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The Fuzzy Front End of New Product Development for Brazilian Technology-Based Companies in the Medical Device Industry: a Causal Model

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Abstract

The Fuzzy Front End (FFE) is considered the first stage of New Product Development (NPD). The fuzzy front end decisions have great impact on product quality, costs, and time spent on new product projects. This paper seeks to identify which fuzzy front end activities and practices contribute the most to new product success of Brazilian Technology-Based Companies (TBCs) in the medical device industry and to provide a causal model for the fuzzy front end of new product development. The data were obtained by a survey carried out in 30 small companies including 49 new product projects. The companies were requested to choose new successful and unsuccessful product projects. The results demonstrate that successful projects are distinguished from unsuccessful projects due the follow practices: marketing orientation, the company competence to translate client needs into product characteristics, proficiency in idea generation, the interface between Marketing and R&D in the fuzzy front-end and the role performed by the leader project. Having got these findings, it was possible to propose a causal model with the critical success factor in four dimensions: strategic; process; organization; and leadership.
Keywords: *Fuzzy front end, New product development, Medical device industry.*

Introduction

New Product Development (NPD) is considered a complex business process since it includes a great number of activities and decisions. Researchers and managers involved in the NPD have Focuse on the Fuzzy Front End (FFE) of NPD due to its impact on the product quality, time spent to develop the project and development costs. Several studies (Backman *et al.*, 2007; Kahn *et al.*, 2006; Cooper *et al.*, 2004c; Ernst, 2002; Griffin, 1997; Cooper and Kleinschmidt, 1995) show the importance of this stage to the success or failure of the new products.

Reinertsen and Smith (1991) were the first authors to use the term "*fuzzy front end*". It is considered the first stage of NPD process and it covers the period and activities between the idea generation and the decision as to whether or not to invest resources in the further development of the new product. The fuzzy front end is also known as predevelopment phase of NPD.

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According to Moenaert *et al.* (1995), the FFE activities contributes for reducing the uncertainties resulting from market conditions, the technological development and the dynamics of competition. Hence, the companies should enhance communication between the functional areas, use decentralized structures to organize the project teams and to adopt formal control mechanisms during the FFE.

Although considered very important for the new product success, the FFE is not easy to manage. Khurana and Rosenthal (1998) present some problems related to this phase and argue that a holistic management approach with multiple dimensions such as strategy, process, control, personnel and culture could help to overcome those problems.

Since FFE decisions influence the NPD performance, the effective management of this phase can result in competitive advantages for companies. Therefore, it is important to identify the fuzzy front end activities and decisions that have greater impact on the NPD performance.

This paper aims to identify which fuzzy front end activities and practices really contribute to new product success of Brazilian Technology Based Companies (TBC) in the medical device industry and to provide a causal model for this NPD stage. Therefore, it addresses the critical success factors for the fuzzy front end of NPD.

The medical devices companies were selected because they are strongly associated with high technology development. According to the taxonomy adopted by the Organization for Economic Cooperation and Development (OECD), the medical device industry is a high technology based industry. Bell and Pavitt (1993) classify this sort of company as "based on science" or "specialized supplier". In addition, in Brazil, they play an important role in substituting imports.

Research on NPD critical success factors has been carried out by many authors (Kahn *et al.*, 2006; Cooper *et al.*, 2004a; Ernst, 2002; Song *et al.*, 1997; Poolton and Barclay, 1998). However, according to Song and Noh (2006), many studies about critical success factors in NPD tend to emphasize more general results applicable to different industries rather than specific results applicable to a particular industry. This paper relates an industry-specific study by examining Brazilian technology-based companies in the medical device industry.

The research was conducted in four stages. Firstly, the NPD literature was studied to define a guiding model establishing relation between the fuzzy front end practices and the new product success. Secondly, a questionnaire was developed and applied to measure retrospectively the correlations between the fuzzy front end practices of the NPD projects and new product commercial performance. Thirdly, statistical analyses were undertaken of the collected data to indicate differences and similarities between successful and unsuccessful projects. At last, a causal model was formulated considering the literature studied and the results to help NPD managers.

The paper is organized as follows. All relevant studies from the fuzzy front end literature are reviewed in the second section, after this introduction. The research method is reported in the third section, followed by data analysis and results in the fourth section. In the fifth section the results are discussed and implications are explored.

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Literature Review

The Fuzzy Front End

The FFE phase covers the generation of a new product idea to its approval for development or its termination. Cooper (1988) distinguishes four stages in the FFE: idea generation, idea screening, preliminary evaluation and new product concept evaluation. According to Khurana and Rosenthal (1998), the FFE includes: the formulation and communication of new product strategy, opportunities identification, generation and screening of ideas, product definition and planning and design activities.

The FFE activities can be separeted into two groups regardless of the product innovativeness. The early FFE activities are based on opportunity analysis, strategic alignment of the new product project, market research and preliminary evaluations. The late FFE activities are based on the new product concept definition, commercial and technical feasibility analysis and project planning. The early activities are less formal and less structured, whereas the late activities are more formal and better structured (Reid and Brentani, 2004).

Zhang and Doll (2001) argue that the uncertainties can create difficulties in establishing the goals of each project and in making decisions throughout the NPD process. Gupta and Wilemon (1990) note that the market uncertainties (client needs, for example) can contribute to problems in the product concept definition. Difficulties in selecting technology can lead to product project delay and higher costs. The dynamics of competition uncertainties make it difficult to evaluate the new product's financial return.

According to Reid and Brentani (2004), the uncertainties vary depending on the product innovativeness. The new product projects based on incremental innovations (developed using technology and processes that are already available) would be in a lower degree of uncertainty when compared to discontinuous innovation projects (projects that are considered new for the company or for the market).

Veryzer (1998) note that differences between the incremental innovation projects and discontinuous innovation projects is the FFE phase. Nevertheless, Verworn *et al.* (2008) state that there are no significant differences in the FFE of projects with different innovation levels. It would be prudent to adopt a holistic management approach capable of overcoming the problems and making it suitable for each different project.

Khurana and Rosenthal (1998) present the problems resulting from FFE phase in four areas: product strategy, product definition, project definition, and organizational roles. Chart 1 presents the summary of the problems identified by the authors.

The adoption of FFE models is a way to overcome these problems. Reid and Brentani (2004) proposed a model for FFE based on information flow and decision making process for discontinuous innovation products. Zhang and Doll (2001) introduced a causal model that shows the relationships among uncertainty sources, new product management practices, development team planning and the new product success. Langerak *et al.* (2004) present a model that investigates the relationship among market orientation, fuzzy front end proficiency, new product performance and organizational performance.

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Khurana and Rosenthal (1998) introduced FFE model that includes process view, strategic orientation, project review and support of the top administration (Figure 1).

The new product project starts in the pre-phase zero. For innovative new product, the first assessment is often qualitative, although information gets more reliable and uncertainty reduces along the process. The result of a first qualitative screening is an idea portfolio, which has to be aligned with the existing projects and the overall

Chart 1. Common problems related to the fuzzy front end stage.

Problem areas	Common problems
Product strategy	Too many projects under development Difficulty in establishing project priorities The projects are not aligned with the company strategy
Product definition	Inadequate product definition Clients' needs are not satisfied Product requirements frequent changes Technical problems are not solved
Project definition	Product objectives are not well defined Trade-off difficulties during the process development Project resources are not allocated properly Lack of contingency plans for the product inherent technological risks
Organizational roles	Responsibilities are not equally shared among the departments Lack of top administration leadership Members of the development team do not understand the objectives of the product clearly resulting in frequent product changes

Source: Khurana and Rosenthal (1998).

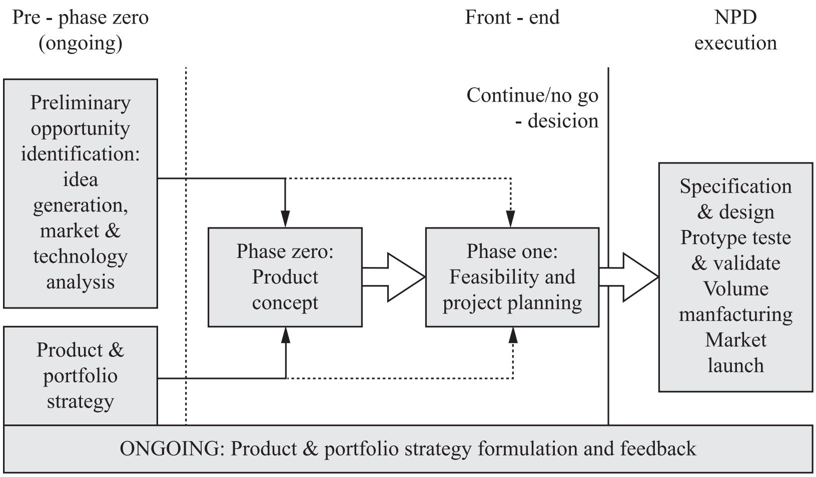

Figure 1. Fuzzy front end model (Khurana and Rosenthal, 1998).

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project portfolio. Phase zero defines the product concept that includes a preliminary identification of the client needs, market segments, competitive situations, business prospects, and alignment with the existing plans. In the phase one, business and technical feasibility are assessed, so the product is defined and the NPD project is planned. Therefore the FFE deliverables are a clear product concept, the product definition and the project plan. If a product concept is approved, the NPD execution starts.

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NPD Critical Success Factors

Despite the advances of both research and practice, the success rate for new products still remains relatively low. Approximately one in ten products concept succeeds commercially (Cooper *et al.*, 2004a). Hence, managers and researchers are interested in increasing the success rate of new products and they are concerned with avoiding failures. In this article, the attention has been given for discovering critical success factors (best practices) related to FFE that could increase the success rate of new products.

Critical success factors associated to NPD are practices that can contribute to increase the likelihood of a new product success if they are well employed. The use of Critical Success Factors (CSFs) is associated to a pragmatic and technical view that tries to reduce uncertainties and incorporate rationality in NPD. Thus, many researchers and managers have been conducting studies to understand the relationship between actions and success and the best way to adapt such practices to specific companies (Kahn *et al.*, 2006). According to Ernst (2002), this research has become more popular in the last decades due to its practical relevance and inherent appeal to researchers.

The literature (Song and Noh, 2006; Kahn *et al.*, 2006; Cooper *et al.*, 2004a, 2004b, 2004c; Ernst, 2002; Griffin, 1997; Song and Parry, 1996; Song *et al.*, 1997; Souder *et al.*, 1997; Poolton and Barclay, 1998; Cooper and Kleinschmidt, 1995; Montoya-weiss and Calantone, 1994) has introduced many factors associated to the new products success.

Cooper *et al.* (2004c) note that the difference between successful and unsuccessful companies in NPD is due the quality of execution of the FFE activities. In this case, the FFE is treated as a single factor. However, we must investigate which critical success factors related to FFE most influence the new product success.

Constructs suggested for the combination of FFE factors are shown in Chart 2. They were based on Khurana and Rosenthal's model, on the management

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Chart 2. Fuzzy front end factors.

Constructs	Critical success fators	References
Strategy	- Product uniqueness - Innovation level - Technology sources - Market orientation - Strategic project planning - Portfolio management	Montoya-Weiss and Calantone (1994); Poolton and Barclay (1998); Yap and Souder (1994); Song and Noh (2006); Scott (2000).
Organization	- Integration level among departments - Development teams' organization - Pre-development abilities - Pre-development performance evaluation	Sherman *et al.* (2005); Lee *et al.* (2000); Larson and Gobeli (1988); Song and Parry (1996); Souder *et al.* (1997).
Process	- Predevelopment activities engagement quality - Technical activities performance - Marketing activities performance - Predevelopment performance measurement	Atuahene-Gima (1996); Cooper and Kleinschmidt (1995); Kahn *et al.* (2006)
Leadership	- Engagement and support of top administration - Role of project leaders - Development team motivation	Brown and Eisenhardt (1995); Ernst (2002); Thieme *et al.* (2003); Cooper *et al.* (2004a,b,c);
Market	- Size and potential of the target market - Level of competition	Yap and Souder (1994); Song and Noh (2006);

processes of planning, organization, direction and control and exploratory interviews conducted by the authors in the medical device TBCs.

The critical success factors considered in this study were separate into five constructs: strategy, organization, process, leadership and market factors. There is no pretension to consider all the NPD factors mentioned in the literature, but the list presented in Chart 2 is comprehensive to cover the main FFE factors.

The strategy construct refers to the strategic decisions aimed at developing and improving new products, including its characteristics, innovation level, new technology, market orientation, portfolio management and new products alignment with the companies' competitive strategies.

The organization construct refers to the organization factors that interfere in the new product outcome such as the level of integration of the functional areas in the FFE phase, the NPD teams' organization method and company skills (Lee *et al.*, 2000; Ernst, 2002).

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Leadership is essential for the development of new products (Brown and Eisenhardt, 1995; Kim *et al.*, 1999; Thieme *et al.*, 2003). According to Khurana and Rosenthal (1998), there are some important actors in FFE phase. The project team is a multifunctional team that works together in the FFE activities. The project leader is a facilitator, communicator and motivator. The top administration should provide strategic orientation and material support during the FFE. They are also responsible for the evaluations of the ongoing project. Therefore, the leadership deals with the project leader skills, the top administration support and the project team commitment.

The process construct refers to the quality of execution of the FFE. The FFE activities are based on the proposals of Cooper (1988), Khurana and Rosenthal (1998), Koen *et al.* (2002). Among the factors investigated are: FFE proficiency, marketing and technical activities performance and results evaluation.

The market construct includes the factors that are not controled by the company. One of the objectives of the FFE phase is to collect information in order to reduce the market uncertainties (Reid and Brentani, 2004).

Research Method

The research was organized in four stages. Firstly, a literature review identifying the critical success factors related to the FFE phase was conducted and a conceptual model was created. Next, a questionnaire about best practices in the FFE phase was developed. Thirdly, the authors collected data from the TBCs in medical device industry. Lastly, statistic analysis of the data was performed.

Conceptual Model

Figure 2 shows the research conceptual model. The CSFs were gathered in five constructs: strategy, organization, leadership, process and market. The relationship of these factors (independent variables) with the new product success perception

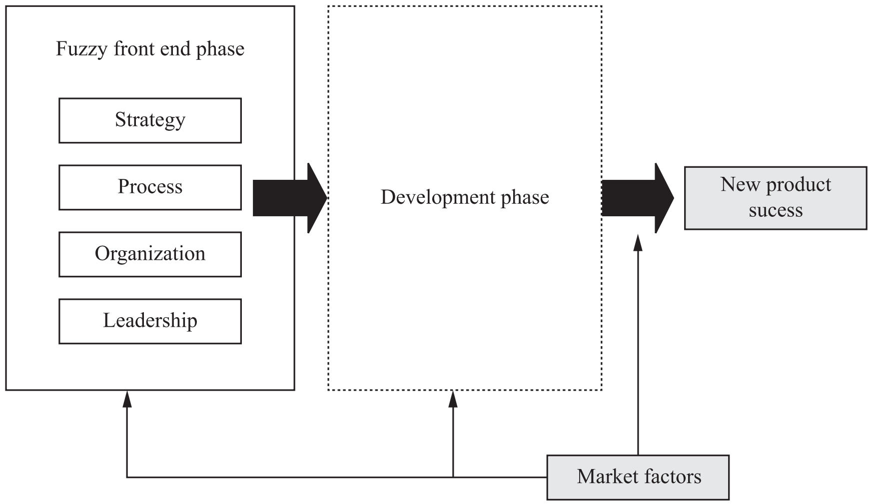

Figure 2. Research conceptual model.

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(dependent variable) is hypothetical. Since the development stage is not included in this study, it was omitted from the conceptual model.

With the results obtained and the NPD literature review, a conceptual model was proposed in order to understand better which FFE practices influence in the new product success.

Sample of Companies and Projects

According to Abimo (2008), the Brazilian medical device industry is comprised of 374 companies, including manufacturers, importers and device retailers for dental care, laboratories, radiology and medical services. Based on criteria such as size (small companies with less than 100 employees and mid-sized companies with more than 100 and less than 500 employees), industrial segment (device manufacturers) and the existence of active NPD, a total of 52 companies in the State of São Paulo fit the desired profile. From this number, 30 SMEs agreed to participate in the research.

A contact via email or phone was made to confirm that the selected companies fit the criteria adopted: small or medium companies, which had new product development activity and had finished projects and launched new products in the last five years.

The researchers interviewed face to face the person responsible for the projects under analysis, usually the project leader or manager, but sometimes the owner himself was the person interviewed. The objective was to examine two new product projects in each company, one being a success and the other a failure. The term “new product” was defined as any product developed and produced by the company in the last five years, preferably those with greater innovation content. All the answers were supposed to be grounded on the history, facts and situations experienced at the time of the project execution, so the respondents were screened for knowledge and responsibility of the project at that time.

Taking into consideration the retrospective nature of the study, the products with a development history more than five years old as well as those in which the key personnel had left the company were excluded, in order to increase the validity of the data to be collected.

The adherence to such criteria resulted in a sample of 30 companies and 49 new product projects, out of which 30 were considered as successful products and 19 failures. The classification as successful or failure was taken by comparing the performance of the product in relation to the company’s expectation previous to the launching of the product. In cases where performance equaled or surpassed expectations they were classified as successful. The failures projects corresponded to products with performance below expectations.

Research Instrument

The questionnaire used for data collection was structured to identify the FFE practices adopted during the execution of projects of new medical devices. It was tested in four companies before being employed in the survey, to ensure the clear understanding of the terms and contents of the questions and that the scales adopted were appropriate.

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Five constructs describing possible factors that affect the project success have been considered: strategy, organization, process, leadership and market. Each construct is composed of a set of factors (individual variables) identified and defined from the literature review. Construct reliabilities (Chromback's alpha) were calculated and they exceeded 0.70, which is considered acceptable.

The individual variables were presented as statements in the questionnaire and the interviewees expressed their perception about the degree in which the practice adopted in the project agreed with the statement. The classification of a new product project in either success or failure followed a 5 points Likert scale. Cases given 1 or 2 points (well below expectations or below expectations) were classified as failure, while those reaching 3 (as expected), 4 (above expectations) or 5 (well above expectations).

Statistical Analysis

Several statistical Analysis were conducted in order to test the hypothesis concerning the constructs and each individual variable. In order to measure the correlation between each individual variable and the new product outcome, the Spearman correlation coefficients were calculated. They indicate the dependency level between two ordinal variables. The coefficients greater than 0.50 were considered as strong positive correlation, while those between 0.30 and 0.49 were considered as moderate positive correlation. Bellow these values there is evidence of weak statistical correlation or no dependency between the variable and the new product outcome (success and failure).

Confidence level tests (p-value) were calculated to observe the degree of such relations. Correlations which had p-values above 95% were considered positive, while values below 95% confidence level were considered to have no correlation. The Mann-Whitney test for the comparison of averages was done to verify the existence of significant differences in the answers of successful and failed projects concerning individual variables. The levels of significance for the differences between averages were also calculated.

Analysis of Results

Table 1 shows the results of the average comparison tests (Mann-Whitney) and correlation analysis (Spearman) between the factors that were considered (individual variables) and the new product outcome. The factors with coefficient factor over 0.30, with correlation significance level below 5% (p-value ≤ 0.05) and with average comparison test that indicate differences between the successful and unsuccessful projects were considered statiscally significant. Fulfilling those requirements, there are statistical evidences that prove that the factor contributes to the new product success.

A number of strategic decisions related to the definition of the characteristics of the new product, the level of innovation product, strategic alignment of the new product with the competitive strategies and the technologies that will be used are taken during the FFE. The main objective of this phase is to guarantee that the requirements of the project are understood, in order to define the new product concept correctly.

Only three of the factors of the strategy construct present positive correlations with the the new product success. This result indicates that in medical device industry,

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Table 1. Individual variable results.

	Mann-Whitney test[a]		Spearman test[b]
	Success means	Failure means	Correlation
I - Strategy			
The new product performance level is higher than the competition's	3,93	2,71**	0,46*
The new product has cost advantages over competition	3,83	318	0,28
The new product has the same characteristics of the competition's	2,97	3,13	0,11
The new product is aligned with the company competitive strategies	4,21	3,29*	0,44*
Simultaneous cooperation between the market and the new product	3,79	3,28	0,24
Setting performance goals for the product and project	3,66	2,94*	0,24
The project resulted in a new product	3,24	2,50	0,19
The project resulted in a new product for the company	4,38	3,44	0,31
The project resulted in a platform product	4,17	2,61**	0,41**
The project resulted in a derivative product	2,30	3,17	–0,25
The new product technology was developed by outsourcing	2,18	1,67	0,19
The new product technology was developed through licensing	1,31	1,11	0,10
The new product technology was developed in partnership with clients	3,00	2,67	0,04
The new product technology was developed in partnership with suppliers	2,59	2,61	–0,13
The new product technology was developed with the cooperation of research centers and universities	2,55	2,39	0,03
The new product technology was developed in partnership with other companies	1,90	1,61	0,05
The new product technology was developed in the company	4,17	3,67	0,23
II – Organization			
The company fulfilled all the new product project technical requirements	4,31	3,83	0,20
The R&D department had technical skill for this project	4,17	3,78	0,18
The marketing department had technical skill for this project	3,72	3,18	0,06
The manufacturing had technical skill for this project	3,83	3,39	0,05
The technical assistance department had technical skill for this project	3,66	3,72	–0,11

[a]Mann-Whitney significance test: $**p < 0.01$, $*p < 0.05$; [b]Correlation with successful projects: $**p < 0.01$, $**p < 0.05$.

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Table 1. Continued...

	Mann-Whitney test[a]		Spearman test[b]
	Success means	Failure means	Correlation
There was integration between marketing and R&D for this project	3,83	3,06*	0,30*
There was integration between manufacturing and R&D for this project	4,14	3,56	0,16
The functional areas took part in the and idea generation and screening	3,48	2,06**	0,54**
The functional areas took part in the feasibility analysis activities	3,14	2,06**	0,27
The company used a functional structure to carry out the Project	2,61	3,71*	–0,15
The company used a matrix structure to carry out the project	2,11	1,53	0,10
The company used a project structure to carry out the project	2,07	1,75	0,06
III – Leadership			
There was an engagement and support of the top administration	4,45	3,67*	0,33*
The project leader had the technical abilities to carry out the project	4,41	4,06	0,29*
The project leader had the interpersonal abilities to carry out the project	4,17	3,67*	0,35*
The project leader had the managerial abilities to carry out the project	3,93	3,22*	0,29*
Capacity for motivation the development team	4,31	3,11**	0,47**
The project leader had the authority to make decisions about the project	4,14	4,11	0,10
The leadership approach (communication and conflicts management) adopted was appropriate	4,17	3,44*	0,35*
The development team members took part in the decision making about the project	4,00	3,67	0,10
The development team was motivated to carry out the project	4,34	3,50*	0,32*
IV - Process			
Quality of execution of ideas generation and screening activities	4,34	3,61**	0,51**
Quality of the evaluation of the market potential	3,82	2,65**	0,45*
Quality of feasibility analysis (technical and economical evaluations)	3,97	3,06**	0,40*

[a]Mann-Whitney significance test: $**p < 0.01$, $*p < 0.05$; [b]Correlation with successful projects: $**p < 0.01$, $**p < 0.05$.

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Table 1. Continued...

	Mann-Whitney test[a]		Spearman test[b]
	Success means	Failure means	Correlation
Quality of execution of translating the customer expectations into product specifications	4,18	2,33**	0,61**
Quality of evaluations during the development of the new product	3,79	2,94*	0,32*
V – Market Factors			
The new product was a growing market segment	4,00	3,39	0,35
Consumers wanted the new product	4,31	2,89**	0,44*

[a]Mann-Whitney significance test: **p < 0.01, *p < 0.05; [b]Correlation with successful projects: **p < 0.01, **p < 0.05.

the successful products derive from platform projects (r = 0.41). Those products also presented higher performance than the competition (r = 0.46), which depends on the correct definition of the clients' requirements and the correct marketing positioning of the new product. Finally the new product was well aligned with the company's competitive strategies (r = 0.44).

The companies develop devices, which will be mass-produced, destined to clients (hospitals and clinics) which use and demand certain features, but do not know technical aspects incorporated into the products. The successful products (platform) were those that presented significant changes concerning the technology of the product or process. Also they could originate new products with small modifications, which contribute for improving customer satisfaction.

It was expected that the technology acquisition or transfer processes were critical in the FFE of medical device companies due to their technological aspect. Nevertheless, this hypothesis was not proven by the results. The investigated companies hardly utilize outside technology acquisition mechanisms. Technology is developed internally and companies acquire components they do not produce (electronic components for example) from suppliers that provide low costs components. Basically, they use the same technology acquisition strategy for all their projects, whether successful or unsuccessful. Thus, it was not possible to gather evidences to confirm whether this is a critical success factors.

Regarding the organization construct, only two factors related to the cross-functional integration proved positively correlated to the success of the new product. The integration of the Marketing and R&D areas (r = 0.30) was critical because in those companies the marketing area is closer to the customers and to the market itself. It is in the generation and screening idea activities (r = 0.54) that this integration is more critical. It was perceived significant difference between the means of successful projects (3.48) and non-success (2.06).

There was no evidence to prove the correlation between the company skills and the new product success. Both the successful and the unsuccessful projects relied on the same skills and resources involved. The unsuccessful cannot be explained by reasons such as low technical capacity. Since the companies studied are small and

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medium, it is possible that the capabilities of the project leader can substitute for the company skills.

In addition, no significant relationship between the type of organizational structure of the project team and the new product outcome was found. The functional, matrix or project strucutures practically did not influence the success of the new product. This is due, possibly, to the fact that the satisfactory levels of communication and collaboration among the different functional areas are facilitated by the small size of the companies.

Four factors related to the project leader were positively related to the new product success. The importance of the leader interpersonal skill (r = 0.35) during the execution of the new product projects was verified, which is related to the leadership style adopted (r = 0.47) for the development project. The motivation level of the projec team is another critical success factor (r = 0.32) and the difference between the averages of the successful projects (4.34) and the unsuccessful ones (3.50) confirm its importance.

The top management support correlation index (r = 0.33) indicates a moderate positive correlation of this factor with the new product success. According to Clark and Wheelwright (1993), the top management has an important role in the FFE. The definition of the projects to be developed and resources allocation should be based on the portfolio management defined by the company.

The results in Table 1 show the importance of the quality of execution of FFE activities. The idea generation and screening (r = 0.51) and viability analysis (r = 0.40) activities should be properly managed since these results indicate they are positively related to the success of the new product.

The idea generation activities are related to the search for new ideas to satisfy needs, solve problems or generate profit to the company. Such ideas should then be selected, so that only those with higher success potential should become development projects. Due to the high uncertainty related to FFE, the ideas should be evaluated on technical, economical and market criterias. Although those activities are difficult to structure and formalize, the results indicate that they were performed completely.

The results also indicated the need to guide the FFE towards the market orientation, which demands greater partcipation of the Marketing area in this NPD stage. The successfull projects were those in which the uncertainties were reduced by a better understanding of the market potential (r = 0.45). Another critical success factor is the skill of companies to translate customer’s needs into product’s requirements (r = 061). The last critical success factor from process construct is the quality of execution of the project evaluations along the FFE phase (r = 0.32).

Involving the end user or customer in the NPD is important to ensure that the product meets the real needs and increase the likelihood of its success. In medical devices industry, the customers can be doctors, nurses, healthcare professionals and patients themselves. It is therefore crucial the engagement of the end users and the understanding of the needs of these groups. Since Marketing responsibility in the companies studied is carried by personnel from the marketing areas, who maintain a close relationship with those groups (doctors, nurses, patients etc), they have vast knowledge related to market needs. Thus, the Marketing areas should transfer information to the technical areas for the development of new products with technical superiority.

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Favorable market conditions could contribute to the new product success. Regarding the market construct, the results indicate customers' desire for the new products (r = 0.44). Nevertheless, this does not mean the market was growing since such condition was not confirmed statistically.

Conclusion

The FFE is one of the most complex phases of NPD. It is the one that creates more improvement opportunities. This phase should not be understood only as a linear process composed of activities. The FFE must be seen as a multiple-dimension system just like the constructs of this study.

This research investigates the management practices adopted during the FFE and their impact on the new product success in Brazilian TBCs in the medical device industry. It is one of the few articles that aim to identify critical success factors related to FFE in Brazilian companies and, therefore, it allows a more comprehensive understanding of the success drivers in executing new products projects.

The critical success factors that characterize the FFE management from investigated companies were obtained by a survey research. The causal model incorporates a set of factors deemed critical for the NPD success. Some of them were statistically confirmed and they deserve special attention from researches and managers. The results of this study will assist companies to adopt an evidence based approach when improving their NPD process. From this study, it is possible to highlight the theoretical and practical implications of the FFE phase.

Theoretical Implications

Although it does not provide all information needed to establish the best way to manage the FFE phase, the indentification of best practices highlights critical areas in which the management concerned with strengthening NPD. The findings from the statistic tests, allowed us to find several factors that influence positively the success of the new product.

Several critical success factors of the FFE were identified in the small and medium size medical device companies. The results prove some the factors reported in the NPD management literature by many researchers (Clark and Wheelwright, 1993; Griffin, 1997; Souder *et al.*, 1997). The model presented has enabled to improve the understanding of the dynamics of the FFE. It provides several insights that will help managers to improve the success of their NPD activities.

The model developed has a systemic approach when considering several constructs in the FFE management: strategy, organization, leadership and process. It has a cause-effect relation when indentifying the critical factors that influence the success of the new product the most. Specifically, the causal model showed in Figure 3 highlights the following practices.

The causal model is also innovative since it incorporates critical factors in the FFE identified in the TBC in the medical device industry. Therefore, the model is based on the real experimentation. These factors need to be done comprehensively, since a deficit in one factor cannot, as a rule, be remedied by another factor. In conclusion, if the fuzzy front end can be improved via the efforts noted, then one can influence the overall performance of NPD in several ways.

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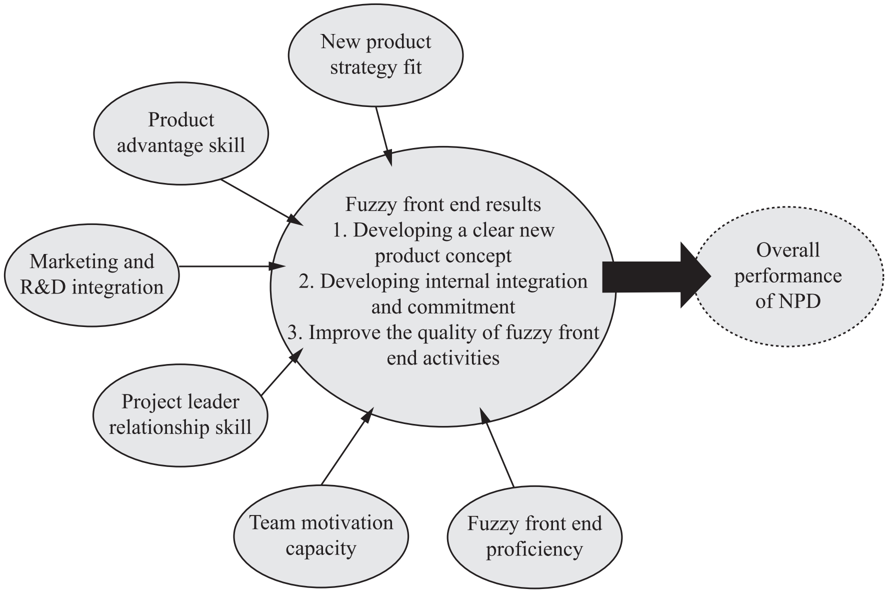

Figure 3. The causal model of the fuzzy front end.

Managerial Implications

Several managerial implications can be drawn from this study. First and foremost, the findings can serve as a guide for strengthening NPD in Brazilian TBCs in medical devices industry. In particular, the findings on strategy, organization, leadership and process highlight critical areas in the fuzzy front end.

The first managerial implication is that those companies should emphasize marketing skills. Interpreting the market is essential in the FFE phase because several success factors revealed are related to the better performance of the market evaluation, generation and screening of ideas and development of a correct new product concept.

The need for cross-functional integration is the second managerial implication of this study. The FFE is composed of activities that are executed by functional areas such as Marketing, R&D and others. The need for integration has been emphasized in the initial stages of the development cycle.

Organic characteristics were found in the NPD management due to the small size of the companies studied. This can be evidenced in those companies' behaviour such as the emphasis in oral communication, partial adoption of informal norms and procedures and a natural integration among those involved in fuzzy front end. This study found that the level of information flow and contact between the R&D and Marketing areas were strongly correlated to the new product success. Cross-functional interface plays an important role in the new product success. Thus, integration must be encouraged by top management.

The third managerial implication refers to the proficiency of FFE activities. It was observed the earlier stages of the NPD process have a greater effect on the outcome

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of a new product. We also found that the product advantage factor is crucial. Therefore, it is believed that the appropriate guidance of FFE activities is capable of facilitating the influence of some characteristics desired by the consumer and the company's strategic view during the entire development cycle.

The fourth managerial implication is the role of the project leadership. The project leader has the important job of conducting NPD since he is responsible for organizing and directing the development team members. Besides leading the team, the leader needs to negotiate with the top management to get new resources for the project. In order to do so, the leader should have managerial and relationship skills to establish an environment of trust, coordination, and control. The findings reinforce the importance of the presence of a leader who has managerial skills and strong ability to work with a team. In sum, the companies should focus on this profile when selecting leaders for the new product projects.

Limitations and Future Research

This study presents some limitations. The attempt to obtain the primary data demanded considerable effort in order to select only companies that could considered technology-based companies. The first limitation is the study of a small number of TBCs in the medical device industry. The results obtained cannot be generalized because of the methodological approach adopted; even though the results can be used to subsidize the causal model proposed. Another limitation is due to the broad topic of this research.

In the future, researchers should try to work on the interaction among constructs and the individual factors studied. In addition, studies of the fuzzy front end should be extended to different industry sectors. Furthermore, ideally, further research should endeavor to collect longitudinal data.

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