane, 2002). Generally, academic researchers neither have the knowledge nor the experience to commercialize their research results (Litan and Mitchell, 2007). To facilitate technology transfer from academic research to industrial applications many universities have implemented technology transfer offices (TTOs) (Goldfarb and Henrekson, 2003). Most TTOs recognise start-ups as an interesting method of technology transfer and thus help scientists in their entrepreneurial efforts (Feldman and Feller, 2002; Markman et al., 2005; Meyer, 2006).

Acquiring enough capital is a serious challenge for many start-ups, especially in early stages. Particularly for high-tech start-ups the necessary resources are relatively high in the first stages, due to the steep cost of research and product development. There are three financial sources which founders can rely on. The first is the government, which can inject money into start-ups through governmental programmes. The second financial source is private investors like business angels, who are normally referred to as informal investors. The third source is formal investors, for example venture capital companies (Fried and Hisrich, 1994; Kaplan and Strömberg, 2001). Venture capital companies normally invest only in companies that have at least proceeded beyond the product development stage (Branscomb and Auerswald, 2002) and they even prefer to invest when the technological potential is demonstrated by working together with first customers. Therefore, the informal venture capital market is vital for early stage high-tech companies (Wetzel and Frear, 1996) and since the early nineties, politicians and researchers have increased their interest in understanding how the informal venture capital market works and how it can be optimised. For example, in the US and the United Kingdom (UK), the largest source of risk financing comes from business angels (Mason and Harrison, 1996). Globally speaking, the business angels’ investment in new technology-based firms is twice as large as formal venture capitalists’ investment (Bygrave and Quill, 2007).

Support by business angels

Due to their function of the “missing link”, business angels help bridge the financial gap in the high risk early stage phase (Mason, 2006; Maunula, 2006). Having been financed by business angels raises the credibility of the company in the eyes of potential partners and thus increases the chances of the company receiving further investment. Ideally, business angels complement venture capital companies, especially with regard to the size of the investment, the value added and the investment phases (Crawley, 2007) and provide a deal flow for venture capital funds (Madill et al., 2005). BAs in the U.S. account for double the amount of investments (in terms of deal size) in start-ups when compared to VCs (Riding 2008; Bygrave and Quill 2007). On the other hand, a recent Canadian study has shown that the 3f funding (from family, friends and fools) accounts for more than three times as much annual investment as BAs (Riding 2008).

Business angels choose to invest in specific sectors based on their previous experience and a strong network (Van Osnabrugge, 2000). Mason and Harrison (2002) have noticed that business angels are, in general, looking for more investment opportunities. This is mainly due to the fact that most of the proposals they receive do not coincide with their investment criteria. For example, in the industry or technology sector, the company stage or location may not fulfil their conditions. Also, many investors do not
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possess the necessary technical knowledge required for investing in high-tech areas. Finding a good opportunity takes much effort due to a lack of access to the academic researchers and the long selection process (Mason and Harrison, 1992).

Because of this time consuming procedure, more and more investors have neglected small investments in order to focus on bigger deals (Murray, 1999). This theory is confirmed by Mason and Harrison (1995) who attribute the equity gap to the high search cost of business angels seeking investment opportunities. According to Zhang (2009), this can also be overcome with the help of experienced people. They are faster than novices in acquiring resources due to an established network and working experience with people like venture capitalists and customers. They also know how to handle information asymmetry during the financing process, which is due to the fact that founders rarely paint a precise picture of the company (Binks et al., 1992).

Especially during the creation of a start-up, scientists as entrepreneurs face several challenges in order to develop the technology, strengthen the company and generate revenue as early as possible (Baron, 1998). The scientist is often absorbed by his daily duties and challenges in research and has quite often a biased view on how his research output could be used. Besides capital, new technology based companies very often lack business know-how, as the founders are usually highly research orientated scientists. This means, that besides enough capital, a start-up also heavily relies on operational assistance in order to be successful and additional knowledge provided by informal investors is often required and sometimes valued as a financial investment, in return for shares (Crawley 2007). Thus, the working relationship between founders and business angels is important and it should start as early possible (Landström, 1998). The earlier in the development process the relationship between founders and investors are established, the less likely conflicts regarding goals or tasks will occur, whereas these conflicts have been demonstrated to lead to investors’ or entrepreneurs’ exit (Collewaert 2011). Unfortunately, business angels normally do not have enough time to build a solid relationship with the founders (Ensley et al., 2002). Another important aspect is that because business angels normally only invest in existing companies, their work cannot help bridge the gap between academic research and industrial application if insufficient start-ups are founded.

Founding angels as a new investment model

An analysis of established business models in the area of start-ups shows that known players, such as technology transfer offices at universities and research institutes and business plan competitions, are only active in parts of the value chain (Figure 1). Business angels and venture capital companies are normally focused on already founded companies. Especially venture capitalists do not play an important role in early stage technology investments. This gap in the pre-seed and seed phase before start-ups are founded can be closed by the founding angels business model (Festel and Bouteiller, 2008).

Founding angels are engaged with the scientists before the start-up is founded and they are part of the founding team (Festel and Bouteiller, 2008; Festel et al., 2010). They play an important operational role in the build-up phase of the start-up based on their specific industry or functional know-how e.g. in the field of financing, intellectual property (IP) management or licensing.

The founding angels investment model can be realised by both private persons and professional teams. By way of comparison to business angels, the private persons can be defined as founding angels. Like business angels they are generally not visible so it is very difficult to identify them - especially as they themselves are unaware of the fact that they are founding angels, as the term “founding angels” in this context is relatively new. For this reason, the research in this paper is focused on professional teams using the founding angels investment model. These are organised similar to venture capital teams with most of them coming from the venture capital area. In the field of nanotechnology there are some interesting examples of these very early stage technology investors, especially in the US.

The founding angels investment strategy offers clear advantages (Festel, 2011). Due to their engagement at an early stage in the new start-up company, there is little competition with other investors and a large opportunity to ensure attractive investment possibilities with a high value creation potential. Due to this fact and the relatively low initial investment volume needed for the pre-seed stage, a large number of investments or engagements can be achieved. This diversification will allow founding angels to expect higher returns due to a lower total risk.
**Methodology**

**Research approach**

The research is explorative in nature and therefore applies a case study research. The single case study focuses on unique, representative, extreme or not accessible cases which have been analysed over a longer period of time. It aims at falsifying theoretical insights or to provide new insights in unexplored phenomena (Yin, 2003; Yin, 2006; Borchardt and Göthlich, 2007). The multiple case study method compares cases and highlights resulting insights through similarities and dissimilarities between the cases (Borchardt and Göthlich, 2007). We selected to apply a multiple case study approach, as numerous authors consider results from multiple case studies as more convincing, trustworthy, and robust (Eisenhardt, 1989; Yin, 2003). Within this research design different sources of data, qualitative and quantitative data, can be included (Flick, 1995; Yin, 2006). The data collection methods for case studies are document and literature analysis, interviews, and observations. Our multiple case study includes desk research with a focus on document analysis and interviews with 35 nanotechnology experts.

**Empirical data**

Between 2006 and 2008, 35 nanotechnology experts from industry, government, academia and the finance sector were interviewed to learn more about the identification and analysis of the mechanisms to successfully commercialize nanotechnology as well as the hurdles and the solutions to overcome these hurdles. A reference set of questions was developed as a guideline for the interview, leaving enough room for spontaneous answers, which gave a semi-structured nature to the interviews. Before each interview, the authors had gathered in-depth information on the company or institution through various public sources (e.g. databases, website, press releases), enabling an efficient conduct of the interviews.

Literature analysis was conducted in 2008.

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*Figure 1 Business models in the area of start-ups (Festel and Boutellier, 2008)*
in order to be able to describe and understand the founding angels business model. This was the first time that the expression founding angels was used in the scientific literature to describe very early stage investors engaged in prefounding projects (Festel and Bouteiller, 2008). A second phase of literature research took place from 2010 to 2011, during which the results of the first literature research were updated and, furthermore, additional founding angels identified in order to better analyse the business model. Based on the interviews and literature analysis, 12 founding angels case studies were created from which the five most interesting and fitting case studies are presented in this paper.

Analysis and research quality assurance

Particularly when conducting explorative research, applying a multiple case study approach and analysing qualitative data research quality assurance based on the criteria reliability, validity, and objectivity becomes very important (Albers et al., 2007; Lamnek, 2008; Bortz and Döring, 2005; Yin, 2003). As Yin (2006) stated, reliability of qualitative research can only be achieved by a structured way of proceeding and by exactly documenting the research process and its results. Therefore, all facets and steps of our qualitative research were discussed with other researchers and performed in a structured way. The analyses of the data were conducted systematically and in multiple iterations. First, all information gathered through our literature research was categorised, explored and analysed. Second, based on step one, a semi-structured interview guideline was developed and tested. Third, 35 interviews were conducted. Fourth, the interviews were transcribed and condensed over several iteration steps up to a point at which only the key insights of each case was remaining. During the analysis, each case was analysed by describing it and performing a short within-case analysis. Afterwards, all cases were compared to each other by executing a cross case analysis. And finally fifth, the resulting output from the interviews and literature research were combined and discussed with other researchers and practitioners.

Validity of the research was achieved by data and method triangulation, documentation of chains of evidence, or the discussion of preliminary case study results with the research participants (Yin, 2003). Objectivity was ensured by having the same person conducting the semi-structured interviews, guaranteeing execution objectivity, and by recording the interviews with an audio device, ensuring evaluation objectivity (Yin, 2003).

Results and discussion

Innovation process and start-ups

Nanotechnology know-how is mainly used in the early stages of the value chain, i.e. the stage of components and intermediate products or production and analysis technologies. The value added is normally reached through performance enhancement in the whole system or the end product, the commercialization of which is carried out by end product producers in different industrial sectors. A good example is CNTs, which was especially investigated through the expert interviews. This innovative nanomaterial enhances the mechanical properties of plastics and other materials. In sporting goods, for example, Wilson uses nanotech to produce tennis balls that do not deflate as quickly as traditional ones. Another application example is in the production of tennis racquets with improved properties. Due to the high price of CNTs and their high production costs, these racquets are significantly more expensive than traditional ones.

From an end product producer’s viewpoint, these materials can only establish in the market on a broader basis through lower prices. In order to realise lower prices, producers of CNTs, who are at the beginning of the value chain, need to invest in new production processes and facilities. This problem could be solved through cooperation between the material producers, polymer compounders, system suppliers and end product producers combining “technology push” and “market pull” effects. Practice shows, however, that with cooperation between established companies such developments take a long time. This lies mainly in the fact that such projects are neglected for daily business and, of course, the well-known problems of innovation processes in large organisations.

Start-ups can play an important role in the rapid transfer of research results into products as they are highly motivated, very focused and flexible. For example, start-ups in the area of CNTs, like Future Carbon, speed up the innovation processes along the value chain. They develop and provide the technology to produce special CNT formulations which are necessary for product development on the following value chain step (Figure 2). Polymer processing companies, like Freudenberg, have only low
experience and resources to develop these formulations in-house. CNT producers, like Bayer on the other hand, are too large to focus on this kg business as their strategy is to produce thousands of tonnes.

**Founding angels case studies**

The aim of presenting the case studies is to show their approach to foster the creation of start-up companies.

Some of the case studies are only active in the area of nanotechnology, like Advance Nanotech, Arrowhead Research Corporation or Molecular Manufacturing Enterprises, while others have a broader technological scope, like Angle Technology or Arch Venture Partners (Table 1). Most of the activities are located in the US and one in the UK.

**Advance Nanotech**

Remark: The provided information is from 2008, as no current information could be found (e.g. the company website is no longer available).

Founded in 2003, Advance Nanotech focused on nanotechnology for applications in electronics, biopharma and materials. They identified patented, patent-pending and proprietary technologies at leading universities and funded the additional development of such technologies in exchange for the exclusive rights to commercialise any resulting products. In-house competence was used to accelerate the development of multiple early stage research programmes to proof-of-concept or demonstrate manufacturability within three years.

Advance Nanotech maintained a controlling interest in a broad portfolio of nanotechnology projects, each with a defined capital commitment. In order to ensure a high success rate for the portfolio, each project went through an assessment process to ensure that each technology was still en route to successful commercialization. As the project progressed, preset milestones had to be accomplished for continued investment. These milestones were reviewed on a regular basis for continued funding, redirection of funds or withdrawal of investment. The projects were generated within partnerships with academic institutions like the Universities of Cambridge and Bristol as well as Imperial College London. By partnering with universities and leveraging the infrastructure and human resources of the university partners, individual project costs were low.

After prototypes were proven within the lab and a product roadmap and business plan had been developed, majority owned subsidiaries around the specific technology were formed. Additional money was sought through the sale or licensing of the technology, by securing additional financing from either the venture capital community, or by successfully executing the business plan and consolidating its income as the majority shareholder. Once a product was ready for market, in some cases, further funding was accessed from the capital markets by listing companies on the stock market.

Portfolio companies of advance nanotech were Advance Display Technologies, Advance Homeland Security, Bio-Nano Sensium, Nanofed, Nano Solutions and Owlstone Nanotech. From 2007, Advance Nanotech was publicly traded in the US on the over-the-counter (OTC) market. Starting as “over-the-counter bulletin board” share with the requirement to file current financial statements with the US Securities and Exchange Commission (SEC) or a banking or insurance regulator they became “pink sheet” shares (symbol AVNA.PK) with no need to meet minimum requirements or file with the SEC.
The founding angels investment model - case studies from the field of nanotechnology

Table 1 Case studies of the founding angels investment model

<table>
<thead>
<tr>
<th>Name</th>
<th>Internet</th>
<th>Locations</th>
<th>Technology areas</th>
<th>Financial sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arch Venture Partners</td>
<td><a href="http://www.archventure.com">www.archventure.com</a></td>
<td>Chicago, Seattle, Austin, San Francisco (all US)</td>
<td>ICT, lifesciences, physical sciences, nanotech, biotech</td>
<td>Private</td>
</tr>
<tr>
<td>Molecular Manufacturing Enterprises</td>
<td><a href="http://www.mmei.com">www.mmei.com</a></td>
<td>Saint Paul (US)</td>
<td>Nanotech</td>
<td>Private</td>
</tr>
</tbody>
</table>

Currently (end of May 2011), the share price is nearly zero.

Angle Technology

Angle was founded in 1994 and is headquartered in the UK with a technology commercialization subsidiary in the US. The company focuses on the commercialization of technologies and the development of technology-based start-ups. Besides its consulting business on a fee-for-service basis and the operation of science & technology parks, Angle has founded and developed a portfolio of start-ups in which it retains substantial equity stakes. Technologies sought are those at pre-seed/seed stages and were selected for their strong IP platform. The IP should have been granted or close to being granted and it has been demonstrated that the technology works. The Angle team consists of professionals with backgrounds that combine business, finance and entrepreneurial expertise, with scientific and technical knowledge. The management support for the start-ups includes the building of the senior management team, conducting market research, developing the business plan, and overseeing product development, as well as market entry strategies.

The portfolio spans from medical and life sciences, cleantech and physical sciences to IT and software. The current portfolio consists of the six companies Acolyte Biomedica, Genomics, NeuroTargets, Novocellus, Parsortix and Synature. For example, Novocellus is a diagnostic company founded to commercialize technology from the University of York for non-invasive testing of the viability of in vitro fertilisation embryos. Additionally, Angle has performed two exits with Exago and Provexis. The projects are sourced from world class research establishments, such as UK Defence Science & Technology Laboratory, the universities of Bristol, Cambridge and York and the Rowett Institute, and in the US, from the universities of Southern California and New York.

Angle seeks to retain a substantial shareholding in these companies with a view to ongoing returns from dividend, milestone, royalty and capital returns. The average age of the portfolio companies is six years and they have been developed to the stage where the portfolio, as a whole, is substantially cash-independent of Angle, thereby presenting Angle shareholders with the potential for substantial upside returns without a corresponding downside risk of further investment. Over the last two years, Angle has deployed a deliberate strategy to focus its efforts and resources on the winners within the portfolio recognising that, with early stage technology investment, successful returns are likely to be concentrated in a relatively small number of investments, which may be big winners.

Angle is quoted on the London Stock Exchange at the AIM market (symbol AGL.L). AIM
is the London Stock Exchange’s international market for smaller growing companies. A wide range of businesses including early stage, venture capital backed as well as more established companies join AIM seeking access to growth capital. Starting in June 2006, with a share price of 86 GBP and the minimum in December 2008 with 7.5 GBP, the share price is currently (end of May 2011) at 25 GBP.

Arch Venture Partners

Arch Venture Partners was spun off from an initiative by the University of Chicago in 1986 as a not-for-profit affiliate corporation. Although the company separated from the university in 1992, the university still remained a special limited partner and investor. Arch Venture Partners is one of the largest providers of seed capital in the US with over USD 1.5 billion under management. Its first fund was launched in 1989 and the sixth in 2003. A partnership led by partners joined by a team of investment managers and advisors. It has offices in San Francisco, Seattle, Austin, Chicago, and Boston.

Arch Venture Partners has cofounded with scientists and entrepreneurs or led the seed round for more than 130 start-ups using scientific discoveries from over 40 major research universities. Arch Venture Partners focuses on IT, life sciences, and physical sciences, with 95% of its investments at the seed and start-up stage. Special competence is in the building of start-ups from research originating in academic and research laboratory settings. Their business model is to invest conservatively in a seed round and then to lead and colead additional rounds to liquidity. They also play an active role in assisting portfolio company management.

Arrowhead Research Corporation

Arrowhead Research Corporation sponsors research at university level in exchange for rights to commercialize the IP that results. The company works closely with universities to source early stage deals. By funding the launch of companies, rather than investing in them at a later stage, Arrowhead obtains rights to the IP without having to pay for all of the overhead costs associated with R&D. When the technologies are ready to leave the lab, start-ups are formed and additional financing and support services are provided and, if necessary, a broader investor syndicate for a follow-on round is organised. Arrowhead maintains a majority interest in its subsidiaries and provides financial, administrative, corporate and strategic resources. As a public company, there is access to the public markets for the purpose of raising capital and provide meaningful incentives in the form of stock options to attract the most talented managers and scientists. By offering financial, administrative, corporate and strategic resources to their subsidiary companies, each individual management team can maintain focus on specific technologies and specific markets, increasing the likelihood of successful technological development and commercialisation.

Currently, Arrowhead has the four majority-owned subsidiaries Ablaris, Calando, Leonardo Biosystems and Nanotope commercialising nanotech products and applications, including anticancer drugs, RNAi therapeutics, fullerene antioxidants, carbon-based electronics and compound semiconductor materials. Since 2004, Arrowhead is quoted on the NASDAQ Capital Market (symbol ARWR). The NASDAQ Capital Market, previously called NASDAQ Small Cap Market, was renamed in 2005. Starting with 7 USD in January 2004, the highest stock price was 7.50 USD in June 2004 and 7.60 USD in April 2007. The current price (end of May 2011) with 0.56 USD is near the all time low of 0.39 USD in January 2009.

Molecular Manufacturing Enterprises

Molecular Manufacturing Enterprises Incorporated (MMEI) is a seed capital firm helping individuals or small groups to develop a laboratory-bench model into a working prototype that might then, in turn, interest a venture capital firm. MMEI has a good working relationship with the Foresight Institute (FI) and with the Institute for Molecular Manufacturing (IMM). FI is dedicated to educating the public and policy makers about the advantages and consequences of molecular nanotechnology. IMM focuses on providing research funding, with an emphasis on pure research.

MMEI has the resources to provide modest amounts of financial assistance to several high-risk/highleverage efforts to advance the state of the art of molecular nanotechnology. In addition, MMEI can provide technical and non-technical advice and can also serve as a contact point for people working towards advancing the field of molecular nanotechnology. MMEI was founded by three people with strong scientific and financial backgrounds. In addition, MMEI uses several advisors from a variety of areas, both technical and nontechnical. The advisors

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Gunter Festel and Jan Kratzer
include a broad range of business, legal, and financial experts.

**Model of founding angels**

The model of founding angels is the combination of management and capital. They build a bridge between the early stage research and development (R&D) phase and a marketable product by funding additional development at universities and providing access to further funding once a product is ready for the market. After analysing the case studies, it has been found that the following process with five different phases provides a best practice framework for founding angels investments.

**Phase 1: Screening/sourcing of projects**

Project opportunities are sourced and evaluated to identify those which have the highest potential and the best fit. If necessary, founding angels finance early stage research at universities or research institutions in exchange for IP rights. The founding angels work together with industry and technology experts to identify and pursue these new opportunities in targeted industries. These experts work closely together with the scientists from the universities or research institutions to develop a business plan.

**Phase 2: Foundation of start-ups**

When the technology is ready (e.g. proof-of-concept in the laboratory) a start-up company is established together with the scientists after developing a business plan. The founding angels provide seed capital for the development of the start-ups as well as financial, administrative, and strategic support. An agreement with the universities or research institutions is signed based normally on the exclusive rights regarding all relevant IP. In exchange, the technology partner receives a preagreed payment and/or equity stake of the start-up.

**Phase 3: Building-up of the start-ups**

The new company utilises the founding angel's seed funding and management support to build and operate the company, typically focusing on R&D activities. The research focus is on applied research up to the development of a working prototype. The founding angels also help start-ups to obtain access to additional academic research laboratories and manufacturing facilities should this be required.

Intensive technical and nontechnical advice from the founding angels is provided to the start-ups. This includes conducting market research, supporting product development and establishing market entry strategies. A new management team will take over responsibility from the interim management organised by the founding angels. Preset milestones are used to assess the progress of the research projects with regard to continued investment, redirection of funds or withdrawal of investment.

**Phase 4: Development of the business**

The focus is on building up a sustainable business for the start-up by acquiring cooperation partners and customers. Revenues are generated through the sale or licensing of the technology, by securing additional financing from either the venture capital community or the capital markets, or by successfully executing the business plan and using own cash flow. If necessary, a broader investor syndicate for a follow-on financing is organized by the founding angels.

**Phase 5: Execution of an exit**

The exit will enable founders, founding angels and other investors to get paid off. Universities or research institutions will also profit if they have an equity stake in the company. In most cases a trade sale to existing industrial cooperation partners of the start-up company is realised.

**Comparison with established models**

Comparing founding angels, business angels and venture capitalists shows that these investment models fit perfectly together. Founding angels are engaged in very early stage projects (pre-seed and seed stage), business angels in early stage projects (mostly seed and start-up stage) and venture capitalists more in later stage projects (mostly growth stage and only a few specialised companies in the start-up stage). There are also case examples, like Arch Venture Partners, combining the established venture capital and the emerging founding angels investment model as they primarily invest in companies co-founded with scientists and entrepreneurs. Because founding angels fund pre-seed ventures, their average exit horizon is much longer than their average venture capital fund manager counterpart’s. Due to this long exit horizon, both the entrepreneur and the founding
angel have enough time to increase the value of the start-up, which results in higher valuations when additional funding is sought from large venture capital funds. Increased value also translates into a smaller dilution of stock ownership in future rounds, an important consideration for entrepreneurs and founding angels.

Advance Nanotech, Angle Technology and Arrowhead Research are listed on public stock markets. All of them had lost value continuously during the last years. The negative development of the stock price may lead to the conclusion that the business model is flawed. We argue that the business model in general is not flawed, but that the concept of founding angel investment is in strong contrast to the concept of investing in public stock markets. Public investors focus often on fast returns, but technology start-ups need patient money with an investment horizon of at least five to seven years. Investors in public stock markets need transparency and the information asymmetry between investors and management is generally overcome through financial statements, income and cash flow statements, and balance sheets. But technology start-ups generally have no positive cash flows to analyse and the balance sheet consists mainly of intangible assets, such as patents and knowledge, which are hard to value due to technological novelty and complexity.

Conclusion

After analysing founding angels as early stage technology investors, they can be defined as a relatively new investment model with the potential to increase start-up activities, especially at universities and research institutions. They are active in high-tech sectors and invest at an earlier stage of the start-up development than other investors. Founding angels provide business expertise and operational advice to identify the mechanisms and actions needed to found a new firm. With their innovative model, founding angels are valuable for founders because they i) invest time to support the founders in the daily business, ii) have a vast amount of knowledge, skills and experience, iii) provide access to their networks.

Because of their profound market know-how, founding angels help to broaden the view on potential applications and they also keep an eye out for new scientific breakthroughs which have the potential of being commercialized. Unrecognised commercial potential can be identified, and otherwise undiscovered technologies or ideas make it to the market. Thus, founding angels engagements have a “pull” function in the venture business and they significantly help to close the technology transfer gap between academic research and commercial application. Because they work very closely with the founders, the founding angels will acquire a deep knowledge of the financial situation or the technological potential of the company. When facing important decisions such as whether a large investment should be made, a founding angel will decide differently than a business angel or a venture capitalist, due to his deeper and more complete information of the company, which gives him an advantage.

An important limitation of our study relates to the data gathering methodology, focus on nanotechnology, which is (probably) a distorted sample of the real population, might have influenced our findings. In order to fully understand the dynamics of FA activities, it might be necessary to investigate engagements with a broader technological scope. Given the exploratory nature of this study, this problem should be overcome in follow-up studies on the subject.

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Practitioner’s Section

Standardized cost estimation for new technologies (SCENT) - methodology and tool

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This paper presents the development of a methodology and tool (called SCENT) to prepare preliminary economic estimates of the total production costs related to manufacturing in the process industries.

The methodology uses the factorial approach – cost objects are estimated using factors and percentages on the basis of the purchased equipment cost. The chosen approach is based on an extensive literature survey on methodologies and suitable data. The approach has the advantage that it can be based on a limited amount of data (list of equipment required for the technology). Therefore it is especially suitable for new or emerging technologies. The theoretical accuracy of the prepared estimates is within ±30%.

1 Introduction

Ever since the industrial revolution the process industries have played an important role in improving the quality of human life. Over the last 200 years, the process industries have gained significant importance in society by introducing products which dramatically changed the world. Key examples are pharmaceuticals, food products and food additives, fuels and polymers. At the same time, many technologies have led to controversial societal discussions, leading to the quest for a holistic technology assessment. There is a wide consensus that the three sustainability dimensions – economy, environment and society – need to be taken into consideration when assessing a technology. This paper deals with the (micro-) economic assessment, with the goal of preparing a readily applicable tool-set for the economic evaluation of new and emerging technologies.

In today's world, the economic performance is a conditio sine qua non for the existence and the future application of a technology. New technologies resulting in better, more environmentally friendly products are often more costly. The additional costs might be caused by higher capital investment (e.g. due to improved heat integration or measures for environmental or health protection) and/or higher operational costs. Decision making sometimes implies a trade-off between environmental or social benefits and economic costs. Therefore, careful and precise assessment of all costs related to a technology is of great importance to determine the prospects of a technology.

It is evident that there is a strong need for a reliable estimation of the full costs of a product on the micro level (“small” in Greek; refers here to the costs of a single manufacturing plant). These costs include many components, most of them not easy to forecast and calculate – capital investment in equipment and buildings, expenses for maintenance and repairs, materials and energy costs, salaries for employees.

Different approaches exist to obtain these data. For currently existing technologies, a relatively easy and trustworthy method is the comparison of historic real plant data. Many manufacturing processes have existed for more than 50 or 100 years and tens and hundreds of similar plants have been built on the planet. Such data are, however, not easily available due to their confidential and proprietary nature (e.g.

1 The work presented in this paper is embedded in the European Union-funded project “Development and application of a standardized methodology for the prospective sustainability assessment of technologies” (acronym: PROSUITE). The assessment tool presented in this paper will be made publicly available on the website of the PROSUITE project (www.prosuite.org)
Dysert, 2003). Moreover, when assessing new technologies, it is a further challenge, that historic data is typically of no or only very limited use.

Very often, estimates are made using complex commercial software tools. These tools may require a large amount of input data which are not always available for new technologies. Extensive previous knowledge and training on the software is also necessary. The commercial nature of the tools makes it difficult to compare estimates made by application of different tools. The need to rely on the outcome of one single tool is therefore quite common.

When preparing an economic analysis for new technologies, up-to-date data on prices are needed for many items, such as equipment, instrumentation and controls, chemicals, utilities (electricity, water, and natural gas), salaries for operating and skilled labour. One can obtain this information from vendors, suppliers, manufacturers, government statistics offices and others. All this requires significant effort. Unfortunately, there is no unified database which contains all necessary information for preparing basic cost estimates. Such a database was published in the open literature for the last time in 1990 (Couper, 2003).

There is hence an urgent need for a publicly available estimation method, which could provide sufficiently accurate results. It is apparent that in early stages of the development of new technologies, only study or preliminary estimates can be made. Despite the great deal of uncertainty existing for new technologies, the basic information required for conducting a cost analysis is often rather well known: this includes material balances (raw materials, solvents, catalysts), major pieces of equipment, important service facilities (e.g. steam generation) and energy balances (use of electricity, power).

Consequently, the question addressed by this study is how to use this information to arrive at reliable cost estimates for (new and emerging) technologies, thereby making use of existing cost estimation techniques. By conducting a literary survey covering different types of process cost analyses this paper pursues the following goals:

- To develop a cost estimation methodology to be used as standardized, default approach when making economic analysis for new or emerging technologies.
- To compile a database of all relevant costs and expenses necessary to prepare a study or preliminary estimate for a new technology; these include, for example, prices of major types of equipment, utilities, chemicals, environmental protection expenses and labour costs.
- To combine the methodology and the database into a simple cost assessment tool which would allow a quick and handy estimation and which can also be performed without previous specific expertise in cost estimation.

Many publications (mostly handbooks) deal with economic aspects of plant and process design, but most of them refer to just a handful of authors. From the literature review we performed we concluded that the most authoritative authors dealing with capital investment and production cost estimates are Peter, Timmerhaus and West (2004) as well as Couper (2003 and 2008). This paper is based mostly on their work but we have also accounted for the work of a few other authors (see section 3 “Essence of the factorial methodology”).

2 Classification of the production costs

The classification in this study is mainly based on the work of Peters, Timmerhaus and West (2004). Their classification is the most comprehensive, includes most examples and was updated very recently. They are considered authorities in this area and many other publications refer to them. One important point made by them is that the main source of inaccuracy in economic estimates is actually not under-estimating or over-estimating individual data inputs rather than missing a cost object. Therefore the classification is of lower importance than the diligent application of the tool, thereby avoiding omissions.

The classification presented in this paper (see below) exhibits an intermediate level of detail. In contrast, more elaborate classifications are applied when preparing detailed estimates. Examples of elaborate classifications are given by Couper (2003 and 2008) and by Holland and Wilkinson (1997).

Production costs are the costs required for the plant to manufacture a product and they are expressed either per unit(s) produced (e.g. per tonne of product) or on basis of time: hourly, daily, monthly or annually. In effort of standardization, we recommend to express the production costs on an annual basis because it

1) Examples are ICARUS™ by Aspen, Cost Track™, WinEst®. For more examples see Towler and Sinnott (2008)
Standardized cost estimation for new technologies (SCENT) - methodology and tool

Figure 1 Example of a manufacturing plant: illustration of the processing plant (inside battery limits, ISBL) and the off-sites (outside battery limits, OSBL). Adapted from Brennan (2004)

The production costs are generally classified as (semi-) variable and fixed costs. The variable costs are proportional to the load factor of the manufacturing, while fixed costs are independent of the plant capacity. Some of the variable costs are referred to as "semi-variable" because they have a minimum fixed component in them. The full list of production costs is given in Figure 2.

One of the most important fixed cost objects is the capital cost which includes all the buildings, machinery and equipment necessary for every-day operations of the plant. The initial capital investment (which may easily exceed US$ 50 million for a large-scale manufacturing process; Peters, Timmerhaus and West, 2004) is recovered on an annual basis through depreciation, with the depreciation regime being determined by tax laws. The annual cost is referred to as capital recovery cost, which is a fixed cost. The capital investment is generally classified in two main parts: the fixed-capital investment and the working capital.

The fixed-capital investment is all capital "fixed" to the ground, essentially tangible properties: e.g. equipment, machinery, buildings, and land. Since it may be as high as 80% of the whole capital investment (Peters, Timmerhaus and West, 2004) this cost might pre-determine the profitability of a technology and is a key factor in the decision making for a prospective investment.

For process industry plants, the fixed-capital investment can be divided in two parts: inside battery limits (ISBL or IBL) and outside battery limits or off-sites (OSBL or OBL). Battery limit is a real or imaginary geographical boundary around an area in the processing plant where the actual manufacturing takes place (the conversion of the raw materials or intermediates into the product). Thus the inside-battery limits costs may be defined as all expenses for equipment, including delivery, installation, foundations, structures, piping, electrical works, painting, insulation as well as the cost incurred for instrumentation, control equipment and operation. All these are direct costs. One could say that the battery-limits is a subsystem of the plant, with the raw materials (or intermediates) and the utilities flowing in and the products flowing out (Figure 1).

Next to direct costs also indirect costs are applicable to the battery-limits, such as engineering and design expenses, construction costs, etc. These costs are typically charged to the project as a whole and cannot be assigned to specific cost objects. A list of the indirect costs is given in Figure 2. They normally include engineering and supervision expenses, construction costs for the project including the contractor's fee and all costs required to meet the legal requirements for building the plant. There is an additional "allowance" called contingency capital which is usually a percentage of the value of the whole project. This capital is meant to cover any unforeseen events, such as unpredicted delays due to weather conditions, strikes, transportation issues, etc.

The other direct costs (or the outside-battery limits costs) are expenses for land, yard improvements such as fences or roads, various buildings and service facilities (e.g. boilers, cooling towers, facilities for compressed air or steam generation). The latter are commonly referred to as "off-sites".

Figure 1 Example of a manufacturing plant: illustration of the processing plant (inside battery limits, ISBL) and the off-sites (outside battery limits, OSBL). Adapted from Brennan (2004)
For every enterprise, there is also a sum of money required to conduct every day operations. It is necessary to cover expenses such as salaries, utility bills (electricity or natural gas), to regularly purchase raw materials and other supplies. This sum of money is called the working capital and it is not available for another purpose; therefore it is regarded as an investment item and is part of the capital investment.

Working capital is defined as the total amount of money invested in: raw materials and supplies in stock; finished products in stock and semi-finished products still in process of manufacturing; cash required for regular payments of operating expenses (salaries and other bills for a limited period); accounts receivable; accounts and taxes payable (Peters, Timmerhaus and West, 2004).

It is important to realize that even though operating expenses such as salaries, raw materials supply and others are taken into consideration in the working capital, the working capital is not an operating expense but that it is instead part of the capital investment. It is used to ensure liquidity of the firm. The reason behind this is that a company will have to constantly maintain cash to cover its every-day expenses.

The working capital is constantly regenerated with income from sales and stays at roughly the same level throughout the plant’s lifetime. The working capital is by far smaller than the sum of all operating expenses for the whole year. It typically allows covering for one or two months of salaries, few months of raw materials supplies and other operating supplies. All this depends on the specifics of the business and the regularity of payments. It is also largely dependent on sales: seasonal sales will lead to less regular re-liquidation of the working capital and therefore, higher working capital will be required.

To facilitate the estimation of production costs, the SCENT tool (Standardized Cost Estimation for New Technologies) was developed. It has been prepared in the form of MS Excel file and is organized according to the classification presented above. It incorporates all equations and correlations between the cost objects which will be discussed in the further course of the paper. It follows a simple approach using drop-down menus and pre-defined values which allow usage without previous economic training.

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<tr>
<th>(Semi-) Variable costs</th>
<th>Fixed costs</th>
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<td>Raw materials</td>
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<td>Operating labour</td>
<td>Insurance</td>
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<td>Direct supervisory and</td>
<td>General plant overhead</td>
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<td>clerical labour</td>
<td>Administrative costs</td>
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<td>Utilities</td>
<td>Distribution and marketing</td>
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<td>Maintenance and repairs</td>
<td>Research and Development</td>
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<td>Operating supplies</td>
<td>Capital recovery - annualized percentage of Total capital investment (including interest)</td>
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<td>Laboratory charges</td>
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<td>Patents, royalties</td>
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**Total capital investment**

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<th>Fixed-capital investment</th>
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<tr>
<td>Direct Costs</td>
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<td>Inside battery limits</td>
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<tr>
<td>costs</td>
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<td>Equipment, including</td>
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<td>Indirect costs</td>
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<td>Contractor’s fee</td>
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<td>Start-up capital</td>
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<td>Contingency</td>
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**Working capital**

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3 Essence of the factorial methodology

Based on a literature review it can be concluded that preliminary cost estimates are usually based on the cost of the purchased equipment, with all additional cost objects being estimated by means of specific default “factors”, i.e. certain percentages of the purchased equipment cost. The accuracy of the estimate will vary depending on the level of detail known about the design of the plant. In early stages of the projects only preliminary estimates can be made. In later stages when there is more information about equipment requirements and the design specifications, more accurate estimates are possible (Towler and Sinnott, 2008). Important consideration is also the quality of the cost data (especially prices and scaling up or down for the specific technology).

From the preliminary flowsheets the pieces of equipment are selected and the purchased equipment cost is estimated. Usually prices of equipment are given by manufacturers and vendors as “f.o.b.”. Delivery charges and installation expenses should then be added. The best source for this information are the manufacturers and sellers of the equipment, however, for preliminary estimates, such quotations might be too difficult or time-intensive to obtain (we have therefore compiled default data in the SCENT tool, see below).

From the cost of the delivered equipment the fixed-capital investment is determined. Once the fixed-capital investment has been estimated it is used as a base for estimating other costs: by multiplying the fixed-capital investment with different factors, one can obtain an estimate of the working capital and few major cost objects: e.g. maintenance, insurance, taxes and others (see below).

There are some costs which cannot be estimated on the basis of the purchased equipment cost or the fixed-capital investment since there is no correlation between them. Examples are the costs for raw materials and utilities. Those expenses are estimated from the material and energy balances (raw materials demand, utilities) and the respective prices or directly from the specifics of the technology (e.g. environmental expenses).

Towler and Sinnott (2008) give a short summary of the steps that need to be taken to make an estimate using the factorial methodology. The steps used in the SCENT tool follow a similar pattern (as mentioned above). SCENT also contains databases on prices and estimation factors:

1) From the preliminary flowsheets the estimator should identify the pieces of equipment required, together with specifics such as their capacity, material of construction (e.g. stainless steel versus regular steel), additional concerns such as extreme pressures or temperatures, etc.
2) Determine the purchased costs and - by multiplication with equipment installation factors - estimate the installed cost for each piece of equipment (see below for further explanation)
3) Estimate the fixed-capital investment including all direct and indirect costs
4) Based on the fixed-capital investment estimate the working capital

The approach presented so far leads to the estimated total capital investment (see Figure 2). This cost occurs at the beginning of the project, depending on the time required for planning and construction. Afterwards, the actual manufacturing of the product starts and the total capital investment is gradually recovered. The capital recovery is included in the total production costs by application of the annuity method (see below). Production costs can be expressed as costs per year (or other time frame) or costs per unit of product (e.g. per tonne of product). For the reasons given above we determine in SCENT the costs per year.

5) Based on the material and energy balances, estimate the raw materials (chemicals, solvents), utilities (water, electricity) and expenses for environmental measures
6) Estimate the labour costs
7) Estimate the total production costs including all (semi-) variable and fixed costs

The most significant and also most difficult part in this process is the estimation of the fixed-capital investment. It relies mainly on the accuracy of: the input cost data of the purchased equipment, the installation factors used to account for the installation of the equipment (see below), and the correlation factors to account for all other direct and indirect costs (buildings, engineering, etc.). According to Peters, Timmerhaus and West (2004) the first two items may reach 80% of the fixed-capital investment. The equipment installation factors account for installation material and labour, foundations,
structures, piping, fittings, electrical works, painting, insulation. Depending on the source of the factors, they might also include the required instrumentation and controls and might be based on the purchased equipment cost (f.o.b.) or on the delivered equipment cost (including freight charges). The value of the installation factor is always > 1, resulting in the installed equipment cost when multiplied with the purchased equipment costs.

The accuracy of the input data can be increased by acquiring more recent, up to date information on the purchased cost of the equipment used. Many of the other cost objects are based on these cost data. Therefore increasing its accuracy will ultimately increase the quality of the final estimated cost. The best quality can be achieved by getting exact quotes from equipment manufacturers or suppliers – these are always recent, and will be chosen in accordance with the technical requirements of the process.

This factorial approach was first suggested by Lang in 1948. He differentiated between three types of processing plants: solid (e.g. a coal briquetting plant), solid-fluid (e.g. a shale oil plant with crushing, grinding, retorting and extraction) and fluid processing (e.g. a distillation separation system) and accordingly suggested three types of installation factors. He proposed the sum of all purchased equipment cost to be multiplied with the corresponding installation factor to yield as a result the sum of the installed equipment cost. This approach is illustrated in Figure 3(A).

Later on, these factors were refined by several authors (e.g. Hand, Wroth, and Guthrie (as quoted by Couper (2008)) and more specific “group installation factors” were developed as illustrated in Figure 3(B). More recently, individual factors have been developed. These installation factors are strictly specific for each individual type of equipment: i.e. two different types of pumps have different installation factors in contrary to the group factors where all types of pumps have the same installation factor. These factors are typically much more accurate than the previously presented methods. Woods (2008) gives a detailed list of about 500 different pieces of equipment, each along with individual installation factor. The individual factor approach is illustrated in Figure 3(C).

In the SCENT tool it was decided to use the individual equipment installation factors by

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5) For detailed overview of the existing cost estimation approaches Couper (2003 and 2008) is recommended.
Woods (2008) for the following reasons:

- Higher accuracy – the individual factors are more specific
- Most recent – they were first published in 2007 and re-printed in 2008
- Woods’ approach deliberately excludes instrumentation and controls from its factors while earlier factors include it. The reason behind the exclusion is that instrumentation and controls have undergone major development and accounting for them in a simplistic way by means of a default factor could therefore cause inaccuracies.
- Detailed – Woods also gives capacity exponents, alloy correction factors and additional correction factors for the temperature and pressure level and other process conditions which are all specific for each individual piece of equipment. This gives the estimator the opportunity for higher level of customization, and better accuracy of the estimate
- Labour / material ratio – Woods gives the ratio between the costs for labour and material which are incorporated in each installation factor. This makes it possible to correct in SCENT for the location by country, as will be described in detail in the next section

For all other cost objects in the capital investment and the production costs (e.g. off-sites and maintenance) mainly Peters, Timmerhaus and West (2004) are used as a source for few major reasons:

- Authoritative – the publication by this group of authors has been updated regularly and recently (2004). It has been referenced by many other authors working on the topic of cost estimation.
- Most consistent – many authors present factors to estimate certain cost objects, but the most comprehensive approach proved to be the one by Peters, Timmerhaus and West.
- Additional considerations – this group of authors presents additional considerations and different values for some of the cost objects (for example, they suggest three different values for buildings depending on whether a new plant is built on an undeveloped site or on an existing site or whether it is simply a small expansion on an existing site). These considerations allow for higher accuracy of the estimate. They will be presented in greater detail in the next section.

4 Cost estimation

The process industries represent capital-intensive sectors (Economy Watch, 2010). Therefore, the accurate estimation of the capital investment is of crucial importance. When presenting the methodology the capital investment estimate will be discussed first, partially because it is the first step in project development but more importantly because the value of the capital investment is necessary to estimate other cost objects (e.g. the maintenance and repairs expenses).

4.1 Capital investment estimate

4.1.1 Purchased Equipment

In the SCENT tool the cost data by Woods (2008) have been implemented with all prices given f.o.b. in US $. The purchased equipment cost calculated by the tool includes in total all pieces of equipment from the process flow sheet, spare parts, surplus equipment, supplies and equipment allowance.

All prices in this database refer to a value of the Chemical Engineering Plant Cost Index (in short: CEPCI) of 1000. The CEPCI value for the years 1957–1959 was 100 while the value for 2010 was 585.9. By choosing today’s (or an expected future) CEPCI value in SCENT, the results are adapted to the respective price levels. The CEPCI index is published at the end of each month in the Chemical Engineering magazine (Dyser, 2003).

The prices taken from Woods (2008) were published in the year 2007. In combination with the newest CEPCI values they allow to generate estimates with good accuracy also for a limited period in the future by using these historic cost data. Couper (2003) suggests that it is acceptable to use the same cost data with the correction of a cost index for no longer than 10 years.

All prices in this database are given as base cost with a base capacity. The database also contains equipment-specific scaling exponents which allow estimating the cost of a given piece of equipment with a different capacity:

\[
(Cost\ \text{equipment}_x) = (Cost\ \text{equipment}_base) \times \left(\frac{\text{Capacity}_x}{\text{Capacity}_{\text{base}}}\right)^{0.6}
\]  

(1)

In case the scaling exponent is unknown, a value of 0.6 or 0.7 can be used as default (also referred to as six-tenths or seven-tenths rule). Equation (1) represents the economies of scale because buying a piece of equipment with twice
the capacity is less than twice as expensive (when the exponent is less than 1.0). If, for a specific piece of equipment, this exponent is larger than 1.0, the most cost-effective way of scaling up is to duplicate the equipment. In the SCENT tool, a valid equipment-specific capacity range is suggested to the estimator.

Most of the equipment is offered with standard material of construction, usually cast steel (c/s) or cast iron. If special construction is required (e.g. stainless steel (s/s), nickel or any type of alloy), an alloy factor is applied to estimate the cost of the equipment. The alloy factor is specific for each type of material and equipment. Multiplication of this alloy factor by the cost of the equipment made of the standard material yields the cost of the equipment made from the chosen material as shown in equation (2).

Additional factors are provided to estimate the cost of equipment working at different process conditions or with different specifications: e.g. factors for elevated temperature or pressure. The approach is the same as with the alloy factors: the base cost of the equipment is multiplied with the additional factor (equation (2)). These factors are individual for each type and subtype of equipment (e.g. individual factors for pumps depending on the working pressure).

\[
(Cost_{equipment})_{PURCH} = f_{add} \times f_{alloy} \times (Cost_{equipment})_{base} \tag{2}
\]

Delivery charges for transportation, freight insurance, duties, and taxes are not accounted for by the installation factors. This cost may vary significantly depending on the plant’s location or government regulations. Such estimation is hard to make in a very early stage of the project because the manufacturer or the vendor of the equipment might be yet uncertain as well as the plant’s location might still be in question. Therefore, for preliminary estimates, 10% of the purchased equipment cost is proposed as an average, standardized value as delivery charge (Peters, Timmerhaus and West, 2004). The purchased equipment cost including charges for delivery will be referred to as “delivered equipment cost”.

4.1.2 Installed Equipment

The installation factors account for installation material and labour, foundations, structures, process piping, pipe fittings, valves, painting, insulation, electrical systems and equipment switches, motors, feeders, grounding, wiring, lighting, panels, etc. The installation costs are estimated using equation (3):

\[
(Cost_{equipment})_{INST} = f_{INST} \times (Cost_{equipment})_{PURCH} \tag{3}
\]

When the installed cost is estimated for equipment made of more expensive alloys, equation (3) needs additional correction because labour will generally be the same, structures and foundations will be mostly the same and also the expenses for electrical works might not be affected. When estimating equipment made of special materials, equation (3) therefore leads to overestimation. To correct for this, an alloy correction factor is applied according to equation (4):

\[
(Cost_{equipment})_{INST} = (1 + f_{INST} - 1) \times f_{alloy \_corr} \times f_{alloy} \times (Cost_{equipment})_{base} \tag{4}
\]

The alloy correction factor is applied only when the installed cost is estimated and only when beforehand an alloy factor was used to estimate the purchased cost. The alloy correction factor is presented separately from the alloy factor, because it is only applied to the installed cost (this explains multiplication by the term \((f_{INST} - 1)\) in equation 4), while the alloy factor is used to estimate the purchased cost of the equipment.

The alloy correction factor was introduced by Brown (2000) as modification to Hand’s factorial approach (1958). The relation between the alloy correction factor and the alloy factor is given in Figure 4. It is logical that the higher the alloy factor, the higher the necessary correction is. In the figure the typical ranges for stainless steel and Monel alloy factors are presented, the exact values, however, remain specific for each type of equipment.

As mentioned above the installation factors presented by Woods provide the ratio between the labour and the material for each individual installation factor. This ratio could not be found in earlier publications. Using this ratio it is possible to develop simple country-specific factor to account for differences in labour costs in the various countries. The installation factor is split into two sub-factors, one for materials and one for labour costs as shown in equation (5):

\[
f_{INST} - 1 = M_{INST} - L_{INST} \tag{5}
\]

There are always differences between the installation and construction costs in different geographical locations (countries). Two important assumptions were made:

1) Most of the large equipment, as used in
the process industry, is globally traded. It is therefore justified to use uniform international prices for purchased equipment. In contrast, the labour costs related to installation and operation may differ significantly between countries and sometimes even within a country. To correct for this, SCENT assumes that the difference in costs between geographical locations (countries) is driven mainly by the difference in the labour rates (while the fluctuations in material prices were assumed to be negligible).

2) The installation factors suggested by Woods are based mainly on US data; they take into consideration the US labour rates. When a piece of equipment is installed in the USA, the cost should be accurate; however, when the same piece of equipment is installed outside the USA, the estimation might differ; it is assumed that this difference is driven solely by the difference in labour costs and therefore, a correction for this labour cost difference is applied.

Differences in labour costs are taken into account by introducing a correction factor which is applied only to the labour part of the installation factor. Subsequently, equations (3) and (5) are expanded into equation (6) to include this correction:

\[
(C\text{ost equipment})_{\text{SCENT}} = \left(1 + (C\text{ost labour})_{\text{USA}} \times (C\text{ost equipment})_{\text{USA}}\right) \times (C\text{ost equipment})_{\text{SCENT}}
\]  

(Cost equipment)_{SCENT} = \left(1 + (C\text{ost labour})_{\text{USA}} \times (C\text{ost equipment})_{\text{USA}}\right) \times (C\text{ost equipment})_{\text{SCENT}}

Country-specific labour-related installation factors were created by normalizing the values for all European Union countries (plus Norway) relative to the factor for the USA which is 1.00 (Table 1). The country-specific factor indicates whether the installation of a piece of equipment is cheaper or more expensive compared to the USA, only from labour point of view. When this factor is multiplied with the labour component of the installation factor, it will decrease or increase the total cost.

4.1.3 Fixed-capital investment

The cost objects within the fixed-capital investment are commonly estimated by multiplication of the purchased or the delivered equipment with a suitable factor. It is important to point out that for many types of costs three different values will be suggested according to the three types of processing plants: solid, solid-fluid and fluid processing (see below Table 2; Peters, Timmerhaus and West, 2004). The various types of costs are discussed next.

The **instrumentation and controls** cost includes the purchased, delivered and the installed cost for any instrumentation and control equipment (such as alarms, sensors, valves, etc.), including all expenses for computer control and supportive software. In the SCENT tool there are two ways of estimating this cost, i.e. a detailed and a rough estimation method.

In the detailed estimation method, instrumentation and controls are considered as separate equipment and estimated based on a dataset including prices for control systems,
sensors, alarms and others. The estimation is done in the same way as the estimation of the equipment cost. The source of the database is Woods (2008) and each piece of equipment comes together with individual capacity exponents, installation factors, alloy and additional factors. The purchased cost is linked to the CEPCI cost index and where applicable, exponents are used to correct for scale together with alloy and additional factors.

In the rough estimation method, the factors suggested by Peters, Timmerhaus and West (2004) are used. The corresponding factor, depending on the type of processing plant, is multiplied with the delivered equipment cost, to represent the capital costs related to the instrumentation and controls (Table 2).

The cost object of buildings represents all expenses for process-related buildings (including sub- and superstructures, platforms, stairways), auxiliary buildings (e.g. administration and office, garage, product or spare parts warehouse, safety and security, fire station, shipping office, research and control laboratories), maintenance shops (e.g. electric, piping or machine). This cost includes all necessary building services – plumbing, heating, ventilation, lighting, elevators, telephones, intercommunication systems, painting, fire alarms and others.

The cost of buildings is estimated by multiplying the purchased equipment cost (excluding delivery) with a representative factor. Different values are presented by Peters, Timmerhaus and West (2004) based on three additional considerations: whether a new plant is built at a new site, a new unit is built at an existing site or simply an expansion is made to an existing plant (Table 2). The cost of buildings is lowest in the case of expansion, because most of the required infrastructure already exists and the cost is highest in the case of building new plant at undeveloped site.

The service facilities are all additional process or non-process equipment which are not directly involved in the manufacturing of the end product but are of crucial importance for the whole plant operations. They are commonly referred to as “off-sites” and fall under the category “outside-battery limits”. Brennan (2004) points out that mostly the term “services” is used as synonym for utilities and the term “plant service facilities” also includes buildings.

These include facilities required for the supply of utilities such as steam, water, power, refrigeration, compressed air, and also waste disposal facilities. Other types of facilities which

<table>
<thead>
<tr>
<th>Country</th>
<th>Labour-related Installation Factor</th>
<th>Country</th>
<th>Labour-related Installation Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>1.03</td>
<td>Latvia</td>
<td>0.11</td>
</tr>
<tr>
<td>Belgium</td>
<td>1.04</td>
<td>Lithuania</td>
<td>0.16</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>0.06</td>
<td>Luxembourg</td>
<td>0.99</td>
</tr>
<tr>
<td>Cyprus</td>
<td>0.61</td>
<td>Netherlands</td>
<td>1.28</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>0.28</td>
<td>Norway</td>
<td>1.47</td>
</tr>
<tr>
<td>Denmark</td>
<td>1.10</td>
<td>Poland</td>
<td>0.19</td>
</tr>
<tr>
<td>Estonia</td>
<td>0.30</td>
<td>Portugal</td>
<td>0.34</td>
</tr>
<tr>
<td>Finland</td>
<td>1.09</td>
<td>Romania</td>
<td>0.09</td>
</tr>
<tr>
<td>France</td>
<td>1.05</td>
<td>Slovakia</td>
<td>0.20</td>
</tr>
<tr>
<td>Germany</td>
<td>0.93</td>
<td>Slovenia</td>
<td>0.51</td>
</tr>
<tr>
<td>Greece</td>
<td>0.46</td>
<td>Spain</td>
<td>0.73</td>
</tr>
<tr>
<td>Hungary</td>
<td>0.19</td>
<td>Sweden</td>
<td>1.14</td>
</tr>
<tr>
<td>Ireland</td>
<td>1.35</td>
<td>United Kingdom</td>
<td>1.06</td>
</tr>
<tr>
<td>Italy</td>
<td>0.76</td>
<td>USA</td>
<td>1.00</td>
</tr>
</tbody>
</table>
could fall under this cost object are, for example, water treatment and storage, cooling towers, electric substation, air separation plant, fuel storage, waste disposal plant, environmental controls and fire protection. Non-process equipment required for the plant is also estimated as part of this item – office furniture and equipment, shelves, bins, safety and medical equipment, fire extinguishers, hoses and engines, loading stations, and important distribution and packaging equipment – raw material and product storage and handling equipment, blending facilities, etc.

There are three ways of estimating this cost: detailed and rough factorial estimation and through selecting pieces of equipment.

- In the detailed factorial estimation, the estimator is presented with a short list of some of the more common service facilities at manufacturing sites (Appendix Table A1). One can choose between low, typical or high values of percentages of the fixed-capital investment for each of the given facilities.
- The rough factorial estimation method is based on the delivered equipment cost using factors suggested by Peters, Timmerhaus and West (2004) in Table 2.
- As alternative to the factorial method it is also possible to extract values for the major pieces of equipment required in the service facilities from the cost database (this is possible because Woods (2008) gives cost data for such equipment, e.g. steam turbine or waste water treatment unit).

Engineering and supervision costs include expenses for administration, process design and general engineering, computer graphics, cost engineering, communications; also consultant fees, travel expenses, as well as engineering supervision and inspection.

The category for construction expenses and contractor’s fee comprises all costs for construction, operation, also maintenance of temporary facilities, offices, roads, communications and fencing; all expenses for construction tools and equipment, supervision, accounting, timekeeping and purchasing. Additional costs such as warehouse personnel and expenses, guards, safety, permits, taxes, insurances and interest are estimated as part of this cost object. Peters, Timmerhaus and West suggest separate factors for estimating the contractor’s fee.

In order for the project to be executed, some legal costs are incurred, such as the expenses for the process of identification of applicable federal, state and local regulations, preparation and submission of forms required by regulatory agencies, the process of acquisition of regulatory approval and contract negotiation costs.

When executing new projects, there is high possibility of certain unforeseen events to occur that might cause delays or additional costs. Possible examples are extreme weather conditions (storms, floods), transportation accidents, strikes by transportation or construction personnel, design changes, omissions, errors or inaccuracies in estimation as well as various construction problems. The costs related to such unforeseen events are covered by the contingency capital, which is sometimes also referred to as back-up capital.

It is important to note that compared to other sources (e.g. Couper or Woods) the contingency capital values suggested in Table 2 are on the low side as other sources suggest values around 15–25% of the fixed-capital investment. Therefore, these values are meant for orientation, bearing in mind that for the respective technology studied, different values might be more appropriate. For new technologies the estimator might prefer much higher values, depending on the technology features. It is generally accepted as a rule of thumb that the lower the total value of the project, the higher the contingency capital must be (Table 2).

The land and yard improvements costs include all necessary capital for land surveys and fees, the property cost, and yard improvements such as expenses for site development (site clearing, grading) and landscaping, roads, walkways, railroads, fences, parking areas, etc.

Land and yard improvements are sometimes excluded from the capital investment. Land is considered to be completely recoverable at the end of the plant’s life and therefore does not need to be capitalized. The value for the land cost is suggested to be between 4% and 8% of the delivered equipment cost, with 6% being an adequate average value (Table 2).

The yard improvements are considered to increase the value of the land, so again they do not need to be capitalized (as recoverable) (Silla, 2003). They are estimated using two alternative sets of factors (see Table 2); the first is based on Peters, Timmerhaus and West (2004) and refers to the delivered equipment cost; the second source originates from Silla (2003) and is based on the fixed-capital investment. The first approach (based on the delivered equipment cost) tends to give results that are on the higher side.

Before the plant reaches its regular
operational mode it runs through a so-called “start-up” period. During this time, additional expenses will occur such as allowance for testing and adjustment of equipment, piping and others, the calibration of instrumentation and control equipment. The start-up costs include materials, utilities and labour for checking and testing the plant and initial personnel training. These costs are considered part of the capital investment.

There are two approaches for the estimation of this cost: the single- and the multiple-factor approaches both suggested by Couper (2003). The single-factor approach is a percentage of the fixed-capital investment credited to the start-up expenses. The multiple-factor is based on a few items like the number of months for training of the personnel and for the start-up of production, initial inefficiency expenses as percentage of the production costs and others. The multiple-factor approach will not be used in SCENT as it requires data which might not be available for new technologies.

The single-factor approach for estimating the start-up expenses gives three values of percentages (6, 8% and 10%) of the fixed-capital investment depending on the magnitude of the investment. The factor given in Appendix Table A2 is multiplied with the value of the fixed-capital investment to determine the start-up estimate.

4.1.4 Working capital

By analogy with the estimation of the start-up capital, there are two widely accepted approaches for the estimation of the working capital: the percentage and the inventory method (Couper, 2003). The inventory method takes into consideration few major items: raw materials cost and periods of supply, semi-finished and finished products cost, period of sales and others. Such detailed information is likely to be unavailable for a new technology; therefore, the chosen percentage method is presented next.

The percentage method simply estimates the working capital as a percentage of another cost and can be based on either the capital

<table>
<thead>
<tr>
<th>Type of cost</th>
<th>solid</th>
<th>solid-fluid</th>
<th>fluid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrumentation and Controls</td>
<td>0.18</td>
<td>0.26</td>
<td>0.36</td>
</tr>
<tr>
<td>Buildings† - new plant at new sites</td>
<td>0.68</td>
<td>0.47</td>
<td>0.45</td>
</tr>
<tr>
<td>Buildings - new unit at existing site</td>
<td>0.25</td>
<td>0.29</td>
<td>0.11</td>
</tr>
<tr>
<td>Buildings - expansion at existing site</td>
<td>0.15</td>
<td>0.07</td>
<td>0.06</td>
</tr>
<tr>
<td>Service facilities</td>
<td>0.40</td>
<td>0.55</td>
<td>0.70</td>
</tr>
<tr>
<td>Engineering and Supervision</td>
<td>0.33</td>
<td>0.32</td>
<td>0.33</td>
</tr>
<tr>
<td>Construction Expenses</td>
<td>0.39</td>
<td>0.34</td>
<td>0.41</td>
</tr>
<tr>
<td>Contractor’s fee</td>
<td>0.17</td>
<td>0.19</td>
<td>0.22</td>
</tr>
<tr>
<td>Legal Expenses</td>
<td>0.04</td>
<td>0.04</td>
<td>0.04</td>
</tr>
<tr>
<td>Contingency</td>
<td>0.35</td>
<td>0.37</td>
<td>0.44</td>
</tr>
<tr>
<td>Land</td>
<td>0.06</td>
<td>0.06</td>
<td>0.06</td>
</tr>
<tr>
<td>Yard improvements - higher</td>
<td>0.15</td>
<td>0.12</td>
<td>0.10</td>
</tr>
<tr>
<td>Yard improvements‡ - lower</td>
<td>0.0285</td>
<td>0.0249</td>
<td>0.0211</td>
</tr>
</tbody>
</table>

* All factors are based on the delivered equipment cost except in the cases of:
† factors for buildings are based on the purchased equipment cost;
‡ factors for the lower estimate of the yard improvements are based on the depreciable fixed-capital investment; Source: Silla (2003).
investment or the annual sales. Since for new technologies, there might be a great uncertainty with regard to the sales, the percentage of capital investment was selected as more suitable option. The working capital is between 15% and 30% of the total capital investment. The total capital investment includes two components: the fixed-capital investment and the working capital (see Figure 2). Once the fixed-capital investment is estimated, the working capital is estimated on its basis.

As explained above the working capital is constantly regenerated by income from sales; therefore it strongly depends on the type of sales rate. If a product is sold at relatively constant and uniform yearly rate, then the regeneration of working capital has smaller fluctuations and values between 15% and 25% of the total capital investment are suggested for the working capital. If the product has very high seasonal variations in sales, then higher values are proposed: 20%–30% of the capital investment (Couper, 2003).

### 4.2 Production cost estimate

As explained above, in SCENT the final production cost estimate is on annual basis. The capital investment cost is annualized to represent the yearly capital recovery expense.

The amounts of raw materials required for the manufacturing of the product are estimated based on the material balance. The category “raw materials” consists mostly of chemicals, catalysts and solvents. A database of prices for more than 700 types of chemicals is incorporated in the SCENT tool. The source of these prices is the www.icis.com website (free-of-charge area). These prices were initially published in the 28 August 2006 issue of the Chemical Market Reporter magazine (now existing as ICIS Chemical Business). Most of the prices are from 2006, while some of these prices were recently updated in 2007 and 2008.

The prices in this database are given in US $ and in US customary units (not SI units) – e.g. gal, lb. For this reason – a unit converter is included in the SCENT tool. For most of the prices, the geographic origin of the price is given and it is very likely that in different areas of the world, the price would be different. For this reason the cost data should be used with caution, the prices in the embedded database serves for orientation and preliminary estimates but wherever possible, more accurate data e.g. from quotations made by possible vendors and suppliers should be used.

The expenses for utilities such as diesel oil, gasoline, natural gas, electricity and water are also estimated from the material and energy balances. A database of prices was compiled mainly from Eurostat and the US Energy Information Administration, with all of the prices being country-specific (the prices are included in the SCENT tool).

The cost data for electricity and natural gas are valid for industrial consumers. Country-specific water prices are difficult to obtain. The source used for water prices in SCENT is a 2008 report by NUS Consulting. All of the water prices are unfortunately for household consumers, and some of the countries have country-specific prices, while for the rest – the European average is used. The estimator should note that the prices for household consumers are typically much higher than the local prices for industrial consumers. For preliminary economic estimates, such rough values of water prices are considered acceptable, but they should be replaced by more accurate data when preparing a more detailed estimate.

The labour costs are estimated in two parts: operating labour costs and direct supervisory and clerical labour costs. The direct supervisory and clerical labour costs are estimated to be between 10 and 20% of the operating labour costs, with 15% being an average value (Table 3).

The operating labour is estimated by multiplying the number of required employees by the average labour cost in the manufacturing industry in the different countries. The number of required employees could be estimated in three alternative ways:

1) Based on the type of equipment. Ulrich (1984) developed a table of the most common types of equipment and assigned a representative number of operators per shift to each type of equipment. For example a heat exchanger requires 0.1 operators per shift and a cooling tower requires 1 operator per shift (the specific values are given in the SCENT tool). This allows estimating the total number of operators required per shift for the plant operations. It is assumed that an employee works 5 shifts of 8 hours per week, for 48 weeks per year. Then, on the base of the load factor of the technology, the required number of full-time employees is estimated.

2) Peters, Timmerhaus and West (2004) suggest representative values of required employee-hours for manufacturing 1000 kg of end product. For solid-processing plant, the values are between 4 and 8, for solid-fluid
processing plant: between 2 and 4 and for fluid-processing plant the suggested values are between 0.33 and 2. On the base of the capacity and the load factor of the technology, the necessary number of employees is estimated.

3) Wessel (1952) developed an equation to estimate the labour requirements for production rate of 2000 (short) tons/day (1814 metric tonnes/day). The method gives the number of operator-hours per ton per processing step. A processing step is defined as a step in which a unit operation occurs (Couper, 2003), e.g. filtration or distillation are considered separate steps. Equation (7) below is adapted from Couper (2003):

\[
\log Y = -0.783 \log X + 1.252 + B
\]  

(7)

Y is the operating labour in operator-hours per ton (short ton) per processing step

X is the plant capacity in tons (short tons) per day

B is a constant depending on the type of process: + 0.132 (for batch operations), + 0 (for operations with average labour requirements), − 0.167 (for well-instrumented continuous process).

Once the number of the required employees is estimated through one of the three approaches, this number is multiplied with the country-specific labor cost. The specific salary rates are given in the SCENT tool with the respective sources, namely Eurostat and the US Census Bureau.

The approaches 2 and 3 presented here are based on historical data from the chemical industry and are commonly used as a rule of thumb for preliminary estimates. Ulrich’s approach might be more accurate for new technologies because it is not based on historical data, but on equipment specifics. For this reason it is recommended for new technologies and the other two approaches are simply given as alternatives. As a further argument put forward by Couper (2008) is that Ulrich’s approach is also simpler.

According to Peters, Timmerhaus and West (2004) the maintenance and repairs costs vary depending on the type of chemical process: for a simple chemical process, the maintenance costs are low (2-6%) and tend to rise for an average process (with normal operating conditions: 5-9%) and for a complicated process (or with severe corrosion operating conditions, or with extensive instrumentation: 7-11%). The maintenance and repairs costs refer to the fixed-capital investment and have two parts, namely labour and material. The corresponding factors are given in Appendix Table A3 for a low, average and high cost level for each component.

The costs for operating supplies include expenses for lubricants, test chemicals and spare parts and they are estimated at 10 to 20% of the maintenance and repairs costs (Table 3).

Other (semi-) variable costs include the laboratory charges and expenses for patents and royalties. The laboratory charges are estimated at 10 to 20% of the operating labour (Table 3). Another important cost object are the patents and royalties (0 to 6% of the total product cost is suggested by Peters, Timmerhaus and West, 2004). For new or emerging technologies, however, typical percentages might not be correct and that is why this cost might be very specific to the technology in question. For this reason the costs for patents and royalties were excluded from SCENT.

The factors used to estimate the fixed production costs are presented in Table 3 together with the quantity they refer to (second column from the left). Local taxes are likely to differ depending on the location of the plant – and they are estimated at 1-2% of the fixed-capital investment in less populated areas and at 3-4% in more populated areas. Insurance is accepted to be roughly 1% of the fixed-capital investment (or less).

The general plant overhead comprises all costs for general plant upkeep, packaging, medical services, safety and protection, storage facilities and others. Important part of this cost is the payroll overhead which is suggested to be typically between 30 and 40% of the labour costs (Couper, 2008). Administrative costs include executive salaries, clerical wages, legal fees, office supplies and communication. These costs are estimated around 15-25% of the operating labour. Distribution and marketing expenses are typically spent on sales offices and salespeople, shipping and advertising (Table 3).

Research and Development costs are excluded from SCENT as for new and/or emerging technologies these might be atypically high and a preliminary estimate might be inaccurate.

The initial capital investment is recovered through depreciation which depends on the discount rate and the lifetime of the manufacturing plant. The applicable depreciation regime is likely to differ by country. Financing (in terms of interest on borrowed capital) must also be included as an annual cost. For new technologies, financing, interest rates, government subsidies, etc. are subject to high uncertainties. For this reason, a strongly
A simplified method will be used in SCENT. A capital recovery factor $\alpha$ is calculated according to equation (8):

$$\alpha = \frac{r}{1 - (1+r)^{-L}}$$  \hspace{1cm} (8)

where: $\alpha$ – capital recovery factor (annuity factor), $r$ – interest rate and $L$ – capital recovery period (in years). The annual capital recovery is calculated according to equation (9):

$$\text{(Capital recovery)} = \alpha \times (\text{Total capital investment})$$  \hspace{1cm} (9)

### 5 Accuracy of the methodology

All factors presented above are based on actual manufacturing plants. It is reported that estimates obtained with them provide uncertainty of the results at ±30% (Couper, 2008). Woods as well as Peters, Timmerhaus and West also suggest the same theoretical accuracy for the cost data provided for the purchased equipment and the factors proposed for estimating the remaining costs.

Therefore, it is assumed that the theoretical accuracy of the SCENT tool is also expected to be around ±30%. In order to gain first insight into the accuracy of SCENT, it was validated for three types of manufacturing processes. Due to the confidentiality of the data used, the exact names of the products and overall costs are not presented and only the inaccuracy of this methodology against the cost value reported in the original source is shown.

It was found that the biggest source of inaccuracy is the off-site capital and this is acknowledged as a limitation of this methodology. Therefore the validation was adjusted to exclude the estimation of off-sites and the respective deviations are also given in Table 4.

The main factors affecting the final accuracy are the quality of the input cost data and the accuracy of the factors to estimate the different cost objects. A cost assessment of higher quality can be achieved by investing more resources in obtaining more accurate input prices of equipment as many other cost objects are based on the cost of the purchased equipment.

It is important to note that for preliminary

### Table 3 Factors for estimation of some (semi-) variable and fixed production costs

<table>
<thead>
<tr>
<th>Type of cost</th>
<th>Based on:</th>
<th>low value</th>
<th>average value</th>
<th>high value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct supervisory &amp; clerical labour</td>
<td>Operating labour</td>
<td>0.10</td>
<td>0.15</td>
<td>0.20</td>
</tr>
<tr>
<td>Operating supplies</td>
<td>Maintenance</td>
<td>0.10</td>
<td>0.15</td>
<td>0.20</td>
</tr>
<tr>
<td>Laboratory charges</td>
<td>Operating labour</td>
<td>0.10</td>
<td>0.15</td>
<td>0.20</td>
</tr>
<tr>
<td>Local taxes - less populated area</td>
<td>Fixed-capital investment</td>
<td>0.01</td>
<td>-</td>
<td>0.02</td>
</tr>
<tr>
<td>Local taxes - more populated area</td>
<td>Fixed-capital investment</td>
<td>0.03</td>
<td>-</td>
<td>0.04</td>
</tr>
<tr>
<td>Insurance</td>
<td>Fixed-capital investment</td>
<td>0.01</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>General plant overhead</td>
<td>Labour &amp; Maintenance†</td>
<td>0.50</td>
<td>0.60</td>
<td>0.70</td>
</tr>
<tr>
<td>Administrative costs</td>
<td>Operating labour</td>
<td>0.15</td>
<td>0.20</td>
<td>0.25</td>
</tr>
<tr>
<td>Distribution and marketing</td>
<td>Total production cost</td>
<td>0.02</td>
<td>0.11</td>
<td>0.20</td>
</tr>
</tbody>
</table>

† – Labour costs are the costs for operating labour plus the direct supervisory and clerical labour; Adapted from Peters, Timmerhaus and West (2004)
purposes, 30% accuracy is quite sufficient and widely accepted in literature (see Couper, 2003 and 2008). A cost assessment of this type is not meant to serve as basis for a final conclusion on the economic viability of a technology. Instead, the ultimate purpose of such preliminary estimation is to formulate a recommendation whether the technology is promising and whether therefore a more accurate estimate using better input data should be prepared, e.g., by application of commercial software tools (see footnote 2) or in close cooperation with equipment suppliers and engineering companies offering turn-key plants.

### 6 Conclusion and discussion

The methodology presented in this paper and implemented in the SCENT tool offers a comprehensive approach for preparing preliminary economic estimates for plants operated by the process industries. The SCENT tool was developed in the form of a MS Excel file which is simple to use and is publicly available at www.prosuite.org. SCENT focuses particularly on new or emerging technologies for which the available data is typically scarce and/or uncertain.

The methodology uses the factorial approach – cost objects are estimated using factors and percentages on the basis of the purchased equipment cost. The chosen approach is based on an extensive literature survey on methodologies and suitable data. SCENT is operated on a limited amount of data (list of equipment required for the technology). Therefore it is especially practical for new or emerging technologies.

The most important cost item in the estimation process is the purchased and the installed equipment cost, mainly because it is a major part of the fixed-capital investment (can reach up to 80% of it) and also because it is used as a base for the estimation of the remaining cost objects. Against this background, the individual installation, alloy, capacity and additional factors presented by Woods (2008) were used in SCENT since they increase the accuracy of the estimate.

A limitation of the methodology is the fact that all factorial correlations originate from plants and processes based in the USA. Since the process industry is globalized and typical equipment, materials, and design specifications, etc. are similar throughout the world, the selected approach is likely to produce sufficiently accurate preliminary results also for plants operated elsewhere.

While material costs can also be assumed to be globally comparable, there are substantial differences in labour rates, even between countries from the same region. Therefore, a labour-related installation correction factor is introduced in this paper which accounts for the differences in labour rates among the European Union countries, as well as Norway and the USA. It increases the accuracy of the capital investment estimate.

A database has been compiled with recent prices and costs for nearly 500 pieces of equipment, selected utilities, over 700 types of chemicals and the labour costs in most European countries.

This database also includes a short list of typical environmental protection expenses. It is acknowledged in this paper that this list is not representative and insufficient to estimate all environmental protection expenses which might occur for a technology.

More data would be required in order to reflect more accurately the differences between the countries: country-specific costs for environmental protection expenses or taxes, infrastructure and transportation-related costs (currently delivery charges are assumed to be fixed at 10% of the purchased equipment cost, despite location), regulations, local laws, labour productivity and others.

In effort to develop a standardized approach, few cost items were deliberately excluded from the analysis because they might vary substantially for new or emerging technologies: costs for research and development, patents and royalties, subsidies or interest rates. Possible technological learning with time is also neglected. Technological learning can, however, be incorporated in SCENT when estimating the capital investment. If projects which are similar to the emerging technology have already been exe-

<table>
<thead>
<tr>
<th>Manufacturing of:</th>
<th>Fixed-capital investment incl. off-sites</th>
<th>Fixed-capital investment excl. off-sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>-19%</td>
<td>-10%</td>
</tr>
<tr>
<td>Organic acid 1</td>
<td>-29%</td>
<td>+1%</td>
</tr>
<tr>
<td>Organic acid 2</td>
<td>-22%</td>
<td>-7%</td>
</tr>
</tbody>
</table>

Table 4 Results from validation of the SCENT tool in % as compared to reference values (confidential)
cuted, one can review the different cost objects and conclude whether some of them showed substantially higher or lower final costs as compared to initially estimated. The methodology also allows for accounting for expected higher yields and the improvement of any other parameter, but this is again technology-specific and cannot be included in a standardized approach.

This methodology is hence capable of offering reliable estimates for preliminary purposes. This was confirmed by applying the SCENT tool for three types of manufacturing processes. The resulting estimates of the fixed-capital investment were within the expected accuracy range, with the highest inaccuracy observed for the off-site capital. This is acknowledged as a limitation of this methodology. Based on the validation runs, the literature information on the method and the quality of the data used, we conclude that the results generated with the SCENT tool have a theoretical uncertainty of ±30%.

In conclusion, SCENT is recommended as suitable approach to estimate the production costs of new or emerging technologies.

References


Appendix

Table A1 Factors for estimation of the labour and material parts of the maintenance and repairs costs. Adapted from Peters, Timmerhaus and West (2004)

<table>
<thead>
<tr>
<th>Type of process:</th>
<th>Labour</th>
<th></th>
<th></th>
<th>Materials</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>low value</td>
<td>average value</td>
<td>high value</td>
<td>low value</td>
<td>average value</td>
<td>high value</td>
</tr>
<tr>
<td>simple chemical process</td>
<td>0.01</td>
<td>0.02</td>
<td>0.03</td>
<td>0.01</td>
<td>0.02</td>
<td>0.03</td>
</tr>
<tr>
<td>average process</td>
<td>0.02</td>
<td>0.03</td>
<td>0.04</td>
<td>0.03</td>
<td>0.03</td>
<td>0.05</td>
</tr>
<tr>
<td>complicated process</td>
<td>0.03</td>
<td>0.04</td>
<td>0.05</td>
<td>0.04</td>
<td>0.04</td>
<td>0.06</td>
</tr>
</tbody>
</table>
Table A2 Percentages of the fixed-capital investment for major service facilities. Adapted from Peters, Timmerhaus and West (2004)

<table>
<thead>
<tr>
<th>type of facility</th>
<th>low value</th>
<th>typical value</th>
<th>high value</th>
</tr>
</thead>
<tbody>
<tr>
<td>steam generation</td>
<td>2.6</td>
<td>3.0</td>
<td>6.0</td>
</tr>
<tr>
<td>steam distribution</td>
<td>0.2</td>
<td>1.0</td>
<td>2.0</td>
</tr>
<tr>
<td>water supply, cooling and pumping</td>
<td>0.4</td>
<td>1.8</td>
<td>3.7</td>
</tr>
<tr>
<td>water treatment</td>
<td>0.5</td>
<td>1.3</td>
<td>2.1</td>
</tr>
<tr>
<td>water distribution</td>
<td>0.1</td>
<td>0.8</td>
<td>2.0</td>
</tr>
<tr>
<td>electrical substation</td>
<td>0.9</td>
<td>1.3</td>
<td>2.6</td>
</tr>
<tr>
<td>electrical distribution</td>
<td>0.4</td>
<td>1.0</td>
<td>2.1</td>
</tr>
<tr>
<td>gas supply and distribution</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>air compression and distribution</td>
<td>0.2</td>
<td>1.0</td>
<td>3.0</td>
</tr>
<tr>
<td>refrigeration including distribution</td>
<td>0.5</td>
<td>1.0</td>
<td>2.0</td>
</tr>
<tr>
<td>process waste disposal</td>
<td>0.6</td>
<td>1.5</td>
<td>2.4</td>
</tr>
<tr>
<td>sanitary waste disposal</td>
<td>0.2</td>
<td>0.4</td>
<td>0.6</td>
</tr>
<tr>
<td>communications</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
</tr>
<tr>
<td>raw material storage</td>
<td>0.3</td>
<td>0.5</td>
<td>3.2</td>
</tr>
<tr>
<td>finished product storage</td>
<td>0.7</td>
<td>1.5</td>
<td>2.4</td>
</tr>
<tr>
<td>fire protection system</td>
<td>0.3</td>
<td>0.5</td>
<td>1.0</td>
</tr>
<tr>
<td>safety installations</td>
<td>0.2</td>
<td>0.4</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Table A3 Factors for estimating the start-up capital. Factors are based on the fixed-capital investment, Adapted from Couper (2003)

<table>
<thead>
<tr>
<th>fixed-capital investment</th>
<th>factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 100 million US $</td>
<td>0.06</td>
</tr>
<tr>
<td>10 – 100 million US $</td>
<td>0.08</td>
</tr>
<tr>
<td>&lt; 10 million US $</td>
<td>0.10</td>
</tr>
</tbody>
</table>
The chemical industry has been put under considerable time pressure by the European Community Regulation REACH (Registration, Evaluation, and Authorization of Chemicals). The work outlined here has been developed at the BASF SE’s Experimental Toxicology and Ecology Unit with the objective of promoting a faster reaction to the testing demand generated by the new legislation. A considerable increase in forecasted demand for tests has created the necessity to increase the Toxicology Unit’s outsourcing activities. The first goal was to optimize the selection and management process of Contract Research Organizations (CROs), so that toxicological studies can be performed with minimal risk while maximizing quality and cost advantage. A second objective was to develop performance measurement system in form of a balanced scorecard to evaluate contracting efficiency by monitoring major drivers in the outsourcing process to ensure the alignment between strategic objectives and actual performance.

1 Introduction

The BASF Experimental Toxicology and Ecology in Ludwigshafen is a global internal service provider that performs toxicological studies for chemical and agrochemical substances as well as ecological studies for chemicals.

Because REACH came into force in June 2007, the demand for registration of all chemical substances produced in or imported to the European Union is having a considerable impact on the BASF SE business units, forcing them to comply with such new registration requirements in a short period of time, not only in terms of workload, demanding new structures and processes, but also demands a substantial financial investment in registration of substances.

This paper is a hands-on work, and discusses how concepts and theoretical approaches are applied under real conditions and how diverse tools and methods can be used for strategic decision-making. Companies are constantly facing new challenges that come from market competition and the supply chain as well as political or economic environments, such as regulations. These force organisations to change their operations and processes and to develop new strategies to survive or grow in a changing environment.

The first method to be used here is the Strategic Management Model (Wheelen and Hunger, 2005), which is the guideline for the challenges assessment that BASF Experimental Toxicology and Ecology in following named
“Toxicology Unit” has been facing and offers a structured form to develop a solution.

The author Grönroos (1990) defined the service concept, which was applied to the Toxicology Unit’s strategic role and to explain how it can contribute to improve the outsourcing activity. Literature researches of outsourcing-related themes lead to the conclusion that one of the first industries that operate outsourcing is the information technology industry. For this reason, most examples of best practices in this field have come from authors that have been studying outsourcing in this industry (see references).

The authors Power et al. (2008) propose a method to evaluate the development, or maturity, level of outsourcing strategies that helped identify the improvement points in the current strategy as well as risks pertinent to outsourcing (Carvusgil et al., 2008). A model from the US General Accounting Office (2001) gave inputs to define the outsourcing lifecycle for toxicological studies. Besides, experiences from the pharmaceutical industry published on books (such as Winter and Baguley, 2006) and on this journal along with inputs from an external consultant were major drivers to determine strategic guidelines, to improve the workflow, to enhance the supplier’s selection and evaluation and to implement an effective study monitoring process.

As elucidated by the Strategic Management Model, an important part of any strategy is the monitoring of the results obtained with the strategic plan. The controlling system ensures that the strategy delivers the expected results or, in this case, that the contracting and management of service providers are being conducted efficiently and in alignment with the strategic objectives.

To address this point, the author Cullen (2009) has provided her experience with performance measurement of contracts. The contract scorecard as defined by her is a balanced scorecard developed for the context of contract management. This paper applies it to monitor the outsourcing performance by evaluating the activity from different perspectives. It aims to be a feedback mechanism to the entire lifecycle, ensuring the strategic objectives achievement and the process continuous update.

In the end, some of the trade-offs in the decisions involving outsourcing will be discussed and the authors will expose their conclusion and the possible next steps of this work.

2 Current outsourcing strategy of Toxicology Unit and its results

The contract management team is responsible for requesting and evaluating quotations, selecting and contracting service providers, so called CROs (contract research organisations), and ensuring compliance with international and BASF SE standards, e.g. Animal Welfare Policy, OECD guidelines for testing, GLP

<table>
<thead>
<tr>
<th>Price/cost ratio conclusion</th>
<th>BASF Group essential</th>
<th>Number of suppliers available</th>
<th>Value for BASF Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;130 = 3</td>
<td></td>
<td></td>
<td>A = must have (&gt;5)</td>
</tr>
<tr>
<td>115-130 = 2</td>
<td>yes = 2</td>
<td>0 - 2 = 2</td>
<td>B = nice to have (4-5)</td>
</tr>
<tr>
<td>100-115 = 1</td>
<td>maybe = 1</td>
<td>3 - 5 = 1</td>
<td>C = indifferent (2-3)</td>
</tr>
<tr>
<td>&lt;100 = 0</td>
<td>no = 0</td>
<td>&gt; 6 = 0</td>
<td>D = outsource (0-1)</td>
</tr>
</tbody>
</table>
Development of an effective outsourcing strategy for toxicological studies in the chemical industry

A: Studies receiving more than 5 points are highly critical and are performed in-house. They represent the unique strengths of BASF SE, like screening tests, metabolomics and special repeated-dose studies.

B: Studies receiving 4 or 5 points are studies of high interest for the Group and are performed preferably in-house. This category includes studies where BASF SE is competitive in price, offers superior experience and there are few alternative suppliers available. Particular attention must be paid to confidentiality agreements.

C: Studies receiving 2 or 3 points are standard studies and have a moderate price/performance ratio and there are plenty of suppliers available. The decision of contracting to a service provider depends on internal capacity availability.

D: Studies receiving less than 2 points reflect a low interest for the BASF SE. They have a low price/performance ratio and/or are expected to be replaced by alternative methods. Here an active outsourcing strategy will be applied.

The outsourcing group’s responsibilities also include:

- Communication with internal stakeholders
- Communication with CROs
- Providing specific project information regarding, for example, deadlines

The studies were evaluated according to three criteria:

- the ratio between market prices and internal cost
- the importance for the BASF Group, i.e. the existence of intellectual property issues (IP) on substances, a critical aspect for testing new developments
- the number of suppliers (CROs) available for each expertise field.

On regular meetings between the top management and technical experts of the Toxicology Unit, each parameter receives points, according to the criteria explained above. The subjectivity of the whole evaluation is minimized by the definition of clear criteria, i.e. the number of available suppliers in the respective study type field. The sum of the given points for the different criteria leads to the classification of the studies in four categories (A, B, C and D), which corresponds to the value for the BASF SE showed in Table 1. The list of classified studies has been named Priority List of Studies.

Figure 1 Outsourcing workflow – current state

CRO = Contract Research Organization, SIEF = Substance Information Exchange Forum, REACH = Registration, Evaluation and Authorization of Chemicals

Source: Contract Management Team
The contract management strategy will be critical in maintaining the BASF SE’s competitive advantage by outsourcing services that do not add technological or economic value to the Group. By making use of the core competences of external service providers, it allows a more flexible and efficient approach towards internal capacity management.

Additionally, decision-making based on the Priority List safeguards the BASF SE’s interests in intellectual property issues on substances, regarding the study method and test substance information. Different suppliers’ selection and contracting approaches are taken depending on the study classification. In the case of categories C and D, the focus is set on quality and costs while for A and B the major concern lies in maintaining quality and confidentiality in the external environment.

The previous strategy was adequate however it could not be sustainable or efficient in a future scenario of increasing demand for studies. According to the Outsourcing Management Maturity Model (Power, et al., 2008), organizations go through different development stages during an outsourcing program. The authors’ experience has proved that the faster an organization learns from its mistakes and changes the intrinsic behaviours that cause the mistakes, the better it is positioned to be successful in the future.

In the first stage of its outsourcing development, the BASF SE’s Experimental Toxicology and Ecology Unit has put in place many processes to facilitate outsourcing. The contract team has been formed, strategic objectives have been set and some processes such as a selection procedure, contract facilitation through framework agreements, invoice management and controlling and the administration of test substances have been established.

However, to deal successfully with the scenario of increasing demand, the strategy should be enhanced based on the lessons learned so far and by applying industry best practices.

While the strategic assessment has been conducted and some parts of the process defined, the whole lifecycle lacks a complete integration. Some issues have become critical to a faster reaction time, such as the previous workflow, supplier selection and evaluation processes.
3 Enhancing the outsourcing activity

3.1 Establishing the service vision

A new organizational structure for contract management was established in the middle of 2010. The establishment of the group’s service vision helps elucidate its role within the Toxicology Unit regarding outsourcing activities, as well as to provide orientation to the development of an outsourcing strategy and to facilitate communication of its objectives. The service concept design has also the potential of reducing double work, aligning objectives and stimulating cooperation between stakeholders. The starting point is the BASF SE’s expectation of the Toxicology Unit. This issue has been addressed by the Toxicology Unit’s management by involving also other main stakeholders like business units and corporate management. This research shows that the Unit is expected to:

1. Provide results in time to meet REACH deadlines;
2. Take responsibility for guaranteeing compliance of outsourced studies, e.g. regarding Animal Welfare and GLP;
3. Take responsibility for guaranteeing compatibility of study and report quality with established standards.

According to the author Christian Grönroos (1990), the definition of service may depend on the way the customers or clients interact with the provider when the client receives the study final reports and during the process of production itself – the client is an integral part of the outcome production; he participates actively in how, what and when the study is to be conducted.

BASF SE’s Toxicology Unit’s mission concept will be used to determine in which markets it should operate and which kind of services it should provide. The basic material for a service concept development is market research, conducted through a series of interviews with the product stewardship and the business units. Based on this definition, the service vision of the Service Group aims to:

- Understand the clients’ needs, how they perceive value from the BASF SE’s Experimental Toxicology and Ecology Unit and how to meet those needs
- Guarantee that studies, both in- and outsourced, are conducted in compliance with Animal Welfare, GLP and contractual obligations
- Provide infrastructure to the BASF SE’s Toxicology Unit to conduct and archive studies internally
- Manage in- and outsourcing activities, which means:
  - Providing infrastructure for conducting studies internally and externally
  - Being a central point for contracting studies for internal or external clients
  - Being a central point for selection, monitoring and evaluation of suppliers and contracts.

The following section is dedicated to the outsourcing process itself, identifying the outsourcing lifecycle and establishing the general guidelines for outsourcing to enable a smoother communication among the stakeholders and a more efficient process.

3.2 Identifying the outsourcing lifecycle for toxicological studies

Although outsourcing/off-shoring has the potential to increase the available capacity and increase flexibility at an international level, it also involves many risks, pointed out by experts in global outsourcing (Cavusgil et al., 2008 and Power et al., 2008). After studying many engagements, the authors have concluded that the main decisions to mitigate such risks involve defining the strategic outsourcing objectives, selecting the suppliers based on multiple criteria, investing in supplier development and collaboration as well as safeguarding the sponsor’s interests.

The outsourcing lifecycle framework is a tool that provides a step-by-step guide, integrating the strategic and the operational level of outsourcing objectives and results. Table 2 has been developed based on an outsourcing lifecycle model provided by the US General Accounting Office (2001). It shows the identified outsourcing phases for the toxicological studies as well as the major practices associated with each stage.

This framework allows the visualisation of all the activities included in the toxicological services outsourcing process. Besides, it can form the basis for identifying the optimization points in the strategy. The focus of this paper is to:

1. Establish the outsourcing guidelines: communicate the parameters that are important for its success
2. Improve CRO selection through clear and multiple criteria and the process itself
3. Establish supplier management: evaluate
Table 2 Outsourcing Lifecycle for pre-clinical testing; Adapted from the US General Accounting Office model (2001)

<table>
<thead>
<tr>
<th>Phase</th>
<th>Objectives</th>
<th>Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Plan</td>
<td>Investigate and elaborate the sourcing strategy</td>
<td>o Gather experts insights on a variety of sourcing arrangements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Benchmark internal services prior to the decision</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Determine goals and expectations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Collect market intelligence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Peer/risk assessment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Estimate impacts on the internal organization</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Define sourcing arrangement</td>
</tr>
<tr>
<td>II Define Operational</td>
<td>Needs' analysis</td>
<td>o Define strategic objectives</td>
</tr>
<tr>
<td>Model</td>
<td></td>
<td>o Create and define contract management structure with operational points of contract and managers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Understand the suppliers' organizational structure and authority for decisions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Establish outsourcing guidelines</td>
</tr>
<tr>
<td>III Select the suppliers</td>
<td>CROs assessment</td>
<td>o Define selection criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Gather information from suppliers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Do audit visits (due diligence process on pre-selected suppliers – Animal welfare and GLP compliance)</td>
</tr>
<tr>
<td></td>
<td>CRO selection</td>
<td>o Establish a matrix for decision with the information gained and own experience</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Establish the selection process</td>
</tr>
<tr>
<td>IV Develop the contract</td>
<td>Contract and negotiation management</td>
<td>o Define negotiation strategy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Establish negotiation team</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Conduct negotiations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Contract facilitation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Contract monitoring</td>
</tr>
<tr>
<td>V Transition to CRO</td>
<td>Transfer responsibility</td>
<td>o Establish work flows</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Setup governance (structures, roles, authorities)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Change management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Knowledge management</td>
</tr>
<tr>
<td>VI Operational phase</td>
<td>In life phase</td>
<td>o Place work – request quotes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Test substance information and pre-existing data. Availability of substance</td>
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<tr>
<td></td>
<td></td>
<td>o Test substance supply, provide Material Safety Data Sheet to suppliers</td>
</tr>
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<td></td>
<td></td>
<td>o Dose selection</td>
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<tr>
<td></td>
<td></td>
<td>o Protocol review &amp; finalise</td>
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<td>o In life monitoring</td>
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<td></td>
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<td>o Day to Day interactions</td>
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<td></td>
<td></td>
<td>o Draft report</td>
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<tr>
<td></td>
<td></td>
<td>o Return comments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Finalise report</td>
</tr>
<tr>
<td>VII Manage provider(s)</td>
<td>Relationship management</td>
<td>o Define internal capabilities needed for managing outsourcing</td>
</tr>
<tr>
<td>performance</td>
<td></td>
<td>o Establish evaluation team and KPIs</td>
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<tr>
<td></td>
<td></td>
<td>o Establish mechanisms for continuous evaluation of suppliers</td>
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<tr>
<td></td>
<td></td>
<td>o Periodic meetings</td>
</tr>
<tr>
<td>VIII Ensure Services are</td>
<td>Continue or exit?</td>
<td>o Contract outcomes</td>
</tr>
<tr>
<td>provided</td>
<td></td>
<td>o Lessons learned</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Refresh requirements</td>
</tr>
</tbody>
</table>
and monitor performance to develop relationships further
4. Establish some key performance indicators (KPI) for performance measurement.

3.3 Establishing the outsourcing model

The strategic decisions in outsourcing have been stressed in the referenced literature as the most important ones, forming the starting point to determine the outsourcing arrangement and to identify potential suppliers. Some aspects have to be considered in these decisions, like the study complexity and its operational impact as well as the strategic importance for the business. To guide this assessment, a recent report published in the Journal of Business Chemistry (Festel et al., May 2010) showed the different levels of cooperation models used in the pharmaceutical industry, which are similar to the toxicological studies in the chemical industry.

According to this report, the pharmaceutical industry invests much management time and capacity in choosing appropriate service providers to achieve goal congruence. Inspections of the suppliers’ facilities, quality, best practices, trained staff and certified processes are crucial in the selection process, as well as the assessment of their financial stability.

The principles of risks mitigation (Cavusgil et al., 2008) and the outsourcing model are the basis for establishing guidelines for an outsourcing strategy. The following aspects have been identified as critical for the success of the strategy and therefore should be followed by the whole company:
- Animal Welfare compliance by suppliers is a long-term critical aspect
- Adherence to all agreed and established outsourcing processes by stakeholders
- Observance of stakeholders’ accountabilities
- Compliance with a clear accreditation process
- Use of preferred and approved CROs only, at a global level considering regional needs
- Regional placement of work is allowed only with accredited CROs and through a process established by the global contract management team
- Establishment of internal contact points to each project
- Definition of governance structures in the process

3.4 Establishing a new management approach

Within large organizations, an unstructured and inefficient workflow may cause problems for the outsourcing management. For example:

1. Poor Animal Welfare compliance
2. Loss of control over the number and type of tested substances, the suppliers used and the observance of compliance and legal requirements
3. Difficult assessment of quality differences and performance
4. Different approaches regarding purchasing and legal aspects
5. Difficulty in reporting to central controlling

There is therefore a high probability that the overall relationship cost, in terms of time, money and resources, will outweigh the potential benefits of working with the CROs. For this reason, the relationship should evolve to a more structured one, as shown in Figure 2. A more centralized outsourcing workflow will help minimize the risks identified above and will enable the organisation to achieve its strategic objectives. The contract management team will act as a central contact point for outsourcing activities of toxicological studies at a global level within the company.

The previous relationship with suppliers, where many different members of internal staff talk to other members of external staff without prior coordination can be seen in Figure 1. There is a requirement to move to a structured relationship, as illustrated in Figure 2 (Winter and Baguley, 2006). The contract management team will coordinate the interactions between technical experts, purchasing, legal, etc. to optimize the information flow, allowing the experimental unit to concentrate on performing studies and to focus on the assessment of complicated cases that might arise on the suppliers’ side. The key goal is to gain efficiency through the structure alignment with suppliers and internal stakeholders.

An outsourcing management group must take responsibility for reporting every animal study to the relevant authorities according to the BASF SE Animal Welfare policy and rules for reporting procedures for animal studies (see Appendix I). A mechanism to guarantee this compliance is essential. Through this newly structured workflow the contract management team coordinates and manages the information about testing and ensures all company compliances, bringing some additional benefits:
Clear standards
Selection, evaluation and control of suppliers according to these standards and expectations
Appropriate and clear penalty
Global coverage

3.5 Improving the CROs selection process

Similar to a marriage, the supplier selection strategy should be designed to lead to a long-term, mutually beneficial relationship. Selecting the right supplier for each study type or technical discipline is essential to maximize the benefits and minimize the risks and costs associated with contracting out.

After having chosen a multisourcing model, i.e. the use of more than one CRO (Oshri et al., 2009), the next step will be to choose the criteria to select suppliers, considering the critical criteria to ensure the desired service level for the sponsor. It also represents a potential opportunity for the development of a sustainable supply chain management, as there is growing concern from the public about how companies are dealing with social standards and obligations such as animal testing, as reported in an article in the Journal of Business Chemistry (Peukert and Sahr, May 2010). In this sense, a sustainable procurement has to include, among other factors:

- Compliance assurance with legal and procurement guidelines
- More transparency of the outsourcing process
- Contract facilitation
- Increase in supplier management effectiveness
- Facilitation of the establishment of a global outsourcing team
- Selection criteria have be set to evaluate the suppliers’ competencies in delivering the services, transforming (supplier’s ability to deliver improved service both in terms of quality and cost) and building a relationship (also called “easy-to-work” competency, it includes the supplier’s willingness and ability to design its business model to the values, goals and needs of the customer) (Oshri et al., 2009).
- Based on the risk mitigation principle, these criteria, determined by the technical experts and the business specialists from the Toxicology Unit, form the technical and non-technical reference for the evaluation of the suppliers’ competitiveness, technical capabilities and capacities, investment plans and robustness from a long-term perspective.

A questionnaire, based on the criteria shown in Table 3, was developed to deliver information in four areas (Appendix II gives the main topics). CROs completed it with their data regarding scientific expertise and experience, financial development and projections, human resources management approach, and company market focus. The data will flow to a supplier matrix and will generate a supplier ranking that will

Figure 2 Outsourcing flow diagram – desired state

![Outsourcing flow diagram – desired state](image-url)
Development of an effective outsourcing strategy for toxicological studies in the chemical industry

Table 3 Criteria for CRO selection

<table>
<thead>
<tr>
<th>Selection criteria</th>
<th>Evaluation object</th>
<th>(First) information source</th>
<th>Weighting</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal welfare</td>
<td>Animal Welfare compliance “level”</td>
<td>Animal Welfare questionnaire + audits</td>
<td>5</td>
<td>After audit visit and monitoring visits</td>
</tr>
<tr>
<td>GLP</td>
<td>Existence of GLP-OECD or national certificates</td>
<td>GLP Certificate + audits</td>
<td>4</td>
<td>After audit visit and monitoring visits</td>
</tr>
<tr>
<td>Scientific expertise</td>
<td>Technical expertise areas</td>
<td>Questionnaire</td>
<td>3</td>
<td>Annually</td>
</tr>
<tr>
<td>Terms &amp; conditions</td>
<td>Degree of difficulty in reaching a Master Agreement</td>
<td>Experience</td>
<td>4</td>
<td>Annually</td>
</tr>
<tr>
<td>Regulatory acceptance</td>
<td>Compliance to guidelines (OECD)</td>
<td>Certificate</td>
<td>3</td>
<td>Annually</td>
</tr>
<tr>
<td># of studies performed</td>
<td>Experience level</td>
<td>Questionnaire</td>
<td>3</td>
<td>Annually</td>
</tr>
<tr>
<td># of experts on site</td>
<td>Scientific capacity on site</td>
<td>Questionnaire</td>
<td>3</td>
<td>After audit visit</td>
</tr>
<tr>
<td>Price ratio</td>
<td>Price level compared to BASF Experimental Toxicology and Ecology</td>
<td>Quotation</td>
<td>2</td>
<td>Annually</td>
</tr>
<tr>
<td>Liquidity/financials</td>
<td>Financial sustainability</td>
<td>Questionnaire, internet, reports</td>
<td>2</td>
<td>Annually</td>
</tr>
<tr>
<td>Broadness of technical capability</td>
<td>Investment to develop special features</td>
<td>Questionnaire</td>
<td>1</td>
<td>Annually</td>
</tr>
<tr>
<td>Human resources (training)</td>
<td>Importance of personnel training</td>
<td>Questionnaire</td>
<td>1</td>
<td>After audit visit</td>
</tr>
<tr>
<td>Capacity/year 5 (employees; fast accessibility)</td>
<td>Capacity utilization level</td>
<td>Questionnaire</td>
<td>1</td>
<td>Annually</td>
</tr>
</tbody>
</table>

Table 4 Criteria importance level and its implication for suppliers’ accreditation

<table>
<thead>
<tr>
<th>Weighting</th>
<th>Importance level</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>essential</td>
<td>PREFERRED (only for scores 4 and 5)</td>
</tr>
<tr>
<td>4</td>
<td>critical</td>
<td>NOT ACCEPTABLE (for scores 1 and 2)</td>
</tr>
<tr>
<td>3</td>
<td>very important</td>
<td>NOT ACCEPTABLE (for scores 1 and 2)</td>
</tr>
<tr>
<td>2</td>
<td>important</td>
<td>evaluation from 1-5</td>
</tr>
<tr>
<td>1</td>
<td>not critical</td>
<td>evaluation from 1-5</td>
</tr>
</tbody>
</table>
form the basis for selecting companies that will be audited for Animal Welfare and GLP compliance, along with technical competence evaluation, a procedure that assures a transparent and sustainable outsourcing process, saving valuable time and money.

The questionnaire and Animal Welfare checklist improve the quality of the collected information and acts as a preparation for an audit visit. The audit of selected CROs (considering, for example, expertise, location and recommendations) is to be conducted by a team, normally comprising an internal technical expert or experts, the Animal Welfare specialist or officer and a member of the contract management team (responsible for business criteria).

After the audit visit, scores for Animal Welfare and GLP compliance will be assigned to the supplier and determine if it can be accredited. The scoring system works according to a punctuation principle: the contract management team establishes to each criterion receives a weight between one and five. The weighting value of each criterion represents an objective form of quantification of its importance level in achieving the desired effectiveness of the outsourcing activity. As shown in Table 4 below, essential aspects for the outsourcing success receive the higher weight value 5. A regular revision of this weighting system ensures that the contracting of suppliers is being conducted according to the risk mitigation principle mentioned above.

The evaluation team gives to each criterion a score from one (very bad) to five (very good), and the product of the two dimensions (weight x score) results in a total score for the CRO. The score ranking indicates which CRO is closer to the “ideal” supplier, the one that would receive the greatest possible total score.

The suppliers are classified into four categories in the Supplier Matrix: preferred, approved, marginal and not acceptable suppliers, as summarized in Table 5. Depending on the attributed importance level, the supplier must receive a score of at least 4 to be accredited as a preferred supplier (see Table 4). An example is the Animal Welfare evaluation. This evaluation system also delivers study specific information, considering differences in compliance levels and quality of one supplier.

Before the placement of any studies with a CRO, a Terms and Conditions (T&C) Agreement should be in place with the preferred and approved CROs, to avoid any potential future legal or relationship issues. It is recommendable to select at least one preferred supplier for each technical area or discipline.

3.6 Continuous evaluation of suppliers

A further important step in outsourcing risk mitigation is the continuous evaluation of suppliers’ performance. Feedback should be collected after each study/project conclusion based on evaluation according to a defined set of criteria. The evaluation criteria comprises technical and non-technical aspects, focusing on study parameters like quality, delivery on time, project management and cost deviation.

The evaluation criteria and respective importance level are shown in Table 6. The study monitor provides feedback on the supplier
performance by attributing a score between one and five to each criterion. The product between score and weight will generate the total score that the CRO reached for the specific study type (the same as for the selection process).

This second stage provides information for the annual Supplier Matrix update, together with other factors such as staff movements, new competitors or price changes. Another key advantage is that it generates a performance data bank, enabling comparisons between different suppliers and different study types.

Regular meetings involving both the sponsor and CRO representatives should take place, depending on the volume and frequency of work placed with the supplier. This should be a forum for discussions about the issues highlighted in the evaluation and is designed to contribute to the on-going relationship development with the supplier. For major suppliers it is recommended that reviews take place more often. Supplier meetings should:

- Provide an arena for dialogue between suppliers and clients at both team and senior level
- Encourage mutual understanding of roles and responsibilities, goals and objectives
- Promote knowledge sharing based on objective metrics, surveys and lessons learned.

The benefits of such forums can be experienced by both partners. Good performance can be transferred to other study types and/or CROs. Conversely, bad performance, unrealistic requirements, outdated performance indicators, portfolio changes, current and potential pricing changes, etc., should be discussed in these meetings as the basis of corrective and preventive actions. The lifecycle can be improved through activating the controlling mechanisms, and the stage where the lifecycle re-starts depends on the action required.

### 3.7 Defining metrics for the outsourcing performance measurement

It is not sufficient to understand how efficient and well a supplier performs studies but also how effective the relationship is or to what extent the relationship brings added value to the sponsor.

Performance measurement is a critical element to any strategy; it acts as a “reality check” between the planned strategic objectives and the results. The principle of “what is measured is managed” highlights that KPIs provide a realistic picture of what is in place and allow strategic and tactical corrections. The author Sara Cullen (2009) proposes performance evaluation through a contract scorecard – a balanced scorecard in the context of the contract management. It is composed of four quadrants: quality, finance, relationship and strategy, as illustrated in Figure 3.

Some KPIs have been defined to monitor the supplier selection and evaluation processes, e.g. study quality, study and report deadlines as well as project management evaluation. They are the essential measurement points of both output quality and the efficiency of the relationship. The study monitoring effort represents another critical factor for success of outsourcing. The scores attributed by the study monitors are the
basis for a qualitative measurement. A ratio between the cost of personal dedicated to study monitoring and the number of studies outsourced is included in the finance quadrant of the scorecard because it quantifies the demanded effort level to monitor studies.

Still with regard to financial performance, the transaction cost is included in the quadrant as a metric of outsourcing efficiency. The CRO cost and the additional internal costs incurred to manage the outsourced studies should not be higher than the internal cost of performing the study in-house. If the internal and external costs are equal, it is not worthwhile outsourcing from an economic perspective.

A further financial measure that is included in the scorecard is the project cost deviation, indicating the planned and the actual amount spent. Additional KPIs to measure the outsourcing efficiency are required to monitor the cost evolution of the contract management: the increase in the contract management team costs in comparison to the increase in the total contract budget as well as a ratio between the contract-out team cost and the outsourcing volume.

With the gathered information about internal costs and the suppliers’ quotation the margin generated in each outsourcing transaction can be calculated. This reveals a potential cost reduction in some outsourced study types. However, other studies have to be outsourced due to a lack of internal capacity. In these cases, cost reduction is not the major driver and the outsourcing may even have an acceptable negative cost impact. The internal additional management and monitoring effort are not compensated by the small margin. In some cases, it is necessary to absorb extra costs to gain extra capacity and ensure the required study delivery for the internal clients.

4 Evaluating trade-offs

The additional monitoring costs are one of the trade-offs to be balanced when outsourcing toxicological studies. The costs estimated for studies required by REACH do not take into consideration the additional internal resources required for work placement and monitoring, which involves additional personal in the contract management team and the capacity increase through external consultants. How will the current monitoring costs develop with the new structure?

Increasing internal personal levels at a higher
rate than the increased volume demand for work may demonstrate that contract management costs can be higher than predicted. However, the workflow centralization could decrease costs in other areas, e.g. product stewardship and business units, or could free up capacity in these areas for other tasks: a sort of cost transfer. An alternative strategy could be the increase of internal study capacity. However, physical space for laboratory expansion would involve significant financial investment and the pay-off in the long run may not be high enough. The buildings cannot accommodate more equipment or personal, which means that an expansion would be much more costly than only hiring new technicians. It would require significant investment in infrastructure, involving not only the construction of a new building, but also additional infrastructure for animal feed storage, pathology, etc. Besides, another factor is the time required.

5 Conclusion

State-of-the-art literature and industry best practices have helped to develop further the strategy and some factors can be identified as critical for its success. The entire outsourcing lifecycle has experienced a much higher level of activity, which demands closer monitoring and coordination in order to keep it aligned with the strategic objectives. The changes also rely on a more centralized workflow that requires extra resources to be put into place, for example additional capacity to monitor studies.

The establishment of outsourcing guidelines in the field of toxicology impacts not only local teams but also regional businesses. As the local processes have already been defined and implemented, they have to be adapted to the regional conditions and structures, so that, in addition to the existing guidelines on compliance (e.g. Animal Welfare), the organizational standards can be globally followed. Strategy coordination and study placement monitoring worldwide generates an additional workload.

An important information source was the questionnaire, developed during this work to obtain information about the CROs regarding the most important aspects for selection and evaluation. Combined with the Animal Welfare questionnaire, it acts as a basis for decision-making when selecting new suppliers, delivering information to the organization about the supplier’s capabilities and strengths.

The supplier matrix represents a further potentially sensitive point for internal staff, because it depends on the understanding and adoption by the contract management team and study monitors. To ensure the system’s effectiveness, the people that interact with CROs must feed it with accurate information and update it regularly. The evaluation system is essential for supplier management, because it provides information about their performance and enables corrective actions.

The supplier matrix and performance evaluation concepts are dynamic systems. As the process evolves, KPIs can become irrelevant while others can be augmented to help the organization improve its efficiency and therefore should not represent an extra workload but have a direct benefit. A next step would be to define the desired standards for each metric and follow them periodically.

Appendix I - BASF SE animal welfare policy (extract thereof)

- BASF’s animal testing is conducted according to legal requirements and [in Germany] in compliance with the German Animal Welfare Act, and the relevant EU directives. Furthermore, BASF is committed to high ethical and scientific animal welfare standards. Its experimental toxicology and ecology unit is accredited by AAALAC (Association for the Assessment and Accreditation of Laboratory Animal Care). Most of the practical work with animals is carried out by BASF’s Experimental Toxicology and Ecology.

- In those cases where BASF needs to commission animal studies to external contract research organisations, scientific and animal welfare monitoring is performed by experts of BASF’s Product Safety to ensure that our internal ethical and animal welfare standards are maintained on a global level.

Appendix II - Suppliers’ questionnaire

Supplier’s Name: __________________________
Contact Person: ___________________________
Function: _______________________________

1. Human Resources

We would like to gain an overview of the human resources in your company, i.e. number of employees dedicated to the different fields. Please specify number of scientists and technical staff.
a) What educational background do the Study Directors have?
b) How are the technical experts trained?

2. Expertise and experience

We would like to gain further information about the technical expertise and experience of your company.

a) How long have you been performing studies?
   Toxicological __________ years
   Ecotoxicological __________ years
b) How many studies (per type) are performed a year?
c) Please indicate the 3 main areas in which your company specializes.
d) In which areas do you consider your company to be most competitive?

3. Economics

We would like to gain an insight into the size and financial performance of your company.

a) Please indicate in percent the revenue distribution of your company for the industries and regions quoted.
b) How has your company developed financially over the last 5 years?

4. Technology development

We would like to gain an overview of investment plans on pre-clinical testing for the next years.

5. Market information

a) Please estimate your percentage of market share in the regions.
b) Please indicate in percent your expectation for development over the next five years.
c) Is REACH impacting your business? How?

6. Additional comments

This section may be utilized for any additional comments and/or site-specific information regarding your company.

References