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Successful New Product Development by Optimizing Development Process Effectiveness in Highly Regulated Sectors: The Case of the Spanish Medical Devices Sector

Annemien J.J. Pullen, Carmen Cabello-Medina, Petra C. de Weerd-Nederhof, Klaasjan Visscher, and Aard J. Groen

Introduction

Innovation is a key driver of sustainable competitive advantage and one of the key challenges for small- and medium-sized companies (SMEs) (O'Regan et al., 2006). Therefore, SMEs need to remain active in new product development (NPD). It is difficult for SMEs[1] in regulated sectors to development new products, because heavy regulatory involvement imposes a number of difficulties on the NPD process. Products have to meet these strict regulations in terms of quality, safety, functionality, and manufacturability, which makes it difficult for SMEs to differentiate in terms of the effectiveness of the product concepts. However, there are big differences in the NPD performance of SMEs. Then, the questions are (1) how do SMEs in regulated sectors distinguish themselves in terms of innovation performance? And, (2) how can SMEs in regulated sectors be successful in NPD?

During this research, the Spanish medical devices sector is used as an illustration of a highly regulated sector. The medical devices development process is characterized by a heavy regulatory involvement (Shaw, 1998). Companies in the medical devices sector are experiencing a need to develop new products more rapidly to satisfy expanding and changing customer requirements in light of new technologies and intensifying global competition (Millson and Wilemon, 2000). The ability of organizations in the medical devices sector to develop and commercialize new products fast is a major competitive advantage (Atun et al., 2002), as speed is an important driver for NPD performance (Lynn et al., 1999; Calantone

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and Di Benedetto, 2002; Takayama et al., 2002; Langerak and Hultink, 2005).

It is important to realize that in highly regulated sectors, such as the medical development sector, the product concept effectiveness of all acting companies almost per definition will be high, and variance in this performance measure will be low. This is so because all (new) product (concepts) have to comply with the same strict regulations. In these types of sectors, and especially for the SMEs in it, the effectiveness of the NPD process effectiveness stands a much better chance to make a difference. The development process effectiveness represent a measurement of the current NPD performance beyond the requirements imposed by regulations of the sector. This means that it is to be expected that the SMEs we looked at in the Spanish medical devices sector would try to achieve competitive advantage in terms of speed, productivity, and flexibility of their product development process, rather than in terms of manufacturability, functionality, and cost of the product concept, which would be comparable for all players in the field.

According to DeWeerd-Nederhof et al. (2008) both the current and future NPD performance are heavily influenced by the way the NPD function is organized (that is the NPD configuration). The organization of the NPD function consists of the strategy, structure, climate, and process of the NPD function (DeWeerd-Nederhof et al., 2007, 2008). Building on this, and in light of the peculiarities faced by SMEs in highly regulated sectors, we set out to search for a shared pattern in the organization of the NPD function of Spanish SMEs in the medical devices sector, which can be related to high NPD process effectiveness, and ultimately to outperforming competitors.

Thus, our main research goals are first to explore differences in product concept effectiveness and development process effectiveness among SMEs in the Spanish medical devices sector, to see whether or not the current NPD performance would indeed be mainly influenced by the development process effectiveness; and second, to explore whether a shared pattern in the organization of the NPD function can be recognized to affect current NPD performance positively.

In the next section we first provide the theoretical framework on both the current NPD performance, and the variables that are included in the organizational configuration of the NPD function (NPD strategy, structure, climate, and process (DeWeerd-Nederhof et al., 2007). Next we provide the research design and methodology. We then present the research results based on a structured survey among 11 SMEs in the Spanish medical devices sector. The results are further illustrated by two real-life case descriptions. In the discussion and conclusion results are further elaborated and managerial implications are explicitly addressed.

Theoretical framework

NPD performance

The NPD performance consists of the product concept effectiveness on the one hand, and the development process effectiveness on the other hand. The product concept effectiveness is used to define how well a new product concept fits with internal and external characteristics of the company. Whereas the development process effectiveness concept is used to define how effective the development process is executed (Brown and Eisenhardt, 1995). Figure 6.1 shows a schematic overview of the different constructs that together build NPD performance.

The NPD performance is a dynamic concept that has both a short-term and a long-term component. The short-term component is the Operational Effectiveness and refers to the effectiveness of today's work, whereas

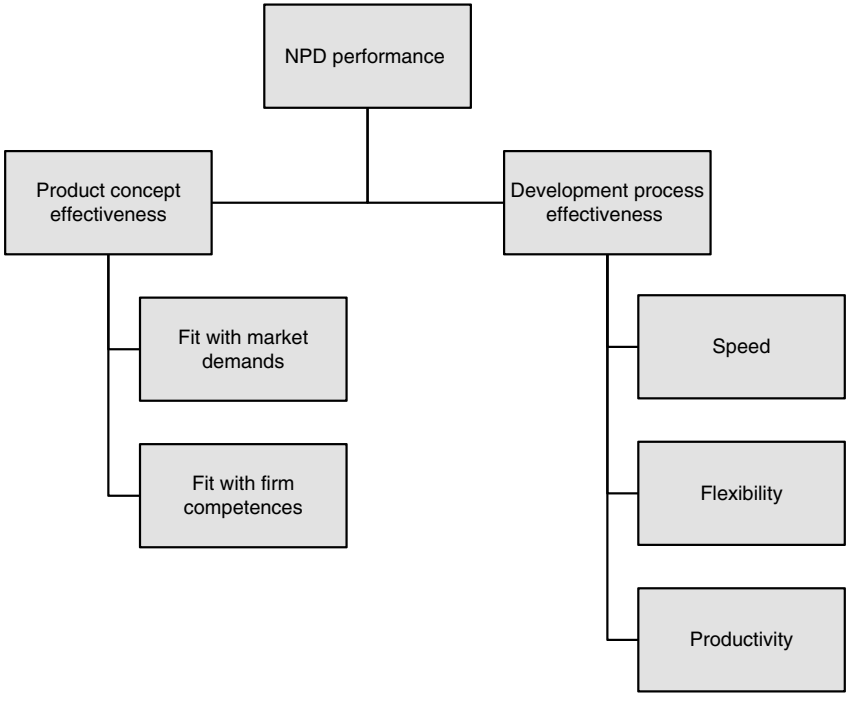

Figure 6.1 Schematic overview of the constructs that together build NPD performance

the long-term component is the Strategic Flexibility which relates to the readiness to adapt to, anticipate or even create future NPD performance requirements (DeWeerd-Nederhof et al., 2008). For this research the focus is on operational effectiveness as the aim is to measure the current NPD performance.

Pettigrew and Whipp (1991) studied organizational change and differences in NPD performance similarly using a content-context-process framework. Content represents the objectives, purpose, and goals of the organization (Pettigrew and Whipp, 1991). Context represents the environment of the company, and process represents the product development process of the organization. The content and context dimensions of Pettigrew and Whipp (1991) can be linked to the product concept effectiveness of Brown and Eisenhardt (1995), whereas the process that Pettigrew and Whipp (1991) describe is similar to the development process effectiveness that Brown and Eisenhardt (1995) describe.

Strict regulations are a unique characteristic of the medical devices sector, and this heavy regulatory involvement characterizes the medical devices development process (Shaw, 1998). The product concept effectiveness is highly tied to this regulatory process, which makes it difficult for companies to differentiate in terms of this dimension. Also, Pettigrew and Whipp (1991) suggest that companies that operate in the same sector (like in the medical devices sector) share environmental characteristics such as regulations, dynamism, and fragmentation of the sector. The medical devices sector is similar to other industries in that SMEs dominate the sector. Medical devices companies often don't compete on price but rather seek to deliver products with a good quality/price-ratio. However, the processes these companies use to achieve their goals and develop new medical devices do differ as does the organization of the NPD function of these companies.

The current NPD performance of SMEs in the medical devices sector varies greatly. Since the product concept effectiveness is heavily influenced by the set regulations, we hypothesize that SMEs in the medical devices sector emphasize on development process effectiveness rather than on product concept effectiveness to achieve high NPD performance. Takeuchi and Nonaka (1986) point this out by stating that the higher the speed with which changes occur and the more the competence in the field of NPD grows, the more firms must focus their processes on speed and flexibility (Takeuchi and Nonaka, 1986). Furthermore the framework of Pettigrew and Whipp (1991) indicates that the content and context of companies in the medical devices sector does not differ, and that they can only distinguish themselves in terms of the process. This supports our previous assumption that companies can distinguish themselves more by focusing on development process effectiveness rather than

through product concept effectiveness, and leads to the investigation of our proposition:

Proposition 1: SMEs in the medical devices sector focus on their development process effectiveness rather than on their product concept effectiveness to achieve high NPD performance.

Our study is focussing on the importance of development process effectiveness as part of the current NPD performance. The NPD performance is influenced by the way the NPD function is organized, also called the NPD configuration. Contributing to sustained competitive advantage requires a fit of the NPD configuration with the NPD system and between the NPD system and its context (DeWeerd-Nederhof et al., 2007). The way the NPD function is organized affects both the development process effectiveness, and (to a lesser extent as we proposed) the product concept effectiveness. Differences in development process effectiveness therefore might be explained by the difference in NPD configuration. This leads to the second proposition.

Proposition 2: SMEs in the medical devices sector that achieve high development process effectiveness share a pattern in the organization of their NPD function.

We utilize the concepts of NPD strategy, NPD structure, and NPD climate to further specify the organization of the NPD function (DeWeerd-Nederhof et al., 2007). These concepts are further explained in the following subsections.

NPD strategy

The NPD strategy of a firm can be defined as: "the aggregate pattern of product introductions that emerge from the firm over time" (Firth and Narayanan, 1996). The purpose of the new product strategy is to link the products to the overall objectives of the firm and to assist in the search for new products (Firth and Narayanan, 1996). SMEs with a clear strategy perform better than SMEs that lack a clear strategy (Kargar and Parnell, 1996; O'Regan et al., 2006). Clark and Wheelwright (1993) identify three orientations of the strategy; the technology strategy, the product strategy, and the market strategy. The technology strategy refers to the acquiring, developing, and applying of technology for competitive advantage. The product strategy should contain a clear plan for the development of future products. Finally the market strategy should focus on the question what the target customers will be (Clark and Wheelwright, 1993).

Gatignon and Xuereb (1997) propose a similar typology of strategic orientation (technology orientation, competitive orientation, and customer orientation), and link this to the demand uncertainty in the market. In the medical devices sector the hospital budgets heavily influence the buying behavior of the customers. This buying behavior is also strongly influenced by informal communication between buyers. This causes demand

uncertainty in the medical devices sector (Biemans, 1989). When demand uncertainty is high the strategic orientation should be a customer orientation (Gatignon and Xuereb, 1997). In the field of NPD in Spanish firms, Varela and Benito (2005) find that firms that are market oriented get better NPD results than those that do not use this strategic orientation.

Next to the strategic orientation, the project portfolio is an important part of the NPD strategy (Wheelwright and Clark, 1992). Wheelwright and Clark (1992) view NPD strategy as the project portfolio of an organization. It must be clear which type projects are present in the organization. Wheelwright and Clark (1992) distinguish between incremental projects (derivative projects), radical projects (breakthrough projects), and platform projects (between incremental and radical projects) (Wheelwright and Clark, 1992; Gatignon et al., 2002). Incremental innovation projects range from cost-reduced versions of existing products to add-ons or enhancements for and existing production process (Wheelwright and Clark, 1992). Radical innovation projects involve significant changes to existing products and processes. It involves the development or application of significant new technologies or products to markets that are either nonexistent or require dramatic behavior changes to existing markets (Wheelwright and Clark, 1992; Feller et al., 2006).

NPD climate

The second aspect of the organization of the NPD function is the NPD climate. The climate is regarded as a conglomerate of attitudes, feelings, and behaviors which characterizes life in the organization, and exists independently of the perceptions and understandings of the members of the organization (Ekvall, 1996). In order to operationalize climate we use the ten climate dimensions of Ekvall (1996) that stimulate the NPD performance. Cabra (1996) found problems with the challenge dimension by conducting factor analysis with North American samples. Later Isaksen and Lauer (2002) found that the dynamism dimension was not discriminating. In this research we use the dimensions proposed by Ekvall (1996), excluding the dynamism dimension. In this research, a climate that stimulates innovation (innovative climate) is a climate with high levels of "challenge, freedom, idea support, trust, playfulness, debates, risk taking, and idea time" and a low level of conflicts.

NPD structure

The third concept of the organization of the NPD function is the structure of the NPD function. This structure refers broadly to the structure of project teams and the way the people in the NPD function are organized. This work is based on efforts of (Clark and Wheelwright, 1992) who showed that effective product and process development requires teams that integrate people with multiple specialized capabilities. These teams

are also referred to as cross-functional product development teams. Cross-functional development teams have become increasingly important due to complexities in the pace, diffusion, and the use of multiple technologies to solve customer problems (Walsh and Linton, 2001) as well as burgeoning global competition (McDonough III, 2000). This is also in line with the research of Sosa et al. (2004) who state that complex product development requires structuring the organization into groups of cross-functional design teams to design systems and components, and with the research of Cooper et al. (2004) who have identified the presence of cross-functional teams as a common fact in organizations they rated as best performers.

Clark and Wheelwright (1992) have characterized a number of structures for project teams. It depends on the environment, organization size, and innovation type which project structure is best suitable (Clark and Wheelwright, 1992). They distinguish between the functional, lightweight, heavyweight and autonomous team structure. The team structure that is used by the company needs to fit in the context. For new product development in the medical devices sector it is very important that all functional areas are involved in the development of a new product, because of the rapid changes in technology and competition. However it should be prevented that a project team gets carried away by its own ideas and fails to meet regulations, or that senior management looses the control over the team (which is likely to occur in the autonomous team structure). Therefore we expect that the heavyweight team structure is likely to be the most successful in the context of the medical devices sector. Also the success factors for cross-functional teams (McDonough III, 2000) can be found most clearly in the characteristics of the heavyweight team structure.

Another aspect of the NPD structure is the formalization of the development process (Griffin and Page, 1993). Formalization refers to the degree in which the process is subject to rules, procedures, and structures previously specified (Johne, 1984). Walsh and Dewar (1987) link the degree of formalization with the organizational life cycle. They state that the more mature the organization, the more formalized the processes are (Walsh and Dewar, 1987). For NPD, it is stated that companies with a formal development process are more successful in the commercialization of new products (Booz and Hamilton, 1982).

We investigate both propositions based on the above literature. The next section describes the methodology we follow to: (1) investigate if SMEs in the Spanish medical devices sector should focus on development process effectiveness to achieve high innovation performance, (2) explore if there is a pattern in the organization of the NPD function that these companies share, and (3) what this organization of the NPD function looks like.

Methodology

We utilize a case based method as described by Yin (2003) and Eisenhardt (1989). We leveraged the international Patterns in NPD project. This project is aimed at developing knowledge in the NPD area, by describing, exploring, and analyzing the organization of the innovation journey. We focus on the population of Spanish SMEs in the medical devices sector.

Sampling process

Consistent with the case study method, we gathered data of a full population in one specific sector, to reduce extraneous variation (Eisenhardt, 1989). Data was gathered in the Spanish medical devices and disposables sector. The medical devices sector is the focus of this research because (1) differences in innovation performance of the companies depend (due to strict regulations) on management issues, and not on environmental or product concept issues, and (2) innovative capability is in this sector of vital importance (Atun et al. 2002). Data gathering took place in the spring of 2006.

Leveraging the Data Universal Numbering System (DUNS) database we used the Spanish SIC codes (CNAE) 33100 and 33200 to identify a number of organizations. A total of 109 companies were selected. These companies were first screened on origin and number of employees. The companies with CNAE 33200 were also screened on the fact whether they were active in the medical devices sector or not. Companies with other origins than Spanish, organizations with a total number of employees of five or less, and organizations (with CNAE 33200) not active in the medical devices sector were deleted from the list. Fifty-seven companies remained and were contacted to find out whether they had an NPD function. From this 35 companies remained, of which 31 companies were interested in participating in the study.

Data description

To the NPD managers of the 31 companies that were interested in participating, a questionnaire about the organization and performance of the NPD function was sent. This questionnaire was developed as part of the international "Patterns in NPD project." We ended up with 12 completed questionnaires from companies in the Spanish medical devices sector, which resulted in a response rate of 34,29 percent.

One of the cases was deleted from the sample, as the number of Full-time Equivalents (FTE) of the particular company was 650 FTE whereas the focus of this research is on small- and medium-sized companies (FTE ≤ 250). This resulted in a dataset of N=11 companies, with which the propositions were further explored. Table 6.1 gives general information about the companies in the dataset.

Table 6.1 General information of the companies in the dataset

Case#	FTE	Products	Profit	Sales	Profit/FTE	Sales/FTE
1	12	Interventional cardiology products	€ 113.004,31	€ 4.000.000,00	€ 9.417,03	€ 333.333,33
2	120	Products based in three main lines: Infusion, Respiratory and Bandages	€ 1.064.975,42	€ 10.000.000,00	€ 8.874,80	€ 83.333,33
3	35	Solariums, professional equipment of aesthetic and aesthetic medicine	€ 124.263,70	€ 7.000.000,00	€ 3.550,39	€ 200.000,00
4	80	Four product groups: measuring, quality and metering, industrial electric protection, and power factor protection	€ 5.334.493,30	€ 80.000.000,00	€ 66.681,17	€ 1.000.000,00
5	36	Prostheses and implants	€ 260.478,55	€ 5.000.000,00	€ 7.235,52	€ 138.888,89
6	32	Female protection slips, female hygienic bandages, and children's diapers	€ 44.271,19	€ 3.200.000,00	€ 1.383,47	€ 100.000,00
7	12	Orthopedic elastic products	€ 64.910,78	€ 4.000.000,00	€ 5.409,23	€ 333.333,33
8	167	Medical disposables for neurosurgery and endosurgery		€ 54.000.000,00	€ –	€ 323.353,29
9	80	Wide range of single use and reusable lab ware for chemical, clinical, research, and industrial testing laboratories, swabs for sample collection and transport of microbiological material, sampling containers, blood collection tubes, test tubes	€ 72.800,98	€ 18.000.000,00	€ 910,01	€ 225.000,00
10	49	Dental equipment and optical units	€ 683.275,34	€ 9.600.000,00	€ 13.944,39	€ 195.918,37
11	60	Laboratory equipment	€ 765.986,92	€ 18.000.000,00	€ 12.766,45	€ 300.000,00

Measurements

NPD performance is a dynamic concept. It is divided in the current NPD performance (operational effectiveness) which refers to the effectiveness of today's work, and the future NPD performance (strategic flexibility) which relates to the readiness to adapt to, anticipate or even create future requirements (see also Figure 6.1) (Brown and Eisenhardt, 1995; DeWeerd-Nederhof et al., 2005). This research focuses on the current NPD performance, which consists of the development process effectiveness, and the product concept effectiveness. Table 6.2 shows the constructs and items that together form the product concept effectiveness and the development process effectiveness. Table 6.2 also shows the reliability of the constructs and the literature that was used to build the constructs. All items are measurement on a 7-point Likert scale, ranging from "1 = Not at all achieved" to "7 = Very well achieved."

Current NPD performance is measured by using all the scales of the product concept effectiveness and development process effectiveness. Product concept effectiveness is measured as the average score of the constructs "fit with market demands" and "fit with firm competences." Development process effectiveness is measured as the average of the constructs "speed," "flexibility," and "productivity."

We use the development process effectiveness to determine whether a company is high or low performing. If the development process effectiveness of the company is higher or equals the average development process effectiveness of the dataset (which is 4,5), then the company is "high performing." Else the company is "low performing." Table 6.3 shows the scores on product concept effectiveness, and development process effectiveness of the companies in the dataset. Table 6.3 also shows whether the companies are high or low performing based on the above described method.

The NPD climate was measured by asking the respondents to indicate on a 7-point Likert scale to what extent employees have the freedom to define their own work and to what extent there is time for people to develop unplanned new ideas (Pullen et al., 2009). This measurement of NPD climate is based on work by Isaksen and Lauer (2002), and Ekvall (1996), who developed nine items to measure activities related to the climate of the respondents' NPD function. A climate that stimulates innovation is a climate with high levels of "challenge, freedom, idea support, trust, playfulness, debates, risk taking, and idea time" (Ekvall, 1996).

To measure the variable NPD structure, the team structure types of Clark and Wheelwright (1992) were used. In the survey, respondents were asked to indicate whether they use a functional, lightweight, heavyweight or autonomous team structure (Pullen et al., 2009).

Table 6.2 Overview and reliability statistics of the performance scale

	Current NPD performance				
	Product concept effectiveness (pce)		**Development process effectiveness (NPDpe)**		
Construct	**Fit with market demands**	**Fit with firm competences**	**Speed**	**Flexibility**	**Productivity**
N of items	6	6	6	6	6
Measurement scale	7-point Likert scale	7-point Likert scale	7-point Likert scale	7-point Likert scale	7-point Likert scale
Cronbach's alpha	$\alpha = 0{,}788$	$\alpha = 0{,}747$	$\alpha = 0{,}893$	$\alpha = 0{,}645$	$\alpha = 0{,}778$
Based on	Customer satisfaction, timeliness, product price, quality (Chiesa et al., 1996)	R&D/ Manufacturing integration (Swink, 1999; Yam et al., 2004)	Speed relative to schedule (Kessler and Bierly, 2002)	Average time and cost of redesign, enhancement (Chiesa et al., 1996; Thomke, 1997)	The possibility for lower development budget (Iansiti, 1993)
	Sales and profit impact (Bretani and Kleinschmidt, 2004)	R&D/Marketing integration (Leenders and Wierenga, 2002)	Development time (DT), concept to customer time (CTC), total time (TT) (Griffin, 1997)		Cost relative to budget, competitors (Kessler and Bierly, 2002)
			Speed and commitment of the NPD decision-making process, (Griffin and Page, 1993)	The ability to change specs late (Thomke, 1997)	Engineering hours, cost of materials, cost of tooling (Clark and Wheelwright, 1993)

Table 6.3 Performance scores of the companies in the dataset

Case #	Product concept effectiveness	Development process effectiveness	High/ Low performing
1	5,9	2,5	Low
2	4,3	4,0	Low
3	4,0	4,1	Low
4	5,3	4,7	High
5	4,3	3,3	Low
6	4,8	4,5	High
7	5,3	5,3	High
8	6,4	5,1	High
9	5,7	4,9	High
10	6,1	5,9	High
11	4,8	4,7	High
Average	5,2	4,5	

The level of formalization and presence of cross-functional teams was measured by presenting multiple descriptions of development processes of a business unit. Based on descriptions of the NPD system by Griffin and Page (1993), the respondents were asked to indicate which development process most closely describes the development process that is used in their business unit (Pullen et al., 2009).

The strategic orientation was measured with a seven-point Likert scale ranging from "1 = strongly disagree" to "7 = strongly agree." Respondents were asked to indicate the level of agreement with statements considering the technology strategy, product strategy, and market strategy (Clark and Wheelwright, 1993).

To measure a company's NPD portfolio the respondent was asked to indicate the percentage radical, incremental and next generation projects in the portfolio (Wheelwright and Clark, 1992). The percentages had to sum up to 100 percent.

Data analysis techniques

For analysis of the data we first rely on a theoretical proposition (Yin, 1994). We are interested in (1) the variance of both the product concept effectiveness and the development process effectiveness, and (2) the organization of the NPD function that the companies in our dataset possibly share. The variances are calculated in the statistics program SPSS. We conducted a structured survey in 11 SMEs in the medical devices sector. In line with the methodological suggestions of Eisenhardt (1989) we made case summaries

Table 6.4 Single respondent bias results

Test statistics casestudy 1[b]

	NPDmanager_1 Minisurvey_1
Z	–,178a
Asymp. Sig. (2-tailed)	,859

a. Based on positive ranks.
b. Wilcoxon signed ranks test

Test statistics casestudy 2[b]

	NPDmanager_2 Minisurvey_2
Z	–1,244a
Asymp. Sig. (2-tailed)	,214

a. Based on positive ranks.
b. Wilcoxon signed ranks test

and analyzed each case individually. In addition to the structured survey, we conducted 2 in-depth case studies: one in the highest performing company, and one in the one but lowest performing company of our dataset. These case studies (1) show if there is single respondent bias or not (see next paragraph), and (2) give background information and enlighten the results we found with the structured survey.

Single respondent bias

One of the problems of response in survey research is single respondent bias. We compensated this by controlling for single respondent bias. From our dataset of 11 companies we selected two companies for case studies on the climate variable. The companies were selected on their scores on development process effectiveness and current NPD performance (highest scoring company and lowest scoring company). Besides the full questionnaire that was filled in by the NPD manager, at least five employees in both companies filled in a mini survey that was solely focused on the NPD climate. In this way we could compare the filled in answers of the NPD manager to those of different employees in the company. For both cases we found no significant difference (Sign. p> 0.00 for both cases) between the answers of the NPD manager who filled in the full questionnaire and the answers that were given by the employees in the mini surveys (see Table 6.4). This excludes single respondent bias.

Results

We have presented two propositions which we tested. Our first proposition was that SMEs in the medical devices sector focus on their development process effectiveness rather than on their product concept effectiveness to achieve high NPD performance. Table 6.5 shows the results of the variance

Table 6.5 Variances in product concept effectiveness (PCE) and development process effectiveness (NPDpe)

	N	Mean	Std. deviation	Variance
PCE	11	5,1523	,78841	,622
NPDpe_real	11	4,4693	,95286	,908
Valid N (listwise)	11			

in both the product concept effectiveness and the development process effectiveness.

We calculated the variances in both concepts to see whether the scores of the product concept effectiveness indeed vary less, or are more stable, than the scores of the development process effectiveness. When the variance of the product concept effectiveness between the companies is low, the product concept effectiveness is not the construct that makes it possible for companies to distinguish themselves in terms of current NPD performance. Instead, the development process effectiveness is what distinguished companies in terms of current NPD performance. It becomes apparent from Table 6.5 that (1) the variance of the product concept effectiveness is low and (2) the variance of the development process effectiveness is high (see Table 6.5). This indicates that the development process effectiveness is indeed the variable that distinguishes between the NPD performances of SMEs.

Our second proposition was that SMEs in the medical devices sector that achieve high development process effectiveness share a pattern in the organization of their NPD function. We divided the dataset in high and low performing companies based on the standards described and shown in Table 6.3 in the measurements section. The case summaries in Table 6.6 show the organizational patterns of the NPD functions amongst the high performers and amongst the low performers.

At first glance, the case summaries in Table 6.6 show a lot of variety in the organization of the NPD function. However, when taking a closer look, a number of patterns in the organization of the NPD function become apparent.

NPD strategy

A first pattern can be found in the project portfolio of the companies. The high performing companies focus in general on incremental innovation projects, whereas the low performing companies focus more on radical innovation projects. This might be explained by the highly regulated sectors in which these companies operate. The NPDs must meet fixed standards which leaves little room for radical innovations. It is safer to focus

Table 6.6 Case summaries of the internal organization of the companies in the dataset

Development process effectiveness	Case#	Portfolio	Team_ structure	Formalization	Climate
Low	1	Main focus on radical innovation	Heavyweight team structure	No formalized process	No innovative climate
	5	Main focus on incremental innovation	Heavyweight team structure	No formalized process	No innovative climate
	2	Main focus on radical innovation	Heavyweight team structure	Formalized process	Innovative climate
	3	Main focus on radical innovation	Functional team structure	No formalized process	No innovative climate
High	6	Main focus on radical innovation	Heavyweight team structure	No formalized process	Innovative climate
	11	Main focus on incremental innovation	Functional team structure	No formalized process	Innovative climate
	4	Main focus on incremental innovation	Functional team structure	No formalized process	Innovative climate
	9	Main focus on incremental innovation	Functional team structure	No formalized process	No innovative climate
	8	Main focus on incremental innovation	Heavyweight team structure	No formalized process	Innovative climate
	7	Main focus on radical innovation	Autonomous team structure	Formalized process	No innovative climate
	10	Main focus on incremental innovation	Functional team structure	No formalized process	No innovative climate
Total N	11				

on incremental innovation projects, since these types of projects can easier meet regulations than radical innovation projects.

NPD structure

The second pattern is found in the link between team structure and portfolio. The high performing companies 4, 9, 10, and 11 combine an incremental project portfolio with a functional team structure. These findings suggest that the combination of an incremental project portfolio with a functional team structure leads to high development process effectiveness. This is also in line with the research of De Visser et al. (2009) who find that "firms that manage to apply a cross-functional integration structure for their radical NPD processes and a functional integration structure for their incremental NPD processes will be the most successful in terms of balancing derivative and breakthrough innovation performance" (De Visser et al., 2009).

Furthermore our findings suggest that the combination of a radical project portfolio with a heavyweight or autonomous team structure (as seen in case companies 6 and 7) can also lead to high development process effectiveness, when combined with an informal NPD process and innovative climate, or with a formal NPD process and climate that is not innovative.

NPD climate and NPD process

From the (low performing) case companies 1, 3, and 5 in our dataset, it seems that lacking both a formalized NPD process and an innovative NPD climate doesn't lead to high development process effectiveness, unless combined with a functional team structure like in the high performing case companies 9 and 10. In these two latter cases, the functional team structure compensates the lack of formalization to some extent. Also having both a formalized NPD process and innovative NPD climate, like in case company 2, doesn't lead to high development process effectiveness. Combining a formalized NPD process with a NPD climate that isn't innovative and vice versa, seems to lead to high development process effectiveness. This can be seen in the high performing case companies 4, 6, 7, 8, and 11 and is the third pattern we find.

The above results show that, companies in the Spanish medical devices sector indeed share a pattern in their NPD function. This supports our second proposition. To summarize, we found a number of patterns in the organization of the NPD function of high vs. low performing companies.

First of all, indeed the companies in the dataset which focused on the effectiveness of their development process, stood out in NPD performance. Further, the higher performing companies did have a number of commonalities in the organization of their NPD function:

1. The majority of the higher performing firms had an NPD strategy characterized by a predominantly incremental project portfolio.

2. a) Successful firms with an incremental project portfolio combined this with a functional team structure.
3. b) Successful firms with a radical project portfolio combined this with a heavyweight or autonomous team structure.
4. A negative reciprocal relationship exists between formalization of the NPD processes and the climate of the NPD function, in that a formalized NPD process and an innovative climate do not seem to reinforce each other. Innovative climate combined with an informal NPD process does however contribute positively to NPD performance. This effect was stronger in combination with a radical project portfolio.

What the above summarized research results mean in everyday business practice is illustrated in the following two cases. Both companies are part of our dataset of Spanish medical devices companies. Company 5 is the last but one lowest performing company, Company 10 is the highest performing company.

Case company 5: a low performer

Company 5 is a low performing company that focuses on the development, production, and commercialization of prostheses and implants. They want to offer a complete range of products to their clients (surgeons) even though a number of these products are not profitable. In addition, time is not regarded the most important. Over the years, the company has focused more and more on R&D, and they also work on their image of an innovative company. The role of senior management in this is to set an example to the employees and improve the work where possible. However, employees are not stimulated nor compensated to come up with new ideas or new developments. When employees come up with new ideas, the management listens to the ideas of the employees and approves or disapproves and gives advice about other possibilities. Most of the time these new ideas are shared only among fellow employees, as employees are not stimulated (nor compensated) to come up with innovative ideas or new developments. Conflicts between R&D and commercial functions arise when a time plan and quality are promised to customers which are not feasible in practice. Risk taking in NPD by the employees and the management is low.

The level of risk taking in company 5 is low and, as described in text box 1, the focus is on incremental new products (in line with pattern 1). The focus on incremental innovation projects is combined with a heavyweight team structure in which project teams are to a large extent autonomous and project team leaders have the authority to decide about the division of the budget and people within the project. This type of team structure is more applicable to radical innovation projects, since these projects need more freedom to think "outside-the-box," without being constrained by

everyday company boundaries. In incremental innovation projects this heavyweight team structure is often too heavy in that in incremental innovation projects the project team should remain close to everyday company business, without getting carried away. A functional team structure is in the case of incremental innovation better applicable. However company 5 combines a focus on incremental innovation with a heavyweight team structure (conflicts with pattern 2). From text box 1 it becomes clear, that the climate in company 5 is not innovative, since employees are not stimulated nor compensated to come up with new ideas or new developments. Management decides about new product development projects, which are executed in a development process that isn't formalized. This combination of a process that isn't formalized and a climate that isn't innovative conflicts with pattern 3.

Only pattern 1, a focus on incremental innovation projects, can be found in company 5. Neither pattern 2 (the presence of a functional team structure in combination with an incremental product portfolio), nor pattern 3 (the reciprocal relationship between formalization of the NPD process and the climate of the NPD function) are present in company 5. The fact that the majority of the organizational patterns that were found to positively contribute to NPD performance miss in company 5 might explain its low NPD performance.

Case company 10: a high performer

Our second case company, company 10, is a high performing company that focuses on dental equipment and optical units. They offer solutions to other companies (they work for) and increase patient comfort with their products. They want to concentrate on further exploitation of the markets they currently serve, instead of focussing on radically new products. They want to grow, but also stay a medium-sized company. It should be a controlled increase. Part of the products are developed for other companies and part of the products are developed for the market. Meeting the – tight – time schedules is of highest importance. The senior management coordinates all the work and ideas in a functional team structure. Every three months product meetings are organized which people from every department must attend. In these meetings ideas are shared with the management, and are selected. The selected ideas are tested by the technical department and if the idea fits within the current technologies and products it will be further explored. However, the final decisions are made top-down. Risk taking is only accepted if it is in line with current technologies and products.

Case company 10 clearly focuses on incremental innovation projects (in line with pattern 1). Text box 2 explains that company 10 wants to exploit their current market further and new product development projects should fit with current technologies and products. This focus on

incremental product development projects is combined with a functional team structure (in line with pattern 2) in which management coordinates all the work. The climate is more innovative than in case company 5, because employees in company 10 have room to discuss their ideas in organized informal product meetings (see text box 2). However the climate in company 10 is not that innovative since only incrementally new ideas are appreciated and final decisions are all made top-down. The go/ no go decision about the development project is formal. However, the development process itself is not formalized. The combination of a development process that is not formalized with a climate that is not innovative is compensated in company 10 through the functional team structure (in line with pattern 3).

The organizational patterns 1, 2, and 3 that were found to contribute positively to NPD performance are all present in case company 10. The fact that all three patterns are present in company 10, and the fact that the majority of these patterns is missing in company 5 might explain the difference in NPD performance between both companies.

Discussion

Our findings raise some questions about the organization of NPD in highly regulated sectors. We find that companies in the highly regulated medical devices sector should focus on incremental innovation projects for high current NPD performance. Does this mean that these companies have to neglect radical innovation projects? The fact that our research findings state that a majority of incremental projects should be present can be explained by our focus on current NPD performance, which reflects the NPD performance on the short term. To be able to also achieve high future (long-term) NPD performance a company should not only be operational effective, but also strategically flexible (DeWeerd-Nederhof et al., 2008). To achieve high future NPD performance the project portfolio should also contain projects that gain future revenues even though they aren't profitable at first glance. This is often the case with radical innovation projects. We expect that when the focus is on future NPD performance, radical innovation projects should be more dominantly present in the project portfolio. When the focus shifts from current to future NPD performance we expect that the organization of the NPD function shifts from an operational effective organization with a focus on incremental innovation projects, to a strategically flexible organization with a focus on radical innovation projects.

With regard to the formalization of the NPD process and innovativeness of the NPD climate, we found a negative reciprocal relationship, in that a formalized NPD process and an innovative climate do not seem to reinforce each other. Innovative climate combined with an informal NPD process does

however contribute positively to NPD performance. These findings conflict with theory. On the one hand, theory stated that a climate that stimulates innovation is a climate with high levels of "challenge, freedom, idea support, trust, playfulness, debates, risk taking, and idea time" (Ekvall, 1996). On the other hand, theory states that, companies with a formal development process are more successful in the commercialization of new products (Booz and Hamilton, 1982). Now, is theory wrong, or not applicable? Theory is not wrong and is also applicable, but the theoretical approach towards these variables should be more subtle. Companies do not consist of only one variable or characteristic, but of a multitude of variables and characteristics that are all interrelated.

Finally, we focused on a highly regulated sector and found that companies in this sector can only compete on development process effectiveness. This is caused by the fact that the product concept effectiveness is to a great extent predetermined by the set regulations. The product concept effectiveness of companies in sectors that are not highly regulated is not predetermined, which means that companies in nonregulated sectors have not only the possibility to compete on development process effectiveness, but also on product concept effectiveness. Then, to what extent do our research findings also apply in nonregulated sectors?

The short-term/ long-term effects of the project portfolio on the NPD performance also apply in nonregulated sectors. Incremental innovation projects lead to higher revenues on the short term, whereas radical innovation projects lead to higher revenues on the long term. The other patterns we found (pattern numbers 2 and 3) are strongly related to the achievement of high development process effectiveness. We expect that these patterns also apply in nonregulated sectors. However only increasing the development process effectiveness in companies in nonregulated sectors has probably less effect on the NPD performance as increasing the development process effectiveness in highly regulated companies. In nonregulated sectors, also the differences in product concept effectiveness are heavily influencing the NPD performance and need to be taken into account.

Conclusions

The contribution of the research outlined above is that it shows SMEs in regulated sectors how competitive advantage in terms of NPD performance could be achieved, namely by optimizing their development process effectiveness and by choosing an appropriate organization of the NPD function. The research explicitly focused on the combination of organizational variables instead of focusing only on one variable, which adds value to other scholarly work on the same topic.

In line with our theoretical proposition, we find that small- and medium-sized companies in the Spanish medical devices sector can indeed improve the performance of their NPD function by focusing on the speed, flexibility, and productivity of their NPD function. Furthermore we find that, companies with high current NPD performance in terms of development process effectiveness have a number of commonalities in the organization of their NPD function. These companies either combine an incremental project portfolio with a functional team structure, or they combine a radical project portfolio with a heavyweight or autonomous team structure. It should be noted that most of the firms with high development process effectiveness employed an NPD strategy focusing on incremental innovation. Further, a reciprocal relationship between formalization of the NPD processes and the climate of the NPD function was found, in that a formalized NPD process and an innovative climate do not seem to reinforce each other. Innovative climate combined with an informal NPD process does however contribute positively to NPD performance, especially for the minority of firms in the set with an NPD strategy focusing more on radical innovation.

It should be noted however, that as was explained in the theoretical framework section, the NPD performance is a dynamic concept that has both a short-term (Operational Effectiveness) and a long-term (Strategic Flexibility) component. For this research the focus is on operational effectiveness as the aim is to measure the current NPD performance. Although the results of our study might lead one to believe that in highly regulated sectors the only way to innovate is in incremental steps, this is somewhat misleading because of the short-term operational effectiveness view employed in the research. For radical innovation to lead to competitive advantage some organizational characteristics also have been found, but the beneficial effect on both development process and product concept effectiveness might be subject to considerable time delay, especially in the medical devices sector.

For further research we strive to conduct longitudinal research in this field. The data of this research was gathered at one point in time, but since NPD is dynamic, longitudinal research might be interesting. Furthermore, it could be worthwhile to test our research findings in other countries and other strictly regulated sectors. We specifically looked at the context of the Spanish medical devices sector, but since the strict regulations for new medical devices are comparable in most countries, our findings might be applicable in other countries. Also, there are a number of other sectors that have similar characteristics in terms of regulations. Although further research is needed, we expect to find a similar pattern in the internal organization of the NPD function of successful companies in other highly regulated sectors for a larger dataset. Suggestions for other sectors are the

biotechnology (Senker, 1991) and commercial space sector (Carayannis and Samanta Roy, 2000).

Managerial implications

So, what do the research findings mean in everyday business practice? It's not possible to give a full recipe for successful NPD, but we can demonstrate the value of certain ingredients, and, just as importantly, warn for the excessive use of some other ingredients. There are several myths about the organization of NPD that are among CTOs and managers of NPD. In this research we tackled four of these myths.

- Myth 1: First, focus on the quality, safety, and manufacturability of the product, then take a look at your NPD process.

We have shown that, in a regulated sector, the quality, safety, and manufacturability standards are predetermined through regulations. High quality, safety, and manufacturability of products are a precondition, regardless of the company, and not leading to competitive advantage. As a manager, you should focus on your NPD process. The development speed should be high (don't waste time), the development process should be flexible (be able to change fast if specifications change), and the development process should have high productivity (don't exceed costs nor budgeted hours).

- Myth 2: The more innovative, the better.

Managers are often confronted with the idea that radical innovation is just it. We have shown that taking little steps in the innovativeness of new products is – at least in regulated sectors – more successful. Managers should take a look at the portfolio of different innovation projects in their companies. How is the balance between incremental and radical innovation projects? If the portfolio mainly contains radical innovation projects and lacks incremental innovation projects, they should try to shift this balance by attracting more incremental innovation projects. However, keep in mind that the pursuit of radical innovations should not be fully abandoned, since they are needed for future profits.

- Myth 3: Project teams should be autonomous and not restricted by organizational procedures.

There is not one best way to structure your NPD teams. The best way to organize projects heavily depends on the type of development projects. As a manager you should take a look at your project portfolio and at the team structure you use. In an incremental project portfolio, the projects are

not so new and unknown that you need self-steering project teams. Rather, project teams are required that remain close to the company and do not get carried away. For incremental innovation, you should create project teams in which members remain on their current locations, in which different functions coordinate ideas through detailed specifications, in which occasional meetings are organized to discuss issues that cut across groups, and in which the responsibility passes sequentially from one function to the next. The more radically new the project is, the more the final project responsibility shifts towards the project leader and the more responsibilities the project team should get in general.

- Myth 4: The NPD climate should be innovative and the NPD process should be formal.

We have shown that the innovativeness of the climate and the formalization of the NPD process do not reinforce each other. It is either-or, not both. This means that, there are two roads to success: you, as a manager, either work on an innovative climate, or you work on a well formalized NPD process. Considering the NPD climate, questions you need to pose to yourself are: how much time, freedom, support, and trust do employees get to develop new ideas? Are employees challenged? Are employees allowed to take risks? If you answer most of these questions positively, the climate in your NPD function can be considered innovative. If you answer most of these questions negatively, you haven't got an innovative climate. Considering the formalization of the NPD process ask yourself if your organization follows a formally documented NPD process or not. For high current NPD performance either an innovative climate or a formalized process should be present.

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Note

1 According to European standards, SMEs are defined as companies that have 250 or less full time equivalents, Commission of the European Communities (2003),

"Commission Recommendation of 6 May 2003 Concerning the Definition of Micro, Small and Medium-Sized Enterprises *(notified under document number C (2003) 1422)* 2003/362/EC." *Official Journal of the European Union* 46 (L124):

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