BENCHMARKING OF A MEDICAL DEVICE COMPANY'S PRODUCT DEVELOPMENT PROCESS

by

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B.S. Biomedical Engineering (2004)

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SUBMITTED TO THE SYSTEM DESIGN AND MANAGEMENT PROGRAM

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE IN ENGINEERING AND MANAGEMENT

AT THE

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

May 2012

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ABSTRACT

In todays' global economy, having a lean operation is no longer considered a competitive edge; rather has become the new necessity and norm [15]. The new source of this competitive edge is innovation [15]. What sets an organization apart from its competitors is the ability to develop products that constantly meet customers' demands. An organization must have a New Product Development Process (NPDP) that enhances, expedites and fosters development of innovative products on consistent basis in order to tie innovation to market success. Many organizations have a difficult time determining whether or not the NPDP they are using is adequate because there are no standard methods or processes that organization can use to assess their NPDP [16]. In order to assist a specific medical device organization to assess its NPDP, a partnership with Performance Measure Group (PMG) was established. PMG is a leader in benchmarking and performance measurement. This thesis gives insight into the various new product development and benchmarking processes that are in practice today. It

also explores the challenges and benefits associated with conducting benchmarking. Finally, this thesis reveals some of the challenges that this particular medical device company confronts with their NPDP.

ACKNOWLEDGEMENTS: FAMILY AND FREINDS

Thank you to my father and mother, Moussa and Parvaneh, who have made many sacrifices in their lives so I can have better opportunities in my life. I would also like to thank my brother and sister, Sami and Sahar, who have always been supportive of what I do.

Thank you both Michal Berdugo and Cynthia Yee for editing this paper. You are both wonderful friends and I am very lucky to have you. I would like to thank you both for all the time you spent editing this paper.

DEDICATION

This thesis is dedicated to the memory of my grandfathers and grandmothers: Sasson Zelkha, Victoria Zelkha, Abraham and Anbar Navian.

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Professor Daniel Whitney is a great mentor and teacher. Throughout this thesis he has guided me to think differently and explore new ideas. I have learned many things from Professor Whitney, but above all, he has thought me the art of asking the right questions. I am forever grateful to Professor Whitney and I am very fortunate to have him as my advisor and mentor.

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I would like to thank other members of Massachusetts Institute of Technology who have always supported and helped the SDM students achieve success. I have never worked with a finer group of people who have tirelessly committed themselves to making SDM a better place. Thank you to Pat Hale, Chris Bates, David Erickson, Helen Trimble and Bill Foley.

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I would like to give a special thanks to member of PMG without whom this thesis would have been possible. PMG is a great organization that has pushed the boundaries of benchmarking and performance measurement throughout the years. I have been very fortunate to have had an opportunity to work with the PMG group and to learn from the best professionals in the industry. I would like to especially thank the following members of the PMG organization who allowed me to utilize their knowledge and their processes to conduct this benchmarking study. Thank you to Brad Householder, Glenn R Heywood, Steven Coates, Sharad Narayan and Douglas Billings.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF ACRONYMS

Acronym	Meaning
BIC	Best In Class
BOM	Bill Of Material
CLIA 88	Clinical Laboratory Improvement Amendments of 1988
CM	Contract Manufacturer
COGS	Cost Of Goods Sold
E.U	European Union
EBIT	Earnings Before Interest and Taxes
ECO	Engineering Change Order
FDA	Food and Drug Administration (U.S)
FEL	Front-End Loading
IVD	In-Vitro Diagnostics
KPIs	Key Performance Indicators
KPIs	Key Performance Indicators
KPLs	Key Performance Levers
ND	No Data
NPDP	New Product Development Process
NR	No Response
ODM	Original Design Manufacturer
PAC	Product Approval Committee
PACE	Product And Cycle-time Excellence
PD	Product Development
PDP	Product Development Process
PIB	Product Innovation Benchmark
PLC	Product Life-Cycle
PMG	Performance Measurement Group
POC	Point Of Care
PPP	Pre-Project Planning
PRTM	Pittiglio, Rabin, Todd & McGrath
PwC	PricewaterhouseCoopers
R&D D1	R&D Division One
R&D D2	R&D Division Two
RDEI	R&D Effectiveness Index

SG&A	**Selling General & Administrative Expense**
SMBG	**Self-Monitoring of Blood Glucose**
TDT	**Technology Development Time**
TTM	**Time To Market**
U.S	**United States**
WIC	**Worst In Class**
FFE	**Fuzzy Front End**
WWII	**World War II**
NASA	**National Aeronautics and Space Administration**
PRP	**Phased Review Process**
DCG	**Design Control Guidance**
510 (K)	**Premarket Notification**
DSM	**Design Structure Matrix**

1 INTRODUCTION AND MOTIVATION

1.1 INTRODUCTION TO MEDICAL DEVICE INDUSTRY

The United States Food and Drug Administration (FDA) is the regulatory body that defines and regulates the medical device industry in the United States. Other nations, such as the members of the European Union (EU), Japan and China have their own regulatory bodies. Throughout this paper, medical devices are defined according to the formal FDA definition: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals" [13]. The FDA definition of medical devices is broad and covers everything from a tongue depressor to pacemakers to a variety of medical imaging devices.

Medical devices have been used by humans for centuries. Medical devices such as tweezers and ear scoops dating back to 3000 B.C have been found in Egypt. Human remains from the Roman and Greek eras have been recovered with drilled holes in their skulls suggesting that some kinds of surgeries were performed using various tools [17]. Al-Zahrawia, a physician who lived in the In the 10th century, published a book titled Kitab al-Tasrif in which he describes various medical devices from his time used to perform medical surgeries shown in XXX [10]. While some of the medical devices from this time are still in use, the highly specialized medical device industry in the United States of today dates back to the early Nineteenth century. Prior to the FDA regulation of the medical device industry, medicine was decentralized and consisted of general practitioners [18]. Today the medical device industry is

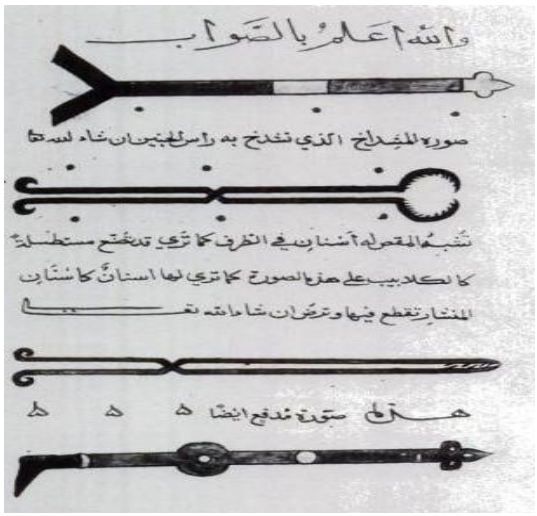


Figure 1: Al-Zahrawia Illustration of Various Medical Devices of 9TH & 10TH Century [10]

a result of the shift from the use of subjective evidence provided by the patient to objective evidence obtained by mechanical and chemical technology devices [18]. This, coupled with a demand for better care by the patients, and advancement in physics and chemistry, fueled the formation of specialized medical device industry [18].

1.1.1 Medical Device Industry Market Overview

The medical device industry is a major part of today's global economy. As of 2010, the medical device industry's total global revenue reached $296.81 billion and it is estimated that this market will grow by 6% to reach total revenue of $314.62 billion by 2011 as shown in Figure 2 [5]. The red arrows in Figure 2 shows the growth trends that is predicted from 2008 to 2011.

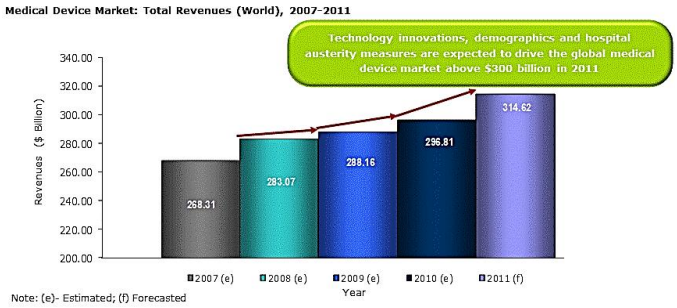


Figure 2: Medical Device Market-Total Revenue: 2007 to 2011 [5]

The 2008 recession did have an impact on revenue for the medical device industry. The recession primarily impacted the industry's revenue in the United States and the European Union. The EU region experienced a largest decline in revenue from 2008 to 2009 as shown in Figure 3 with red arrow. However, this reduction in revenue was offset by rise in demand from Asia Pacific countries as shown in Figure 3. Research conducted by Frost and Sullivan concluded that the industry recovered swiftly from the 2008 recession.

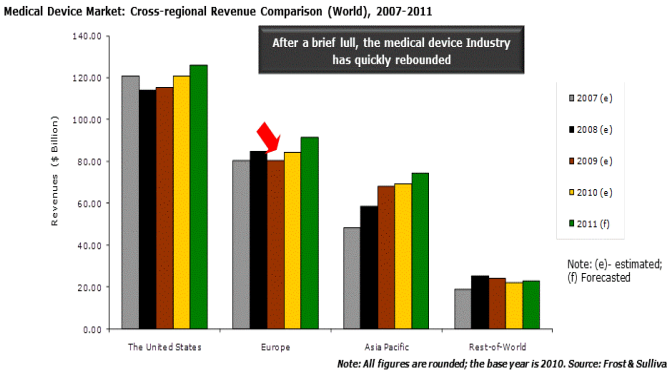


Figure 3: Total Revenue Based on Major Markets:2007 to 2011 [5]

In 2009, the United State alone spent $2.5 trillion dollars on healthcare; this amounted to 18% of its total GDP (U.S Healthcare spending).Today, 40% of the total global medical device industry revenue is from United States, which is by far the largest market. This is followed by the European Union and Japan [4].

In 2007, there were as many as 5,300 medical device companies competing for revenue in the United States [19]. Interestingly, the medical device industry, with revenues approaching $300 billion per year, is primarily controlled by only 30 major companies, which comprise nearly 80% global revenue (Figure 4). The remaining 20% of the medical device market revenue is shared by multitude of medium and small organizations [19]. Seventy-three percent of medical device companies in the United States employed less than 20 people and as such are categorized as small businesses.

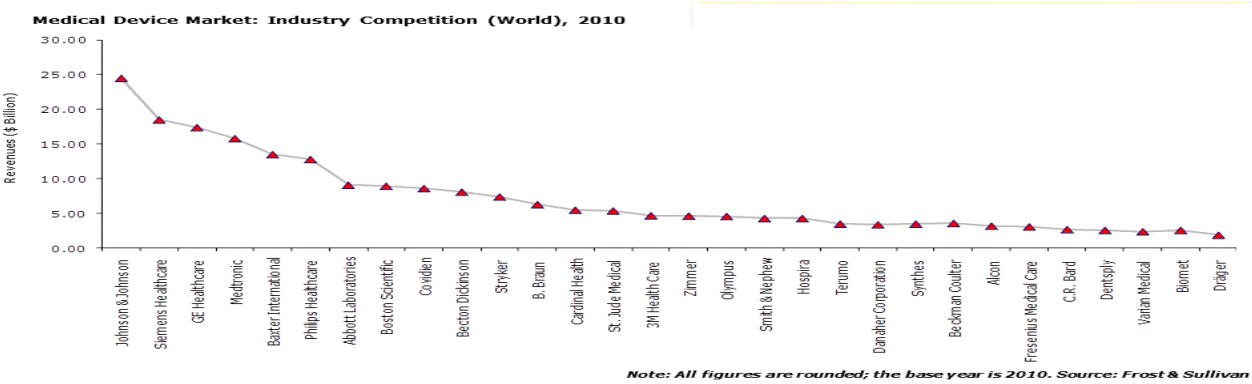


Figure 4: Medical Device Market: Top 30 Companies Ranked Based on Revenue [4]

Market research has categorized medical devices into twenty-one specific subcategories based on different medical field specialties. The Compound Annual Growth Rate (CAGR) versus current market size for each category is shown in Figure 5. Ten of the largest segments include: Orthopedic, Cardiovascular, Vision Care, Wound Care, Hospital

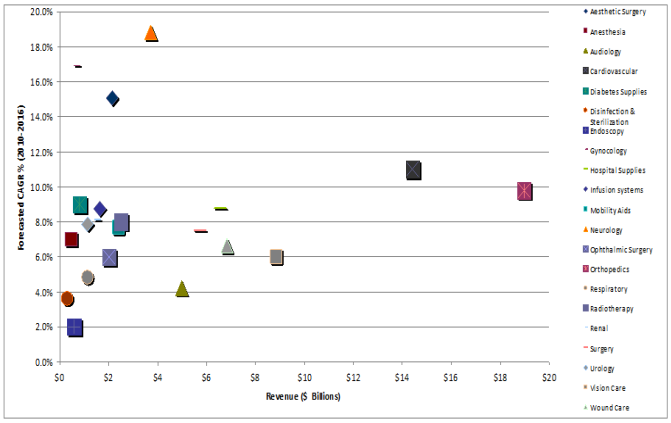


Figure 5: CAGR and Total Revenue Each Medical Device Category [5]

Supplies, Surgery, Audiology, Neurology/ Neurovascular, Radiotherapy and Mobility Aids. This method of categorizing the medical device industry provides a means to view the big picture perspective of the industry because the definition for the medical device is so broad. Figure 5 offers insight into both the annual growth and the size of medical device specialties; however, it does not identify the specific sources of growth within each medical device specialty.

The overall outlook for the medical devices market is positive with an annual growth rate projected at 6%, which could further increase if the world economy recovers. Currently, the demand for medical devices will likely increase with the increasing demands for better care from East Pacific region and the increasing life span of Baby Boomers who will require ever more medical care as they age. However, if the world economy fails to recover leading, higher unemployment and or further austerity measure taken by nations could potentially impact the growth of the medical device industry.

1.1.2 Medical Devices-In Vitro Diagnostic

To obtain a clearer picture of the medical device industry, medical devices are categorized based on function, settings of use and purposes of use. Medical devices have four main functions: diagnosis, therapy, monitoring, and telemedicine. The diagnostic function is further broken down into in vitro and vivo diagnostic. The primary focus of this thesis is medical devices used for In-Vitro Diagnostics (IVD) for use in laboratory and Point of Care (POC) setting. In-Vitro is a Latin word which means in glass, and it refers to tests conducted outside of living organisms on specimens taken from the subjects [4]. The breakdown of IVD market based on revenue and function is shown in Figure 6.

Type	%	$ Billion
Hematology	7.9	3.1
Tissue diagnostic	5.5	2.1
Self Monitoring Blood Glucose	20.5	8.0
Hemostasis	3.3	1.3
Molecular Diagnostics	9.6	3.7
Point of Care Testing	11.6	4.5
Microbiology	5.6	2.2
Immunochemistry	35.8	13.9
Total	100	38.8

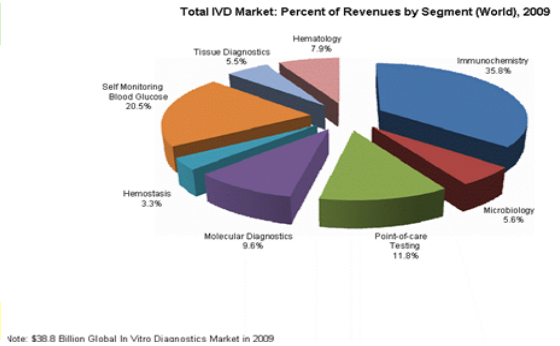


Figure 6: IVD Total Revenue Break Down [4]

IVD devices are typically complex systems that include reagents, consumables and analyzers. The integration of information technology with IVD devices has morphed these devices into intelligent systems. Just like cars today, which provide the driver with more than means of transportation, the IVD devices are capable of providing the users with functions beyond their intended primary use. Today IVD devices are multifaceted; they can generate billing information and automatically log patient test results into databases, give training to the users, perform automated quality control checks and serve as accessing terminals.

1.1.2.1 In Vitro Diagnostic Market Overview

The IVD can be further refined into the following subcategories: Hematology, Tissue Diagnostics, Self-Monitoring of Blood Glucose (SMBG), Hemostasis, Molecular diagnostics, point of care testing, Microbiology and Immunochemistry [4]. In 2009, companies producing IVD devices generated combined revenue of $39 billion dollars, which is expected to reach $50 billion dollars by 2014 [4]. As of 2009, 80% of IVD market was controlled by only 14 companies as can be seen in Figure 7 [4]. Interestingly, this number is up from 2002 where the majority of the IVD market was controlled by only 6 major companies [20]. 2 out of the 6 companies that used to dominate the IVD market in 2002 no longer existed as of 2009 due to mergers and acquisitions. The 14 companies that make up the 2009 IVD market are as follows:

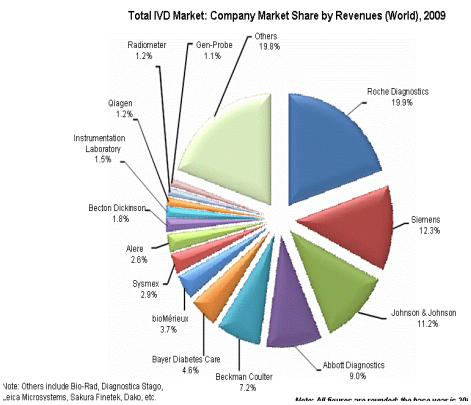


Figure 7: Company Market Share as Function of % Revenue [4]

Roche Diagnostics, Siemens, Johnson & Johnson (J&J), Abbott Diagnostic, Beckman Coulter, Bayer Diabetes Care, bioMerieux, Sysmex, Alere, Becton Dickinson, Instrumentation Laboratory, Qiagen and Radiometer. Several of these companies such as Roche Diagnostic compete in all types of IVD, while others such as Radiometer specialize in one or two types of IVD area.

It is important to note that not all parts of the IVD market will experience same level of growth in the future. The forecasted growth for different segments of IVD market is displayed in Table 1.

Table 1: Predicted Revenue as Function of IVD Type [4]

Total In Vitro Diagnostics Market: Revenue Forecasts by Segment (World), 2007-2014

Year	Immunochem. Revenues ($ Million)	Microbiology Revenues ($ Million)	Point-of-care Revenues ($ Million)	Molecular Dx Revenues ($ Million)	Hemostasis Revenues ($ Million)	SMBG Revenues ($ Million)	Tissue Dx Revenues ($ Million)	Hematology Revenues ($ Million)
2007	13,041.3	2,078.7	3,942.6	3,032.2	1,187.0	7,695.7	1,702.7	2,951.2
2008	13,791.2	2,120.3	4,187.1	3,387.0	1,228.5	7,965.0	1,918.9	3,054.5
2009	13,876.6	2,158.5	4,584.8	3,708.8	1,274.6	7,965.0	2,139.6	3,054.5
2010	14,292.9	2,208.1	4,814.1	4,079.7	1,331.9	8,004.8	2,394.2	3,045.4
2011	14,979.0	2,269.9	5,117.4	4,508.0	1,398.5	8,084.9	2,683.9	3,045.4
2012	15,847.8	2,349.4	5,470.5	5,003.9	1,475.5	8,230.4	3,008.7	3,045.4
2013	16,877.9	2,443.3	5,858.9	5,569.3	1,564.0	8,419.7	3,375.7	3,091.0
2014	18,076.2	2,538.6	6,269.0	6,209.8	1,657.8	8,680.7	3,794.3	3,152.9

For example it is expected that the Molecular Dx revenue will double from 2007 to 2014 while Hematology revenue will only grow by 7% total for 7 years or by 1% per year.

1.1.2.2 IVD Market Drivers Challenges and Trends

Frost & Sullivan conducted a market research of IVD market in 2010. Frost & Sullivan reports the major drivers, challenges and trends for overall IVD Market; this is shown in the following Figure 8. The overall message of this report suggests that the IVD market will remain competitive and that the competition will increase. Relative to the device itself, the two most significant trends are automation and connectivity.

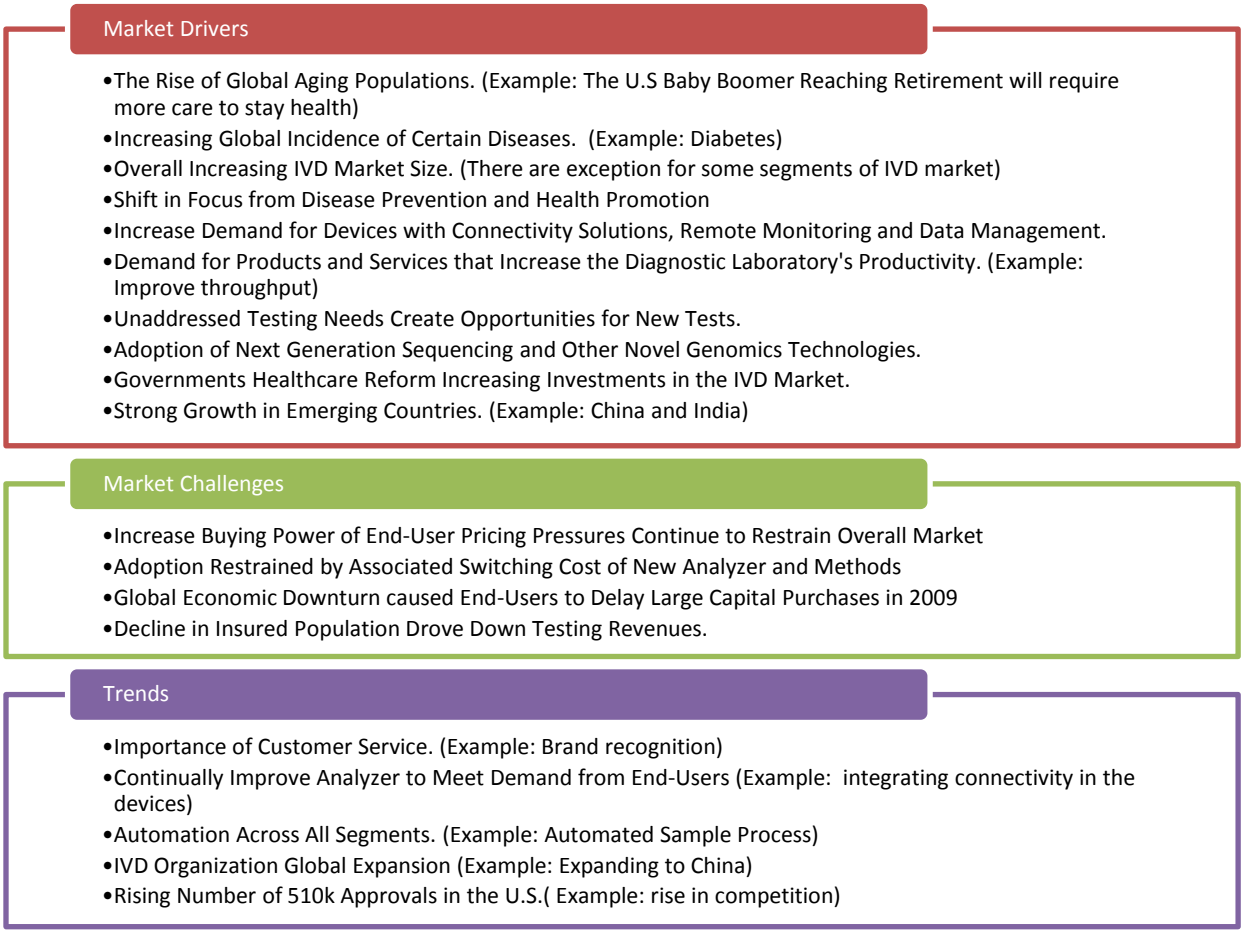


Figure 8: Market Driver, Challenges and Trends [4]

Opportunities for the use of medical devices within emerging markets are growing; but the demands in these regions of the world are not well-understood. While the demand in emerging markets such as China and India is growing rapidly, a large segment of the population is still poor and live in rural areas. While major urban hospitals will acquire the latest and most advanced medical devices for their care centers, there are major potential markets in rural areas that have not yet been capitalized upon due to obstacles in affordability. Some organizations are beginning to recognize the potential of this segment of the market. For example, “In 2009, GE introduced a $1,000 electrocardiogram device and a $15,000 portable ultrasound machine that it had developed in rural India and in rural China, respectively. That new paradigm, dubbed "reverse innovation," has the promise to bring lifesaving technologies

to developing countries and to establish lower price points for products in existing markets therefore presumably generating a healthy stream of sales in both markets." [21].

1.1.3 Regulation of Medical Device Development

The FDA is one of the most important stakeholders for medical device companies given that it is currently the gatekeeper to the larger IVD market in United States. Starting in 1976 FDA became actively involved in regulating the medical device. Prior to 1976, medical devices were loosely regulated where, companies did not even have to follow any Good Manufacturing Practices (GMP), maintain records or report product requirements. Most importantly, IVD manufacturers did not have to get FDA approval for their product[22]. In 1976, FDA passed an amendment to required medical device companies to register with FDA. Medical Devices were categorized into three classes. Class I medical devices consisted of devices such as tongue depressor. These devices are simple and not used for sustaining or supporting life and are subjected to least regulatory control known as "general controls"[22]. Class II medical devices are devices such as glucose meter, X-ray, MRI perform functions that require more regulatory oversight. These devices have the potential to harm individuals. The FDA has more stringent rules for approval of such medical devices. These devices must meet both the "general controls" and "performance standards" to be qualified by FDA [23]. The Class III is the last class; this class includes devices such as pacemaker, artificial heart. These are medical devices that support or sustain life or critical to preventing impairment to humans, thus they are subjected to the most stringent oversight by FDA [22]. Class III devices are required by the FDA to obtain a premarket approval prior to distribution.

In 1990, the Safe Medical Devices Act (SMDA) was passed which gave the FDA the power to impose civil penalty and recall authority over medical device companies [23]. THE SMDA also gave FDA two tools, which are "post-market surveillance" and "device tracking". Both of these tools are applied to class II and III devices and require medical device company to monitor their products performance after the product is sold to customers. In, 1996 FDA came up with the Quality System Regulation (QSR) which adopted the ISO 9002 and required medical device companies to have processes for design, purchasing and servicing of medical devices

[22]. QSR also requires medical device organizations to trace user needs throughout the New Product Development Process NPDP to the final product (Figure 9). The FDA does not require medical device company to follow any particulate NPDP as long as the process satisfies the FDA traceability requirement.

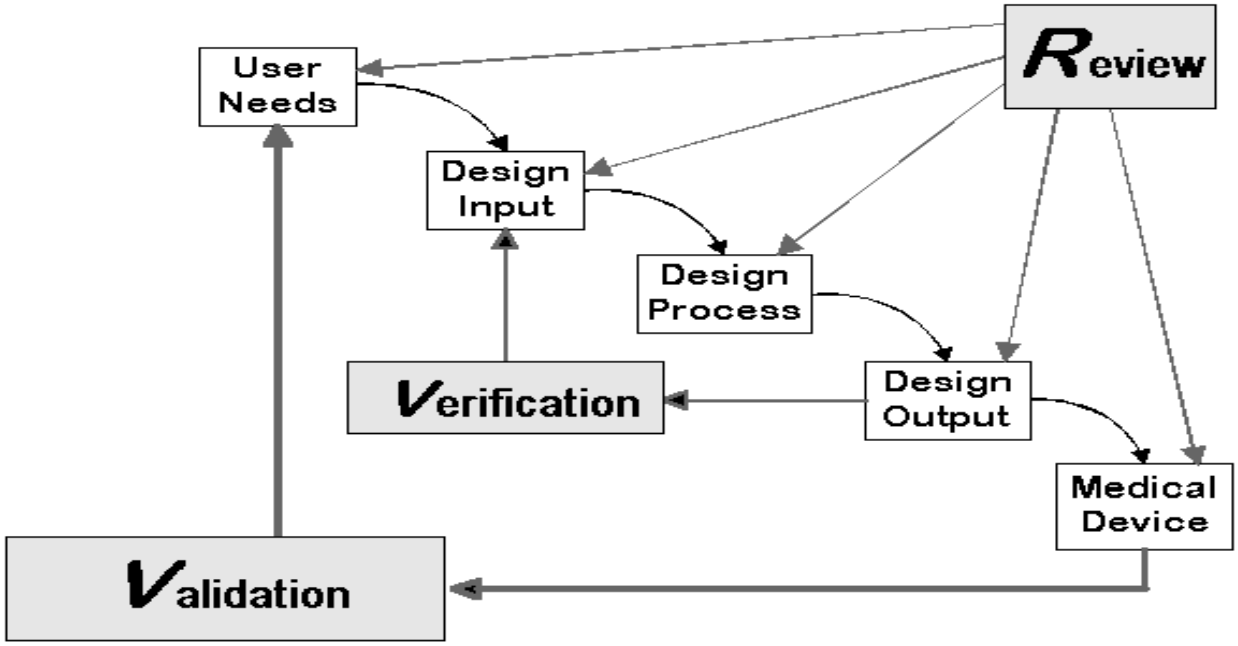


Figure 9: Application of Design Controls to Waterfall Design Process [13]

However, in order to meet the QSR, medical device organizations are required to choose NPDPs that enable the organization to maintain full traceability.

1.2 OBJECTIVES

The IVD market segment is going through a tectonic change. Some segments of this market that are currently profitable will experience stagnation and while other segments will experience rapid growth and increased market size. IVD companies that specialize in specific IVD segment or segments which are experiencing stagnation must work hard to maintain product differentiation and innovation of new test menus to spur demand in order to survive. These companies must reduce manufacturing costs and invest in new tests for existing

platforms. The main innovations in this field will be limited to the addition of new features to existing product architecture rather than developing new platforms. The reason for this strategy is because this market will grow at slow pace and investing significant dollars to develop a new platform will be perceived as fruitless, because by the time the product is complete the demand will be furthered diminished by entrance of new competitors from Asia Pacific. R&D failure is not an option because a failure may spell the end of era for such organizations. As a result, some of these companies may choose to expand to other IVD segments that are experiencing growth. This requires such organizations to invest in the R&D groups that can act fast, which requires R&D group to acquire new competencies in order to enter new segments of the market.

The current incumbents in the IVD segment experiencing growth will be under significant pressure to innovative. These organizations will face stiff competition due to market growth opportunities. Growth in emerging markets such as China and India may require these organizations to develop new products that meet the specific market needs of these nations.

One of the most vital qualities of successful organizations in today global economy is innovation. In a 2010 survey conducted by McKinney group, it was found that 84 percent of executives say innovation is extremely important to their companies' growth strategy. In addition, all of companies surveyed expressed that they are actively seeking to grow in the coming years [24]. Today's global economy requires organizations to have a product development process that can consistently produce successful products. Research and surveys conducted over several decades by PRTM, Booz-Allen-Hamilton, McKinsey & Company, Robert Cooper and others have shown that sixty percent or more of the total revenue of successful organizations comes from new products. A new product is defined as product that has not yet reached its halfway point of its Product Life-Cycle (PLC). In order to maintain constant revenue from new products, organizations need to constantly develop new products that maintain the organization's current market share and allow for growth into new markets.

Given the importance of innovations to future of IVD companies, companies must benchmark their NPDP in order to identify the strengths and weaknesses of their NPDP. Once

NPDP is benchmarked, a company must act swiftly to address the weakness of its NPDP. By adopting NPDP best practices, companies will be able to increase their chances of maintaining their competitive edge in this ever-changing and competitive environment.

This benchmark will examine the NPDP of an IVD Company, to identify the weaknesses and strengths of its NPDP. The benchmarking outcome also serves as an independent check to verify if the steps being taken to improve NPDP are valid and that the new NPDP is consistent with FDA application for design and control. The particular company under examination is experiencing rapid growth both in its market shares and in organization size. The R&D group alone has gone from 60 to over 120 employees in less than 5 years. The top management of this organization have always acknowledged that the R&D department is the backbone to the company's success, and consider the R&D group as the key to maintaining future growth. In 2009, the R&D department underwent a major restructuring to address rapid R&D and market demand growth for new products. The process of restructuring included everything from a new workplace which promotes more employee interaction to a new management structure. The strengths and weaknesses of previous NPDP are known to some degree due to a limited 2008 study conducted by a consulting group. As a result, by benchmarking known data, one can verify if the PMG benchmarking method is valid for benchmarking this organization. The following two questions were proposed and addressed as part of this thesis.

1. What are the gaps and strengths of this organization's NPDP?
2. Is the Performance Measure Group (PMG) method of benchmarking valid for this organization?

1.2.1 Methodology

The benchmarking of an organization's PDP is not a trivial task; measuring the overall success of the product development effort has been challenging because there is no widely recognized standard used to measure NPDP effectiveness [9]. In the same vein, using a proven methodology to benchmark NPDP is very important. This thesis was completed in cooperation with PMG a division of PricewaterhouseCoopers (PwC) and a medium size IVD medical device

company. PMG is a well-established organization that specializes in benchmarking. PMG has over 30 years of experience in benchmarking as well as a database that consists of more than 700 organizations.

The benchmarking process conducted for this thesis was completed using two tools: questionnaires and interviews. The questionnaires were developed by PMG. The questionnaires were segmented into five major sections and were given to various individuals who were involved in the projects. After individuals completed the questionnaires, they were interviewed and asked to explain their answers to the questions. The questionnaire results are summarized in a table format in the Results section and the interviews were used to explain the questionnaire results.

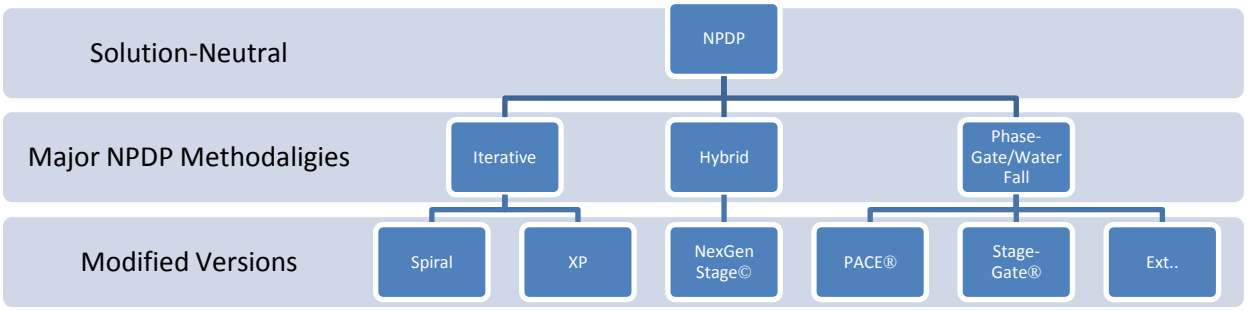
2 LITERATURE REVIEW

2.1 INTRODUCTION

The literature review consists of two topics: New Product development Process and Benchmarking. The New Product development Process literature review will focus primarily on two schools of NPDP philosophy: Phase-Gate and Spiral process. The Spiral and Phase-Gate processes are further explained individually in this Literature Review with examples of their application and use. Bear in mind, NPDP is not limited to only these two methods and there are various approaches that fall in between these two styles of NPDP. The benchmarking literature review examines various benchmarking methodologies. It also covers characteristic of good benchmarking questioner and the process that makes a benchmarking a successful.

2.1.1 What Is New Product Development Process

The NPDP is known by various names that are either too process-specific or too generic. Examples include such names as follow PDP, New Product Process (NPP), Gating System, Phased Review Process, Phase-Gate System, Product and Cycle-Time Excellence (PACE), Spiral Produce Development, Product Launch System and Stage-Gate System (Robert G 1994). The term NPDP is used throughout this thesis because it represents a solution-neutral PDP. The intent of this thesis is to portray a complete picture of NPDP and allow the IVD organization to choose a NPDP that best fits its culture, product lines, and organization complexity.



Just as there are many names for NPDP, there many definitions for NPDP. The NPDP definitions range from fairly simple to complex. Examples of various NPDP definitions by well-known NPDP researchers are compiled below:

"NPDP is a sequence of steps or activities which an enterprise employs to conceive, design, and commercialize a product" -[25]

"NPDP is the "recipe" for producing a product" -[26]

"New Product Process: a formal blueprint, roadmap, template or thought process for driving a new product project from the idea stage through to market launch and beyond" -[27]

NPDP coordinates the cross-functional activities of various disciplines including engineering, marketing, manufacturing, quality assurance, service, purchasing and partners/contractors, that all work together to develop a product that delivers value to its customers [14]. The main intent of the NPDP is to drive ambiguity out of the product development process by providing a framework or template for the development of project plans, milestones, definition of tasks and defining the roles and responsibilities for each discipline with the overall goal to mitigate or eliminate budget overruns, delays, risk and quality problems.

2.1.1.1 Origination of Today NPDP

Organizations have been developing products since the Industrial Revolution [28]. However, the New Product Development Process of today stemmed from NASA's early project management practices [29]. Prior to 1968, the NPDP was not well researched/standardized or even a well-known segment of R&D process [30]. While organizations did practice some form of phase or stage process to develop products, the processes were neither unified and defined nor [31]. NASA's practices became the foundations for today's NPDP such as Stage-Gate system [29]. Post World War II (WWII), the United States' civilian and military industries experienced growth and prosperity which elevated the United States' status among world leaders in the military industry. In order to maintain its competitive status, the U.S created National Aeronautics and Space Administration (NASA) in 1958 with the mission to develop complex

products and conduct cutting edge research to maintain the United States' competitive edge relative to the former Soviet Union [32]. The National Aeronautics and Space Act of 1958 created NASA, which gave NASA governance over 8,000 employees and a budget of $100 million dollars [32]. In order to manage development of complex products, NASA needed to develop a standardized process to manage all of its product development activities to make planning more realistic, to test the validity of the planning, to "harden" concepts into development projects, to serve as a mode of continuous review, develop a standard process across the entire organization and to increase competitions among various R&D labs within NASA [31]. NASA officially introduced its NPDP in 1968 and it called the "Phased Review Process" (PRP) [31]. NASA's PRP was adopted by the U.S military and from there it diffused into the mainstream organizations [29].

2.1.1.2 Adoption of Standard NPDP by Main Stream Organizations

As NASA officially announced its PRP in 1968, academic and consulting companies began research and investigation of the NPDP. Organizations were becoming aware that producing successful products was not a random act. Further, Globalization was already affecting the market environment as early as 1968 and American organizations began experiencing intense international competition [28]. Rapid technological changes required R&D departments to become more efficient and flexible in order to keep pace with rapid market changes [28]. Finally, consumer expectations were changing in the early Nineteen Seventies; consumers started caring about nuances, ease of product use and product differentiation. This resulted in a fragmented and demanding market [28]. The changes in the market along with that desire for an NPDP that could give organizations a competitive edge launched an interest in NPDP. There were two fundamental questions raised at the time that researchers wanted to answers:

1. Does investing more in R&D result in more profit?
2. Does having NPDP give an organization a competitive edge?

2.1.1.2.1 Does Investing More in R&D Result in More Profit?

In 2004, Booz, Allen and Hamilton (BAH), one of most well respected consulting firm in world and the pioneer of R&D best practices tracking, conducted one of the largest and most comprehensive studies to date to answer the question of whether spending more in R&D will result in more profit. 1000 publicly traded organizations from around the world participated in this study. The results from this study was published in 2005 and concluded there is no statistical correlation (Figure 10) between R&D spending and sales growth [6].

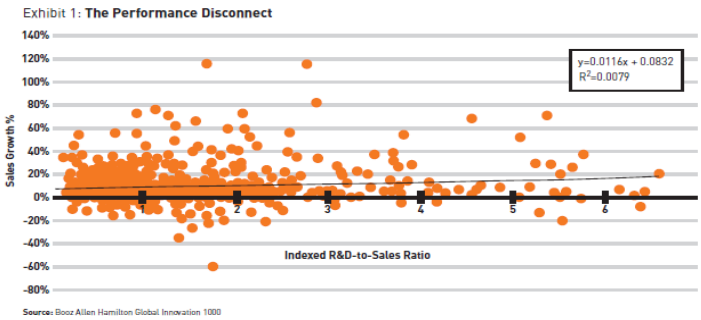


Figure 10: R&D Spending vs. Sales Growth. [6]

"It's absolutely a myth that money alone will solve vexing technical problems. Rather, reckless funding largesse is actually a barrier to transformative innovation as it turns scientists into constituents with an incentive to maintain the status quo. Reasonable constraints are a spur to progress. Entitlement programs for scientists and engineers are a drag."-Dr. Allan O. Steinhardt

While the conclusions showed that spending more did not result in more profit or revenue for an organization, the study also concluded that spending too little on R&D activities hurt organizations in the long term [6]. The BAH study fell short of prescribing a universal percentage of total sales organizations should spend on R&D to guarantee return on investment or to promote growth. The reason that there is no universal prescription for how much money organizations should invest in R&D is determining an ideal budget for R&D spending is a complex task. This task depends on many variables and decision points influenced by endogenous and exogenous forces (Figure 11) such as industry trends, portfolio management, market demand, government subsidies and other variable that are unique to an

organization [6].

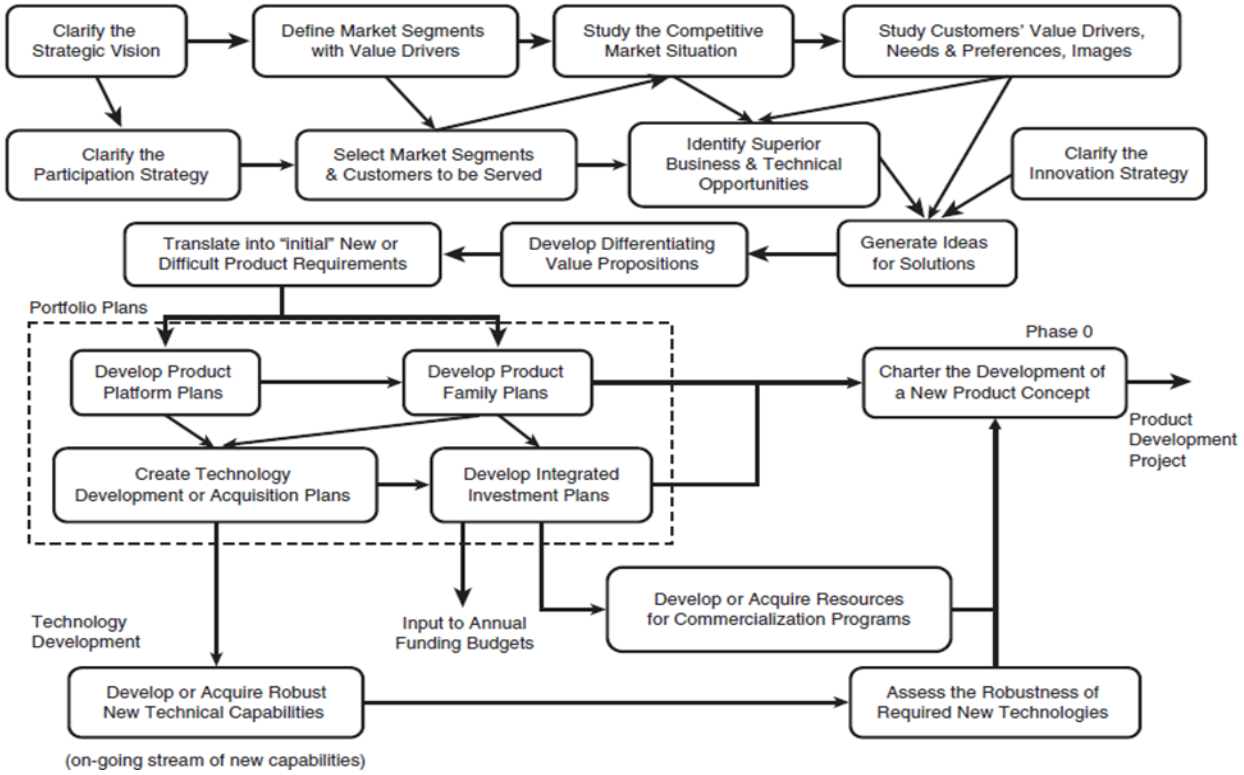


Figure 11: Managements Decision Points [14]

The overall summary of BHA research concludes that successful R&D spending has the right level of investment that is coupled with intelligent processes to select ideas and projects, efficient product development processes and a R&D group that provides interaction between functional groups such as manufacturing and marketing in development process [6].

2.1.1.2.2 Does Having NPDP Give an Organization a Competitive Edge?

Finding the correlation between having a formal NPDP and competitive edge has been challenging. The main challenge has been the fact that implementation of NPDP is difficult and that it takes several years of using NPDP before the implementation can bear fruit [33]

"In 1970s, it took Toyota 7 years to implement a simple product development process in place"- Paul O'Connor 1994 [34]

NPDP adoptions, despite evidence that they can give organizations a competitive edge, have taken place at evolutionary pace rather than at a revolutionary pace because of the complexity associated with NPD [30].

"A firm with static NPD processes, policies and methods will find themselves falling behind. However, not even the Best firms have radically changed the face of product development, or its outcomes."- Abbie Griffin [30]

There have been many benchmarking studies of R&D department conducted in the past 40 years by various consulting firms. Most of these studies have concluded that having a formal product development process will lead to a higher new product success rate [12, 30, 35, 36]. The latest PDMA handbook concluded that top performing organizations all had several common characteristics. One of these characteristics is that they all had developed a well-defined product development process unique to their market and technologies which gave them a competitive edge[33].

2.1.2 Phase-Gate/Waterfall NPDP

2.1.2.1 Introduction

BAH 1968 research found that organizations did practice a form of phase-gate NPDP prior to 1968 [36]. The NPDP practices prior to 1968 was mainly developed in house and was therefore not well-understood [36]. Today's Phase-Gate or Waterfall process is based on research conducted from the 1970s to the 1990s. This was developed on the backbone of NASA's NPDP the Phase Review Process [29]. The PRP was not a successful process for various reasons; it was slow, involved a great deal of built-in bureaucracy and did not involve groups outside of R&D [29, 35]. The Phase-Gate process has been heavily researched since PRP and has been the most widely adopted NPDP by U.S organizations [35, 37-39]. The Phase-Gate NPDP is known by various name such as Waterfall, Life-Cycle Process, Toll Gate, Check Point, Product Launch System, Stage-Gate System and others, but for the sake of simplicity and uniformity in this thesis, the name Phase-Gate will be used [16, 29, 40]. The classic model of

Phase-Gate has 6 phases (Figure 12); however there are various versions of this process that range from four to seven phases [15, 41].

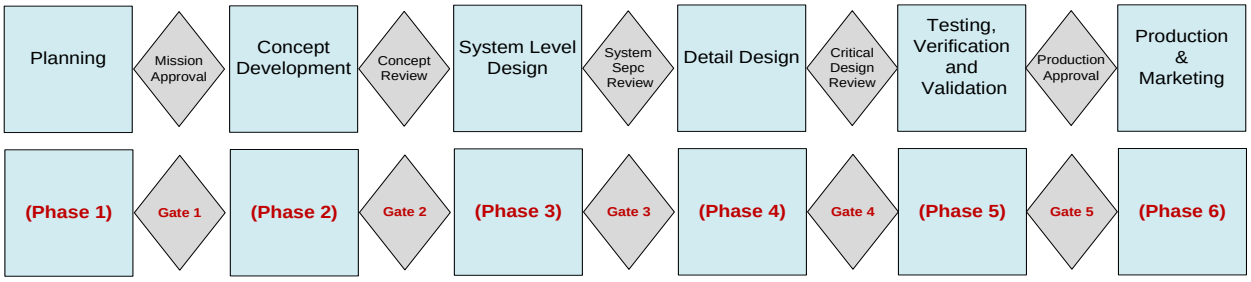


Figure 12: Generic 6 Phase NPDP- The Non-Iterative Version

As the name Phase-Gate suggests, this method breaks down the product development into discrete phases and at the end of each phase there is a gate that serves as a checkpoint to verify that goals for each phase have been met [35, 39, 42]. If goals for a phase are not met, the group will repeat the phase until the goals are met for that phase, as shown by iteration circle (Figure 13). As for Cross-Phase Iteration (CPI), as shown with blue arrow in Figure 13, while it is possible, CPI is expensive and counterintuitive to Phase-Gate Process [40].

The intent of Phase-Review which occurs at each gate is to present the stakeholders with project status and to allow the group to decide whether to proceed to the next phase, stop, or repeat the phase [12]. The group which attends Phase Review is called the "gatekeepers" and usually consists of a cross-functional team including marketing, finance, R&D, management executives, quality assurance (QA), and regulatory and manufacturing personnel [12, 33, 35].

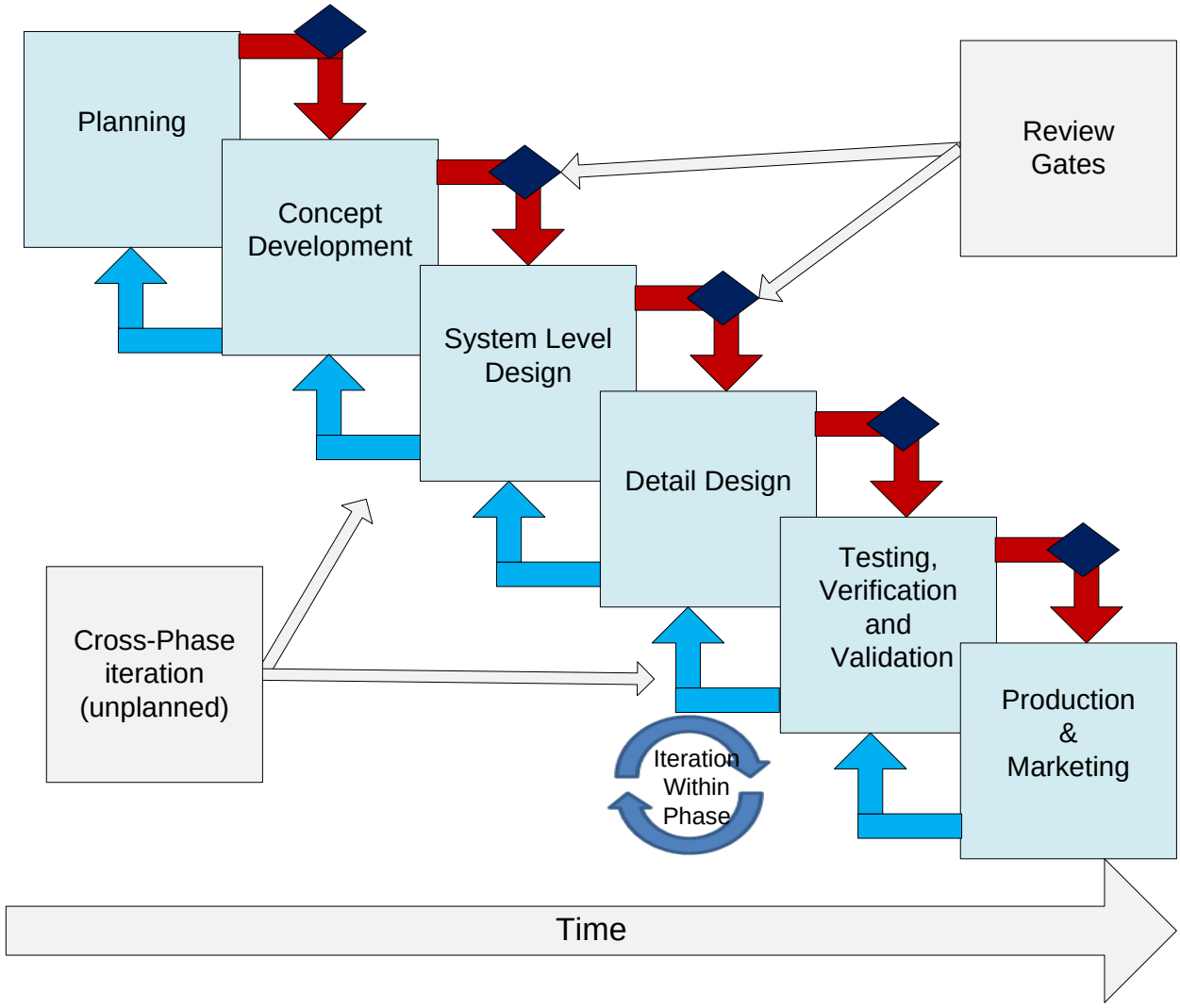


Figure 13: Iterative Phase-Gate/Waterfall

2.1.2.1.1 Advantages

The advantages of Phase-Gate NPDP is having a clear framework that forces the PD group to approach the process in sequence with clear delivery at each gates [43]. If the Phase-Gate process is followed and implemented as prescribed, product definition, requirements and user needs are defined early in the product development process [40]. Another advantage of the Phase-Gate process is that is allows for the discovery of errors early in the product development process when the cost of rework is low [40]. Another advantage of Phase-Gate NPDP is that it brings the transparency of the project development process to upper management and cross-functional groups, such as marketing, QA and manufacturing. Cross-

functional group involvement in Phase-Review passes the responsibility of product success to these groups as well, thus demanding that these groups be proactive in the product development process [12]. For example, by involving the manufacturing group in Phase-Reviews, the manufacturing personnel can confirm that the PD team has met the manufacturing needs. The broadest advantage of the Phase-Gate process is the structure that it brings to the product development process. Finally, the Phase-Gate process reduces R&D spending by eliminate projects where the investment in project is low , very early in phase development [12]. As shown in Figure 14 the management has the option to stop a project at any Phase-reviews.

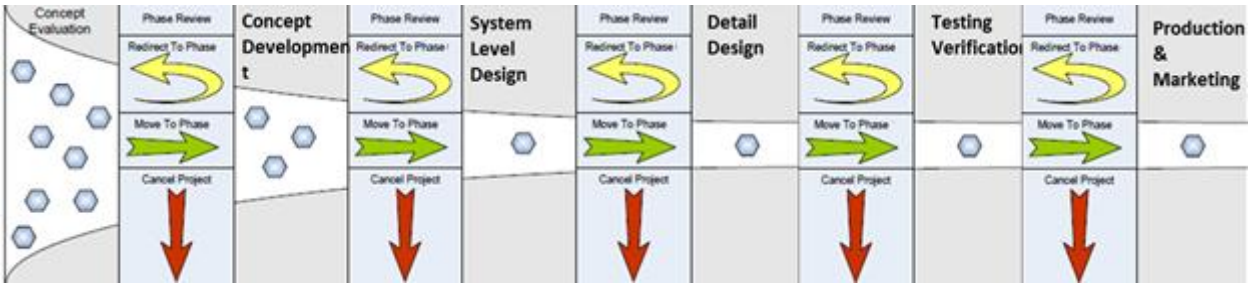


Figure 14: Phase-Gate Go or No-Go Decision Points [12]

2.1.2.1.2 Limitation and Disadvantages

One of the most well-known limitations of classic Phase-Gate is its inflexibility. The Phase-Gate process is sequential. Therefore, if a step within Phase is delayed, this would result in a delay of a Phase-Review which would ultimately delay the whole project [44]. Phase-Gate NPDP does not favor Cross-phase iteration because of the significant cost associated with repeating a phase and added time to the overall product development [44]. These characteristics make the Phase-Gate process unfavorable for use in cases when the user needs, market opportunity, and business case, are not well defined [16, 40, 44]. The Phase-Gate does not handle change or feature creep, the process is not designed to handle scope creep that can occur late phase.

Another disadvantage of the Phase-Gate process is the bureaucracy that it can introduce to NPDP. The intent of Phase-Review is to ensure that the goals for phase have been

met. However Phase-Review can turn into the micromanaging of the technical team by upper management as was the case for NASA during 1970s [31]. McGrath research concluded that the amount of contribution from upper management is reduced as the product advances from one phase to another (Figure 15) [12]. Having all stakeholders at all phase reviews is important, however it is most important to invite the right stakeholders to phase reviews in which they are in a position to bring valuable input [12].

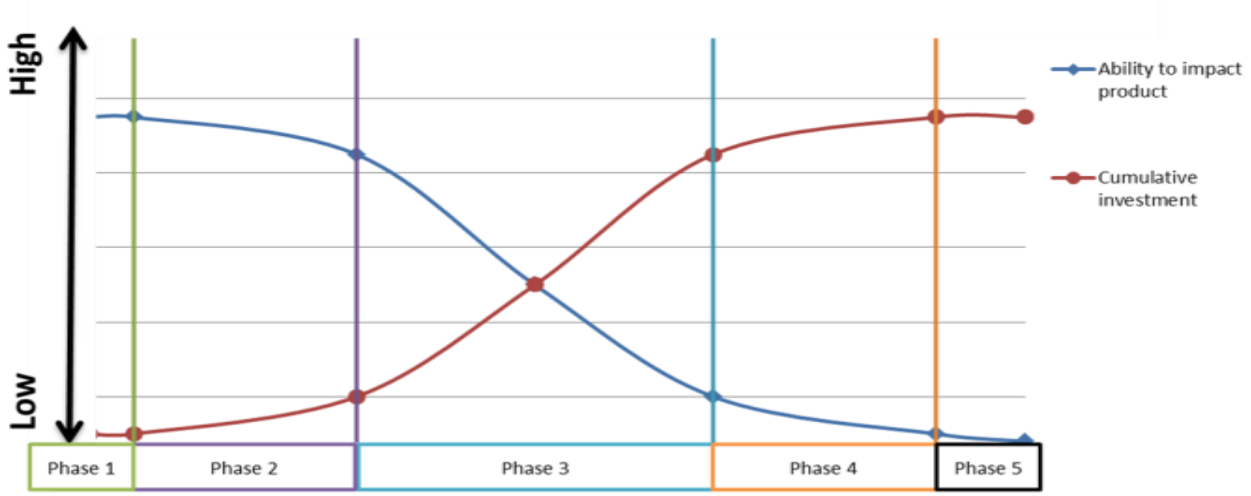


Figure 15: Management Contribution and Impact [12]

2.1.2.1.3 Modified Variations of Phase-Gate

Due to Phase-Gate popularity in United States, many refined and specialized variations of the Phase-Gate process have developed. One popular process is the V- model (Figure 16). This process turns the Phase-Gate process into V shaped process. It takes out Validation and Verification Phase (V&V) and instead it uses V&V as link between phases. This process breaks down the technical risks in order to increase traceability and quality control during the product development process.

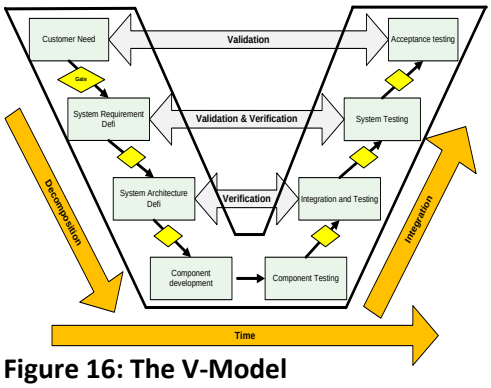


Figure 16: The V-Model

These variations of phase-gate are designed to enhance the generic Phase-Gate process and to address various shortcomings of the Phase-Gate process. At first glance, the major differences between these processes is the number of phases [14]. For example, Basic concurrent engineering by Don Clausing has 4 phases, Product and Cycle-time Excellence (PACE®) and Stage-Gate® Process - two of the well-known Phase-Gate Processes - have 5 phases and Elaboration on the cross-functional Product development process has 7 phases as shown in Figure 17. The real difference between modified Phase-Gate processes is the description of each phase and gate and the emphasis on what best practices the organization should employ [14].

Product and Cycle-time Excellence ("PACE")							
Phase 0: Concept Evaluation	Phase 1: Planning and Specification		Phase 2: Development	Phase 3: Test and Evaluation			Phase 4: Product Release
Stage-Gate Process							
Stage 1: Preliminary Investigation	Stage 2: Detailed Investigation		Stage 3: Development	Stage 4: Testing and Validation			Stage 5: Full Production and Market Launch
Basic Concurrent Engineering described by Don Clausing							
	Concept Phase	Design Phase		Production Preparation			Production
Concept–Development–Optimize–Verify ("CDOV")							
	Phase 1: Superior Product Concept (C)	Phase 2: Baseline Design (D)	Phase 3A: Subsystem Robustness Optimization (O)	Phase 3B: System Integration, Stress Testing and Balancing (O)	Phase 4A: Product/System Design Capability Verification (V)	Phase 4B: Manufacturing Process and Supply Chain Capability Verification	
Elaboration on the Cross-functional Product Development Process							
Phase 0: Clarify business objectives; charter the project	**Phase 1:** Clarify the requirements select and develop architecture and subsystems	**Phase 2:** Complete the requirements optimize system development	**Phase 3:** Design product specifications, processes for manufacturing, service, sales. customer support	**Phase 4:** Verify product designs; begin production and supply chain preparations	**Phase 5:** Prepare for production product launch, sales, service and customer support	**Phase 6:** Verify readiness for market entry	**Phase 7:** Launch production and customer support

Figure 17: Various Versions of Phase-Gate Processes [14]

The most important difference between the generic and modified processes is the implementation of parallel activities that can occur in these modified processes [25, 38, 42, 44-

46]. For example as shown in Figure 18, multiple subsystems design activates can occur in parallel.

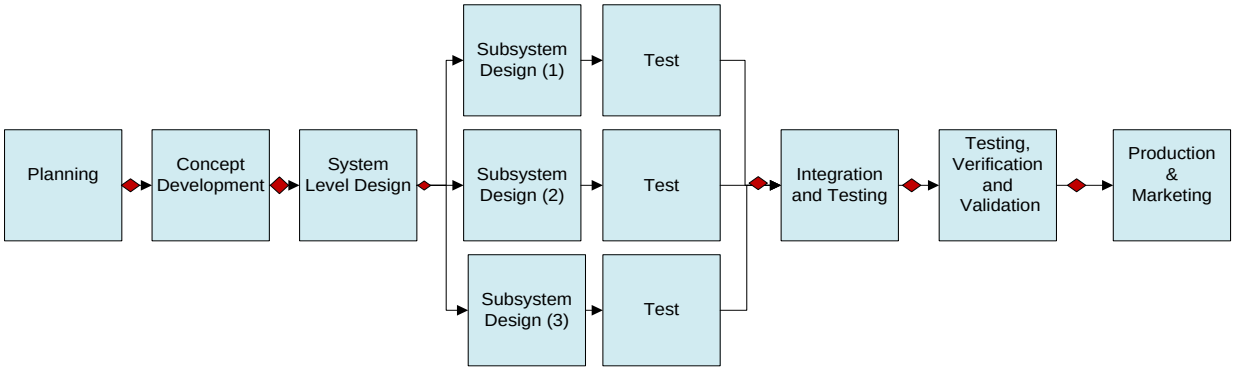


Figure 18: Typical Modified Phase-Gate

There are other added values that these modified Phase-Gate processes bring that go beyond boundaries of NPDP. The major added value relates primarily to portfolio management. There are other benefits, however covering all of these benefits is beyond the scope of this thesis. These added values could provide wider differentiation among these processes if the organization decides to go with the Phase-Gate process.

2.1.3 Iterative NPDP Process

2.1.3.1 History:

The Iterative NPDP Process has become synonymous with the Spiral NPDP Process and software development. However the Iterative NPDP has a rich history that dates back several decades. 1930 Walter Shewhart developed "Plan-Do-Study-Act" (PDSA) cycle as a means to make continuous improvement to processes [47, 48]. PDSA became the backbone of the Iterative and Incremental Development process practiced during development of X-15 (1950s), Mercury and later adopted by IBM Federal System Division [48]. The software development community of 1970s and 1980s was frustrated with Phase-Gate product development [49]. The main source of frustration stemmed from the development of a detailed specification for a

product where user needs where not fully understood. These specifications proceeded with development which resulted in a product that didn't meet the user need [49].

"The Waterfall Model is Wrong!" -Fredrick Brooks 1995

"The waterfall model is dead, No it isn't, but it should be"-Barry W. Boehm 1988

In 1980s Barry Boehm developed the first formalized iterative product development process called Spiral Process to help streamline and manage risks associated with software development [47-49].

2.1.3.1.1 Spiral Product Development Process

Spiral product development process manages the risks associated with not fully knowing the user needs, market size and technologies capabilities, by providing a framework that allows for continuous iterative process until all risks have been resolved. The framework for the Spiral PDP, shown in Figure 19, starts with several iterative cycles in which the team goes through risk analysis, prototype

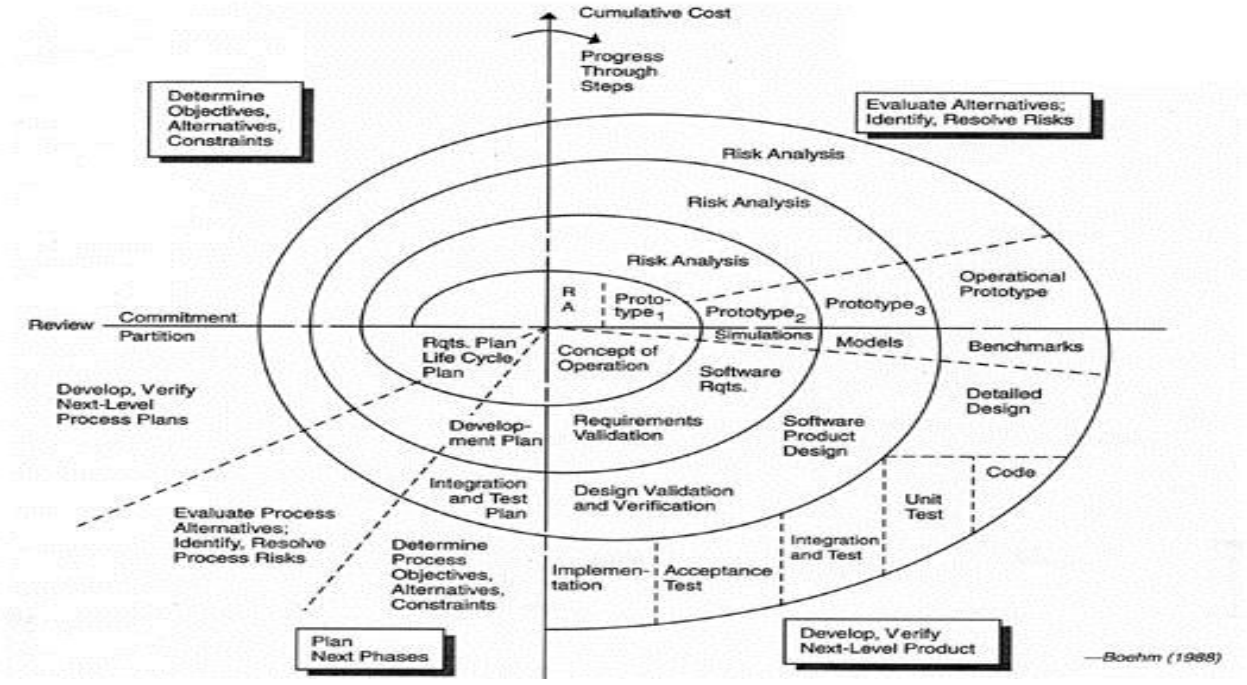


Figure 19: Spiral NPDP [7]

development, requirement gathering, requirement validation development plan until all risks

have been resolved before proceeding with development process which follows a waterfall process [7, 40, 49]. The initial cycles are meant to be rapid and short; the team develops prototypes that can be given to users to better understand workflow, intended use and such.

2.1.3.1.2 Advantages

The main advantage of the Spiral process is the flexibility that it offers to team. The development team can start a project without having the full requirements. The development team is not slowed down by paperwork until all the gaps in requirements are identified and addressed. The development team can easily iterate between phases. Risks are spread over multiple cycles and as a result risk is managed in a controlled environment [50]. The Spiral process promotes a flexible design in which dynamic environments can be advantageous to the organizations and would allow for implementation of change in later phases [40].

2.1.3.1.3 Limitation and Disadvantages

The Spiral process' main disadvantage is its complexity, as a number of cycles within the Spiral process increase the complexity of managing product development increases. The Spiral process puts greater pressure on managers to manage cross-functional activities and to keep the development team focused on the end goal [50]. With flexibility comes cost and longer development time. In cases when the budget and schedule are the drivers of the project, the Spiral process can be disadvantage [40]. Traceability can be lost over time if design decisions are not well documented in the early cycles.

2.1.3.1.4 Hybrid NPDP Processes

There are several hybrid processes such as Evolutionary Prototyping and Delivery, Extreme Programming (XP), Ad Hoc (example: Code-And-Fix), Design-To-Schedule or Budget, Scrum, Rapid Application Development (RAD),

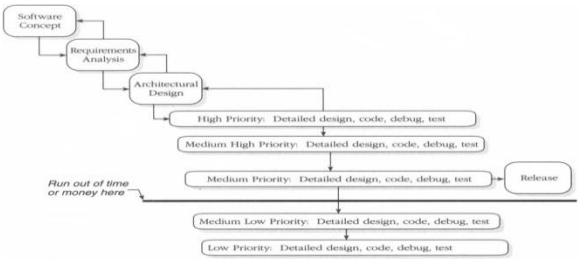


Figure 20: Design-To-Schedule or Budget [8]

Commercial Off-the Shelf (COTS) and others. These hybrids' NPDP are specific to a driver of product development. For example Design-to-Schedule or Budget (Figure 20) is a Waterfall process that has been modified to accommodate product development which are under budget or time constraints. Application of these NPDP must be done under full evaluation of product development goals and organization strategy. For example, Design to Schedule should not be applied to projects where the drivers are quality.

A comprehensive evaluation of each of these NPDP would be out of scope of this thesis. Steve McConnell's book Rapid Development: Taming Wild Software Schedules does a great job of explaining each of these processes in detail. McConnell compares ten NPDPs side by side using eleven criteria which capture the strengths and weaknesses of the NPDPs (Figure 21). In Figure 21 the strengths are noted as Excellent, and weaknesses are noted as Poor, and indifferences are noted as Fair[8].

Capability	Pure Waterfall	Code-and-Fix	Spiral	Modified Waterfalls	Evolutionary Prototyping	Staged Delivery	Evolutionary Delivery	Design-to-Schedule	Design-to-Tools	Commercial Off-the-Shelf Software
Works with poorly understood requirements	Poor	Poor	Excellent	Fair to excellent	Excellent	Poor	Fair to excellent	Poor to fair	Fair	Excellent
Works with poorly understood architecture	Poor	Poor	Excellent	Fair to excellent	Poor to fair	Poor	Poor	Poor	Poor to excellent	Poor to excellent
Produces highly reliable system	Excellent	Poor	Excellent	Excellent	Fair	Excellent	Fair to excellent	Fair	Poor to excellent	Poor to excellent
Produces system with large growth envelope	Excellent	Poor to fair	Excellent	Excellent	Excellent	Excellent	Excellent	Fair to excellent	Poor	N/A
Manages risks	Poor	Poor	Excellent	Fair	Fair	Fair	Fair	Fair to excellent	Poor to fair	N/A
Can be constrained to a predefined schedule	Fair	Poor	Fair	Fair	Poor	Fair	Fair	Excellent	Excellent	Excellent
Has low overhead	Poor	Excellent	Fair	Excellent	Fair	Fair	Fair	Fair	Fair to excellent	Excellent
Allows for midcourse corrections	Poor	Poor to excellent	Fair	Fair	Excellent	Poor	Fair to excellent	Poor to fair	Excellent	Poor
Provides customer with progress visibility	Poor	Fair	Excellent	Fair	Excellent	Fair	Excellent	Fair	Excellent	N/A
Provides management with progress visibility	Fair	Poor	Excellent	Fair to excellent	Fair	Excellent	Excellent	Excellent	Excellent	N/A
Requires little manager or developer sophistication	Fair	Excellent	Poor	Poor to fair	Poor	Fair	Fair	Poor	Fair	Fair

Figure 21: NPDP Strengths and Weaknesses [8]

2.1.4 NPDP Conclusion

"Customize the NPDP framework for each business unit. One process does not fit all."([51]).

Today, there are many NPDPs that an organization can adopt, each with its own individual weaknesses and strengths. The important conclusion is that there is no one NPDP that would fit all of the needs of an organization. Product development drivers can vary from product to product; therefore having a single NPDP is no longer viable. The days to conform each product development effort to a single product development process are over. In today's dynamic environment, NPDPs must match the risks and characteristic of each given product. A holistic approach to product development process is to accept the NPDP as a tool; each NPDP is designed for a specific job. A medical device is system of systems made of complex software, mechanical, electrical and chemical components. In some cases multiple NPDPs might be applicable to large project. For example, the software development of product can follow a spiral or XP product development process while the hardware can follow the Phase-Gate process. Research has shown that many successful organizations have multiple processes for product development.

2.1.5 What Is Benchmarking?

2.1.5.1 Brief History

In the 1980s, Xerox and Robert C. Camp helped establish benchmarking as an important tool for organizations to continuously improve their processes, practices and performance [52-54]. It is important to note that Xerox and Camp introduced benchmarking to the mainstream; however other firms such as PRTM and Booz-Allen-Hamilton had developed benchmarking processes before this period [30]. In 1979, Xerox faced stiff competition from Japanese organizations who were able to manufacture products at lower costs with higher quality when compared to Xerox [52]. Xerox realized that as organization it needed to continuously improve the manufacturing process in order to remain competitive [54]. Xerox responded to these

threats by benchmarking its American operation versus its Japanese subsidiary FUJI XEROX [52]. The benchmarking was intended to identify gaps in its manufacturing unit when compared to the parallel Japanese manufacturing unit and to learn from new practices that the Japanese employed to make their manufacturing more efficient [52]. In 1989 Robert C Camp and Xerox published a book called Benchmarking: The Search for Industry Best Practices that Lead to Superior Performance which details Xerox's experiences with benchmarking. Since 1989, American Express, IBM, Kodak, AT&T, Chevron, 3M and Xerox have employed benchmarking as important tool to improve their organizations' performance [55-57].

2.1.5.2 What Does Benchmarking Mean Today?

"Benchmarking: to study (as a competitor's product or business practices) in order to improve the performance of one's own company"- Merriam-Webster

Over the years, many scholars have devised unique ways of defining benchmarking; thus benchmarking has many definitions. Table 2 lists some of the most widely accepted definitions of benchmarking as established by major scholars and firms. Having so many definitions for a single word is overwhelming; however, there is a common theme to all of these definitions. Benchmarking is a systematic process of measuring an organization's process (es), practice (s) or product(s) by comparing and measuring them against external or internal standard(s). The purpose of determining the organization's weaknesses and learning from BIC organizations on how to improve these weaknesses [52, 53, 57-63].

Table 2: Lists of Benchmarking Definitions [53, 58, 61]

Authors	Definitions
Camp (1989)	"The continuous process of measuring products, service and practices against the toughest competitors or those companies recognized as industry leaders"
Geber (1990)	"A process of finding the world-class examples of a product, service or operational system and then adjusting own product, services or

	system to meet or beat those standards."
Alstete (2000)	"An ongoing, systematic process for measuring and comparing the work processes of one organization to those of another by bringing an external focus to internal activities, functions or operation"
Codling (1992)	"An ongoing process of measuring and improving products, services and practices against the best."
Watson (1993)	"The continuous input of new information to an organization"
Cook (1995)	"A kind of performance improvement process by identity, understanding and adopting outstanding practices from within the same organization or from other businesses."
APQC (1999)	"The process of continuously comparing and measuring an organization against business leaders anywhere in the world to gain information that will help the organization take action to improve its performance"

2.1.5.3 Types of Benchmarking

Benchmarking has been utilized in many areas of industry and several types of benchmarking types have been developed over years. Not all of these benchmarking types have been well studied by major scholars. There are seven standard benchmarking types that have been studied and published by a number of scholars and firms. The eight standard benchmarking types are known as process, performance, functional, strategic, internal, external, competitive and generic benchmarking [64]. Each type of benchmarking has unique applications. Process, functional, performance and strategic benchmarking process refer to what is being benchmarked while internal, external, competitive, and generic processes refer to who the benchmarking is being compared to [57].

- Process benchmarking is a process by which an organization seeks to better understand its critical process, weaknesses and strengths when compared to BIC organizations with similar processes [55]. Data for this type of benchmarking can come from any industry with a similar process. This benchmarking is not suitable for benchmarking of the whole organization because it is intended to focus on a single process at a time [57] such as billing, complaint, inventory, schedule management and other processes [52, 59, 64]. Short term gains are normally expected from implementation of recommendations resulting from this benchmarking
- Performance benchmarking is a process that compares the performance of an organization's product(s) and service(s) relative to its competitors [59]. This benchmarking is commonly conducted by organizations to establish their ranking within their industry [11].
- Strategic benchmarking is a process that compares an organization's core competencies and capabilities, organizational structures and management practices to other organizations [63, 65]. It is used by top level management professionals to assist them with the development of the organization's long-term plan. Strategic benchmarking has an impact on the organization as a whole.
- Internal benchmarking is a process in which the performance of a unit, division or subsidiary within an organization is compared and measured to other units, divisions or subsidiaries [59]. This benchmarking has two popular applications. The first application is to learn best practices from a unit, division or subsidiary within the organization and apply these best practices to the rest of the organization. The second application, popular with consulting firms, is to motivate, consolidate or terminate unproductive units within an organization.
- Competitive benchmarking is process that measures an organization's product designs, processes, and technological competencies relative to its direct competitors [11]. This benchmarking is limited to direct competitors. This benchmarking can be difficult and complex because obtaining information on direct competitors' core competencies,

processes and strategies may not be possible [53]. When possible, gathering such information can require significant research.

- Functional benchmarking is a process that compares and measures the functional or process performance in a specific area of an organization to measures of functional and process performance in the same areas as of BIC organizations [11]. The data for such benchmarking can come from various industries. This type of benchmarking is applicable to logistical distribution, purchasing functions and other similar activities [57]. Like process benchmarking, functional benchmarking is effective when used to benchmark a single functional area.
- External benchmarking is a process that enables an organization to measure its performances in the areas of ideas, methods, products and services against those in organizations within the same industry [53]. External benchmarking is similar to competitive benchmarking with the exception that data for this benchmarking can come from organizations with in the same industry rather than direct competitors [66]. An example would be a car company benchmarking itself against computer and aircraft manufactures to learn how to improve its overall manufacturing process [53].
- Generic benchmarking is a process that measures and compares an organization's processes and functional performance against BIC organizations across industries [53]. Generic benchmarking is the same as functional benchmarking with exception that it benchmarks multiple processes simultaneously.

2.1.5.4 Benchmarking Processes

There are as many benchmarking processes as there are benchmarking definitions. Various scholars, firms and organizations have developed a total of over forty different benchmarking processes [53]. The major differences between these processes are the number of phases and number of steps involved. A benchmarking process can have between four to six phases and multiple steps within each phase. The standard benchmarking process has five phases and fourteen steps. The typical benchmarking process was built on Deming's four stages: plan, do, check and act, which is shown in Figure 22 [53].

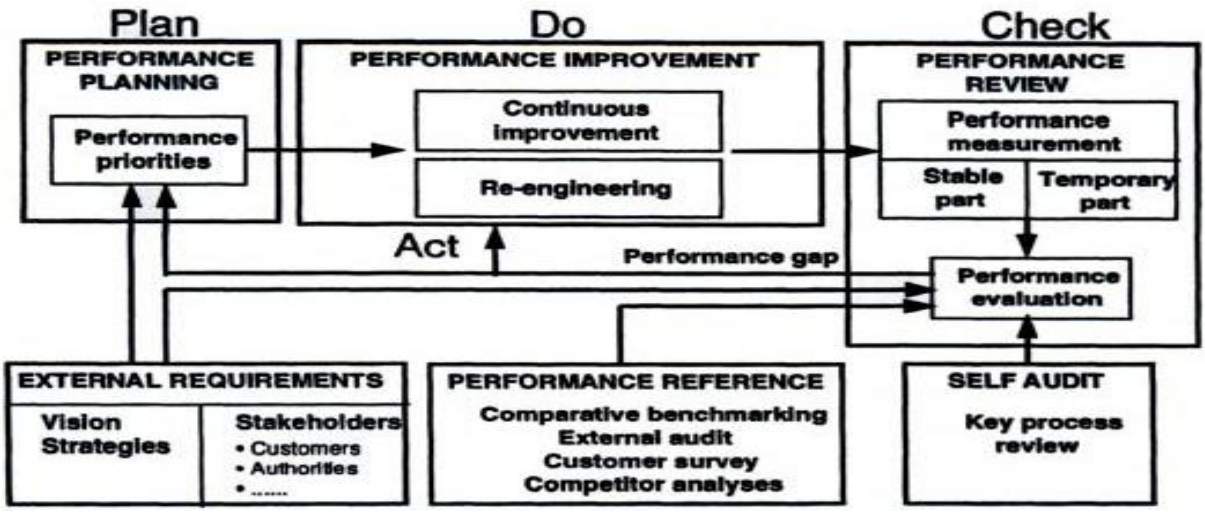


Figure 22: Deming Four Stages Applied to Benchmarking [11]

The following is a typical benchmarking process developed by Bjørn Andersen and Per-Gaute Pettersen and published in the book, The Benchmarking Handbook: Step-by-Step Instructions.

1. Phase One is Planning:
    a. Determine what is to be benchmarked and the type of benchmarking required
    b. Define criteria of success
    c. Select benchmarking process
    d. Document the process
    e. Develop a performance measure
2. Phase Two is Searching:
    a. Identify benchmarking partners
3. Phase Three is Observing:
    a. Understand and documents partners' process
    b. Understand and documents partners' practices
4. Phase Four is Analyze:
    a. Analyze the data collected
    b. Identify performance gaps

c. Find root causes for the gaps

5. Phase Five is Adapt
    a. Choose best practice applicable to the organizations
    b. Adopt to best practice to the organization
    c. Implement benchmarking recommendations

2.1.5.5 What types of data collected for benchmarking?

A typical benchmarking process consists of either quantitative or qualitative data. Benchmarking that combines quantitative and qualitative data is called a balanced scorecard.

Quantitative data must be measured and collected in numerical form [53]. Examples of quantitative data are revenues, costs, outputs of assembly line, total numbers of products sold in a period of time and other measureable values. This type of data is preferred by scholars, academics and organizations because quantitative data is easier to measure and identifying gaps is simpler [53]. This type of data is very useful in benchmarking the performances and features of similar product(s) or service(s). An organization can use quantitative data as part of internal benchmarking to identify performance gaps between two of its plants that produce same product. However, quantitative data does not always answer the question as to why there is gap [53].

"Qualitative measures (input) indicated the performance of an organization in relation to its operation practices based on perceptual evaluation by assigning numerical value to each perceptual degree"- Metin Kozak [53]

Qualitative data consists of information such as employees' perceptions of management, management perception of core competency, customers' needs, customer loyalty to the organization and other similar data. Qualitative data has been very popular with marketing and customer driven measurement services for some time [57]. For example, qualitative data can be collected during competitive benchmarking to find out why customers prefer a particular brand of a given product. Such data can give an organization an important insight into parameters that are not measureable using quantitative methods.

"You may have heard the world is made up of atoms and molecules, but it's really made up of stories. When you sit with an individual that's been here, you can give quantitative data a qualitative overlay." -William Turner

A balanced scorecard refers to the methodology of analyzing both quantitative and qualitative data to reveal existing gaps and reasons for these gaps [67]. For example, when General Motors benchmarked Toyota plants in the early 1980s, it discovered, using quantitative data, that Toyota had a superior process for assembling cars. Using qualitative data, the benchmarking discovered that the success of Toyota was primarily due to the empowerment of employees [67]. This methodology has been adopted by many organizations such as Toyota and Ritz-Carlton Hotels to improve their overall performance [67, 68].

2.1.5.6 Summery

It is very important to remember that benchmarking is a tool that helps organizations continuously learn from others and from themselves. In order for benchmarking to be effective, organizations need to spend time upfront determining what needs to be benchmarked and who they will compare themselves to in the benchmarking process. It is important to include organizations in benchmarking that bring value, such as BIC organizations, as they constantly evaluate and improve their processes. It must be remembered, however, that being the BIC organization today does not guarantee being the BIC organization tomorrow because BIC organizations must consistently remain up-to-date and efficient with all internal processes. Benchmarking can speed up an organization's process of improvement as it produces new information about best methods. Ultimately, it is not the benchmarking process itself that improves the quality of an organization. Rather, it is the implementation of the resulting benchmarking recommendations that facilitate the improvements.

3 BENCHMARKING METHODOLOGY AND RESULTS

3.1 INTRODUCTION

In 1976, Pittiglio, Rabin, Todd & McGrath formed a consulting firm called PRTM. In the Nineteen Eighties PRTM and Booz-Allen-Hamilton were among the first companies that had developed a process to measure the relationship between PDP and success of organization [30]. In early 1980's PRTM developed a benchmarking process to benchmark product development and supply chain management [30]. PRTM benchmarking of R&D best practices showed that there are many deficiencies with current NPDPs used by organizations. In 1988 PRTM introduced its own version of Stage Gate PDP called Product and Cycle-time Excellence (PACE)[12]. PACE is a framework that consists of both heuristic and other tools used to streamline innovative product development processes from conception to the end of product life.

In 1992, as part of its NPDP benchmarking process enhancement, PRTM developed an index called the R&D Effectiveness Index (RDEI) [9]. The RDEI measure the effectiveness of R&D group by comparing the profit from new products to the investment in development of new products [9]. A simplified version of RDEI formula is shown below:

$$RDEI = \frac{[New\ Product\ Revenue\ \% * (Net\ Profit\% + R\&D\%)]}{\mathrm{R\&}D\%}$$

In the above formula, the percentage of New Product Revenue refers to revenue from products that have not yet reached half of their Product Life-Cycle (PLC) [9]. PLC is defined from time of product introduction to market to time the product is no longer produced [9]. The R&D percentage is current R&D budget on new product development only, divided by current revenue [9]. McGrath admits that obtaining an accurate R&D percentage is difficult because in many cases, organizations do not have granularity in their accounting breakdown. A reasonable approximation of R&D spending is satisfactory and will not have major impact on final result [38]. Net profit percentage is the actual or a representative average profit from new products

launched in the last five years which have not yet reached their PLC half-life [9]. PRTM research concluded that many companies faced difficulty accurately calculating their profit. As a result, an average was considered acceptable for their purposes [38]. A comprehensive RDEI is far more complicated than the simple formula shown previously. A complete RDEI calculation is more involved and would look similar to Figure 23.

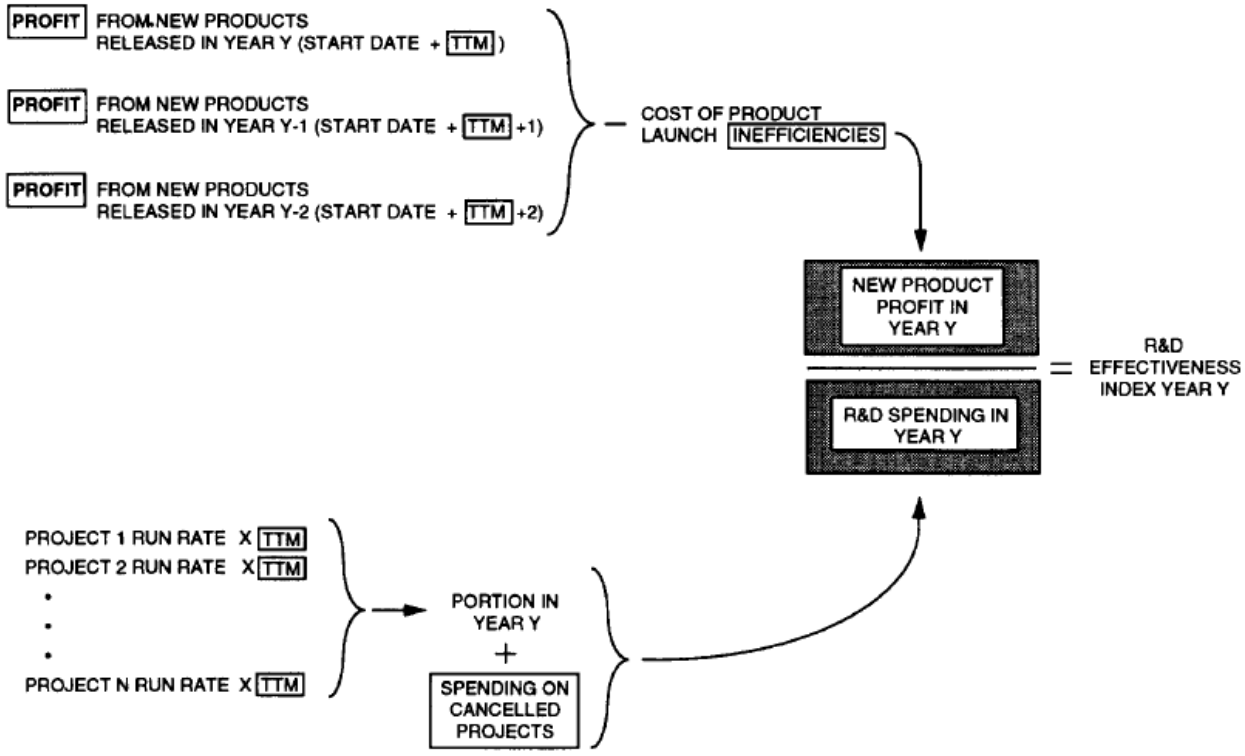


Figure 23: A Comprehensive RDEI Calculation [9]

In 1998, PRTM spun off its benchmarking division and created a separate entity called the Performance Measurement Group (PMG) to provide its clients with unbiased benchmarks. While PRTM continues as consulting group, the PMG group focused on improving organizational benchmarking. PMG had four unique characteristic that made it ideal for this study. These characteristics are as follows:

1. Large database of companies (over 700 companies surveyed across multiple industries)
2. Industry specific benchmarking (PMG' benchmarking questionnaire tailored for each industry. For Example: medical devices)
3. Experience in Benchmarking (over 30 years of knowhow)

4. PRTM developed PACE® which has been adopted by many medical device companies
5. Experience across the entire healthcare value chain (Figure 24)

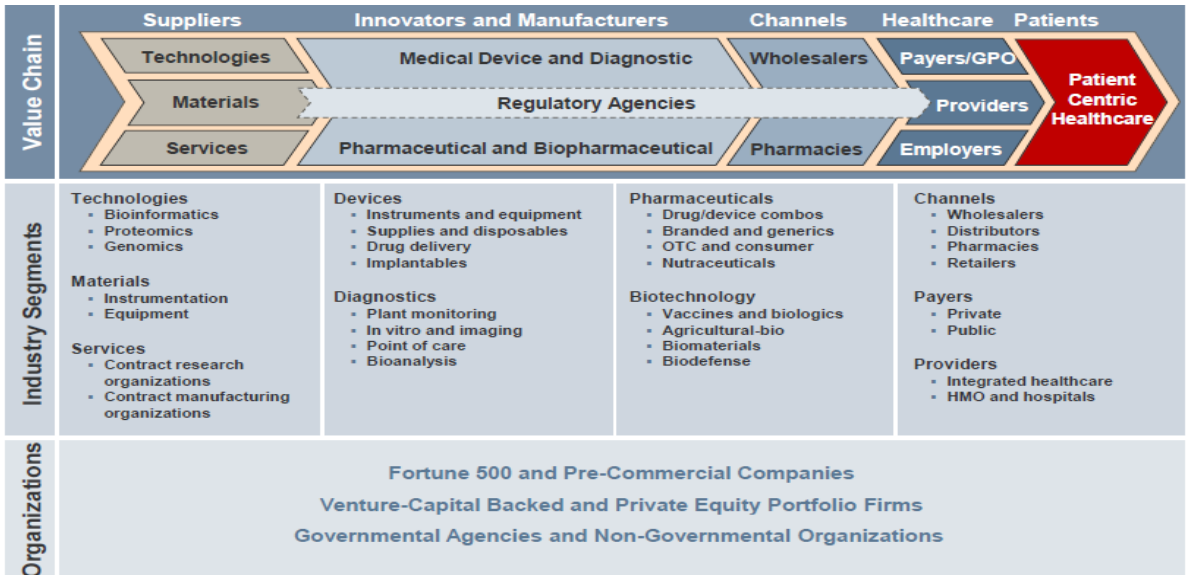


Figure 24: PMG Experienced Working Across the Healthcare Value Chain [3]

3.1.1 PMG Methodology

3.1.2 Basic Principles behind PMG Methodology

PMG benchmarking is built upon PRTM knowhow. The roots of PMG's benchmarking questionnaire survey can be traced back to PACE and RDEI. PMG benchmarking consists of five major sections: quantitative, qualitative, population comparison, PRTM insight and analysis and recommendation or balance scorecards (Figure 25). These five components are used to diagnosis gaps and opportunities within organizational practices. It should be noted that in 2011, PRTM and PMG were acquired by PricewaterhouseCoopers LLC. PRTM Insight is now known as PwC Insight.

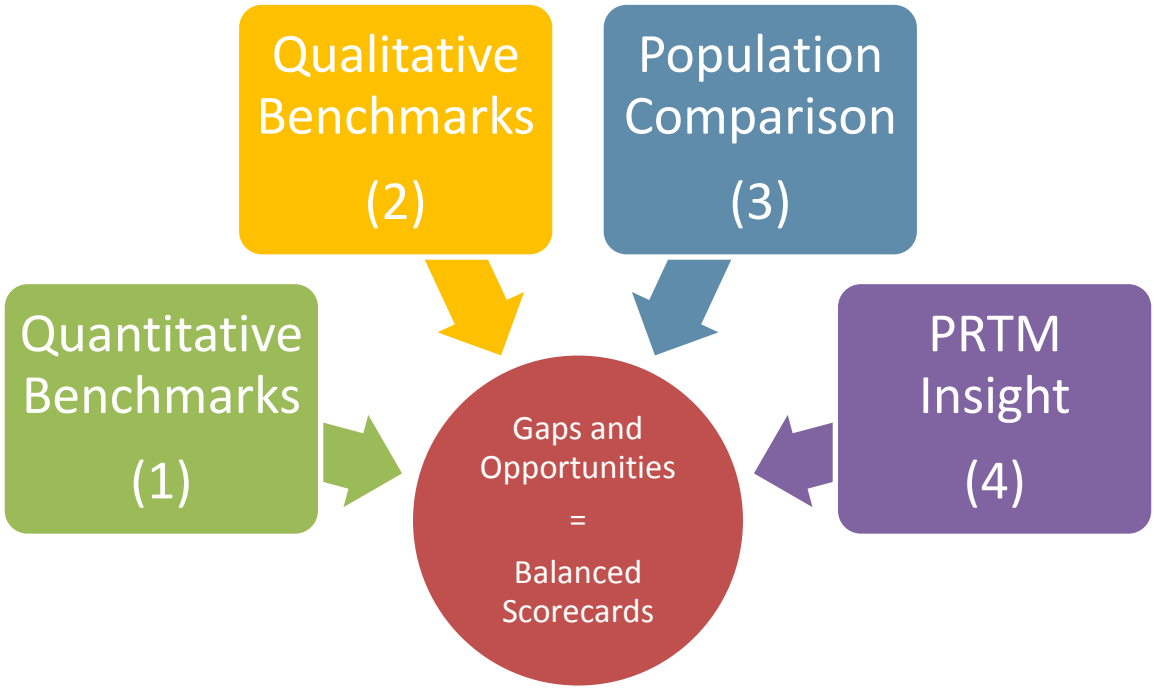


Figure 25: PMG Approach to Benchmarking

3.1.2.1 Quantitative Section

The quantitative section of benchmarking, shown in green in Figure 25, is designed to measure multiple Key Performance Indicators (KPIs) that measure the value of R&D to the entire organization. The purpose of this section is to use various metrics such as organizations' practices and performance and benchmark organization innovation strategies to peer organization. KPIs measure organizational behavior in five areas. These areas are innovations, productivity, response time, cost management and quality for products and NPDP. The quantitative section also measures the value (importance) of each of these behaviors to the organization. Using data collected in the quantitative section, the RDEI can be calculated. Two examples for each of types of KPIs measured in the quantitative section are shown in Figure 26. A more comprehensive list is shown in Results section.

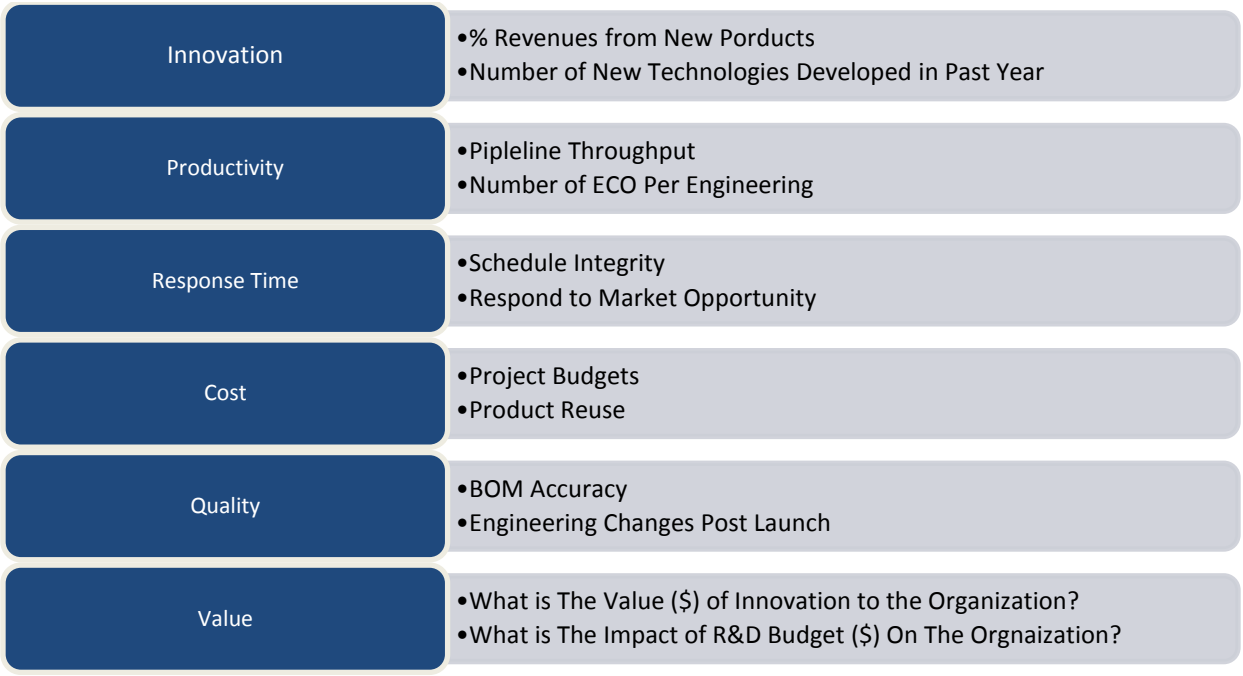


Figure 26: Examples of KPIs Measured [3]

3.1.2.2 Qualitative Section

The qualitative section measures specific Key Performance Levers (KPL) in twelve primary domains within an organization. These domains are: Innovation Excellence®, Product Lifecycle Management®, IT Enablement®, Software Practices®, Resource Management®, Design Excellence®, Technology Excellence®, Functional Excellence®, Development Chain Excellence®, Portfolio Excellence®, Product Excellence® and Project Excellence®. The purpose of this section is to understand the maturity of an organization's innovation selection, NPD, and lifecycle management processes (Figure 27).

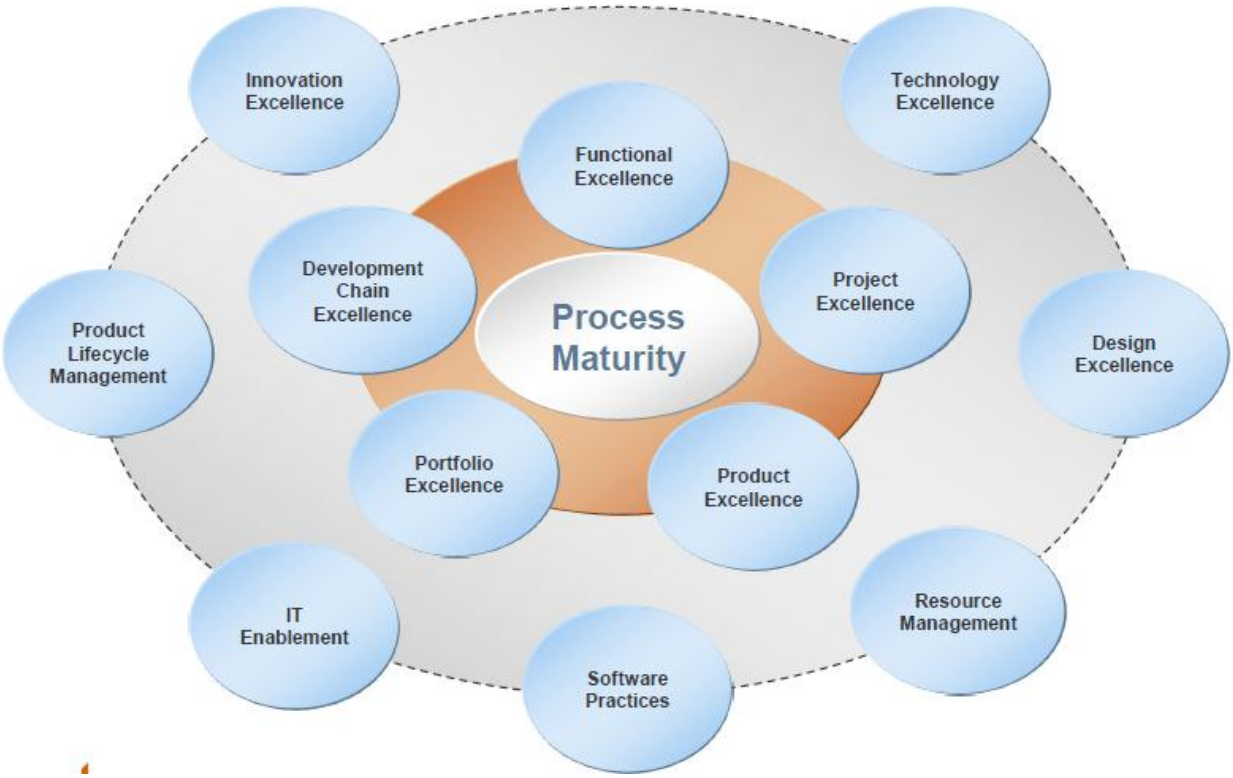


Figure 27: The Qualitative Section Focuses Process Maturity [3]

3.1.2.3 Definitions:

1. The Best-In-Class (BIC) represents the average data for the top 20% of organizations from the selected populations. In the case of this benchmarking, it represents the average of two organizations. On a normal distribution graph, the BIC represents the 95th percentile of the distribution[69]. In case of this benchmarking, the data from the benchmarking were compared to 10 organizations. The BIC represents the average data for two organizations from selected data base.
2. The Average represents the average data for 60% of population selected. In the case of this study, it represents the average data for six organizations.
3. The Median represents the middle values [69].Ten organizations from PMG's database were selected for this study, thus Median is average data from two organizations who data fell in middle of the database. If the data are normally distributed, the mean and the median will be close. If the data are not normally distributed, and then both the

mean and the median may give useful information. For example, for On-Time Delivery Performance, if the BIC is 95% and median value is considerably less than the average, then the data are skewed and more than half the companies have significantly lower performance than average [69].

4. The Worst-In-Class represents the average data for the bottom 20% organizations from the selected populations [69]. In the case of this benchmarking, it represents the average of two organizations.
5. NR: Not Relevant
6. ND: No Data or Insufficient Data
7. TOP or Bottom refers to the average of the top or bottom 20% of respondents for that metric [69]. For example in some cases the data is not compared to other organization but to the data collected within organization the data was collected.
8. Medical device organizations were selected for this study based on two factors. First criteria was based the product architecture, whether a product had integrated or modular architecture. The second criteria was based on similarity of the product, preferred organization would have been direct competitors or operate in the same industry with similar products. For more information see section 3.1.4.

3.1.3 Use Context and Challenges

3.1.3.1 What was Benchmarked

3.1.3.1.1 Background of the Organization Benchmarked

Until the year 2008, this organization had two R&D divisions. The two divisions were known as the Division One and the Division Two. Each R&D division was dedicated to one product line. The two R&D divisions were approximately the same size and worked in complete isolation from one another. Each division had its own unique process and approach to NPDP and the two product lines were very different from each other. There were no overlaps in technologies or services that each product line provided.

As part of organizational restructuring in 2008, the company morphed the two R&D divisions into one. Since the restructuring took place recently, there is not much data about the current PDP. Influences from the previous R&D divisions are still strong in the consolidated R&D department. The organization is currently in the process of developing a new PDP; therefore it was concluded that a single benchmarking assessment would not be sufficient to determine the gaps in the current PDP. To compensate for the organizational restructuring, two benchmarking surveys were conducted in 2010. The two R&D divisions had started and finished a platform development project around the same time. This was the last platform development effort that these two divisions had undertaken as separate entities. Each benchmarking result was then compared to a separate custom population of previously benchmarked companies by PMG/PRTM with similar products and functions. Due to the recent merging of the two departments, this benchmarking assessment could not fully assist the organization in identifying the best NPDP to address both product lines' needs. The organization structure is shown in Figure 28.

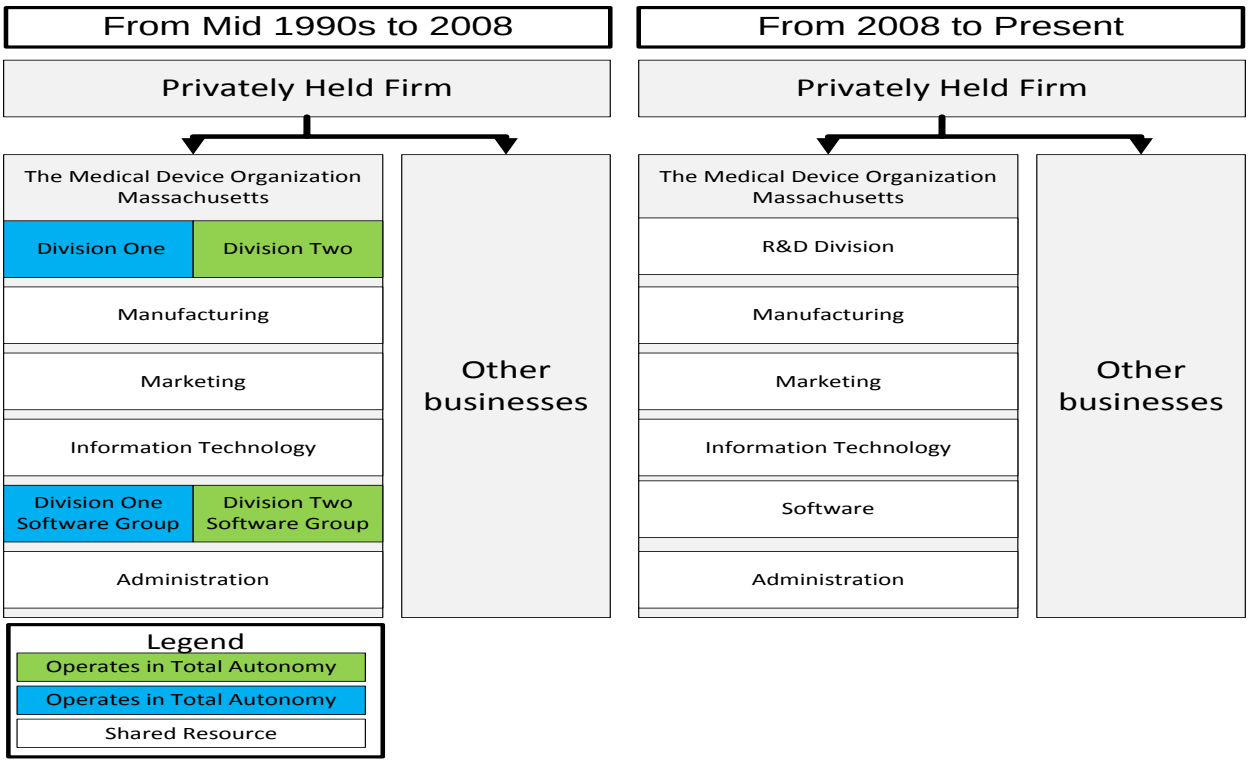


Figure 28: Organization Structure

3.1.3.1.1.1 This Organization's PDP Process

In 1999, after a major restructuring of the R&D department, the organization switched its NPDP from phase-gate to spiral. The intent of adopting the spiral PDP was to allow the R&D department to respond faster to issues discovered during the development phases and not to get slowed down by gates. There is one fundamental difference between the spiral PDP discussed in the literature review section and the spiral PDP that this organization adopted in 1999. In traditional spiral PDP process (used to develop software), prototypes are built early in development process and are given to the user and iterations occur based on customer feedback. In the early phase of the spiral PDP, this organization customized the process by building breadboards and evaluating various functionalities and individual performances of critical subsystems. The rationale for the variation of the spiral process was to validate that the concepts selected for the product met the organization's goals for the project. This phase of the PDP is called the Feasibility phase. Once all the goals were met, the project moved into design control that consists of four phases that fall into of the design control category. The four phases are Prototype Design, Pre-production Design, Production Design and the Launch Phase. After the Feasibility phase, the rest of the process was typical of a spiral PDP. A summary of high level tasks associated with this organization's NPDP is shown below.

1. Concept Phase
    a. Tasks
        i. Idea Generation
        ii. High Level Requirement Generation
        iii. Business Justification
        iv. Product Line Strategy Review
        v. Risk Analysis
2. Feasibility Phase:
    a. Tasks
        i. Develop Product Architecture
        ii. Develop Specific Subsystem to Reduce Risk

iii. Perform Iterative Breadboard Testing to Validate Feasibility of the Concepts Selected
iv. Refine Design of Various Subsystems

3. Prototype Phase
    a. Tasks
        i. Preliminary Integration of Software, Electrical And Mechanical Components.
        ii. Limited Functionality Testing
        iii. Limited Analytical Development
4. Pre-Production Phase
    a. Tasks
        i. Full Hardware And Software Integration
        ii. Proof Of Integration
        iii. Analytical Parameter Development
        iv. System Proof Of Performance
5. Production Pilot Phase
    a. Tasks
        i. System Validation Testing
        ii. Marketing And Service Group Training
        iii. Beta Site Evolutions (Usability And Performance Evaluation By The User)
        iv. Seeking Regulatory Approval 510K
        v. Transfer Of Documents And Training Of Manufacturing Personal For Production
6. Launch Phase
    a. Limited Distribution Phase
        i. Tasks
            1. Business Risk Review
            2. Marketing Literature Are Updated

3. Business Analysis Are Updated
4. Process Are Audited

b. Full Distribution
   i. Tasks
      1. Worldwide Product Launch

3.1.4 Who was Benchmarked

For the benchmarking study of the Division One, ten companies were selected from PMG benchmarking data base. The following organizations were selected because they were direct competitors or had products with similar complexity: Abbot, Affymetrix, Alcon, Bayer Corporation, Boston Scientific, Hollister Incorporated, Hospira Inc., Johnson & Johnson, Smith & Nephew and Tyco Healthcare. For the Division Two, ten companies were selected from PMG benchmarking database. The ten companies selected for the second benchmarking are: Bayer Corporation, Becton Dickinson Diagnostics, Bio-Rad, Hollister Incorporated, Medtronic, Ortho-Clinical Diagnostics, Philips, Siemens AG, Smith & Nephew and Spectranetics.

Throughout this section, the results are presented in table format. Each table compares the results from organization to Best, Average, Median and Worst in class. The Best, Average, Median and Worst in class are relevant to the populations selected for the benchmarking study and it is not comparable to the whole medical device industry. As part of the survey, the data providers were interviewed to gain soft information, such as how strictly employees follow the NPDP, to explain the results. These interviews also helped to determine the relevance of survey results to the organization.

3.1.4.1 Challenges

There were several challenges to the benchmarking process. The first major challenge was getting data for two platform projects that had taken place over 10 years ago. Each project took over several years to complete. Acquiring and organizing data was very challenging. In some cases, finding accurate data was impossible. In such cases, a best estimated guess by

subject expert was sought. An example of this case involved finding the number Engineering Order change (ECO) submitted to manufacturing six months after product was released. The company had changed from paper format to electronic format to track ECOs. The data that was needed for this benchmarking was in paper format and accessing and analyzing this data was beyond the scope of this thesis so the best estimate guess by subject matter expert was placed. Other challenges stemmed from the organization's restructuring. As result of the restructuring of two R&D divisions, some positions where consolidated. Finding individuals who still possess the necessary knowledge became a major task in and of itself. Another major challenge was acquiring exact individual data regarding administrative and IT spending as both departments shared a single account. In addition, IT spending did not differentiate between NPDP and support for released products. According to McGrath, one of founders of PRTM and an avid researcher in the field of PDP, use of a single account for several purposes within a company is common practice in many organizations. To determine the company's individual spending on IT and administration, the shared account was simply divided in half and reported.

3.2 Method of Collecting Data for PMG Benchmarking

For this benchmarking study, PMG created two separate online accounts for each R&D division. The benchmarking questionnaires were available electronically through these secure accounts. Data entry was also done using these secure accounts. After the questionnaires were completed and reported to PMG, PMG would lock down the editing features on accounts and would conducted data validation. The data validation process checks the quantitative data for inconsistencies. For example in cases where replies to several questions had to add up to 100% if the data did not add up to 100% the system would generate error and requested for clarification. Once the data validation is completed, the data is analyzed using PMG proprietary methodology. It is important note that the exact formulas and methodology used to calculate these results were not shared with this research

3.3 RESULTS

This results chapter is divided into three sections. The section 3.3.1 is comprised of results from a public case study by PMG. The sole purpose of this section is to serve as a reference point for publication readers to get a sense of output result by PMG. No actual work was done by the author of this thesis to produce these results. Due to confidentiality, the actual results for the benchmarking are not shared with the public. The organization benchmarked is a privately held corporation, who does not share any financial or technical information with public.

In section 3.3.2 the benchmarking data is analyzed using Design Structure Matrix (DSM). In this section, a model of the organization NPDP is created and the interdependencies of tasks within the NPDP are examined. Section 3.3.3 reports the advantages and disadvantages of organization's NPDP based on employees interviews.

3.3.1 Result from PMG Case Study Company A

The data presented in this section are not based on real organizations. This data is shown as an example of results presented to the benchmarked company. All of the results presented here are the copyright of PMG. The intent of this section is to present the reader with sample results presented to the client, since the actual results section of this thesis is confidential and not available to public. The client's results are not publishable due to confidentiality. Instead, PMG provided us with sample results exhibited in their marketing brochure. Company A does NOT exist and results for company A are sample results used by PMG for marketing.

3.3.1.1 Company A Background

Company A is a medical device company that makes a handheld full body scanner and analyzer. Company A has become the market leader in field of imaging thanks to Phoenix 2000. Phoenix 2000 is the world's first handheld full body scanner and analyzer which was released 5

years ago. After the release of the product, Company A experienced rush of demand. The company experienced rapid growth, and head counts went from 50 employees to 800 employees within 2 years. The company lunched 13 other products since the Phoenix 2000. At the moment, company A's overall competitive strategy (Figure 29) is to continue being an innovative company followed with investments in understanding and improving customer intimacy. Finally, Company A is committed to reducing manufacturing costs. In the year 2000 and in the last year the company was listed on stock exchange. Since being listed on stock exchanges the company has been under pressure to continue its double digit growth. The management considered innovation as key competitive advantage. Thus, they hired PMG to benchmark their R&D process. After two months of work, the following results were delivered to the upper management of Company A.

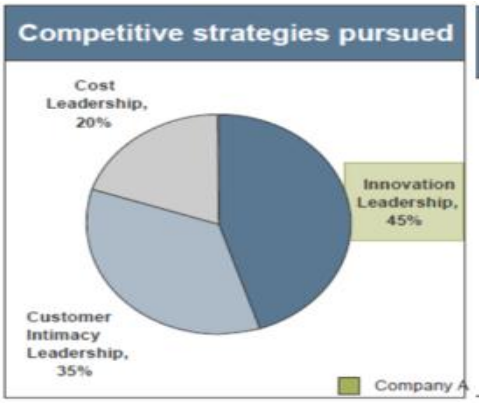


Figure 29: Competitive Strategies [3]

3.3.1.2 Results

3.3.1.2.1 Quantitative Results

Figure 30 lists the results for PDP maturity for the whole organization. Organization A has robust practices for all stages except for the portfolio platform stage where the process can be improved to be competitive with BIC organizations.

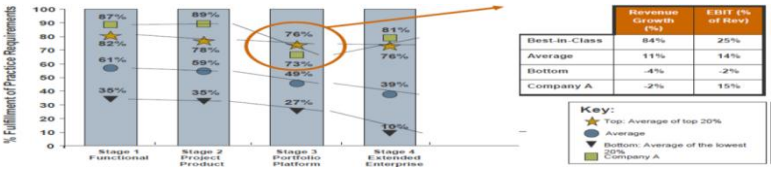


Figure 30: Organization A Product Development Practices [3]

The financial comparison results are shown in Figure 31. The result shown in Figure 31 indicates that Company A revenue growth (CAGR) is not on par with (other) BIC groups. Company A needs to improve its revenue growth to maintain its competitive market edge. As for reset of the financial indicators, the organization has average performance and there is

room for improvement.

Category	Metric	Bottom	Median	Top
Financial Performance	Revenue Growth (CAGR), %	-4% 2%	17%	41%
	Cost of Goods Sold (% of Rev)	82%	62% 58%	36%
	R&D Spending (% of Rev)	17%	7% 6.6%	1%
	SG&A Expenses (% of Rev)	41% 22%	21%	2%
	EBIT (% of Rev)	-39%	6% 15%	33%

Company A

Figure 31: Financial Performance Comparison [3]

In Figure 32, the left graph shows the average breakdown of R&D spending for Average organizations. In total, these organizations spend nine percent of their budget on advanced technology, sixteen percent on product platform, twenty one percent on minor product modifications, twelve percent on platform for major markets and lastly thirty seven percent on platform for major existing markets. Company A R&D breakdown is the graph shown on the right side of Figure 32. The breakdown of R&D spending for company A is follow: advanced technology (17%), product platform (0%), minor product modification (10%), platform for major new markets (30%) and lastly platform for major existing markets (40%) and the rest of R&D budget is spent on non-product related actives.

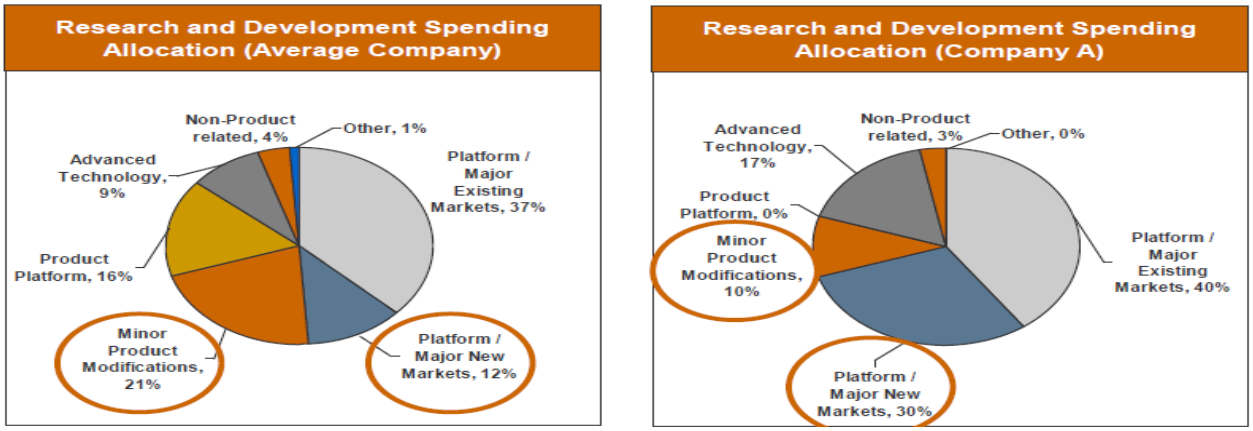


Figure 32: R&D Breakdown Spending for Average and 'A' Organization [3]

In Figure 33, breaks down the total revenue for bottom, BIC (Top) and Company A. This figure shows the percentage of total revenue those results from new product launches from the year 2002 to the year 2006. About 71% of Company A's total revenue from product launch in the last two years is on par with BIC organizations.

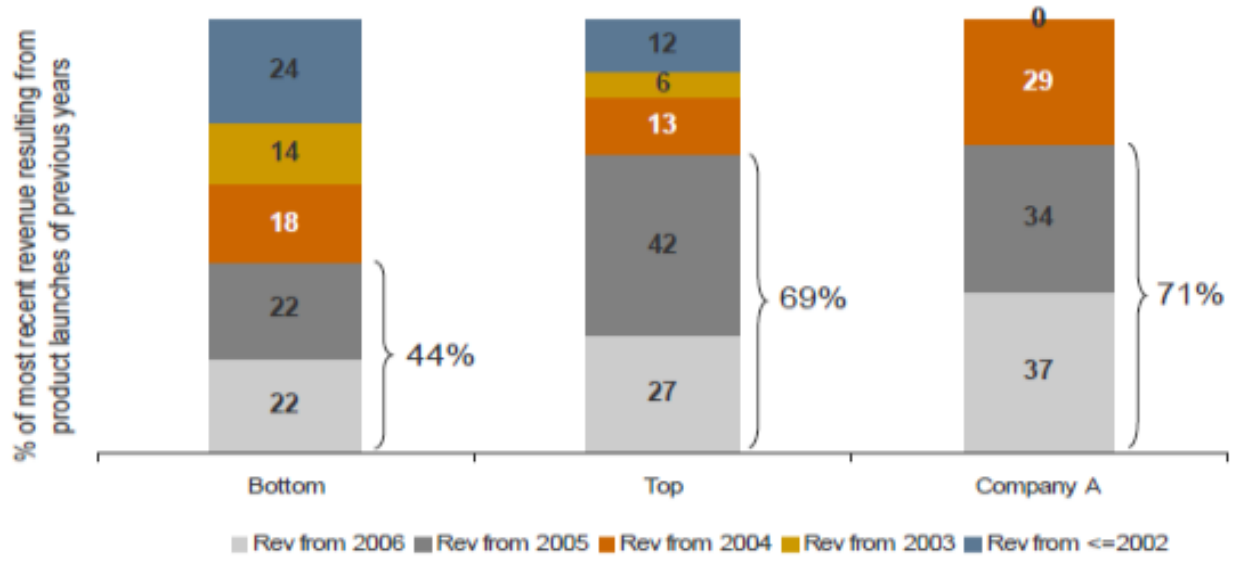


Figure 33: Impact of New Product on Total Revenue [3]

Product development time and the time it takes for major products to break even for company A are shown in Figure 34. In the medical device industry, the average project takes about 30 weeks to break even. In Company A, the slowest project took 94 weeks and the time to break even was 70 weeks, while the fastest projects took 37 weeks to complete and 7 weeks to break even. This data indicates that the gap between the fastest and slowest project is around 120 weeks, which is large gap between the two extremes within this organization.

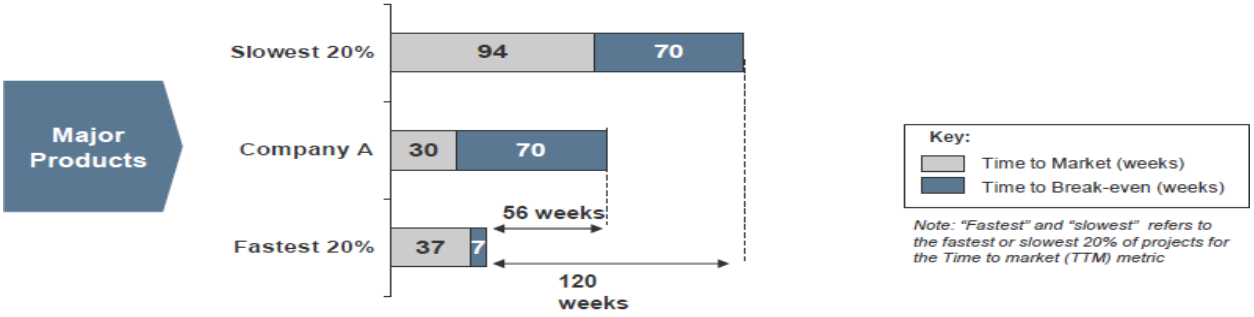


Figure 34: Product Development and Break-Even Time. [3]

Figure 35 lists the KPIs measured in the area of innovation and strategy, leverage and quality for organization A and compares the data with BIC and average organizations. The data shown in Figure 35 exposes an area of improvement for Company A, as there is a large gap between Company A and BIC organizations. The data shows that organization A is not leveraging its platform product and is not spending a sufficient amount of its R&D budget on developing product platforms. However, Company A is performing equal to, or better than, average organizations.

Category	Metric	Bottom	Median	Top
Innovation and Strategy	Spend on Product Platforms, %	0% 0 %	10%	33%
	Revenue From New Products, % (Launched in last two years)	21%	70% 71 %	100%
	Technology Development Time, Weeks	70	30 26	18
Leverage	Platform Product Leverage, #	.2 .3	2	14
	Product Reuse (Major), %	30%	59% 60%	86%
	Partner Leverage (Lo-Cost Asian),%	0%	6% 10%	57%
	Partner Leverage (Design Content),%	3%	25% 45%	72%
	Staff Utilization, %	58%	70% 72%	81%
	Managers to Contributors, %	22%	11%	6% ND
Quality	R&D Budget Spent on Quality, %	21%	7% 5%	2%
	# Customer Quality Complaints (Platform)	164	15	4 ND

Company A

Figure 35: Innovation and Strategy, Leverage and Quality result [3]

In Figure 36, the percentage of staff working on projects that generate revenue for Company A, and top and bottom organizations are shown. Company A's utilization of staff is 13% below the top organization, but 16% higher than bottom organizations. 40% of R&D staff are working on projects that are not R&D related such as customer support, training and functional improvement.

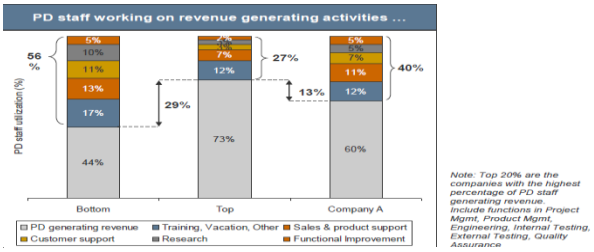


Figure 36: % PD Staff Activities Breakdown [3]

Figure 37 shows the number of management levels for Company A, top, bottom and average organizations. In the Top 20% of organizations, there are three levels of management while in Company A there are 5 levels of managements. Finally, in the bottom 20% organizations there are 6 levels of management. As shown in Figure 37, there seems to be correlation between number of management levels and staff productivity.

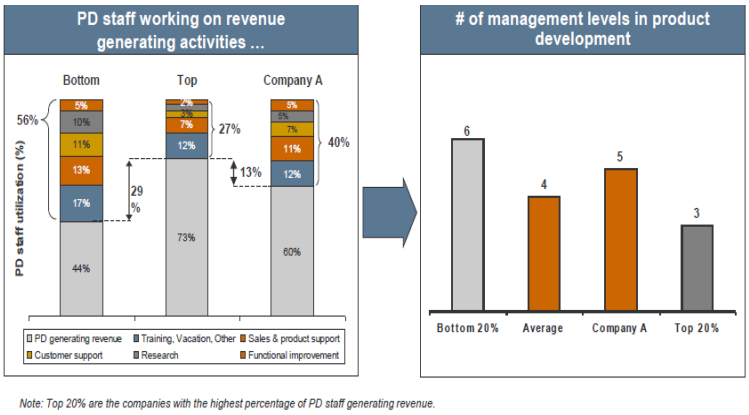


Figure 37: Number of Management Levels in R&D [3]

In Figure 37, the results for following KPIs speed, cost, quality and productivity as function of R&D spending are exhibited for Company A, top and bottom organizations. Company A did not provide data for cost section of the benchmarking; therefore this section is left blank. Company A's results shows that when compared to top organizations, it performs poorly in response time, time to breakeven, schedule slip and number of products launch per equivalent R&D spending for major products.

Category	Metric	Bottom	Median	Top
Speed (without Semiconductors)	TTM Platform Products, Weeks	147	85 (60)	47
	TTM Major New Products, Weeks	94	56	37 (30)
	Response Time, Weeks	37 (13)	8	3
	Time To Break-Even (Major), Weeks	70 (70)	26	7
Cost Management	Schedule Slip (Major), Weeks	21	6 (4)	1
	Project Cost Variance (Major), %	44	11	3
	Product Cost Variance (Major) %	45	5	0
Quality (without Semiconductors)	Quality Issues at Launch,% of Products	91	15	1
	BOM Accuracy %	1	93	99.8
Productivity	# major products launched per equivalent R&D spend	(1.3) 3	14	89

ND
ND
ND
ND

Note: Top or bottom refers to the average of the top or bottom 20% of respondents for that metric

Company A

Figure 38: Speed, Cost Management, Quality and Productivity [3]

In Figure 39, the results for hardware and software reuses for platform development are displayed. As shown in Figure 39, top organization platform products reuse up to 58% of hardware and software from previous generations, while Company A used only 20% of previous generation hardware and software. The bottom organizations only used 10% of their hardware and software from previous generations.

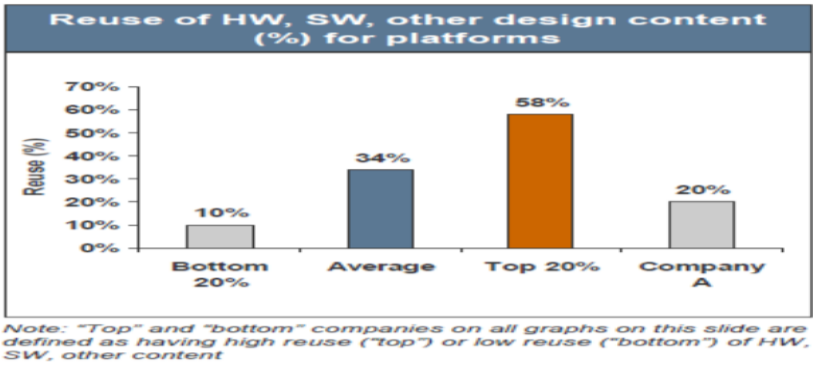


Figure 39: Hardware and Software Reuse for Platforms Development [3]

3.3.1.2.2 Qualitative Result

This section of results covers qualitative results of the benchmarking. These results are more subjective and are dependent on the individuals who responded to interview questions. In order to make these results less biased, the questions were given to various individuals with an organization and results were then averaged. The individuals were able to answer the questions according to standards of ‘rare’, ‘occasional’, ‘frequently’ or ‘always’.

Figure 40 compares Company A’s functional, project, product, portfolio and extended enterprise excellence to BIC and Average organizations. Overall, Company A performed well in all categories except for the areas of project performance management, portfolio governance, portfolio management process, portfolio performance management, collaborative projects, road mapping process and partner performance management.

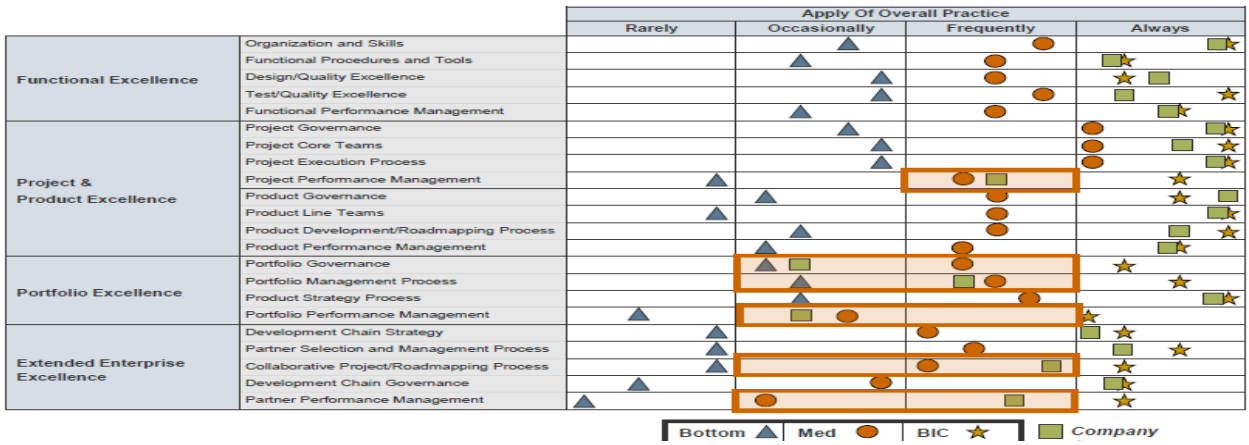


Figure 40: Portfolio Maturity Practices and Governance and Process [3]

Figure 41 lists the results for Resource and Product Lifecycle managements, Innovation, and Technology excellence. The results in Figure 41, shows that Company A does not perform as well as BIC organization in innovation governance, innovation process, requirements management and product lifecycle performance management. As for the rest of KPIs shown in this table, Company A performs as well as BIC organizations.

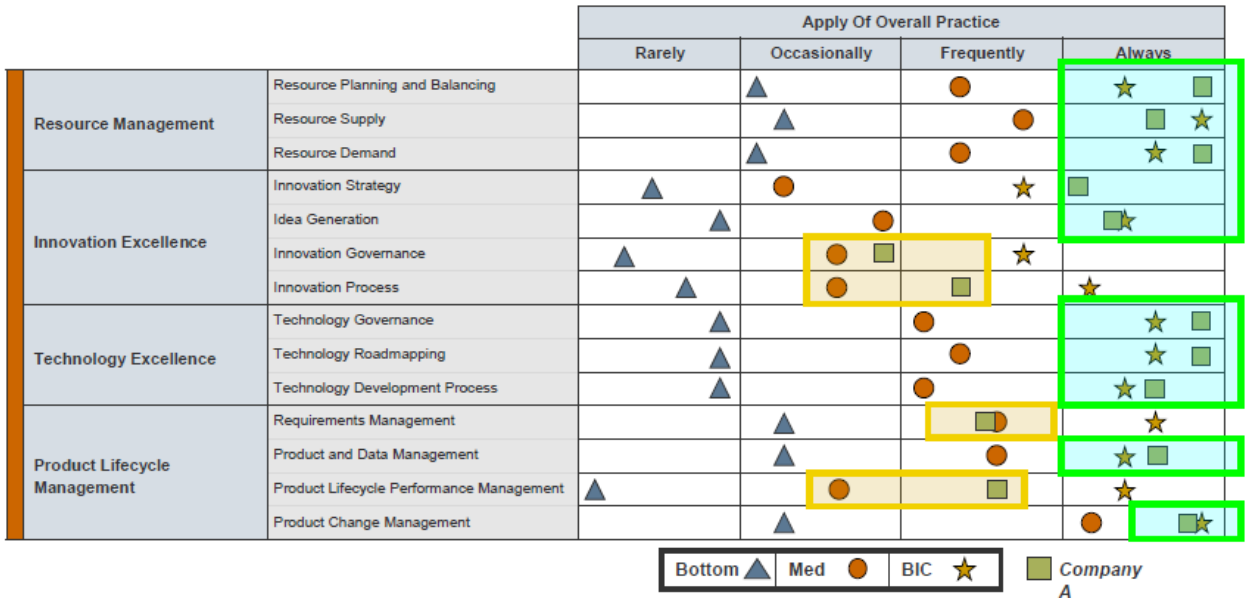


Figure 41: Resource, Innovation, Technology & Product Lifecycle Management [3]

The overall results summary for qualitative section is represented in Figure 42. These results show that various decision makers within Company A view the organization as doing poorly at portfolio, innovation, resource and technology management.

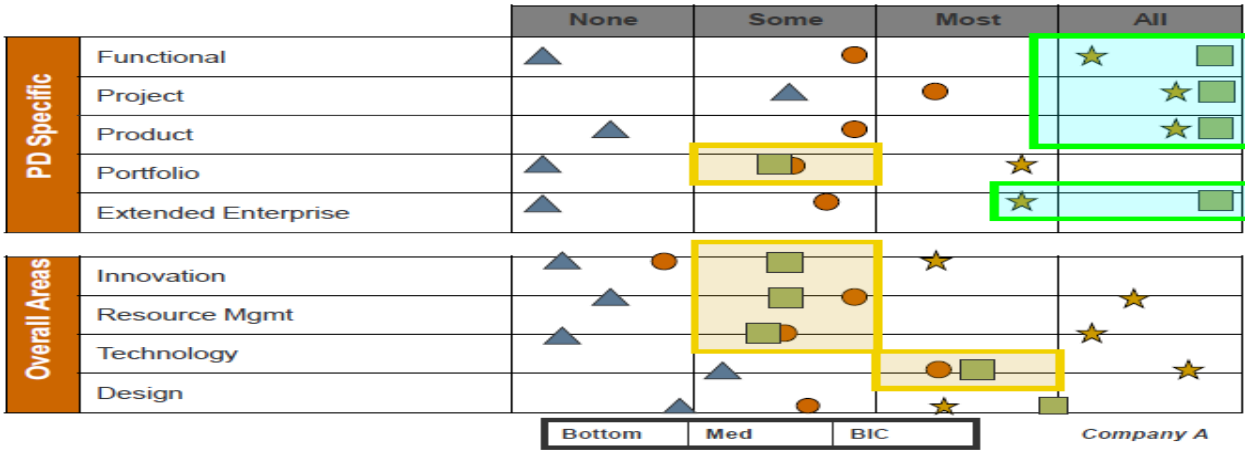


Figure 42: PD specific and Overall Qualitative Results [3]

3.3.2 DSM Analysis of the NPDP

3.3.2.1 What is DSM

"The DSM method is an information exchange model that allows the representation of complex task (or team) relationships in order to determine a sensible sequence (or grouping) for the tasks (or teams) being modeled"- Ali A. Yassine

DSM stands for Design Structure Matrix. DSM is a visual modeling tool that enables one to breakdown a complex system into subsystems while maintaining the relationships that exist among these subsystems [71]. DSM was developed in early 1980 to assist individuals to better understand the interdependency that exists between people and tasks, functions and components in complex systems[71]. DSM has been used to represent and/or analyze new product development process, project planning, product architecture and organizational design [71]. There are two main categories of the DSMs: Static and Time-based [71].

1. Static DSM is applicable to cases where components of a system exist at the same time. An example of such system is product architecture [71]. Static DSM is analyzed using clustering algorithms.
2. Time-based DSM is applicable to cases where components of a system exist at various time and the sequence of the component indicates a flow through

time[71]. An example of a Time-based system is NPDP [71]. Time-based DSM is analyzed using sequencing algorithms.

A DSM model is a square matrix with identical column and row labels as shown in Figure 43. Figure 43 shows the translation of a process with six tasks into a DSM model. The X marked in column one of Figure 43 means that task 3 provides an input to task one. Columns in DSM matrix represent dependencies between subsystems of a system. Looking at row one of Figure 43 the X mark represents the output of a subsystem. For example task one in row one of Figure 43 provides output to task two and five. The blue filled squares in Figure 43 represent the mapping of subsystems to themselves.

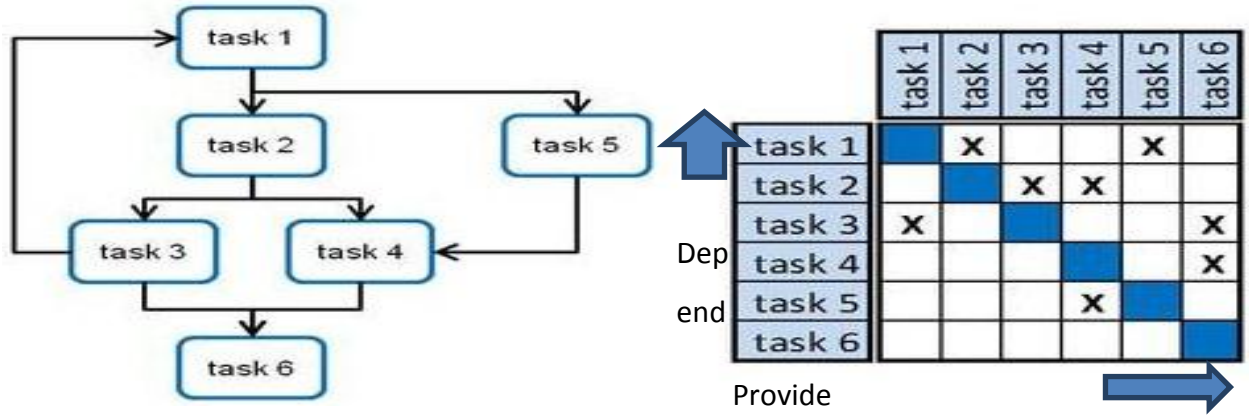


Figure 43: Example of a Process Mapped into a DSM model [1]

There are different methods of analyzing a DSM model; however the outcomes most of these analyses are the same. For analyzing the NPDP, partitioning is recommend method. Partitioning of a DSM model can assist with grouping of subsystems/tasks/actives and determining the interdependency and direction of flow. Figure 44 is DSM analysis of Time-based process using the partitioning method.

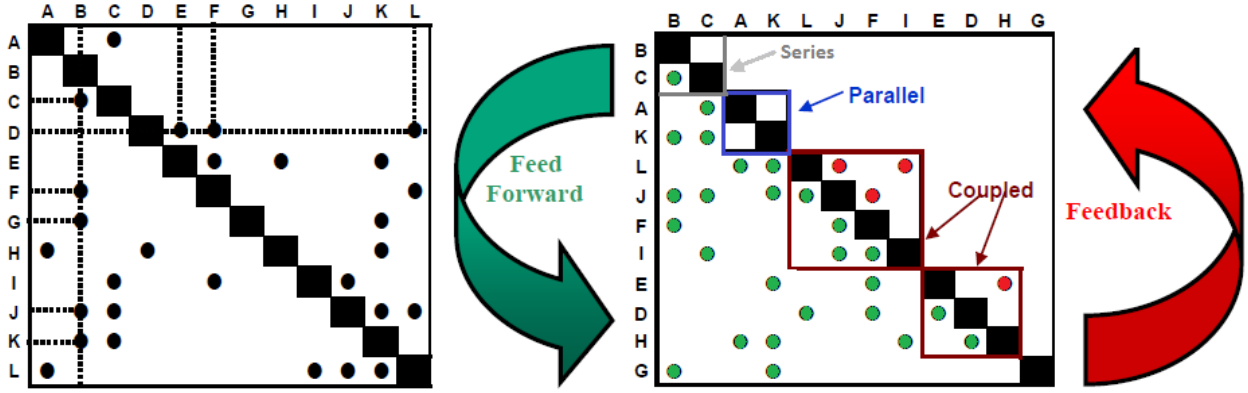


Figure 44: An Example of DSM Analysis [2]

The green dots shown to the left of the black diagonal line in Figure 44 indicate that the downstream activities in a Time-based process depend on inputs from upstream activities. The red dots to the right of the black diagonal line in Figure 44 indicate that upstream activates depend on inputs from downstream activities. The grey box labeled series represents tasks that need to occur in series/sequential order. For example in Figure 44 task B must be completed before task C can start. The blue box labeled parallel represents task that can accomplished in parallel. For example tasks A and K can be performed in parallel and that there are no interdependencies between these two tasks. The brown boxes labeled coupled in Figure 44, represents tasks that are coupled together. Coupled activities require high coordination in order to minimize or eliminate unnecessary iterations.

3.3.2.2 PSM32

PSM32 is power software that enables one to develop DSM model. PSM32 is developed by Donald V. Steward. The software is very simple to use and very effective in analyzing DSM model. The Figure 45 is an example of DSM model given in PSM32 tutorial. Tasks are entered into rows. A zero is entered where ever

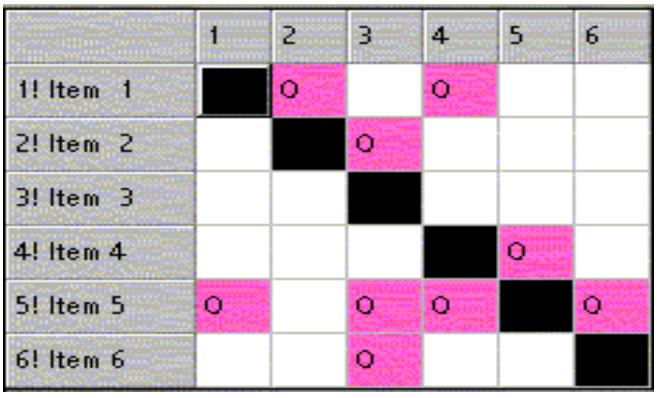


Figure 45: Example of DSM by Donald V. Steward

there is dependency between a task listed in the row and task in column. Here is example from a software tutorial.

For example, in Figure 45, the first row shows that item 1 depends upon items 2 and 4. The second row shows that item 2 depends on item 3. Row three shows that item 3 does not depend on items.

3.3.2.3 DSM Model

The data from the benchmarking in conjunction with interviews were used to build a Time-based DSM model using PSM32 software. The NPDP process used by medical device organization was broken down into 80 critical tasks. Figure 46 shows the translation of the organization's NPDP into DSM model. The result of partitioning of the DSM is shown in section 3.3.2.4. As it can be seen in Figure 46, it is very hard to see if there is any interdependency or relationship between tasks.

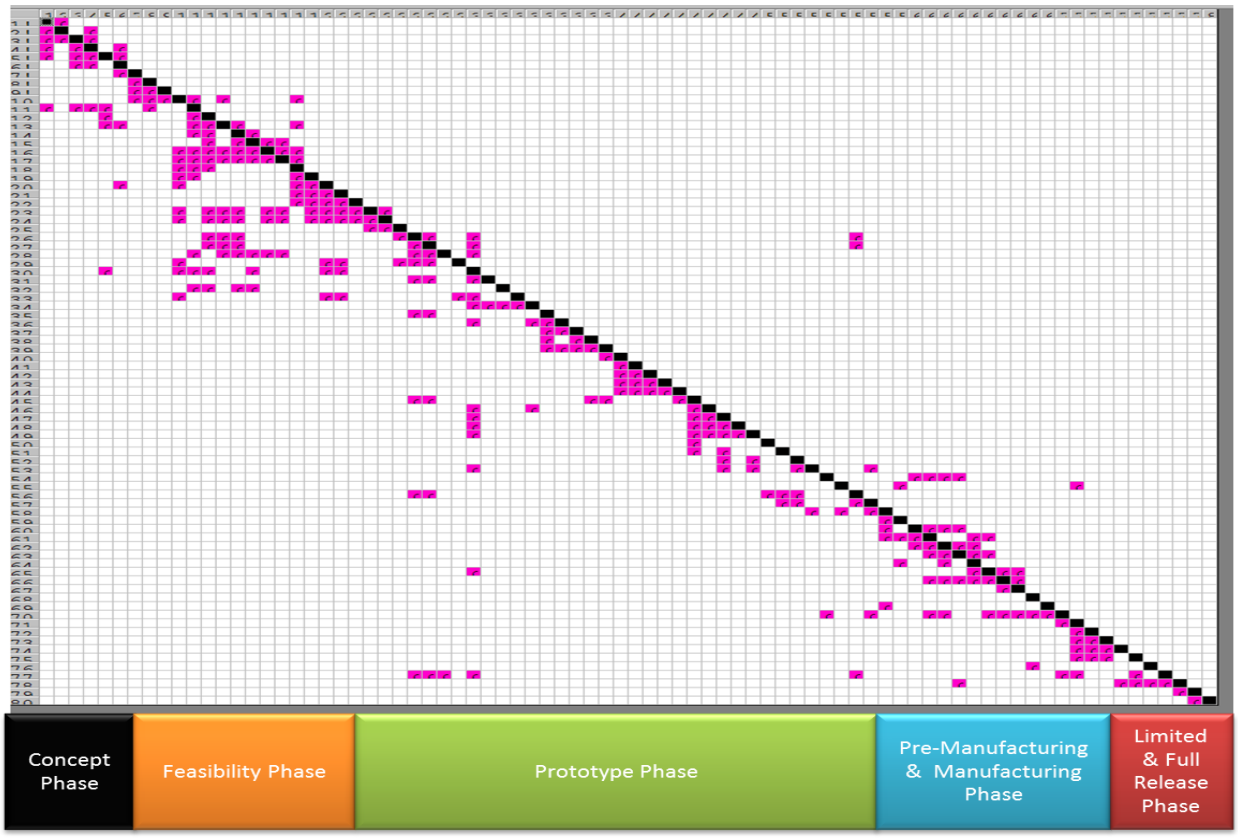


Figure 46: DSM model of the organization NPDP

3.3.2.4 Result of the DSM

The DSM model of the NPDP was partitioned and the result of this partitioning is shown in Figure 47. There are five pink squares, numbered one through five in Figure 47. Each square consist of a group of interdependent tasks. Boxes numbers 1 through 3 shown in Figure 47, are relative small groups. The majority of the tasks shown in Figure 47 are Feed-Forward because they are located to the left of the black diagonal line. There are several tasks that create a feedback loop within the pink squares. An example of tasks causing feedback loop is shown in Figure 47 with red arrow.

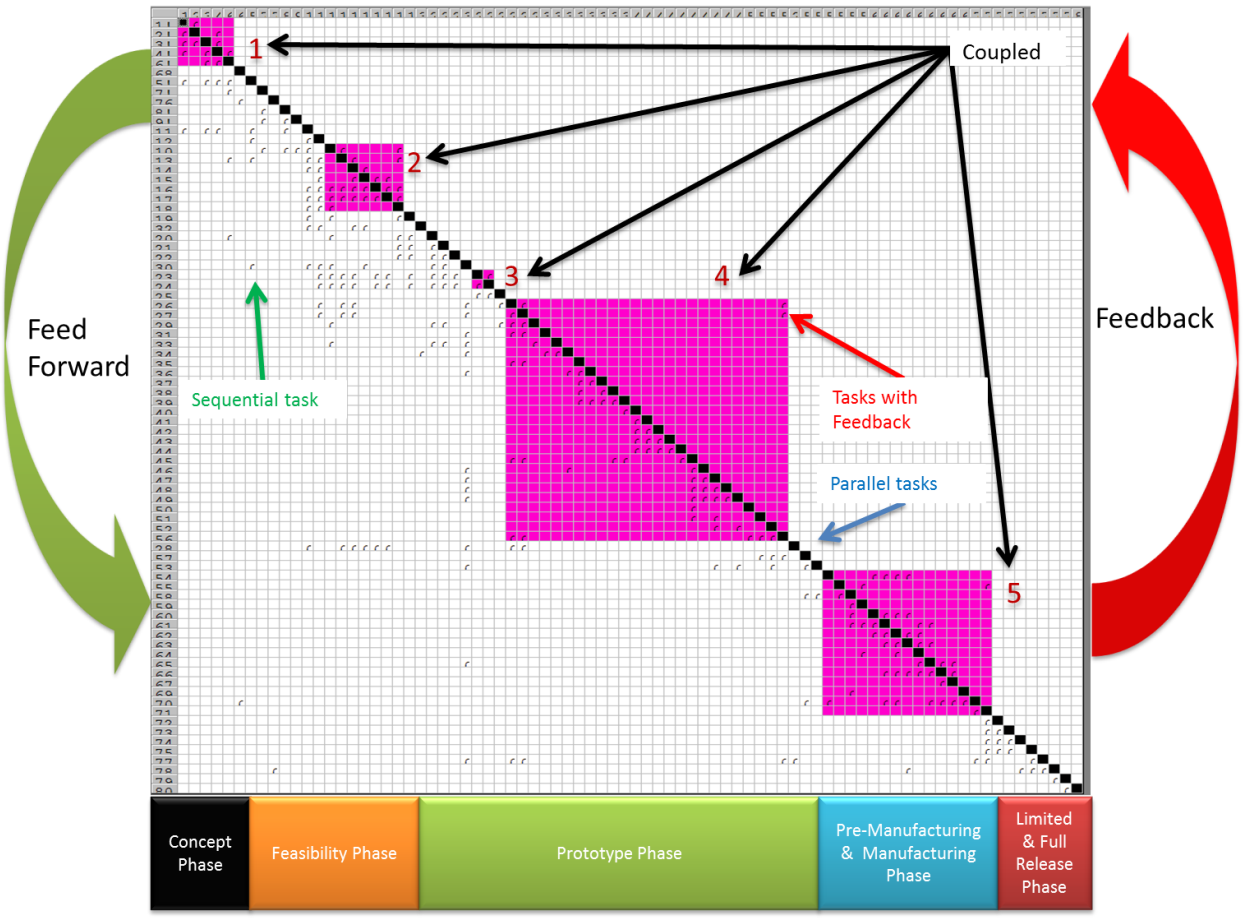


Figure 47: Partitioned DSM

Box number one is shown in Figure 48, represents tasks in concept phase. The majority of tasks in this box is driven by marketing and top executives. The major drivers in this phase are product line strategy and business risk analysis.

	1!	2!	3!	4!	6!
1! Users– Needs (C)		0			
2! Idea Generations (C)	0			0	
3! Business Justification (C)	0	0		0	
4! Risk Analysis (C)	0		0		0
6! Product Line Strategy Review (C)			0	0	

Figure 48: Concept Phase

Box number two shows the interdependent tasks within the Feasibility phase Figure 49. Concept testing is the driver of this phase. This finding is consistent with interviews conducted. What is interesting is that product requirement task is not part of this phase. This shows that the organization does not finalize product requirements until the end of feasibility phase.

	10!	13!	14!	15!	16!	17!	18!
10! Project Plan Draft (F)		0					0
13! Define Software Architecture (F)			0				0
14! Product architecture is developed (F)				0			
15! Define User Interface and Ergonomic Survey (F)			0		0	0	
16! Mechanical Component Requirement (F)	0	0	0	0		0	0
17! Electronic Component Requirement (F)	0	0	0	0	0		0
18! Concepts Testing: Iterative breadboards (F)	0						

Figure 49: Feasibility Phase

Box number three (Figure 50) is driven by initial electronic and mechanical design. These two principles are highly integrated due to the nature of the products this organization

produces.

	23!	24!
23! Initial Electronic Component Design (P)		0
24! Initiail Mechanical Components Design (P)	0	

Figure 50: Coupled Activities

Box number four (Figure 51) is the largest box with highest number interdependent tasks. This box represents the interdependent tasks with the prototype phase. The most interesting revelation in this box is the presence of several tasks from pre-production and production phase.

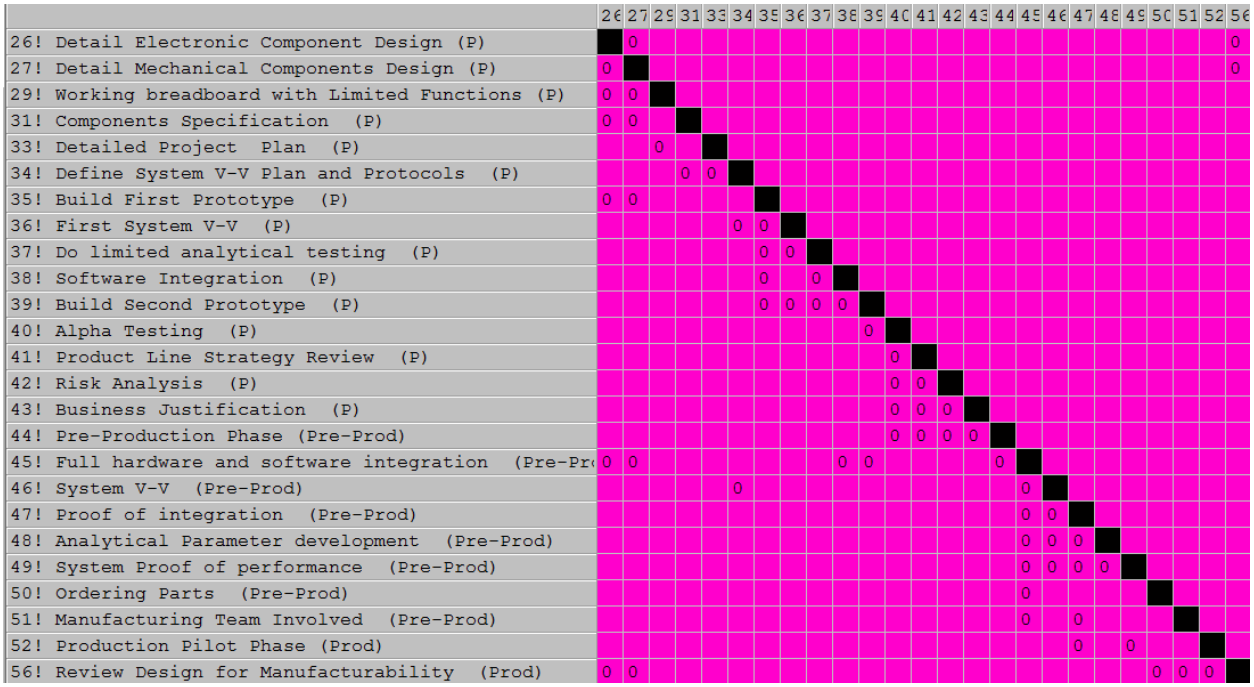


Figure 51: Prototype Phase

Box number five (Figure 52) is the last grouping in partition DSM model. This box consists mainly of tasks in production phase. There is a task from limited release phase that is highly dependent on tasks in productions phase of the developments. This task is the start of limited release phase and cannot start until regulatory approval is obtained. This

interdependency makes sense and suggests that goals for production must be met before limited release phase can start.

	54!	55!	58!	59!	60!	61!	62!	63!	64!	65!	66!	67!	69!	70!	71!
54! Review and Approve Labeling Requirements (Prod)					0	0	0	0							
55! Customer Support and Service Training (Prod)				0											0
58! Beta Testing - 1 (Prod)		0													
59! Small Redesign and Modification (Prod)			0												
60! Develop Worldwide Launch Plan (Prod)			0			0	0	0							
61! QC/QA Clinical Data Preparation (Prod)			0	0	0				0	0					
62! Choose Regulatory Path (Prod)					0	0		0	0						
63! Q6 Coordination (Prod)						0	0		0	0					
64! Beta Trial - 2 (Prod)				0			0								
65! System Optimization (Prod)									0		0	0			
66! Meeting Regulation Saftey Requirement (Prod)						0	0	0	0	0		0			
67! Risk Analysis (Prod)											0				
69! Develop Maintenance Plans (Prod)			0												
70! Limited Distribution Phase (Limited)	0					0	0			0	0	0	0		
71! Limited Release (Limited)														0	

Figure 52: Pre-Manufacturing and Manufacturing Phase

3.3.3 Interviews:

This section lists employee perceptions of advantages and disadvantages of the NPDP process.

Advantages of current NPDP:

1. Informal Approach to Feasibility and Prototype Phase:
    a. Engineers and scientists like the flexibility of the current process. The team is able to detect issues, identify the causes of issues and implement change(s) without having to gain approval from senior management. It should be noted that this flexibility only applies to feasibility and prototype phase. In pre-production phase, this flexibility is restricted however to minor changes. Engineers still have freedom to make changes

without the involvement of upper management, but this flexibility is limited in design mode.

2. Dedicated Core Team:
    a. The NPDP requires the formation of core team early in project life. The majority of the team members like this idea.
3. Daily Stand Up Meeting:
    a. Daily stand up meetings are considered by many team members as an effective way of increasing the awareness of the project status and increasing communication between team members.
4. Pre-Production Phase
    a. Manufacturing engineers like the fact that NPDP has Pre-production phase where manufacturing engineers get to work and learn from R&D engineers before full technology transfer to manufacturing. They prefer to start this involvement at earlier stage of NPDP.
5. Flexibility to Modify the NPDP
    a. Project Managers like the fact that they are able to customize the NPDP based on their project complexity.
6. Very Effective for Development of Major and Minor Products
    a. Groups found the NPDP process very effective for the development of major and minor products as well as the development of product that have defined product requirement.
    b. Very effective in developing of products do not involve technology development.
7. R&D Involvement with product support.
    a. R&D is high involved with issues product support. This allows the R&D engineers to learn from the field and integrated what they learn into the new products..

Disadvantages of the NPDP:

1. Not having formal NPDP
    a. Many engineers' roles and responsibilities are not well defined for members of the NPDP team. The main source of confusion comes from the fact that each product manager can modify the NPDP process. NPDP terminologies have different meanings to different people due many years of customization of the original NPDP. New employees are not trained with the knowledge of the official NPDP process; thus they learn the NPDP through working on projects.
2. The NPDP is Schedule -Driven:
    a. Many engineers found the process ineffective in developing new technology mainly because the NPDP is schedule-driven. The development team is not given enough time to understand the new technology.
3. Requirements are Not Fully Defined
    a. The current process does not demand requirement finalization until the end of the Feasibility phase. The benchmarking result showed that less than ten percent of product requirements change from beginning stage of NPDP to the final stage of the NPDP. Many engineers expressed that two to three critical requirements impacting product architecture are not finalized until the middle of prototype phase. Many found this to be distracting and a source of delay in the project.
4. System Integration is Delayed
    a. System integration is completed relatively late for new products and usually does not allow enough time for engineers to fully understand the impact of subsystems interactions with each other. Many engineers want to have more time to understand system interaction using empirical data rather than using theoretical calculation.

4 CONCLUSIONS AND RECOMMENDATIONS

4.1 PERSONAL INSIGHT

4.1.1 INTRODUCTION

The purpose of this section is to share my personal challenges in conducting this benchmarking study in order to inform those who intend to embark on the challenge of conducting their own benchmarking studies. The benchmarking process is a labor-intensive process. On average, for a midsize organization, it takes PMG two months to conduct a full R&D benchmarking. In order to conduct such a benchmarking, the PMG would send two of its employees, one full-time and one part-time to the organization. A member of the organization would assist the PMG employees for the duration of the benchmarking. For this thesis, two separate benchmarking studies were conducted for the two divisions of the organization. Originally, it was estimated that it would take four months to complete both benchmarking studies. However, it took six months to complete the studies for both divisions. It should be noted that PMG provided one individual part-time to assist with data processing. On average, the standard benchmarking by PMG includes sixty-four hours of interviews with various member of the organization. However, I wanted the interviews to be my own work without being influenced by PMG. Therefore, It should be noted that the information gathered through interviews was not communicated to PMG.

4.1.2 CHALLENGES

"The benchmarking of R&D department is difficult because there is no standard process to R&D development that everyone follows"- Daniel Whitney

While there are some commonalties among various NPDPs, most organizations customized these NPDPs for their own uses. The literature research for this thesis revealed that organizations follow many different NPDPs. My first challenge with conducting this benchmarking study was to convert the specific organization's NPDP to the standard PGM's

NPDP (PACE®). The benchmarking questionnaire was designed based on PRTM's PACE® NPDP. The organization that was benchmarked followed a parallel Spiral NPDP. The organization's parallel Spiral NPDP was converted to a sequential Phase-Gate before any questions could be accurately answered. The task of converting the organization's NPDP from Spiral process to Phase-Gate process took one month because data was pulled from another benchmarking study conducted by the organization in 2008. It had taken the previous benchmarking team of two full-time staff members three months to create this list. This task was only possible because the organization kept track of time spent by project members on various activates within projects. Had this organization not kept a record of time spent on various projects, the accurate conversion of the organization's NPDP to a standard NPDP would not have been possible. This is a major challenge facing anyone who plans to benchmarked R&D processes.

4.1.3 LESSONS LEARNED FROM BENCHMARKING

Quantitative results do not always tell the whole story.

The interviews that occurred as part of the benchmarking are as critical as the quantitative data collected for the benchmarking. This benchmarking was more than just handing out questionnaires to members of the organization and collecting responses. The first step of the process was to partition the questions into groups and distribute the questions to the right people. In cases in which it was not clear who could provide the most relevant answers, questions were distributed to multiple people. The questions were sent to many employees of various ranks. This benchmarking was not a high priority for all employees, so constantly reminding individuals to fill out the questionnaires was essential. The most effective way of getting responses was to email the questionnaires to the individuals in advance and then setting up a meeting in three weeks time to review the completed questionnaires with them. This was effective because it motivated the individual employees to look over the questionnaires and to be prepared for the meeting. During these one-on-one meetings, the individuals were asked to elaborate on their written responses to the questions the questionnaire. This was intended to extract soft information to better understand the context and the endogenous and exogenous forces that influenced result. Often, quantitative

benchmarking questions were followed by interviews of a qualitative nature to get a fuller picture. For example, one of the quantitative questions in the benchmarking study asked the following question:

1. What percent of high level requirements changed during the NPDP?

The answer to this question was ten percent.

The ten percent change in requirements is on par with BIC and did not flag any issues with the organization's NPDP. However during the interviews, it was discovered that a change to one requirement had added one year to project. This important information would have been missed if the final benchmarking conclusion had been based solely on quantitative results and data.

"Empathic listening is listening with intent to understand the other person's frame of reference and feelings. You must listen with your ears, your eyes and your heart." Stephen R. Covey

It is vital to understand the interviewee reference points and how these reference points influence his or her responses. It is also important to expect that some interviewees will become passionate in their responses during these interviews because they are talking about something they care about, so listening empathetically helps facilitate the acquisition of qualitative data. If the interviewee does not feel comfortable during the interview, he or she will not share their insights that are important to the benchmarking processes.

It is also important to know the interviewees' frames of reference during qualitative questioning because this impacts the results of the benchmarking. This is especially important when accurate quantitative data is not available. The following is an example of such situation. Accurate data about the BOM (Bill of Material) was not available because the projects benchmarked for this thesis were over ten years old. In order to answer the questions in regards to BOM, questions were asked of manufacturing and R&D engineers. The R&D engineers' responses differed greatly from the one from manufacturing engineers. After interviewing each team, it was discovered that manufacturing and R&D engineers had different understandings of BOM accuracy because they viewed this question from different frames of

reference. The R&D engineers' understandings of BOM were limited and did not include all processes. In this organization, manufacturing engineers' understandings of BOM accuracy were very broad when compared to R&D engineers. When the manufacturing engineers' responses were reported to R&D engineers, the R&D rejected manufacturing claim. The same happened the R&D response was reported to manufacturing engineers. This finding was very important, because a decision had to be made to determine whose response should be submitted to the benchmarking. Using a comprehensive understanding of each team's frame of reference, an intelligent decision was made to incorporate the manufacturing engineers' responses in the benchmarking.

"For me context is the key - from that comes the understanding of everything".-Kenneth Noland

"In common use almost every word has many shades of meaning, and therefore needs to be interpreted by the context."-Alfred Marshall

Context plays a major role in understanding and explaining interviewee responses for the benchmarking results. Without knowing the full context, one may compare apples and oranges. An example of this happened when PMG compiled the benchmarking data without knowing the organization's full history. This was done on purpose. For the first data compilation, PMG was not provided with interview and organization insight. The PMG team came to conclusion that one division spent excessive time developing new technology when compared to BIC and the second division benchmarked. The real reason one division spent excessive time on technology development was the effect of an exogenous force and was not related to R&D's NPDP.

You think you are done, but you are not! Benchmarking is an iterative process!

A successful benchmarking conclusion is based on a constant feedback loop between the members of the benchmarked organization and the organization that is conducting the benchmarking. This constant feedback loop allows for the development of a complete story of the organization R&D's NPDP. Every time the benchmarking results as a whole are presented to the organization, more questions are raised, more soft information is extracted and a fuller picture of the organization begins to materialize. The more the employees of an organization

are involved in the benchmarking process, the higher the likelihood that the benchmarking recommendations will be implemented. For example, consistent involvement of manufacturing engineers in the benchmarking process motivated them to implement a new methodology of tracking BOM inaccuracies.

Timing is everything!

Nothing comes for free!

Timing of benchmarking is a key. Benchmarking should be done when the organization has the capacity to implement the recommendations from the benchmarking study. Without the intention to commit to implementing the recommendations from benchmarking, conducting benchmarking does not bring full value to the organization. Benchmarking should not be done when the organization is about to embark on major a project or when the organization is in the middle of firefighting. The implementing of recommendations from a benchmarking study requires time, employee training and an expanded budget. Any organizations planning to conduct benchmarking need consider time, budget and training needed to implement the resulting recommendations. Some of key finding from this benchmarking were not implemented because the benchmarking conclusion came after the yearly budgets had been decided and because the organization at this moment did not have bandwidth to implement all the recommendations.

4.2 ADVANTAGES AND DISADVANTAGES OF PMG BENCHMARKING

4.2.1 Advantages

PMG's advantage is first and foremost getting unbiased overview of organization performance by a third party. Whether the results of the benchmarking are positive or negative, the organization usually gives more weight to results from an independent source. By examining the whole organization the PMG is able to determine where communication between R&D and other departments such as marketing, manufacturing, service, and others, needs improvement.

"PDP differences are poorly understood and not yet fully acknowledged in existing literature and practice. As a result, companies have difficulty designing or selecting PDPs" Eppinger [16].

PMG and PRTM have a long history and knowledge in NPDP thus having them analyze NPDP and then having PMG helping the organization develop a personalized NPDP is invaluable. No two organizations are the same thus their NPDP should not be the same either. PMG with help of PRTM would help an organization through the NPDP selection and personalization and implementation process.

4.2.2 Limitation

Benchmarking old projects is very difficult, especially when the organization does not keep good records or if many members of the organizations have left. The benchmarking is designed to take the current pulse of organization, not what it was in the past.

The benchmarking is designed for large organizations that work on 3 or more projects at the same time. The benchmarking is not designed to benchmark only one or two projects. The PMG benchmarking is based on Phase-Gate NPDP, so when benchmarking an organization that is not practicing Phase-Gate NPDP, it has to be converted to Phase-Gate. This process takes time and important information can be lost as NPDP is translated from one process to Phase-Gate.

The PMG benchmarking does include a regulatory section that covers the organization's approach to FDA, EU and Japan regulations; however this section is weak and can be improved. In 2010, 32 Medical devices were recalled and 89 warning letters were sent out to medical device organizations for not complying with 577 GSR subsystem regulations. PMG benchmarking has the potential to expand their regulatory section and put more emphasis on how NPDPs can improve to meet regulatory demands.

The mere existence of a formal product development process had absolutely no effect on performance. According to the benchmarking study, there was no correlation at all between merely having a formal process and performance results. The message is clear: those

companies who mistakenly believe they can "go through the motions" and reengineer their new product processes usually amount to documenting what they're already doing and they are in for a big disappointment.[27].

The presence of PMG members for benchmarking process is not necessary merely because of the benchmarking by itself. The rationale for their presence is the existence of instances where there were discrepancy between what was written and what was actually done. This is not common case limited to the organization benchmarked. This is a common practice among large and small organizations [16].

4.3 CONCLUSION OF ORGANIZATION BENCHMARKING AND RECOMMENDATION

The benchmarking results shows that many of the steps the organization took in 2008 and 2009 to improve its processes were on par with benchmarking findings. The organization spent less time on upfront activities which ended up delaying product launch and increased product development cost. The organization sponsored a team of employees to go back to school to learn the latest methods of developing system architecture, requirement and systems approach to product development and implement these processes in the organization. The benchmarking also found the organization's need to separate technology from project development. The organization came to the same conclusion in 2009 and had begun the process of forming a technology development team. Improving technology transfer from R&D to manufacturing was another area where benchmarking found that the organization could be improved by using information technology. The organization had begun a process of developing a software platform to help facilitate the transfer of technologies from R&D to manufacturing.

The benchmarking also found that current NPDP was not adequate and required improvements. This finding was also confirmed with DSM analysis as well as interviews. The DSM shows that there are many interdependencies among tasks especially in prototype phase. For example, it was discovered that there was no common language for current NPDP used at the organization. Different individuals had different definitions for the various steps in the

NPDP. This is something the organization also agreed that needed to improve. To improve the NPDP the organization hired a director, who has experience working with PRTM implementing PACE® at large two major medical device companies. As a group, it was concluded that this moment is not correct for the organization to implement a new NPDP. The rationale is as follows: implementing a new organizational NPDP requires the organization to focus on learning and implementing the NPDP. Based on average estimate from PRTM it would take 6 months to implement a new NPDP. It was decided that implement a new NPDP should be done at beginning of product developing cycle rather than in middle of product development cycle. The second reason for not implementing a new NPDP at the moment was to give time to all managers to get involve with process. This meant to introduce manager to various NPDP and getting them involve in selecting NPDP process. This is right decision by the organization. It takes time and effort to change a major process such as NPDP. It took Toyota 7 years to implement their NPDP, because they make their NPDP part of their DNA and culture [34].

As part of the benchmarking, many interviews were conducted with managers. Managers for most part favor a flexible NPDP because they felt that Phase-Gate would slow their projects down. However the benchmarking results identified this as a symptom of the fact that the organization does not spend enough time conducting up front activities and developing new technology as part of projects. As result of these two facts, it made sense for project manager to favor a flexible approach to product development. However with the changes the organization is implementing it is recommended that the organization follow a Phase-Gate process for device development. The Phase-Gate process is more controlled. It reduces risks and it is more compliant with FDA GSR. It is also recommend that the organization not to have one NPDP for the whole organization.

"The best do not succeed by using just one NPD practice more extensively or better, but by using a number of them more effectively simultaneously" –Griffin [30]

It is recommended to the organization develop three NPDPs: one for platform development, one for major product development and one for minor product development. It is recommended all three NPDP have common language. Also the organization should repeat

the DSM analysis to confirm that the new process does a better job of managing tasks interdependencies within NPDP.

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