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Best practice project management: an analysis of the front end of the innovation process in the medical technology industry

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Abstract:
There are strong motivating factors for more effective project management practices at the front end of the innovation (FEI) process. Shrewd management of these pre-development activities has proven to be one of the greatest differentials for success. This study presents findings from an empirical case study analysis of a large organization operating in the medical technology industry in Ireland. We synthesized the literature to identify five critical success factors (CSFs) known to be effective in the successful management of the FEI process. From this analysis an instrument to assess best practices was developed. Data was collected from 66 engineers in the R&D discipline. The findings of the study show that the organization's FEI phase aligns well with best practice. However, a difference between the level of agreement about the extent to which the critical success factors are in place in the organization and the level of importance placed on these practices emerged. This paper contributes to knowledge by (a) assessing the relative importance of critical success factors for the FEI in the medical technology industry, (b) examining whether these initiatives are implemented in practice and, if so, to what extent, and (c) providing a series of recommendations to help bridge the gap from theory to practice.

Keywords:
critical success factors; best practice; empirical analysis, medical technology industry.

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1. Introduction

The early stage of the innovation process has many synonyms. It is also known as "*phase 0*" or "*stage 0*" and lauded to incorporate all pre-project activities but it is probably best known as the fuzzy front end [1]. According to Koen et al. [2] the front end of the innovation process (FEI) is the stage that includes all of the activities that come before the more formal new product development (NPD) phase. Kim and Wilemon [3] define the FEI as the period from when an opportunity is first considered to when it is deemed ready to enter the formal development process. Griffin et al. [4], on the other hand, found that successful serial innovators focus on finding the 'right problem' at the beginning of the process rather than an 'opportunity'. Russell and Tippett [5] believe that there are three distinct phases in the FEI including (a) idea collection, (b) idea screening and (c) project selection. Khurana and Rosenthal [6] state that the FEI is complete when the company decides to either finance and initiate the NPD process or call a halt to the project.

The literature notes that the FEI is poorly managed in practice. In fact, it is seen as the greatest weakness in the innovation process [3], [6], [7]. Perhaps this is because the work is unstructured and experimental, revenue expectations are difficult to gauge, and the output does not meet a planned milestone but rather reinforces a concept. There is also a dearth of investment at this stage of the innovation process. According to Barczak et al. [8] this has caused firms to "*become more conservative in their portfolio of projects*". It seems that because of this an increasing number of development portfolios focus on incremental projects rather than on radical innovation and consequently we are witnessing a reduction in rate of innovation. However literature suggests that the FEI has the greatest potential to impact on and improve the overall innovation process. Koen et al. [2] posit that a "*lack of research into best practices (has) made the FEI one of the most promising ways to improve the innovation process*".

There is a clear need for a better approach to managing the front end of the innovation process. This paper attempts to address this deficit and expand the discussion on innovation management practices at the FEI. The purpose of the study is to identify critical success factors (CSFs) that are known to improve management practices in this area and to assess the level of absorbance and acceptance in the medical technology industry. The case organization targeted in this study designs, develops and delivers complex medical device products. The findings of our work are based on quantitative analysis. 66 engineers working in the R&D department were surveyed in the Spring of 2013. The goal of the survey was to gain a deep insight into the level of importance of known critical success factors as well as the degree of implementation of these factors in a real world setting. The remainder of this paper is organized as follows. The next section identifies, categorizes and discusses critical success factors found to be effective in the management of the FEI. Section 3 presents the research methodology employed in this study. Section 4 summaries some of the key findings from our analysis, section 5 analyses the instrument used and section 6 provides some recommendations to practitioners based on our analysis.

2. Critical success factors for effective management at the FEI

A review of the FEI literature reveals different reasons that distinguish innovative companies from non-innovative companies. In essence it is shown that innovative companies are those that adopt best practice critical success factors (CSFs) whereas non-innovative companies do not. CSFs can be defined as explicit statements of the key performance areas of an organization. Cooper and Kleinschmidt's [9] research has shown that certain best practices set top performing companies apart from the others. This is substantiated by Barczak et al., [8] who found that the best companies did not succeed by implementing just one factor but rather by integrating a number of them simultaneously and more effectively. Yet Boeddrich [10] has noted that companies still neglect to pay attention to many of these CSFs. An analysis of the literature revealed that five affinity groups can be used to categorize the majority of best practice criteria [5], [8], [9], [11], [12]. These are (a) strategy, (b) resources, (c) process (d) climate and (e) tools. It is important to add that no singular group contributes to innovation success; rather it is imperative to adopt elements from all of the groups to provide a balanced approach towards effective innovation management.

2.1 Strategy

According to Barczak et al. [8], the best firms emphasize and integrate their innovation strategy across all levels of the firm. Furthermore, they have well-defined objectives and goals that align with the company's strategy. Russell and Tippett [5] note that a clearly defined and well-publicized new product strategy must be in place at the FEI for an organization to be successful. In order for the strategy to be clearly defined, Cooper [13] suggests that the strategy should focus on strategic arenas that will help propel the business's new product effort. Khurana and Rosenthal [6] second this as they believe that a company should have a clear view of the types of product lines and potential platforms that they want to aim at specific markets. Furthermore, a company's innovation strategy at the FEI should also adopt a "*connect & develop*" strategy [9]. This involves partnering with external organizations in order to develop new products. Cormican and O'Sullivan [11] see the value in this as they too have found that external alliances can be mutually beneficial. One of the most pivotal aspects of the strategy employed at the FEI is that it needs to be flexible. Based on the current economic climate it is also vital that a company's innovation strategy is adaptable so that it can be executed if the environment changes [7].

2.2 Resources

Another common denominator or critical success factor that is synonymous with top-performing companies is the devotion of required and dedicated resources to the innovation process [9]. In terms of impact, R&D expenditure was found to be the most influential factor on product development measured as a percentage of sales. Proper resource management is essential to transforming promising ideas into successful products. One common problem at the FEI is that there may be numerous new product ideas circulating but not enough resources to develop them [11]. It has been shown that the best firms support their people by dedicating resources to the innovation effort [8]. According to Koen et al. [2], permanent support from senior management can be considered essential for product innovation success. It is not enough, however, for this to be just apparent through words; this commitment must be demonstrated through actions such as committing the necessary resources [9]. It is evident that without management's clear commitment of resources in the FEI and subsequent effective portfolio management that a company will flounder.

2.3 Process

According to Boeddrich [10], the absence of a structured process at the FEI has a detrimental effect on a company's innovation management. In fact Cooper and Kleinschmidt [9] have found that the most effective driver, in terms of profitability, is the "*existence of a high-quality, rigorous new product process*" that places a large emphasizes on the FEI. Russell and Tippett [5] also advise that a company should have a process or system in place before commencing the formal part of the innovation process. Barczak et al. [8] concur that a formal process should be in place. However, a crucial finding of Cooper and Kleinschmidt's [9] research is that it is not enough to just have a process in place in the company to deal with the FEI and NPD; instead what is important is the "*quality and nature of that process*". They propose an Idea-to-Launch system which is based on the Stage-Gate process. Although Stage-Gate has some positive attributes like aligning gate review and milestones with the natural stages of development [13] there are many who criticize this highly structured process at the FEI. Other models proposed include Khurana and Rosenthal's [6] model which is quite similar to Cooper's [13] as it has a linear layout where each stage helps the company progress through the sequence. This model concentrates on incremental innovations and there does not appear to be any iterative process allowing for feedback. Koen et al.'s [7] model shows the FEI as a cyclical process or relationship model rather than a sequential process. It comprises three distinctive parts including (a) the internal area which consists of five important elements in the FEI, (b) the engine that propels the front end elements, and (c) the external influencing factors. Griffin et al.'s [4] hourglass model purports to focus on implementation and attempts to address how to implement innovation at this stage in the process.

2.4 Climate

The fourth CSF focuses on people. Although it is labelled climate, it is also an umbrella for culture, teams and leadership. If the correct culture of innovation is developed in a company it will generate a self-sustaining engine for innovation. This corroborates Koen et al.'s [7] reasoning for putting the engine as the driving force in their new concept development model. Cormican and O'Sullivan [11] posit that culture and innovation are intrinsically connected. In other words, innovation will not thrive if the proper culture is not there to support it. In contrast Koen et al. [7] state that in all their research, they have never found a link between culture and success at the FEI. Johannessen et al. [14], posit that innovative companies are those that foster a climate of risk-taking, take the initiative and establish commitment. In the best performing companies there is a climate for innovation that is spearheaded by the company's leaders through their actions and their commitment of resources [7, 9]. Koen et al. [7] also believe that the leadership at the FEI is a vital part of this phase. According to Cormican and O'Sullivan [11] leaders help generate and translate the vision of a company so that what is strategized at a high level is actually being implemented at the operational level. Cooper et al. [15] discovered that the highest performing organizations in innovation encourage their creative personnel to take time out from their official work in order to spend time on informal projects. Barczak et al. [8] found that the implementation of cross-functional development teams is highly associated with the best performing companies. Terziovski et al. [16] also found in their research that this is one of the most important success factors and it needs to be implemented at the early stage of innovation. It is not just sufficient, however, to have a cross-functional team, the team must also communicate effectively in order to bring about success at the FEI [17].

2.5 Tools

Many authors have found that one factor that separates the best from the rest is that progressive companies utilize an abundance of tools and techniques at the FEI. For example, Herstatt et al.'s [18] research investigated activities and tools that are useful in the FEI. Cooper [19] examined eighteen tools that are used by companies when trying to create new product ideas. Koen et al. [2] also recommended some tools that would best complement each element of their new concept development model. One of the most prominent tools cited for the FEI is the lead user method proposed by von Hippel [20] who purports that the initial user of a product creates over 75% of breakthrough inventions. Lead Users are people considered to face needs well in advance of the general marketplace and who stand to benefit from the needs being met. While many authors [2], [8], [18], [19] have also found this method to be one of the well-established market research tools, others such as Soukhoroukova et al. [21] argue that it is very challenging to determine potential lead users for the different markets. Another commonly discussed tool is TRIZ (The Theory of Inventive Problem Solving). The literature suggests that it is a highly effective tool that can be used not only to discover problems and but to solve them as well [2], [18], [19]. Idea banks is another tool used to select ideas. This is similar to the Internal Idea Capture system that Cooper [19] evaluated in his study. A notion similar to Idea Banks is the relatively new concept of Idea Markets [21],[22]. Koen et al. [2] concede that Idea Banks have some merit but they suggest that there is a tendency to not follow-up on the ideas submitted to the bank and the negative impact of this is that those who were initially submitting ideas tend to lose interest. In contrast, Idea Markets engages the employee as their ideas are bought and sold on the virtual market and their fluctuating prices act as a measure of their possible merit [21],[22]. One incentive for using a method like this, that generates a lot of ideas, is that there is a positive correlation between the number of new ideas and their value. It is clear that there are many tools that can prove useful at the FEI, however, experts have different views about which tools are appropriate and which are not. Consequently every company must ascertain for themselves what tools best align with the business they are in.

3. Research methodology

A detailed case study was employed in a leading medical technology organization in Ireland to assess the level of best project management practice at the FEI. This organization was selected as it is a leader in medical device design and development with a proven track record in product innovation. According to Hildreth [23] users of a system are the best evaluators of that system, therefore only R&D engineers involved in the product innovation process was targeted in this

study. Cooper and Kleinschmidt [9] advise that there is often a difference between business unit level success and project level success. Consequently the survey was distributed to all 96 engineers in the R&D department who were capable of commenting on FEI management practices. Data was collected between March 2013 and April 2013 using a quantitative approach was used. According to Creswell [24], quantitative research methods are used to test theories. This method is lauded to be effective when empirically measuring people's feelings, beliefs and behaviors. This method was chosen for this study as it is a good mechanism to test theories, it is easy to repeat and findings can be generalized to the greater population [24], [25].

A comprehensive survey was designed, developed and tested. 90 explicit statements were formed based on a detailed synthesis of the literature relating to management practices in the FEI namely (a) strategy, (b) resources, (c) process and (d) climate (see Appendix A). Each category represents an aspect of the business that, according to the literature, is significant to product innovation success. The survey was designed to ask two key questions. First we wanted to learn the extent to which each of the best practice statements was implemented in the organizations. To this end respondents were asked to document whether they agreed or disagreed with the implementation of each of the statements using a five-point Likert scale, i.e., strongly agree, agree, neutral, disagree and strongly disagree. We also wanted to understand how important respondents felt each of the statements was. Therefore respondents were asked to rate the level of importance of each statement on a five-point scale, i.e., critical, very important, important, slightly important or unimportant. In order to identify and prioritize what tools are important at the FEI a list of 40 tools was generated from a synthesis of the literature. Respondents were asked how often they use each of the forty tools in their FEI phase. From here they were asked to rank, in order of their importance, the top five tools from the list of forty tools. Following that they were invited to note any tools that were overlooked in the survey but that are used in their FEI stage. The survey was piloted to establish if there is any ambiguity in the line of questioning and whether any of the questions could be misinterpreted. Amendments were made based on this feedback. Data collected was analyzed numerically using statistical analysis software (SPSS).

4. Analysis of findings

66 people responded to the survey. The majority of the respondents to the survey were either R&D engineers or associate R&D engineers. The majority of respondents are aged between 25 and 34 years old and a chi-squared test was determined that there is a significant association between respondents age and role held within the company ($\chi^2 = 80.228$, $p = .000$, $df = 39$, $n = 66$). Therefore it is likely that the R&D engineers and the associate R&D engineers are mainly made up of people in the younger age categories.

Participants were asked to disclose how many years they have worked in the medical technology industry, the number of years they have worked in R&D and the number of years they have been employed in the company. This information was sought to discern the level of experience the respondents have working at the FEI in the organization. The number of years the respondents worked in the medical device industry ranges from 0 to 28 years (mean $\bar{x}= 8$, standard deviation $SD = 6.78$). The numbers of years the respondents have worked in R&D range from 0 to 22 years ($\bar{x}= 6.37$, $SD = 5.14$). Finally the numbers of years the respondents have worked in Company X ranges from 0 to 27 years ($\bar{x} = 6.36$, $SD = 6.12$).

There was no significant difference between the opinions held by the respondents in the different age categories. This allowed the sample to be considered as a whole and the statistics did not have to be segregated according to the different age groups.

4.1 Strategy

Our results indicate that responding engineers in the R&D department agree that best practice critical success factors relating to strategy are in place at the FEI in the organization studied (i.e. degree of implementation). The employees also consider that critical success factors relating to strategy are important (i.e. level of importance). A Spearman's Rho test was carried out to see whether there was an association between the degree of implementation and the level of

importance attached to the strategy related CSFs. We found that there is a weak correlation between respondents' degree of implementation and the level of importance associated with this category and so the relationship is not statistically significant (r = .186 p = .174). This means that the relationship is so low that it can be considered random.

As there was no significant association between the degree of implementation regarding strategy oriented CSFs in place and the level of importance attached to these CSFs it was decided to carry out a Wilcoxon test to see whether there was a significant difference between them. The results indicate that there is a significant statistical difference between the two (Wilcoxon, Z = -2.419, n – Ties = 50, p = .016). This means that despite the fact that respondents believe that the organization is good at implementing strategy oriented CSFs, the level of importance assigned to these CSF is rated higher. In other words, respondents believe that CSF in the area of strategy is rated higher than what is practiced in reality and so this imbalance needs to be addressed.

4.2 Resources

Respondents believe that CSFs relating to resources are in place at the front end of the innovation process in their company. Furthermore the employees also consider that CSFs relating to resources are important. These findings suggest that resources in the FEI of the organization are managed in accordance with best practice.

A Spearman's Rho test was carried out to see whether there is an association between respondents' attitude towards the degree of implementation regarding whether CSFs for resources in the FEI (i.e. degree of implementation) and the level of importance attached to these CSFs (i.e. level of importance). It was discovered that there is a statistically significant relationship between implementation and importance in this category (r = .289, p = .042). As $p < .05$ the relationship can be considered genuine and not a result of chance. Therefore we can deduce that the more the resource related CSFs align with best practice in the FEI, the greater the importance placed on this CSF. Alternatively, if high importance is put on CSFs resource, they are more likely going to be incorporated into the company.

A Wilcoxon test was carried out to see whether there was a significant difference between the degree of implementation and the level of importance attached to the resources related CSFs. The results indicate that there is a significant statistical difference between both measures of attitude (Wilcoxon, Z = -5.280, n – Ties = 46, p = .000). It seems that a larger number of respondents rated the importance of the resource related CSFs greater than their level of agreement about them being in place in the organization.

4.3 Process

Unlike the previous categories, respondent's scores are concentrated on the lower values of the scale when asked about whether they believe that best practices process oriented CSFs were in place. However, the median score is high which implies that the employees are more in agreement than disagreement about process related CSFs being in place in their company. Respondents also believe that CSFs relating process are more important than unimportant.

A Spearman's Rho test was carried out to see whether there was an association between the level of agreement regarding whether the organization implements process related CSFs and the level of importance attached to these factors. We found a strong correlation between implementation and importance in this category and consequently that the relationship is statistically significant at the 0.01 level (r = .493, p = .001). This means that the higher level of agreement that the CSF is in place in the organization the higher the level of importance is placed on the CSFs.

A Wilcoxon test was subsequently carried out to see whether there was a significant difference between the level of agreement that these factors are in place and the level of importance attached to these factors. Based on the results, there is no significant statistical difference between both measures of attitude (Wilcoxon, Z = -1.850, n – Ties = 37, p = .064). This implies that the level of agreement about the level of implementation of CSFs relating to the organizations process is more in line with the level of importance attached to these CSFs.

The findings indicate that organizations FEI process is effective as the high agreement scores indicate that organizations' process compares favorably with the process related CSFs.

4.4 Climate

The majority of respondents believe that CSF relating to the organizations climate is in place. They also believe that these CSF are important.

A Spearman's Rho test was carried out to see whether there is an association between the level of implementation and the level of importance attached to the climate CSFs. It was established that there is a strong correlation between agreement and importance in this relationship is statistically significant ($r = .484$, $p = .003$).

A Wilcoxon test was also conducted to see whether here was a significant difference between the level of implementation and the level of importance attached to the climate related CSFs. According to the results, there is no statistical significant difference between both measures of attitude (Wilcoxon, $Z = -1.287$, n – Ties = 28, $p = .198$). Our findings show that respondents rated the level of importance and level of implementation of climate CSFs is similar.

4.5 Tools

Table 1 summarizes our findings regarding the perceived importance of tools in the FEI. More specifically, the top 10 most important tools, the top 10 least important tools and the top 10 most unknown tools are presented.

Table 1. Perceived importance of tools in the FEI

Most important tools	**Least important tools**	**Most unknown tools**
Brainstorming	Scenario planning	Idea banks
Rapid prototyping	Unfocused groups	Unfocused groups
Customer visit teams	Customer designs	Peripheral visioning
Design for six sigma	Peripheral visioning	Morphologies
Market research	Partners and vendors	Commercial success probability
Focus groups	External product designs	Strategic buckets
Internal idea capture	External submission of ideas	Lead user analysis
Customer advisory board	External idea contest	Community of enthusiasts
User centric design	Idea banks	TRIZ
Intellectual property activity watch	Evaluation criteria matrix	Technical success probability

Table 2 summarizes our findings regarding the use of tools in the FEI. More specifically, the top 10 most frequently used tools and the top 10 least frequently used tools are presented.

Brainstorming and rapid prototyping are the most popular tools used. However, we found that this organization does not appear to use a great variety of tools at the FEI which is contrary to Barczak et al.'s [8] finding that the best companies use a multitude of tools during this phase. Focus groups were found to be in the top 10 most used tools despite the literature showing that group methods are not effective at the FEI [26]. Design for Six Sigma is a tool that is typically employed during the development phase of the innovation process was found to be regularly used and also quite important at the FEI. Interestingly, market research is only considered the fifth most used tool. This is despite it being

the deemed the second most important tool by the employees. The usage result is unexpected as one would have thought it is essential to be market aware when trying to generate ideas for new products.

Table 2. Use of tools in the FEI

Most frequently used tools	Least frequently used tools
Brainstorming	Idea banks
Rapid prototyping	Community of enthusiasts
Customer visit teams	Unfocused groups
Design for six sigma	Peripheral visioning
Market research	Morphologies
Focus groups	External idea contest
Internal idea capture	TRIZ
Customer advisory board	Strategic buckets
User centric design	Technical success probability
Intellectual property activity watch	Commercial success probability

Some of the most common tools and techniques that were highlighted in the literature review scored very low usage scores in the survey such as idea banks and TRIZ. Surprisingly, a high proportion of the sample that completed this question was unfamiliar with several of the tools that were collected from the literature. Furthermore two of the tools in the top 10 most unknown tools are lead user analysis and TRIZ despite both tools being highly recommended in the literature.

5. Analysis of the instrument

It is essential to determine the internal reliability of the instrument using a statistic known as Cronbach's Alpha. As this is a developmental scale, the individual Cronbach's Alphas were calculated for each of the subscales on the instrument. The overall Cronbach's Alphas for the combined subscales was also calculated. All of the results are > 0.8 which is deemed as "*highly acceptable for assuming homogeneity of items*" [27]. Therefore the items in this scale can be considered to have a high level of internal consistency.

A Spearman's Rho test was carried out to see whether there are associations between subscales measuring the level of implementation relating to the strategy, resources, process and climate CSFs. The results of the test show that there are strong positive correlations between all of these scales and each of these relationships are statistically significant. This means that as agreement about one CSF increases agreement about resources and other sub scales increase. This relationship reaffirms what was suggested in the literature which is that the four factors are linked.

A Spearman's Rho test was then carried out to see whether there are associations between the subscales measuring the level of importance for each of the CSFs. The results of the test show that there are strong positive correlations between all of the importance subscales and each of these relationships are statistically significant. Based on these results, one

can deduce that as the importance placed on the strategy CSFs increases, the importance levels attributed to the other CSFs are likely to increase and so forth. These correlations mean that there is a significant relationship between the four variables and that as the literature suggests, they are linked and cannot be treated independently.

6. Recommendations

Based on our analysis the following is a tentative list of recommendations that the organization studied should take on board so that their FEI phases aligns better with established best practices.

- Focus on new strategic arenas: According to Cooper [19] a company should focus "*R&D efforts on more fertile strategic arenas with extreme opportunities*" as they will help a company to grow and prosper. The organization should consider targeting new strategic arenas that will demand the creation of breakthrough ideas and big concepts.
- Adopt a "*connect & develop*" strategy [9]: It is clear from the findings that the organization studied does not adopt a collaborative innovation strategy. There is evidence to show that many companies have benefited from adopting more open innovation policies [28].
- Deploy more suitable staff at the FEI: The findings of our study show that only a small percentage of employees work full time at the FEI. Furthermore we learned that employees' strengths are not taken into account when assigned to innovation projects. It is imperative to ensure that suitable resources are assigned to the right projects so that there is a well-balanced and effective portfolio of projects.
- Invest more money at the FEI: The organization studied devotes on average 4.2% of turnover to R&D but only 0.2% of this figure is dedicated to the FEI phase. These percentages are considerably less than international expenditure on R&D. We would recommend that the organization should increase their spending at the FEI as it has been found that when the allocation of money (and staff) doubles at the FEI it correlates significantly to product innovation success [13].
- Align innovation metrics to management's personal performance objectives: In order to ensure that management commit the adequate amount of resources to where they are needed at the FEI, new product performance metrics should be integrated into management's personal performance objectives [7]. This link guarantees that management cannot overlook the FEI phase if they want to meet their performance objectives.
- Improve idea management: It is clear that a greater emphasis should be placed on the management of ideas. By incorporating the philosophy of idea banks or idea markets, which allow all employees to contribute and evaluate ideas, would permit a more collaborative effort for determining the value of an idea.
- Evaluate leadership: Stevens et al. [29] found in their research that a leader's personality can greatly affect the FEI. They discovered that a person who demonstrates high tendencies for intuition will select better projects and as a result will generate more profit in comparison to someone who scores low on this psychometric test for intuition. Therefore if leadership is so integral to success in the FEI, companies like the one studied here should consider whether their leaders are effective by carrying out this psychometric evaluation.
- Diversify the tools used at the FEI: There are many idea generating techniques that can provide a rich supply of ideas e.g. idea markets. Organizations should try and familiarize themselves more with the unknown tools, in particular those that are highly referenced in the literature such as TRIZ and lead user analysis. TRIZ is a methodical technique that can be used to solve problems and to generate numerous correct solutions. The benefit of this tool is that it encourages creativity as users must go beyond their own experience and recycle solutions from other scientific fields [2]. The Lead User method involves communicating with people who are likely to face needs sooner than the general marketplace and so will consequently gain from having those needs met.

7. Conclusions

This paper focuses on management practices at the front end of the innovation process in a large organization operating in the medical technology industry. The aim of this research is to provide insights into the level of implementation of known best practices as well as the level of importance assigned to these best practices in a real world setting. The research is important because management practices at the FEI have a significant impact on the performance of the product innovation process. We found that the FEI audit used in this study is internally reliable. The questionnaire, which is based on existing literature relating to the FEI is an effective instrument for gauging the level of best practice in place in a company's FEI. The tool can help practitioners to assess themselves relative to best practice. By analyzing an organization's activities and by quantifying the impacts of these activities the organization can respond in a planned and coordinated way and customized solutions can be implemented.

The findings of our study revealed that CSFs relating to strategy, resources, process and climate are very important at the FEI in the medical technology industry. However these CSFs are not implemented to the extent to which they should be in practice. Our study revealed that if a CSF is considered important by employees it is more likely going to be enforced. In addition, if a CSF is implemented it is also more likely to be considered important. If an organization wants to ensure that they have an effective and efficient FEI phase, it is clear that they must adopt these best practices in these areas uniformly. By incorporating and improving the presence of the CSFs medical technology companies will create FEI phases that align more with best practice.

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Appendix A. Variables used to measure key constructs

Table 1. Variables used to measure strategy

	Strategy
1.	Management have produced a clear well-communicated NPD strategy
2.	There is a defined new product strategy for the R&D unit
3.	The business strategy is active at the start of projects
4.	The business strategy clearly communicates the financial objectives
5.	The business/innovation strategy focuses on attractive strategic arenas, i.e., growth engines
6.	The clearly defined strategic arenas help give direction to the business total new product effort
7.	The business's new product effort has a long term focus – it includes long term projects as well as short term incremental projects
8.	There is a clear vision of product lines and platforms for specific markets
9.	There are clearly defined product innovation goals for the business
10.	Innovations role in achieving business goals is clearly defined
11.	There are goals or objectives for the business total new product effort
12.	The role of new products in achieving business goals is clearly communicated to all
13.	The company has a 'connect & develop' strategy – it works with partners to develop new products outside the organisation
14.	The company often forms alliances with other organisations for mutual benefit
15.	There are people in the organisation to continually scan the external environment
16.	The company looks for opportunities through external analysis – markets industries and sectors
17.	The company looks for opportunities by identifying the unique capabilities of the business in order to leverage them in other markets applications and sectors
18.	The company tries to identify major problems or problem arenas so that it can apply its competencies to solve those problems
19.	The company has the ability to execute the innovation strategy when the environment changes due to its flexibility
20.	If there is uncertainty on any dimensions (e.g. technology or markets) the organisation has a carefully planned alternative approach

Table 2. Variables used to measure resources

	Resources
1.	There is continuous senior management support for innovation and new product development
2.	The company's management enforce company values for the duration of the project
3.	The necessary resources are devoted by senior management to achieve the firm's new product objectives
4.	R&D budgets are adequate to achieve the businesses new product objectives
5.	Priority projects receive the resources they need for execution
6.	New product performance is part of senior management's personal performance objectives
7.	The performance results of the new product programme are measured (e.g. % of annual sales generated by new products, etc.)

8.	The right people are active in the right projects at the time during the innovation process
9.	Staffing policies and project specific staffing are consistent with the new product strategy
10.	The resources needed to meet the projects performance requirements are clearly documented
11.	Project personnel have been tested or trained to develop raw ideas into potential projects
12.	Appropriate "starter" personnel are selected to staff the early stages of the innovation process
13.	The company supports staff learning about other areas of the business e.g. marketing, manufacturing finance etc.
14.	The company encourages job rotation to encourage knowledge sharing
15.	The company urges employees to interact closely with the customers
16.	The company has an effective portfolio management system that aligns well with the business's strategy
17.	The portfolio of projects are well balanced between risk versus return, maintenance versus growth and short term versus long term projects
18.	There is a good balance between the number of projects and resources
19.	There is a continuous pipeline of new products that are of value to the company
20.	The company does a good job in ranking/prioritising projects so that they are consistent with the new product strategy

Table 3. Variables used to measure process

	Process
1.	The innovation process is a high quality process that aligns with the business strategy
2.	The front end of the innovation process is a complete and thorough process where every necessary activity is carried out without hasty corner cutting
3.	The front end of the innovation process is flexible as stages can be skipped or combined depending on the nature of the project
4.	The module/process used in this company is non-sequential, i.e., iteration is part of the process
5.	Established criteria are used at review points to promote or kill a project
6.	Project targets (time, cost, quality) and relative priorities are clear
7.	The company uses metrics to track idea generation, e.g. % of ideas that entered the new product development process, % of ideas commercialised, etc.
8.	There is an emphasis on up front homework i.e. market and technical assessments before projects move into the development phase in order to build a robust business case
9.	Early concepts and other feasibility prototypes are planned tested and completed at the front end so that there are no surprises later
10.	The process includes sharp, early product definition that is well documented before development work begins
11.	The search for opportunities begins with search for customers' problems and/or their unarticulated needs
12.	Customers and suppliers are involved throughout the product innovation process
13.	The company carries out concept testing with users to determine the value to the customers
14.	The company encourages customer and marketplace contact
15.	Customer and market information is used early on to set the scope for a project (e.g. target markets, customer segments, features, price, etc.)

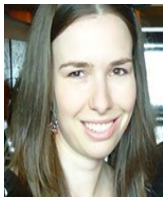
16.	A projected project outcomes' ability to meet the customer need is clearly documented
17.	Major supplier and tooling considerations, manufacturing, logistics and distribution requirements are explicit at the front end of the innovation process
18.	The company has an active formal opportunity identification process that allows fair identification of radical ideas
19.	The company approaches funding problems/opportunities from a strategic perspective
20.	The company has an active idea collection system to support internal and external ideas
21.	Core team members jointly review product concepts using pre-defined and explicit criteria
22.	Idea selection is done through a formal process where prompt feedback is provided to the idea generators
23.	The company has a rapid process in place to screen ideas or concepts for a project
24.	The competitive advantage potential for a project is clearly identified for each new project
25.	Information on ideas generated, problems raised and project status is accessible to all the unit

Table 4. Variables used to measure climate

	Climate
1.	Senior management support innovation by approving projects, securing necessary finance and resources etc
2.	The company has created an environment that is conducive to creativity and knowledge creation
3.	The whole organisation is aware that innovation is fundamental to bringing value to customers
4.	There is a sense of trust and openness that allow people to speak their minds and offer differing opinions
5.	Powerful stories are communicated to staff that reinforce the principles and practices of innovation
6.	The company sets compelling challenges that allow employees to become emotionally committed to the project
7.	There is a dedicated innovation group within the R&D department
8.	Innovation results are one of the key performance metrics/indicators
9.	The organisation permits the emergence of intrapreneurs or product champions by allowing people time to work on projects of their own choice
10.	The company recognises that they need to pay people to be innovative and to also give them the time to be innovative
11.	The company uses incentives or rewards to stimulate the generation and enrichment of ideas
12.	There is a new product idea scheme within the R&D unit which solicits ideas from all employees
13.	Idea screening is done in a way that encourages creativity rather than stifling new ideas
14.	Someone in the company has the formal role of coordinating ideas from generation to assessment
15.	There is sufficient time given for people to think ideas through before having to act
16.	There are funding resources available for new ideas
17.	The company is willing to invest in high risk projects
18.	The project has an assigned team of players that are accountable for the end result
19.	Projects are developed using effective cross functional teams
20.	The project team interact and communicate well through frequent project update meetings
21.	Roles and responsibilities for the core team are clear and well defined

22.	A project team has the ability to get news from outside the company
23.	Partners, suppliers and vendors are integrated into a project team
24.	The company's leaders demonstrate in every decision and action that innovation is important to the company
25.	All projects have a defined team leader who is responsible for advancing the project from start to end

Biographical notes



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