Critical Success Factors in Medium-sized Pharmaceutical Enterprises

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Abstract: The definition of innovation strategies has been widely discussed in literature. Several authors refer to the systematic exploration of critical success factors (e.g. quality, innovation ability and scale effects) as being a useful instrument for strategy development. Previous research has focused predominantly on qualitative descriptions and on setting up a general framework for critical success factors, but not on the correlations between critical success factors and a company’s success. Based upon a study in the pharmaceutical branch, our paper confirms that there are quantitative correlations between corporate-type-specific success factors and the success of a company. Our paper supports the theory that companies that focus on less critical success factors are more successful. Furthermore, the concept of critical success factors has so far been a theoretical approach, but has lacked a practical implementation. By using the methodology used in this study the concept of critical success factors can be adopted by all types of companies.

Keywords: strategic management; critical success factors; strategic orientation; innovation management; innovation productivity.
1 Introduction

Today the pharmaceutical industry in Germany faces major challenges. This is due to the ever-changing framework-conditions which manifest themselves in political and legal terms as well as in transition of the generics market. Furthermore, there is a great importance of research and development, since the pharmaceutical industry is typically known for very long innovation processes. These projects with long durations go along with very high development costs and risks. The innovation process in the pharmaceutical industry is also characterized by high complexity. This is compounded by partly low success rates in R&D projects.

For these reasons, especially medium-sized pharmaceutical companies are facing the challenge, to develop innovative products despite these difficult conditions. These companies often lack of a strategic approach in their innovation projects and conflicts in innovation projects are not solved effectively. To ensure the long-term success, it is necessary to be aware of the relevant core competencies within the own industrial environment and to focus on innovation activities specifically. This strategic positioning results in an increased innovation productivity and a significant improvement of the company’s competitive position.

In this context the Research Association of Pharmaceutical Companies (FAH), a consortium of medium-sized pharmaceutical companies and the Department of Innovation Management of the Laboratory for Machine Tools and Production Engineering (WZL) at RWTH Aachen University collaborate in the project “Increasing the innovation productivity of medium-sized pharmaceutical companies by strategically oriented target formation - in short InnoZiel”. The aim of this research project is to empower medium sized pharmaceutical companies to define individual innovation strategies systematically and convert them into practically effective target systems for their innovation projects. This is accomplished by an application-oriented and industry-specific methodology to enable the medium drug manufacturers to define their innovation strategy and target systems for their innovation projects transparently and to facilitate the internal communication. Thus, this project makes a significant contribution to improve the productivity of medium-sized pharmaceutical companies, since R&D resources can be focused in a better way. A core work package of the whole project deals with the definition and analysis of individual innovation strategies. The results of a study that has been conducted in this work package are presented in this paper.

The paper proceeds as follows. In the second section related work concerning strategic management and critical success factors is presented. In the third chapter the investigation method is described and the descriptive results of the investigation are presented. The fourth section deals with the core results of the study concerning the area of “critical success factors”. In the fifth section, these results are discussed against the background of the research project and in the last chapter the next steps in the research project are introduced shortly.

2 Related Work

Today’s markets are characterized by rapid and sudden changes in time and thus as a company it becomes necessary to position itself as a unique strategic enterprise, in order to allocate research and development resources in a focussed way. In this context, the setup and management of critical success factors are presented briefly.
During the last decades several approaches of strategic management have evolved. “The concept of integrated management” (Bleicher, 1991) is built upon the “St. Gallen management concept” by Ulrich (1984) and can be seen as an essential mindset in management studies. Bleicher creates a reference framework for the complexity controlling within the company by visualizing the central questions of corporate governance (Bleicher, 1991). Although research has taken place in the implementation of integrated management and in the field of innovation management (Gassmann, 2008), the interdependencies between R&D and strategic management remain insufficiently defined. Drucker (2006) can be seen as one of the pioneers in deriving an innovation strategy systematically from the corporate strategy. By means of several examples Drucker describes success factors and principles for the strategic positioning of companies. Christensen (2003) focuses on the conflicting priorities between innovation and improvement as the central question of R&D-strategy. Beside these theories it can be seen in practice that strategy is very often not transferred to the project level systematically which results in a weak relationship between corporate strategy and operative innovation projects (Gassmann, 2008). Only very few authors, such as Gassmann (2004), Gauzuza et al (2009), Friedli et al (2006) and Blau et al (2004) focus their research regarding innovation strategies on the pharmaceutical branch.

Pümpin (2005) called a strategy as a "goal-oriented approach to pursue a long-term plan (...) including clearly displayed ways to achieve these goals". He differentiates between a strategy and a tactic due to the time aspect, which can be separated in long-term strategy and short-term tactics. A strategy defines the basic requirements of the company. A company should clarify for themselves, which products and services are offered on the market, which are the customers or market segments that are to be addressed by the products, and how the customer needs can be satisfied.

Another contribution to the term strategy is given by Porter. His basic idea is the distinction between three basic competitive strategies that give a competitive advantage over the consolidated competitors by selecting different priorities. These three strategies are cost leadership, differentiation and focus on priorities (Porter, 1999).

Focusing on selected competencies form a common approach for the successful management of a company by means of a strategy. Therefore, the concept of critical success factors by Pümpin (1986) is presented and it is shown, how the successful implementation takes place. It is of central importance for a company, how the company can compete with other companies. It is the goal, to develop and secure a competitive advantage over other competitors. Building of a lasting competitive advantage becomes possible by increasing the focus on core competencies. A core competence is the permanent and transferable subject of competitive advantage based on resources and skills. Pümpin defined the term “Critical Success Factors”, an approach to the creation of conditions for the long term success (Pümpin, 1986). A critical success factor is created intentionally by developing important and dominant competences. The development of critical success factors enables companies to achieve a predominance position and above average profits in the long term (Pümpin, 1986). The basic idea of this concept is to focus the strengths, resources and capabilities of a company and thus to develop skills in deliberately chosen areas. Compared to the "core competencer" that creates clear and perceived benefits by the customer, an "eternal bearer of hope" remains eternal second in central competencies and the "all-rounder" gets lost in the set of possible options (see figure 1). While the “core competencer” focuses its resources on some important and deliberately chosen critical success factors, the “eternal bearer of hope” does not focus on
the important competencies. The “all-rounder” tries to improve all competencies, without being extraordinary strong in one competence and thus, remains a master of none.

![Diagram](image)

**Figure 1** Concept of critical success factors (Pümpin, 1986)

The “core competencer” focusses its activities on some critical success factors that can not be copied easily by competitors and can therefore be used in competition. Another important aspect is the focus on factors that are important in the future and that are of great importance. Characterized by a focus on critical success factors, a long-term success and a competitive advantage over competitors can be achieved. To describe the concept of a strategic competitive advantage, two dimensions are important, which are illustrated in figure 2. Firstly, the competence must be relevant for the specific industry and secondly, the company must be highly skilled in this competency. Only at the intersection of these two dimensions competitive advantage can be gained.

![Diagram](image)

**Figure 2** Dimensions to identify critical success factors for competitive advantage

Competencies are positioned in the matrix according to the relevance for the entire branch and the own strength. For the building of critical success factors a company should focus on the upper half. As described before the own strength of enterprises plays an important role for the success of strategic positioning of the company.
Overall, the topic of strategic management has been focused by a wide range of authors during the last years. Earlier attempts have set focus on qualitative descriptions and setting up a framework for general critical success factors, but not on the correlations between critical success factors and a company’s success. Therefore, by this submission the research field will be further improved by analyzing quantitative correlations between corporate-specific success factors and the success of a company. The research project “InnoZiel” addresses the strategic positioning of small and medium sized pharmaceutical enterprises in order to increase innovation productivity. Therefore, a study has been carried out, intending the identification of strategic positions in the pharmaceutical branch and drawing conclusions on the strategic positioning of the company. Furthermore, the status of Lean within R&D of the pharmaceutical industry has been analysed. In the next section the study will be presented in detail.

3 Subjects and Methods

Having described the basics of strategic positioning, this section deals with the structure of the study, the research methodology and the descriptive results of the study.

3.1 Study "Lean Innovation in the Pharmaceutical Industry"

In summer of 2012 a questionnaire study entitled "Lean Innovation - What are the success factors in order to increase the innovation productivity?" was conducted. The aim of the study was to identify patterns of success, which are reflected in the sustained increase in the innovation productivity of medium-sized pharmaceutical companies. Another objective was to investigate the status quo of the “lean concept” as in the pharmaceutical industry. The main results of the study are briefly presented in this chapter.

3.2 Structure of the Study

The study was designed in form of a questionnaire based survey and sent both by post and online to subscribers. The questionnaire booklet comprises a total of 30 questions, which can be divided into four different subject areas.

By analysing the first set of questions, “classification of companies”, companies can be classified in accordance to the definition of six pre-defined company-types. This is necessary for the analysis of the critical success factors, which are of different importance for the diverse branches or company-types. The different types of companies have been defined before the study by pharmaceutical experts.

In the second thematic area “questions about Lean in development” companies are asked about their level of Lean implementation. Lean describes a concept that keeps processes as "waste-free". In this block companies indicate, in which departments, e.g. production or administration, Lean has been implemented, or in what phase of the introduction they are.

The third area of the questionnaire “questions about core competencies” builds the core of the study. Companies can be distinguished in terms of skills and activities apart from their competitors. Enterprises are successful when they are superior over other competitors in certain areas that are relevant for the branch. By focusing on selected areas
of the company itself, (core) competencies can be created or expanded. The questionnaire is about to find out whether the surveyed companies already focus on selected key skills or rather try to position themselves in many different skills. Before the study 25 competencies that are relevant in the pharmaceutical branch have been selected in expert interviews. In the survey the participant indicates how strong it assesses itself in the different competencies. Furthermore, the company indicates the today’s and future’s relevance of these competencies for its branch.

In the fourth and final set of questions, “general questions about the company” companies are classified according to their size and success metrics. These various measures are such variables as number of employees, turnover and number of launches on the market.

3.3 Methodology of the Study

Managers of the R&D-department in mid-sized pharmaceutical companies were asked in a questionnaire-based survey in the context of a research project what are critical success factors in their branch and what is their strength in these factors. Except for the economic questions the data set consists of nominal and ordinal variables. Answers to economic questions are given as categorical variables or free answers.

Regarding the data analysis several methods have been applied. In a first step descriptive statistics were used to examine the most important critical success factors and the anticipated development of those in the future. Similarity analysis was used to group the companies into six enterprise types that were defined by workshops with experts before the study. By analysing the return on sales and the innovation rate (sales of recently launched products) “best-in-class”-enterprises were identified. Linear regression models were used to examine the correlation between critical success factors and the success of a company. These linear regression models were applied both for all participating companies and in detail for the individual enterprise types. The study was followed by in-depth interviews concerning the discussion of the results with experts from leading German mid-sized pharmaceutical enterprises.

3.4 Results of the Descriptive Analysis

A total of 32 companies participated in the survey. About 75% of the study participants hold a leading position in the company and the majority of people are working in the research and development department, which ensures the direct reference to the subject matter. The product spectrum of the participating companies comprises mainly drugs and medical devices. Asked about the research and development areas in which the company operates, only few companies can be described as companies for fundamental research. Most of the companies describe themselves as companies that improve existing products or develop new products. The various types of development projects have been previously developed in a workshop as part of the research project "InnoZiel".

Based on the performance indicators that were obtained in the "general questions about companies", it can be proven, that the intended target audience, mainly small and medium enterprises, has been achieved. More than 75% of the participating companies have less than 500 employees and the majority of the company has a turnover of less than EUR 100 million (see figure 3).
4 Results

After the previous section, where the basic descriptive results of the evaluation study were presented, the presentation of key findings will be addressed in the following chapter. At first core results on the topic "strategic success positions" are shown and afterwards evaluations based on hypotheses are presented.

4.1 Key Findings on the Topic “Critical Success Factors”

This session is divided mainly into three main issues: the hay-term significance of 25 strategic positions in the pharmaceutical industry as well as the importance of these skills in the future and the companies’ strength in these competencies. The potential skills were defined in preparation for the study in expert interviews with pharmaceutical companies, ranging from technical competencies such as manufacturing technology on skills like customer service and orientation to innovation, advertising and image.

The first analysis deals with the question, how relevant the various competencies are for the company today. Individual skills can be sorted according to their importance both for the entire pharmaceutical industry and for the different types of companies. It can be seen that the areas of "customer focus", "personal" and "social responsibility" currently have a great importance for the pharmaceutical companies surveyed (see figure 4).
Figure 4 Today’s most important core competencies in the pharmaceutical branch in descending order

In the next short section the relevance of the competencies for individual business types is addressed. In the first part of the study every company was allocated to one of the pre-defined company types, which are allopathic drug producer, alternative drug producer, contract developer, service provider, niche producer and phytopharmaceutical company. The seventh type of company "generic manufacturer" could not be assigned to participating companies, which is why this type of business is not considered in the following investigations. When considering the relevance of the skills for individual business types, it is striking that the relevance in some cases is significantly different. The importance of specific competencies for the different types of enterprise can be seen in figure 5.

Figure 5 Importance of critical success factors for different types of enterprise

In the second part of the evaluation the future relevance of the skills is analysed. It can be seen that the areas of customer focus and staff continue to have a high relevance. Particular attention is paid to the company's competence "innovation". While innovation for most companies today still has no particularly high relevance, the importance of this
area is growing strongly. While innovation today ranks rather midfield regarding the relevance, attendees see "innovation" as the fourth-most important skill for the future. In figure 8, the competencies are to be seen with the largest absolute increases in importance in the future.

![Figure 6 Most important core competencies of the future in the pharmaceutical branch in descending order](image)

In the third part of the analysis the self-assessment of the participants concerning the individual skills are investigated. It becomes clear that the participants’ overall strongest areas are "social responsibility", "staff" and "customer service" (see figure 7).

![Figure 7 Strength of the participating companies in various core competencies in descending order](image)

By combining the answers to the questions "relevance of the competencies for the particular types of companies" and "their strength across the competencies" a profile can be created for any company that shows how the company is placed in the relevant
competencies. To realize critical success factors both the relevance of a competence as well as the company’s own strong competencies are important. Core competencies are built in areas, which have a high significance for the industry. For various business types selected competencies can be sorted according to their importance for this type of company (see figure 8). In an optimal alignment of the company (the company being a “core competencer”) it is strong in the areas of great importance for the type of company and focusses on individual competencies. In decreasing order of relevance of the competencies the capabilities of the company in this field should tend to diminish. Figure 8 is a profile for a study participant who belongs to the group of Top Performers that have been selected by different criteria. This company is very strong in the areas that are also known as highly significant for its corporate type and is limited on two core competencies. The strength in the competencies (e.g. innovation, customer orientation and advertisement) tends to decrease with declining importance of competencies. Accordingly, due to their importance the mentioned competencies would be in the portfolio in the upper half (see figure 2). The company's ability in these competencies decides, whether the skills lead to competitive advantages. Therefore, the competencies "innovation" and "leadership", the absolute strengths of the company in this example, lie in the upper right quadrant of the matrix and thus form the strategic success of the company.

![Relevance-profile allopathic drug manufacturers](image1)

![Strength profile of a selected top performer](image2)

**Figure 8** Profile of a top performer in the field of allopathic drug manufacturers

Having dealt with the relevance and strength of the different competencies in the previous sections, the following chapter focusses on the number of critical success factors that individual companies try to achieve. The number of strategic positions was determined by investigating for the ten most relevant competencies within an industry, how many skills a company assesses to be very strong at. It becomes clear in figure 9, that more than a third of the companies are already very focused (between one and three core competencies). In turn 10 percent of companies have no single core competence to the above definition, and therefore, target the wrong market. The remaining 48 percent have a large number of core competencies and therefore they are in danger of getting lost in various options and not to focus on the most relevant competencies.
4.2 Analysis of Hypothesis

In this section it is evaluated, whether the theoretically backed relationship between the number of core competencies and the enterprise’s success is given in this sample.

Hypothesis: Companies that focus on up to three success factors are particularly successful.

According to the presented theory of critical success factors those companies would be more successful that focus on selected competencies and have very strong skills in these strategic positions. In this context, this hypothesis was tested by calculating the success and the number of core competencies for each company. Then, the relationship between the success and the number of core competencies was analysed. It can be seen in figure 10 that the companies having one up to three core competencies are more successful than companies with more than three core competencies. These companies in turn are more successful than companies who do not occupy any core competency. Thus, the hypothesis can be empirically confirmed.

Figure 9 Distribution of the number of core competencies of the participating companies
4.3 Conclusion

The results of the study indicate several conclusions. Firstly, the most important critical success factors in the pharmaceutical branch are customer orientation and social responsibility. The relevance of process orientation, innovation, scale effects, and the ability to adapt to changes seems to be gaining more and more importance in the future, since the participants evaluated the importance of these success factors significantly higher for the future. Secondly, a specific set of critical success factors can be identified for each enterprise segment by examining the “best-in-class”-companies. Thirdly, companies that focus on less critical success factors are more successful. Different combinations that fit best to different company segments are identified. Finally, for each company segment strategic directions of impact are derived from the study results.

5 Discussion

In the following section, the results are discussed in light of the objective of the research project and validated firstly. Then the contribution of the study to the theory of strategic management is evaluated. The third section deals with the practical application of the results.

5.1 Validation of Results

The questionnaire study as part of the research project “InnoZiel” had the target, to create an overview of the core competencies in mid-sized pharmaceutical companies. Based on the results of the descriptive analysis it can be noted first that the target group has been addressed so that the participating companies constitute a representative group that allows drawing conclusions on the pharmaceutical companies.
The assignment of the participants to the previously defined types of companies was made in the analysis by a similarity analysis. To ensure the correct mapping and to validate the performance freely accessible profiles of companies were compared with the assignment in the aftermath.

The meaning of individual skills for the various types of enterprises were also discussed and approved unanimously by the Project Support Committee. Accordingly, some significant differences between the meanings and levels of skills for different types of companies can be identified. Particularly interesting appears the fact that innovation could be determined as the competence with the strongest increasing importance in the future.

The study of critical success factors as coverage of enterprise-type-specific relevance and the company-specific strength is of particular relevance for the research project. Very interesting is the fact that the theoretically justifiable context, whereas focused companies are more successful, could also be demonstrated empirically for the sample.

5.2 Contribution to the Theory of Critical Success Factors

Previous research has focused predominantly on qualitative descriptions and on setting up a framework for general critical success factors, but not on the correlations between critical success factors and a company’s success. Our paper confirms that there are quantitative correlations between corporate-specific success factors and the success of a company. Furthermore, the concept of strategic success factors has so far been a theoretical approach, but has lacked a practical implementation. In our paper we present a practical method to apply the concept of strategic success factors, which can be adopted by all types of companies. By using this method of analysis, critical success factors for company segments can be derived and analyzed. Based on in-depth interviews we designed a method for the derivation of company specific directions of impact in accordance to the chosen critical success factors.

5.3 Practical Applicability of the Results

The results presented are aimed both at researchers and practitioners in the industry. With respect to the innovation research community this submission is an important driver for the empirical analysis of the relationship between a company’s success and its critical success factors. This enables further research action concerning the managing of different contrary critical success factors. With respect to the practitioners, the main implications can be seen within the medium-sized pharmaceutical enterprise community, since all the data is collected from this field. Especially enterprises without strategic divisions can use the outcomes of this study in order to identify their own critical success factors.

The empirical results of this study can also be used to adjust the specific innovation strategy towards upcoming niche markets such as the Life Science Market or Lifestyle Medicine. Enterprises from other business segments can use the methods presented in this submission in order to transfer the approach to another segment.
6 Future work

The study is embedded as part of the research project “InnoZiel” in the work package for the modelling of the strategic process. Findings of the study (particularly the promising critical success factor bundles) are discussed in workshops and expert meetings with company representatives of the Project Support Committee. Then, a guide and a software tool give the company a way to derive the innovation strategy based upon their own critical success factor profile. In the course of the research project a methodology for building up portfolio-sets on the project level is being developed, that allows companies to identify successful innovation projects in line with their own innovation strategy. In the final work package of the research project a methodology for strategy-driven prioritization of targets in innovation projects of medium-sized-drug manufacturers is created.

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References and Notes


