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EVALUATION OF A RESEARCH AND DEVELOPMENT PROCESS: HOW TO ACHIEVE THE NEXT LEVEL OF PRODUCT DEVELOPMENT

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ABSTRACT

The global market for medical technology reached $130 billion in 1996, and is projected to grow briskly for the foreseeable future. While more Research and Development (R&D) funding is now provided by industry than in the past, recent changes in the United States Medicare system make it more difficult for medical device manufacturers to be profitable. In parallel with the difficulties generated by U.S. Medicare Reform, international competition in the medical device industry has become more prevalent.

To offset these economic, legislative and competitive challenges, manufacturers must focus on measuring and improving R&D productivity and effectiveness as a means to produce products with improved profit margins, faster to market and that are customer-focused. Because of these changes, Acme Medical decided to evaluate and improve its New Product Development (NPD) process.

This project provided a focused evaluation of the current NPD process at Acme Medical based on the Rogers fifth-generation R&D framework. A Delphi panel of R&D experts evaluated the R&D maturity of Acme Medical. After three iterations, results clearly indicated that a second-generation R&D process was employed. Based on the Delphi panel results, a gap analysis between the second- and third-generation Rogers models was performed. The analysis identified six major gaps. Interpretation of these gaps resulted in 13 corrective action concepts (CACs) that Acme Medical could implement, thereby achieving a third-generation R&D process.

Finally, these CACs were validated employing latent content analysis (LCA) of relevant, recently published literature. With this information, Acme Medical's senior management has a clear path to elevating the performance of their R&D process.

INTRODUCTION

The medical device environment

Every year, hundreds of new medical devices, drugs and therapies are cleared or approved for use by the Food and Drug Administration (FDA) or are self-certified by manufacturers with the CE mark for the European Union (EU). Emerging markets are found in South America and Southeast Asia. The opportunity this provides for a medical device manufacturer is astounding. Because of this profit potential, increasing sums of money are being allotted for R&D.

According to the National Science Foundation, a record setting high of $205.7 billion was invested in U.S. R&D in 1997 and 75 percent of that sum was from industry. (National Science Board, 1998) The trend towards an increasing relative contribution by industry sources has existed for nearly two decades (ibid.). R&D funding for health care is greater than ever before, and is greater than R&D funding for any other non-defense budget item. (National Science Foundation, 1996) However, very little U.S. federal R&D health funding benefits industry directly; nearly 95 percent is directed toward basic research programs of the National Institutes of Health (NIH). (ibid.)

Recent changes in the U.S. Medicare system make it more difficult for medical device manufacturers to be profitable. A sweeping new budget law will result in the most significant changes to Medicare in more than 30 years, possibly reducing Medicare reimbursement for things such as oxygen and patient monitoring devices by up to 25 percent. Thus, hospitals, homecare and other medical providers have changed their purchasing focus from quality to reducing costs and as a result, average selling prices (ASPs) for products are decreasing.

In parallel with the difficulties generated by U.S. Medicare Reform, international competition in the medical device industry has become more prevalent. The Health Industry Manufacturers Association (HIMA) noted that, “Over the past decade, the share of the global medical device market commanded by U.S.-based production has slipped from an estimated 60 percent in the early 1980s to an estimated 46 percent in 1994, a loss of approximately 1.25 percentage points per year.” (Unattributed, 1999)

In spite of these trends, improving the R&D process is no longer a top priority for technology leaders. The Industrial Research Institute (IRI) has been surveying its membership annually since 1993 to identify the biggest problems for technology leaders and the only item evidencing a noticeable decline in relative importance over the five-year period was “measuring and improving R&D productivity/effectiveness”. Until 1996, this item was ranked first in importance; in 1996, it fell to second; and in 1997, it was ranked seventh out of the 10 problem areas.” (National Science Board, 1998) The authors contend that high technology manufacturers must refocus on measuring and improving R&D productivity and effectiveness.

Acme Medical: the company

AUTHORS' NOTE: Names are disguised as a condition for the company's participation.

In 1910, the Midwest Medical Company was organised. In addition to its medical gas and dental businesses, it developed anaesthesia machines. Over the next 88 years, Midwest Medical, Post-Midwest Medical and finally Pre-Acme Medical, and one of its largest competitors, Viking Medical, would provide state-of-the-art advancements in anaesthesia delivery and monitoring equipment. Brought together under one name by Parent Medical Corporation in 1998, Acme Medical is now one of the world’s leading companies in its field, and is the largest global supplier of anaesthesia monitors. Parent Medical Corporation operates under a business unit (BU) organisation with each BU having specific “Centers of Excellence” (COE) responsible for parameters, technologies or knowledge for which it is considered the corporate experts. The Colorado facility of Acme Medical is the Monitors Business Unit, and is the COE for low-cost single and multiple parameter configured monitors and low-cost manufacturing.

Research objective

This study provides a focused evaluation of the current Acme Medical R&D process using the Delphi method and based on a published R&D framework. Corrective action concepts (CACs) on how Acme Medical can achieve the next level in R&D are developed. Finally, these CACs are validated using latent content analysis (LCA) and identifying them in New Product Development (NPD) process literature.

EXISTING R&D FRAMEWORKS

“Product development can be viewed as a process by which intangible product ideas and data on markets and technologies are transformed in new knowledge for commercial production.” (Emmanuelides, 1993) The search for an R&D framework originally was intended to identify an R&D process structure that would be effective and efficient as a process. However, two different concepts were noted during the review of the applicable sources: those that primarily focused on process structure, and those that focused on process characteristics. Although both concepts touch on process structure and process characteristics, the emphasis tends to be on one driving the other. These two approaches provide two different philosophical concepts of R&D.

Process structure

The process structure approach focuses on control and is more characteristic of Fredrick Taylor’s scientific management philosophy where the process is divided into incremental work components. Bowers, Cooper and Vincent all support a stage gate approach with senior management review at each gate. (Bowers, 1998, Cooper, 1990 & Vincent, 1989) McGrath offers a cross-project and risk-based framework that incorporates strategy and metrics into the R&D process. (McGrath, 1992) Each successive article provides more pieces to the puzzle, but they primarily deal with the mechanics of the NPD process and the rigorous adherence to the concepts suggested in the papers for success. However, the mechanics alone are insufficient to ensure success.

Process characteristics

The groundbreaking book Third Generation R&D: Managing the Link to Corporate Strategy describes traits that effective and efficient R&D operations exhibit. R&D is most effective when it is driven by, and supports the needs of, the business. (Roussel, Saad and Erickson, 1991) The R&D generation concept is based on the level of maturity the R&D process and business exhibit in order to produce commercially viable products. Roussel et al. describes three generations of R&D exhibiting increasing levels of maturity through nine characteristics.

Miller integrates the customer into the R&D strategy, and Rogers the entire supply chain to create, respectively, a fourth and fifth R&D generation. (Miller, 1995 & Rogers, 1996) Ultimately, the Rogers fifth-generation was selected for benchmarking the Acme Medical R&D process because it was built on characteristics and incorporated the most comprehensive model available to date.

RESEARCH AND ANALYSIS

Identification of Acme Medical's R&D maturity was completed with data collected using the Delphi method. This consists of a series of surveys completed by subject experts. The surveys are administered iteratively with feedback provided. Ideally, responses converge and consensus is reached. (Dalkey, 1963 & Linstone and Murray, 1975)

Delphi panel results

Three surveys were distributed to a panel of eight experts who exhibited the following profiles: a) current employees of Acme Medical; b) current or past project team members and/or project managers on R&D projects; and c) report to the R&D or marketing function.

The first survey consisted of four exploratory questions about what R&D characteristics increase or inhibit project and/or product success. 168 comments were received and categorised into the six Rogers characteristics: Core Strategy, Performance, Structure, People, Process and Technology Management. These comments were also used to tailor the CACs, derived from the survey results, specifically to Acme Medical's needs.

The second and third surveys consisted of the panellists' quantitative rankings and explanatory comments from the panellists providing rankings in the outer quartiles. Because of the small number of panellists, the median was used to measure the data central tendency and the range was used to measure dispersion. These values were plotted on modified boxplots with the values on the dependent axis corresponding to the generation of the Rogers model. This clearly identifies where the majority of responses lie on the chart while providing a view of data dispersion. For this study, a range less than 1.00 was defined as consensus for a characteristic.

Core Strategy

In the first survey, core strategy was identified as a strong inhibitor of project AND product success. The responses received on this characteristic clearly imply that Acme Medical does not have a clear core strategy.

The second survey resulted in a 2.25 median and a 1.37 range. Despite the strong implication from the initial survey that Acme Medical does not have a clear core strategy, four of the panellists ranked this characteristic at 2.50. After an initial review of the panellists' results, the researchers determined that no clear conclusion could be drawn from the data and a follow-up with each panellists was required due to the wide spread of data and the apparent discontinuity between these and initial survey results.

Two of the four panellists were privy to a new business strategy being developed at the corporate and local company levels. The questionnaire and the anchor terminology on the ranking chart confused the other two panellists. Although the data collected from the second survey on this characteristic did not contribute to valid conclusions, it was key in identifying the confusion within the second survey, and the need for clear and concise feedback to the panellists. The panellists' feedback was used to clarify the questionnaire for the third survey.

The general manager (GM) of Acme Medical presented the new core strategy to the organisation between the second survey follow-up interviews and administration of the third survey. Clearly this brought the panellists onto a more level "information playing field" and the dispersion of the responses decreased accordingly. Even

so, consensus was NOT reached on this characteristic; a 2.13 median and a 1.12 range resulted, so the overall ranking of the characteristic did not change significantly during the survey process.

Performance

The first survey overwhelmingly noted that current R&D performance inhibits project and product success more than it increases success. The lack of R&D process execution, including measuring R&D performance and following the stage gate concept, was a recurring item. Also noted was senior management's involvement or rather lack of involvement. If management holds R&D accountable for the stage gate deliverables and the investment return on R&D, then it is expected that execution of the process would improve.

A 1.50 median and a 1.62 range were obtained on the second survey. The ranking shows that Acme Medical does not execute the R&D process. This supported the conclusion from the initial survey. Two rankings were sufficiently high to require interviews. One panellist answered the question in relation to past projects when he felt project team performance was excellent, while the wording of the questionnaire confused the other panellist. These two panellists' feedback was provided in the third survey and was also used to clarify the questionnaire.

On the third survey, the overall ranking of this characteristic changed significantly with the median value moving from 1.5 to 2.0 and the range decreased by almost 50 percent to 0.88. The changes were most likely due to the improved definitions in the third survey. Consensus was reached on this characteristic.

Structure

In the first survey, structure was noted to have some impact on the whether a project succeeds, but not on product success. The fact that structure is not directly correlated with project success is supported by Urban and Hauser who state: "… some products fail despite the best organisations and some products succeed in spite of a poor organisational structure. There is more to managing people than the formal organisational chart." (Urban and Hauser, 1993) Acme Medical is functionally structured into departments with a weak matrix project team for R&D activities. The responses noted that the current use of cross-functional teams increases the probability of project success, but as noted above, the poor implementation of cross-functional teams results in unstable staffing and fractious team dynamics. Departmental suboptimisation appears to have a negative effect on the R&D process.

Structure was ranked with a 1.57 median and a 1.25 range on the second survey. The data agree with the initial survey, and show a fairly even dispersion of opinions that Acme Medical is between a strict hierarchical, functional organisation and a matrix organisation. Follow-up interviews were performed with the high and low ranking panellists. The panellist that ranked structure highest did so because he has been with Acme Medical for a long time and felt that the current organisational structure and use of cross-functional teams supported R&D project success. The panellist that ranked structure lowest did so because even though R&D projects are structured like a matrix organisation and utilise cross-functional teams, the project team does not always act like a team. Feedback from these two panellists was provided in the third survey.

The median on the third survey was 1.75 with a 0.75 range. The overall ranking of this characteristic did not change significantly; however the range decreased 40 percent. This decrease is most likely due to the improved definitions in the third survey and by the panellists' comments. Consensus was reached on this characteristic.

People

The results of the first survey showed that the capability of R&D people increases AND inhibits the probability of project success. Upon closer inspection of the responses, it became clear that the comments supporting an increase in the probability of project success are primarily based on motivation, desire to be successful, etc. Comments stating that people inhibit the probability of project success are focused on a lack of project management skills and understanding of the R&D process. These results imply that the people have a positive attitude and are motivated to succeed, but in some cases, the employees do not have the appropriate skills to contribute to the level at which they are motivated to contribute.

People characteristic responses provided a median of 1.50 and a range of 1.00 with six of the eight panellists providing responses within a data range of 0.50. These data in conjunction with the structure characteristic data support the conclusion that R&D project team members want to succeed, but do not have the appropriate skills or are not supported by the functional organisation that they represent in the project activities. Two panellists

provided higher rankings that significantly increased the data range. One panellist stated that he has worked at companies where the R&D process was at the mercy of politically-driven R&D people who subscribed to turf wars, information hiding and focusing on other departments' short-comings to hide their own issues. He stated that he had not noticed these activities at Acme Medical. The wording of the questionnaire confused the other panellist. The two panellists' feedback was provided in the third survey and used to clarify the next questionnaire.

On the third survey, the median increased a small amount to 1.69 and the range decreased by a factor of two to 0.50. The range decrease is most likely due to the improved definitions in the third survey and by the panellists' comments. Consensus was reached on this characteristic.

Process

Clearly ascertained from the first survey was that use of a stage gate process strongly increases the probability of project success. This response was expected, and is supported by many literature references including:

> "Disciplined use of the process enables new-product teams to develop products that deliver benefits to customers in a manner that builds on the correlates of success and avoids many of the pitfalls that have led other products to fail." (Urban and Hauser, 1993)

Acme Medical's current NPD process is a six-step, stage gate approach. To some extent, the overwhelming consensus was surprising as many R&D employees complain about the cumbersome process. However, when these results are viewed with the performance results, the reason is clear; execution discipline is an issue. The NPD process is robust but rarely executed as intended.

Consensus was reached on the second survey for the process characteristic with a 2.00 median and a 0.50 range. These results show that R&D is managed on a project-to-project basis. This ties into several of the comments on core strategy, specifically that although projects are based on marketing input and business needs, there is not an overarching view of what products should be in the portfolio. Additionally, the variation in the performance success of past projects also supports this view; there is very little cross-project learning. No follow-up interviews were performed for this characteristic because the data range was within the criteria for consensus. Additionally, this characteristic was not included on the third survey for reranking.

Technology Management

Technology management was not identified as a significant characteristic contributing to project or product success. This conclusion is based primarily on the lack of responses from the panellists. Panellists' comments on technology management were minimal; however three of the seven comments noted that, "NPD process is applied too soon to unproven technology." Technology management may not have been cited by the panellists as an important characteristic because it is not currently addressed in the core strategy. Technology development does occur at Acme Medical; however it is not currently differentiated from product development.

The second survey resulted in a 1.63 median and a 1.37 range. The median identifies the management of technology as between the "embryonic" and the "management of technical data" stages, and notes that it is not a systematic activity at Acme Medical. The dispersion of the results, especially those at the extremes, implies some difference of opinion with regard to this conclusion.

The panellist that ranked technology management highest did so because he disagreed with the conclusion made from the first survey. He stated that technology management is critical to the organisation. When asked if Acme Medical currently performs this activity, he stated that Acme Medical currently manages data and that even though data are typically collected they are not analysed or acted upon. The panellist who ranked technology management lowest did so because Acme Medical tends not to understand the magnitude of the risks and issues of a technology that it intends to use, but has not fully developed. He stated this has occurred more than once.

On the third survey, the ranking of this characteristic did not change significantly with the median value moving from 1.63 to 1.69, but the range decreased by almost 50 percent to 0.75. The range decrease is most likely due to the improved definitions on the third survey. Consensus was reached on this characteristic.

Identification of R&D generation

The previous section identifies the existing Acme Medical R&D maturity just below the second-generation. The results are graphically summarised in Exhibit 1. A few minor modifications would allow the existing process to become a strong second-generation process; however significant benefits would be achieved if the process were advanced to the third-generation.

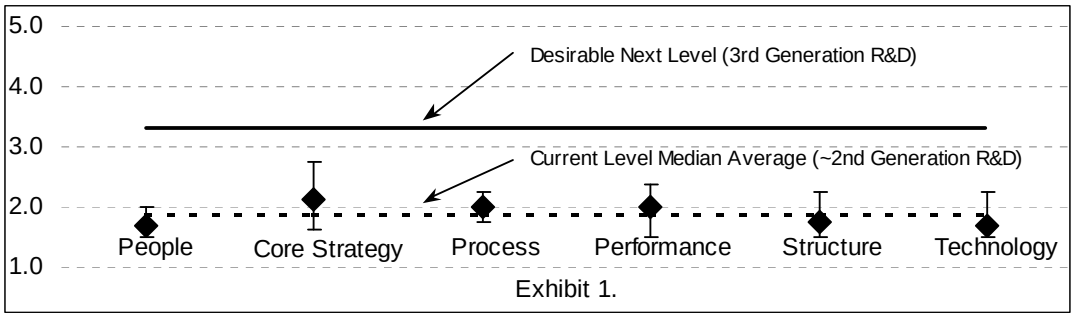

Exhibit 1.

How to achieve the next R&D generation level

With the identification of the current Acme Medical R&D maturity, the focus turns to identifying the gaps between the current second and desired third-generation levels. Six major gaps were identified that spanned the six characteristics. Within each gap, CACs are developed and discussed to provide a deeper insight into each gap without being prescriptive in nature. Because some of the CACs affect more than one characteristic, a comparison to all appropriate Rogers model characteristic(s) is also provided.

Gap #1: Formal, closed-loop link between core strategy and NPD activities does not exist.

A new core strategy was unveiled during the course of this project where none had previously existed. This is a necessary step that also provides partial validation for CAC #1. However, the formal link between the core strategy and the R&D process also needs to be implemented beyond a project-to-project basis. CAC #1 is the implementation of a portfolio management process.

The existing R&D process is a six-phase, stage gate process that encompasses the development of new products. Currently, there still is no process to manage activities prior to the development of new products, such as the identification of key and pacing technologies, or radical and/or fundamental R&D activities, or to link those activities to the core strategy. A new pre-NPD process needs to be developed and implemented. This process would encompass management of the existing and R&D in-process products to the core strategy, separately evaluate and assess the viability of radical and fundamental R&D activities plus key and pacing technology activities. Additionally, by looking at activities from a portfolio viewpoint, Acme Medical will realise that it needs to increase investments in radical and fundamental R&D efforts to ensure long-term prosperity.

CAC #2 is the separation of technology management from product development. Portfolio management also achieves this goal to ensure that undeveloped technologies do not enter and bog down the NPD process.

The identification and proactive use of metrics to assess the portfolio viability is CAC #3. Appropriate portfolio metrics must be identified, defined and monitored in order to determine if R&D activities are producing results supporting Acme Medical's business objectives. Two papers (Cooper, Edgett and Kleinschmidt &, 1997, Cooper, Edgett and Kleinschmidt, 1997) offer many best practices from an array of companies and industries.

Gap #2: All three components needed in the core strategy are not completed and disseminated to the company.

The new core strategy unveiled during this project was incomplete as provided. Exhibit 2 compares the strategy as presented to the recommendations in the book Design and Marketing of New Products. (Urban and Hauser, 1993) CAC #4 is to provide a complete strategy. These gaps in the core strategy need to be closed to ensure that the major driving force behind all R&D activities is unambiguous.

Exhibit 2.

Recommended Strategy Components	Acme Medical Strategy
Systematic diagnosis of the threats and opportunities in the environment,	Coverage on the opportunities in the environment is very good, however, very little information on competitors beyond the expiration of one key patent.
Inventory of the organisation's strengths and weaknesses, and	Virtually none. Acme Medical is set up in "Centers of Excellence", however, some of these sites currently do not have the knowledge to be the Center of Excellence even though they have the responsibility.
An understanding of the key phenomena underlying demand and competition.	Coverage on the key demand phenomena is good; but again, very little information on competitors beyond the expiration of a key patent.

Gap #3: The markets in which the company participates are not clearly understood.

After the sale of Acme Medical, two of the most knowledgeable marketing people left the company. These individuals had in-depth knowledge about the target markets and clinical experience. The result of their departure is limited marketing knowledge at Acme Medical regarding its target markets, and tactics to attack those markets. Therefore, CAC #5 is to pursue and acquire knowledgeable marketing resources. Most of the individuals in the marketing area have limited marketing-based experience or only have sales experience. These individuals tend not to focus on the long-term objective, but rather the immediate customer needs. Acme Medical needs to reassess the marketing skill base against the company needs, and adjust accordingly.

CAC #6 is to perform target market profile analysis and definition as part of the portfolio management process, and then disseminate that information to R&D. As mentioned in CAC #5, too little is done to identify and exploit target markets. Current market research consists of collecting information from focus groups on specific business proposals instead of casting the net wide and seeing what is caught. Most customer needs are based on what customers like and dislike about the products they use today. Although some incremental R&D activities can be based on this information, Acme Medical will not identify any untapped high-potential markets in this manner, or what Noriaki Kano calls Excitement Quality. (Urban and Hauser, 1993)

Gap #4: Disciplined execution of the stage gate NPD process by the project teams is not actively promoted.

The Delphi panellists overwhelmingly agreed that the current stage gate process supports the success of R&D projects. So why has R&D success been lacking in the recent past? Senior management verbally supports the stage gate process, and has expressed the desire to see project managers take more responsibility, exhibit more authority and provide more leadership to the project teams. However, unless the senior management team shows these same attributes, project managers feel that they are being set up. Most project reviews tend to be monologues by the project manager; senior managers ask very few questions, and many exhibit little interest. Therefore, CAC #7 is to motivate senior management to actively embrace the stage gate NPD process, get actively involved early in the R&D process when they have the most influence over the product outcome, thereby fulfilling their critical role as the stage gatekeepers. This is a common problem and is documented by Roberts (Roberts, 1977) and more recently, by the IRI. (Industrial Research Institute, 1999)

CAC #8, identifying and proactively using metrics to assess project and technology viability and progress, is similar to CAC #3, but is applied at the project level. Metrics bring three fundamental benefits to the NPD process: a) they determine where a project is in the R&D process; b) they determine where a project is in relation to where it should be according to the project plan, and most importantly; c) they provide input upon which to act. A good starting point is the list of deliverables required for each of the six phases.

Gap #5: Functional collaboration to achieve business goals instead of functional goals is not actively promoted.

Active promotion of functional collaboration can be a most difficult change as it is cultural in nature. Greg Brenneman, president and COO of Continental Airlines, stated in a recent article regarding the turnaround of Continental: "In the span of a couple of months, we replaced 50 of our 61 officers with about 20 individuals. We were cutting bureaucracy and costs but also putting important stuff – like the right culture – back in." (Brenneman, 1998) There is a lot to say for the positive influence this action has on the general workforce.

Assuming Acme Medical does not want to apply Brenneman's radical approach, CAC #9 recommends that the GM motivate senior management to actively embrace the achievement of collaborative business goals. Since collaboration for the sake of R&D success is important to the company success, this is a core value that must be identified and dynamically supported by the GM and his senior managers. Each manager must be personally responsible for positively contributing to the success of R&D projects, based on the actions and priorities placed on these activities, not solely on the verbal commitment provided. Only the GM can make this happen.

CAC #10 requires the assignment of NPD project team members based on the employee's skill set and desire to succeed. A common assumption by the functional manager is that all representatives from a particular function have the skill set to perform the required project activities. This is a poor assumption. Past projects have shown that particular individuals have the required skills and abilities, and others do not. However, this does not seem to influence the decision of which person the manager assigns to the project team. Too many managers keep the resources they perceive as most effective for their own projects and assign whoever is left to the R&D project. Functional managers need to assess their employees' skills and assign team members based on those skills.

CAC #11 is to develop NPD team members' knowledge of the NPD process and contributions provided by each function. If all functional representatives are able to perform the activities required on a project team, the manager has more leeway in assigning individuals and those employees that have both R&D process and special functional skills can be retained to perform functional projects. Individual learning must also be complemented by team learning. Individual skills brought to the team are fully utilised only when the other team members acknowledge and appreciate the individuals' contributions. Peter Senge calls this "alignment" and states: "… alignment is the *necessary condition* before the empowering individual will empower the whole team." (Senge, 1994) This represents CAC #9, collaboration of individual departments toward a common business goal.

Gap #6: Existing weak matrix organisational structure is not effective.

CAC #12 is to evaluate the current structure and determine if it supports the business goals. Most likely it does not, as the current organisational structure focuses on functional department segregation and contributes to the non-collaborative attitude identified in Gap #5. One Delphi panellist commented that functional managers run projects, not the project manager, because they control the resources. A strong matrix structure should be considered to help develop a collaborative attitude between functional departments. This means that project team members report directly to the project manager. This in conjunction with CAC #13 will provide a greater chance for project success by meeting schedule, budget and all required deliverables.

Training and actively empowering the project manager role is CAC #13. Although Acme Medical employees are motivated to be successful, it is difficult to achieve success if the employees do not have the correct skills and authority. First, project managers must be chosen by the character traits needed to successfully lead a project including: seeing the big picture, having strong facilitation skills, being well organised, having credibility as a leader, and being tuned into team members concerns. Second, project managers must be educated in the skills needed to successfully lead a project. So often great engineers are promoted into management positions without the necessary skills to succeed as if being a project manager is a natural progression. Senior management must assume that new project managers do not have all the appropriate skills and train them accordingly.

VALIDATION OF CORRECTIVE ACTION CONCEPTS

LCA was performed to verify that all 13 CACs developed from the Delphi panel data are important factors in an effective and efficient R&D process. This involved determining whether relevant authors identify the CACs as important characteristics in their literature. (Holsti, 1969 & Krippendorff, 1980)

Study parameters

A protocol was developed that included the objective of the protocol, definition of important terms, the study parameters (assumptions, analysis design, population information, definition of the categories, recording units, context unit, system of enumeration and sample size), the procedure, and the method of data analysis. A total of 326 articles published in the last five years were screened and 164 were selected as the population of information. The sample size was a minimum of 30 articles. The 164 articles were each assigned a random

number by a computer. The highest and lowest 15 number values were selected as the sample. Each of the 30 sample articles was encoded in its entirety.

Latent content analysis results

The encoding process resulted in the collection of 136 data points showing the key was present in the article and important, 614 data points showing the key not was present in the article, and 0 data points showing the key was present in the article and unimportant. The "category present in the article and important" recording unit was crucial, and was the supportive recording unit to validate the CACs. A simple frequency analysis recognised that all CACs were discussed in at least one of the sample articles and as such, the CACs are validated as important factors in an effective and efficient R&D process. This analysis is presented in Exhibit 3.

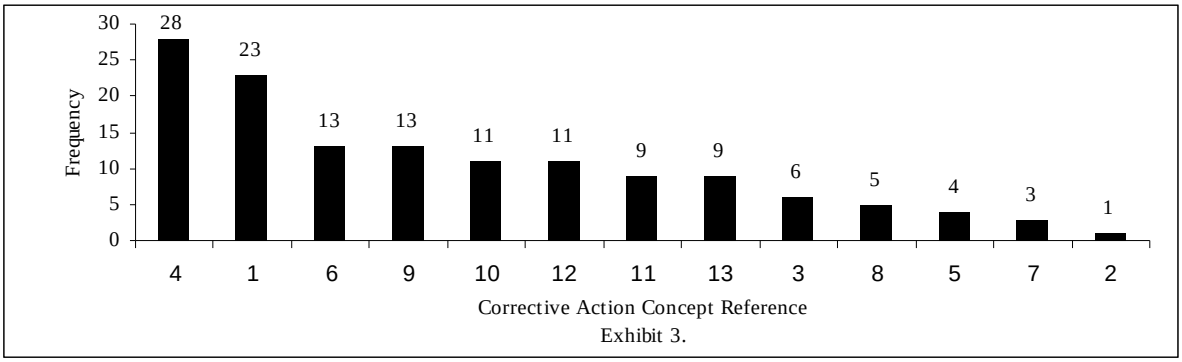

Exhibit 3.

CONCLUSIONS

The researchers recommend that Acme Medical use this paper as a benchmark of the NPD current process and as input for improvement. There is still much work to do; identification of the issues is only the first step toward resolving them. All 13 CACs need to be operationalised to close the gaps between the second-generation and the third-generation R&D processes. However, prioritising and implementing limited resources is a reality of the business world. Therefore, Acme Medical should focus first on at least CACs #4, #1, #6, and #9. These were selected because they account for over 58 percent of the validation data points in the LCA. These four CACs provide the vision, management and collaboration fundamentals needed to move towards a third-generation level of R&D. As with most cultural changes, senior management support and dynamic involvement is critical. With this information, senior management may elevate the performance of their R&D process.

Factors affecting data validity

Due to the selected methods and implementations, a number of factors were encountered during the project that may affect data validity. Both Delphi survey construction and LCA encoding inherently limit the response range and possible findings. However, desire for reliable methods require that some validity tradeoffs be accepted. While the awareness of these factors may eliminate much of their potential negative effect, some are inherent in the methods selected and are unavoidable. To every extent possible, known factors that may impact data validity were eliminated or minimised. The following factors remained:

- During this project, Acme Medical was sold to the Parent Medical Corporation. This dynamic environment may account for some variation in the Delphi panel results, such as those relating to the core strategy.

- Communication or lack thereof within the company created very different perceptions among the panellists on some characteristics. Again, core strategy is a key example. Even after releasing the new core strategy, two panellists interpreted the strategy in different ways. While the feedback mechanism of the Delphi method was utilised, it may not have been implemented in enough detail to convince all the panellists.

- Many of the differences in the panellists' responses can be explained by the panellists past experience with the R&D process, and more specifically, the program from which the panellist came. Prior to the sale of

Pre-Acme Medical, the R&D organisation was structured into two distinct programs: “A” and “B”. These programs had very different levels of success with the R&D process: the “A” program produced four products in the past five years; it has been 10 years since the “B” program has released a new product to the market. Much of the “B” program's troubles have been with management cancelling projects based on changing corporate strategies. The data reflect this when stratified along panellists from these two programs. Two different paradigms currently exist within the R&D department, and they are based on the past success, or lack of success, of the two dichotomous programs.

- Data collection for the content analysis study should have been performed by a group of impartial individuals. This is more important for LCA, since it is more subjective, than manifest content analysis. Due to time constraints, the researchers alone collected the data. While the researchers' awareness of this factor prior to data collection may have eliminated some of the potential negative effect and every effort was made to be objective, these data are perceived as less reliable than if collected by a group of impartial individuals.

Acknowledgments

The researchers would like to thank the eight Delphi panellists from Acme Medical for their help and assistance.

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