Mapping the Medical Device Development Process

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ABSTRACT

This project examined the use of process mapping as a tool to show the process of developing medical devices from a broad perspective that includes research, innovation, development, regulation, and marketing. The medical device development cycle, on a broad scope, is not well defined. The lack of a universal language with which to describe this process has made it difficult to understand and communicate. In this project, data was collected from peer-reviewed sources, summarized in a literature review, drawn out by hand into a series of lower-level process maps and finally assembled into a single process map.

This project is an attempt to work towards establishing a general framework that can be used to better understand how medical devices are developed and marketed. It supports that process mapping may have potential for being used on a higher level than it is traditionally used. The final process map produced in this project has limitations. The map gives a basic understanding of the broader development process. The level of detail and accuracy of the process map is limited by the time and cost of process mapping.
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INTRODUCTION

The processes and transactions of value that take place in the biomedical industry, from research and innovation to device development, and finally the end use of that device, follow a path that is both complex and difficult to visualize. Kaplan et al. (2004) have stressed that understanding the complexities of this process is of utmost importance for ensuring the timely introduction of new medical technologies. Terziovsky and Morgan have also pointed out that no comprehensive documentation or common language exists that describes the entire innovation cycle (2006).

The main goal of this paper is to investigate whether process mapping can be a useful tool for trying to understand the cycle of research, innovation, development, regulation, and marketing for medical technologies on a broad level, and what limitations it may have. What are the steps, or processes, needed to transform basic research into a marketed device? This project represents an attempt to gain a more holistic understanding of this medical device development process. How can this process be understood, and improved, as a whole?

A good first step in understanding this process is having a visual representation of it. Soliman (1998) has argued that process mapping/understanding is the most important element of business process re-engineering. If business process re-engineering can be used to improve processes within a firm, can the same principles be applied to a much broader, more abstract range of activities? This paper documents one such attempt to use process mapping to create an in-depth visual map of these processes, using sources that each discuss only a portion of the entire progression. By assembling these pieces of data together, it is hoped that a wider understanding of the entire system can be gained by individuals that may only be involved in a small part of it, or do not yet have a role in the system, such as a student or an entrepreneur.

Problem Statement

The purpose of this project was to develop a knowledge base of the medical device development process on a macro level, and to map the process to a somewhat high level of detail. There are two main problems that this project addresses. The first is that there is insufficient data on the process as a whole, and no comprehensive language has been developed that describes this process (Terziovsky & Morgan, 2006). The second is that process mapping is used generally to
describe topics that are less broad, and complications arise from trying to collect and display information for such a wide range of activities.

During the project, the author was a senior year student at California Polytechnic State University, and was working on the completion of a Bachelor of Science degree in Industrial Technology. The author was working towards entering the medical devices sector, but had no personal experience with device development. From this perspective, there are several discrepancies with the way that process mapping is normally used in business applications. In Business Process Re-engineering (BPR), process mapping is largely used by businesses to determine the “current state” of a set of processes, and then to radically make improvements to this entire system (Aldowaisan & Gaafar, 1999). However, a student or entrepreneur does not have a “current state process” to work with, and presumably no way to observe each sub process, much less the entire cycle.

Another difficulty in mapping this process is that the time it takes to go through this entire development cycle is much longer than an everyday business or manufacturing process, and each repetition of this cycle (development of a new device) may be radically different from the next. In one study, MacPherson (2001) evaluated innovation output of several companies on a 10-year period, because of the length of time required to go through regulatory controls.

Some processes that are important parts of this cycle may be informal or poorly defined. For example, within the innovation and research portion of medical device development, Berg et al. (2007) has established that many parts of the grant application process are informal and not discussed in literature. However, they are still important aspects of the process that need to be considered, as they add time and costs to research projects. This brings unique challenges to understanding and evaluating (and possibly improving) this cycle. How can process mapping be used by students and potential device developers to better understand the cycle, or to premeditate the terrain that they may have to go through to fully market a device or medical technology?

Needs
The usefulness of a process map depends on the level of detail and accuracy of information shown within the map. Soliman (1998) proposed the idea that there may be an “optimum level of process mapping” (p. 810). In an examination of regular business processes, Soliman has concluded that there is a trade-off between investment in a greater level of detail of process
mapping, and defects associated with an insufficient level of detail. This may correlate to a misunderstanding of the requirements needed for developing a medical device if the time is not taken to fully ensure the detail and accuracy of information. Being able to accurately predict the requirements is effectively a way to manage risk.

Metrics are also useful in process mapping. Carefully selected numerical data can inform (or visually display) specifics of a process. In this case, time is an important factor for each step or process. Again, time may be variable to a high degree with respect to many of the individual processes.

The manner in which the information is displayed may have a great effect on its usefulness. The chart must be visual enough to communicate the somewhat non-linear nature of the process (inclusive of different paths or possibilities), while still remaining easy to read and follow as it is graphed over time.

**Background or Related Work**

Process mapping has been used in a wide variety of applications, from business process re-engineering to software design. It has been examined in sufficient detail, as discussed further in the Literature Review section of this paper.

Currently, there is a large amount of information about regulations, design guidance, and requirements available from the FDA and other sources. Some information has been visually represented with flowcharts and diagrams. For example, the FDA has provided a basic flowchart used to convey the iterative cycle of designing a device, low-level specifications (FDA, 1997). However, broader processes have not represented visually in sufficient detail, and individual components such as this have not been tied together to show a larger picture.

For the most part, the individual lower level processes or tasks within the medical device development cycle have been discussed in sufficient detail (and it will also be assumed that process mapping has the potential for identifying areas that have not been covered extensively enough). Innovation, funding, basic and applied research, device development, clinical testing, regulatory paths, and marketing requirements have all been discussed individually. The background of all of these topics will be further discussed in the Literature Review section of this paper.
Solution Statement/ Potential Solutions
The proposed solution is to compile the information from peer-reviewed sources of literature, and to abstract the information to form a large, detailed flowchart. This has the advantage of possible cross-referencing different articles, providing a sort of check where they overlap. This is clearly not a very scientific or standardized way of collecting data. However, with the provided level of resources, it should be a sufficient method for collecting high level, detailed information, while also ensuring accuracy. The method will be discussed further in the Methodology section of this paper.

Contribution
This project contributes toward the knowledge base of medical device development as a whole. The main output of this project is a simple learning tool for better understanding the entire situation. The author could not find any similar attempt for displaying the development cycle. Ultimately, this project looks for a more in-depth analysis of the medical device development process on a broad scale. This project will hopefully demonstrate the usefulness of mapping this scenario as a starting place for better understanding the process.

Purpose and Applications
The process map created in this project is suited for educating students, potential device developers, or anyone who has a limited knowledge of medical device development. This approach involves a mapping more general scenario, in which several options demonstrate the different possible paths or processes that may be taken to market devices. There are clear limitations in the scope and accuracy of the project.

There are several potential applications of this tool, beyond the scope of this project that are worth discussing. The first is the use of mapping by a firm in a business process reengineering type of scenario, where the goal is to improve the development process as a whole. A complex study could analyze the processes and transfers and total time for each process. Close analysis of the time and involvement could reveal bottlenecks, and the firm could determine which areas need the most improvement or redesign. Another application is to use process mapping to plan for the development of a specific technology or device. In this case, the
specifics of the device and regulatory path may be well-known, and the tool would allow the
developer to better plan the path to market. Both applications involve a considerable amount of
time and cost to ensure accuracy and allow the process to be examined in greater detail.
LITERATURE REVIEW
The purpose of this research project was to study the potential use of process mapping as applied to the medical device innovation and development process. The breadth of the subject matter discussed in this paper calls for review of a somewhat wide range of literature topics. This literature review serves two main purposes. The first is to gain an understanding of process management and re-engineering and its potential for use in describing the entire medical innovation process. The second is to gain an understanding of the current knowledge and consensus on this entire development process, from innovation to commercialization, and to identify any gaps that exist in the information about this process.

Business Processes/ Process Approach
The concept of process management has its roots in the development of scientific management in the early 20th century. Most notably, Frederick Winslow Taylor developed and later advocated the use of “scientific management”, or “task management” (1911). In this system, the elements of work were broken down and carefully studied, and then reassembled in the most efficient way possible. In addition to breaking down individual tasks, Taylor described the management of each individual, and planning based on “elaborate diagrams or maps of the yard” (1911). From these very physical beginnings, the process approach has expanded into a much broader range of activities and applications.

In recent years, International Standards Organization (ISO) has supported using a process approach to business management (Basler and Pizinger, 2004). The quality management system standard ISO 9001:2000 has mandated the adoption of a process approach (ISO, 2000). This mandate was also passed on to the sphere of medical devices when ISO introduced ISO 13485:2003, which explicitly requires a process approach toward quality management for medical device manufacturing (ISO, 2003). ISO 13485 establishes guidelines for a quality management system in a medical device firm, and although it is not a requirement in the U.S., it is a legal requirement in some countries in order for a firm to market a medical device (2004).

Developing new medical devices requires effective risk management, perhaps more so than most industries. Basler & Pizinger (2004) have emphasized the importance of a process approach, versus a procedural approach, to quality management, and have argued that risk management is integrated into the process-based approach to quality management. In
comparison to ISO 13485:2003, The FDA’s Quality System Requirement (QSR) is procedurally based. In other words, it is set up as a list of mandates that must be followed, whereas ISO 13485:2003 is set up and functions as a system. Lindsay, Downs, & Dunn (2003) have supported that there is a general consensus in the business process reengineering that a process-structured organization responds more effectively to environmental change.

**Business Process Mapping.** Marrelli describes process mapping as “the step-by-step description of the actions taken by workers as they use a specific set of inputs to produce a defined set of outputs” (2005). However, process mapping has been used on a wide range of scales and different levels of detail, and has been established as a tool that creates greater understanding and potential for improvement. Biazzo (2002) has established that using process mapping techniques is crucial to improving business processes. Soliman (1998) has stated that “the visual representation of the process tends to isolate crucial information” (p.811). Closer to the subject of medical devices, Terziiovsky and Morgan have identified “innovation cycle maps” as one of 10 tools for accelerating the biomedical commercialization process (2006).

**Definitions and Limitations.** ISO has stated that “Any activity that receives inputs and converts them into outputs can be considered as a process” (2003, p. v). Most definitions are similar to this, but there are other definitions. However, Lindsay et al. (2003) have pointed out that many definitions are conflicting. Also, because of its beginnings in physical labor and manufacturing, the terms used in Process Management are somewhat limiting. Lindsay et al. have also pointed out that there is a lack of a clear definition of "process", and most definitions that have been given in the past are much too limited in scope.

**Cross-Organizational Links.** Medical device development involves a number of organizations in activities and transfers that extend over a long period of time. Cross-organizational communication and processes are a main importance to a firm’s well-being, especially in the medical device industry and in the process of medical device development. Quinn (2000) has argued that one single company alone cannot compete with all of the combined various sources of knowledge and innovation in the world. Outsourcing innovation, and strategically managing these sources of value, is needed for a modern-day company to survive.

In a traditional sense, the term “supply chain management” can be used to describe the management of cross-organizational activities. Lambert, Cooper, and Pagh (1998) have defined supply chain management (SCM) as “The integration of key business processes from end user
through original suppliers that provides products, services, and information that adds value for customers and other stakeholders” (p.1). Hammer (2001) has maintained that a great amount of waste is created by lack of communication between different organizations, for example, by the same exact work being performed by an organization and its supplier. Hammer has argued that “Streamlining cross-company processes is the next great frontier for reducing costs, enhancing quality, and speeding operations” (p.84).

The Medical Device Development Process on a Broad Scale
Medical device development has not been analyzed sufficiently on a broad scale. Terziovsky and Morgan (2006) have concluded that there is almost no documentation on the innovation cycle as a whole, and in effect there is no common language that is used to describe how this cycle functions. The lack of a common language prevents further discussion. Terziovsky and Morgan have argued that the innovation cycle must be controlled and managed strategically across organizational boundaries in order for this process to be improved. New skills need to be developed for managing the collaboration between organizations. Sharing knowledge with other partners is a new challenge that requires trust and strategic development of relationships.

Research & Innovation
Academia and industry are closely tied together in medical device development. Gelkins & Thier (2002) have recognized that medical device firms have a tendency to rely on basic academic research more than other high-tech industries do. Relations between the two have also increased greatly in recent decades. In one study, Harmon et al. found that 21.7 percent of all technologies licensed from one university were for medical devices, and more than half fell under the categories of medicine, health, or nutrition (1997).

A traditional understanding of research is that universities create basic knowledge, and firms apply this knowledge to real world applications. The National Institutes of Health (NIH) has distinguished between two different categories of research: basic and applied (Moses, Dorsey, Matheson, and Their, 2005). However, the roles of industry and academia are far more variable and complex than this perspective acknowledges. Gelkins and Thier have identified a number of industry-academia connections (2002). For example, industry and academia work together in many cases, such as co-authoring research papers. During the clinical evaluation
stages of development, Academic Health Centers (ACHs) perform clinical tests and suggest improvements.

Gelkins and Thier (2002) have also described mechanisms of knowledge transfer between academia and industry. The most common of these mechanisms of transfer are scientists (training), publications, and presentations. Patents and university licensing have become prominent mechanisms of transaction in the last 20 to 30 years. For some universities, technology licensing is a major source of revenue. Other arrangements suggest that universities and companies now work closer together that in the past, and that knowledge transfer happens in both directions. Some universities have long-term research agreements with companies. Staff members may also be involved in creating new companies. Another somewhat new development is the creation incubator space within universities, which contribute to the establishment of start-up companies.

Harmon et al. (1997) have closely reviewed and summarized the transfer of technology into two perspectives. The first approach describes this transfer as a discrete transaction from one organization (a university or lab) to another (a business). This approach focuses on the actual activities of that transfer process. The second involves a more collaborative effort where a long-term relationship has developed between two organizations. This second perspective focuses more on describing the structure of the communication between two organizations. A third approach looks at a combination of both of these aspects. The study also found that two-thirds of these technologies went to larger companies for the purpose of improving existing products or product lines, and that a majority of the ideas researched also originated from the university.

MacPherson (2001) has investigated the effects of “knowledge spillovers” from academia to industry. It was found that innovation is higher in companies that utilize university resources, and that geographical proximity was an important factor in these linkages. Similarly, Harmon et al. (1997) have stressed that most successful transfers of technology take place when there is already an existing connection between a university and firm.

### Funding

Funding is a major contributor to basic research, and also is an important factor for start-up companies. Berg et al. (2007) have explained that research careers are dependent on the security
of receiving NIH grant funds. Moses et al. (2005) have also stressed that biomedical innovations are heavily dependent on public funding, more so than other high-tech industries. As such, funding is a key part of the innovation process.

Moses et al. (2005) examined trends and total levels of biomedical research funding from the four largest sources: the federal government, industry, state or local government, and private non-profit organizations. The National Institutes of Health (NIH) was the largest source of federal funding, and it nearly doubled from 1994 to 2003. Other, smaller federal sources of funding are the Department of Defense, the Department of Agriculture, the National Science Foundation (NSF), and the Department of Energy.

The NIH funds projects through several different routes. Korn et al. (2002) has explained that more than fifty percent of NIH funding goes toward Research Project Grants (RPG), which are initiated by the researcher. Funding for this type of grant typically lasts around four years. The process of applying for a grant can be difficult and time-consuming. This process can be divided into several practical phases: planning, preparing the proposal, final submission, and follow-up. Berg et al. (2007) have emphasized that “These aspects are rarely discussed in the literature, and are instead, commonly learned through trial and error or through informal interactions with experienced investigators” (p.1587).

According to Berg et al. (2007), The NIH grant application process begins with “planning the proposal” (p. 1587). This includes choosing which NIH institute to apply to, exploring available funding opportunities within that institute or center, choosing the type of grant, and building a team of researchers. The second phase, the actual preparation of the grant proposal, has several steps. Following NIH guidance, understanding internal review, creating a budget, and understanding how the NIH will review the proposal are included in this phase. The final phase is the process of submitting the grant proposal and following up. In this phase, the Center for Scientific Review (CSR) evaluates grant applications by means of scientific study sections, and grades each application according to a number of attributes. The grading process may begin four to six months after the application is submitted. Berg et al. suggest actively following up after submittal, including amending the application if it is not approved. If approved, funding may begin several months after approval.
Development of New Devices
A number of perspectives were found that describe the actual development process for new medical devices. These can be grouped into two main categories. Some, such as Kaplan et al. (2004) have looked at the individual events or actions that take place medical device development process. Others have described the process on a more abstract level, at risk of neglecting the individual events that may take place.

Kaplan et al. (2004) maintain that most new types of devices are developed by start-up companies, rather than large, established medical device firms. The development time up until clinical testing takes around 2-3 years and costs around 10 to 20 million dollars. These start-ups are usually backed by venture capital, or sometimes by angel investors. The complexity of the regulatory system in the United States has pushed medical device development activities to Europe, and the difference in total time to market between the U.S. and Europe can be as much as one year. Kaplan et al. also point out that reaching clinical testing is seen as an important first step of success, and that companies try to get to this point as quick as possible. Reaching the point of first clinical use requires a good understanding of the system, and how to reach goals effectively and efficiently.

Panescu (2009) has recognized a common pattern of six phases that occur in this development process: funding phase, concept phase, development phase, verification and validation phase, product phase, and market release phase. A waterfall model has been used (Panescu, 2009; FDA, 1997) to show how each phase flows to the next, and how each step is reviewed (Figure 7). This model shows the customer-oriented requirement of where each step is verified to determine the next course of action, and where the final product of the process is validated by user needs.

Regulation and Approval Process
The regulatory hurdles involved with developing new medical devices present a major risk to the project's success. Panescu (2009) has established that FDA regulatory requirements are the most important factor that affects the ability for companies to develop new medical technologies. In the United States, the Food and Drug Administration (FDA) is responsible for ensuring both public safety and the efficacy of drugs and medical devices. The FDA has a number of elements that work to regulate firms for different activities. These regulations cover manufacturing
activities, risk and potential for harm, classification of devices, premarket evaluation and approval, and post market evaluation. The FDA works to create a balance between medical advancement and safety, mainly by evaluating the risk that a device will bring to the user (Maisel, 2004).

According to Monsein (1997), there are three main routes to market, depending on where the device falls within the three-tiered class system. The FDA assigns each device to class I, II, or III accordingly. Class III devices are present the highest amount of risk, and therefore are subject to a greater amount of regulation. These three classes are a major consideration that affects the path that a firm must take in order to market a device. All medical devices are subject to “general controls”, which establish good manufacturing practices, proper labeling, and other basic safety assurances. Class II devices are also subject to “special controls”, which are specific to the type of device. Class III devices are those which are used for sustaining human life, or new types of devices in which safety and effectiveness has not been established.

It is also usually a requirement for the firm to prove “substantial equivalence” to a previously existing device. This is done in the “Premarket Notification” or “510(k)” process. Some class I and II devices are exempt from this process (Medical Device Classification Procedures, 2009).

Class III devices must usually have a Premarket Approval (PMA), which is a sufficiently more complex process, involving large randomized clinical trials. According to Kaplan et al. (2004), "The specifics regarding study design may have profound impact on the time and cost of bringing a new device to market." Kaplan et al. have also stressed that clinical testing is the greatest financial risk to a new device developer (2004).

**IDE & IRB Processes.** Investigational Device Exemption (IDE) allows a device developer to use a device that has not yet gained market clearance. This process begins the preparation for clinical trials, and involves a large amount of collaboration between the developer and FDA/CDHR. In this phase, the CDRH staff reviews related scientific data and makes suggestions to the firm. The firm may then make changes as submit the IDE application for formal review.

Before clinical trials may be performed, the firm involved must have approval from an Institutional Review Board (IRB). IRBs function to protect the safety and rights of patients involved in clinical research. IRBs are mandated for clinical trials and research that involves
human subjects (Protection of Human Subjects, 2009). The process of applying for approval of Institutional Review Boards for each clinical center can add a considerable amount of time and complexity to research projects.

The process begins with recruiting testing sites for the clinical trial (Larson et al., 2004). Each site must be applied to individually, and the application process may vary. The IRB will review the application and may request changes, and finally approve or deny the application. The firm must then make financial and other arrangements for the clinical trials with each clinical site.

Larson et al. (2004) have found that there is a lack of standardization in IRB processes. In a study done by Larson et al., the total time for the approval process ranged from 1 to 303 days, and averaged 45.4 days.

Clinical Testing. After each IRB has approved the clinical trial, and negotiations have been made, clinical trials may begin. Kaplan et al. (2004) have divided the clinical testing process into two phases: pilot and pivotal. The pilot phase is less extensive, and is done in order to establish safety and to help with designing the pivotal phase. First clinical use is done in this phase, representing a major milestone in the development process. The pivotal phase involves a larger number of people, and establishes what uses and subjects the device is safe and effective for. The phase may require a large randomized study if the device is “first-in class”, but in most trials this phase is done to carefully track the performance of the device and does not require as extensive resources.

Conclusions
Although a sufficient amount of information is known about most of the individual steps, there is a lack of knowledge about the process of development as a whole. There may be variation between firms in the actual development process. The different routes to market represent important differences in the necessary resources for developing a device. Process mapping has potential for creating a clearer picture of these requirements, and identifying key decision points.
PROCEDURE
This section describes the process of collecting data and converting it into a flowchart or map. This process notably lacks scientific direction or analysis at the level in which it was used. Because the topic has not been covered adequately in literature and is too broad to observe directly, the information on the process was collected from secondary and tertiary sources, and assembled based upon the author’s best judgment.

First, literature was reviewed and notes were prepared to lay out the important aspects of each process. A number of resources were used to determine the processes and transactions for each section. Several maps were then created using data from each specific article. Each map was initially drawn out by hand, and later transferred to an electronic copy.

The type of flowchart was selected. Medical device innovation involves a large number of organizations, and many stages involve collaboration or transfer between organizations. A type of process map known as a “cross-functional flowchart”, also called a “swim lane diagram” was selected.

The final process map was then assembled together. The process map was created using Microsoft Visio software. The layout was set at size of four feet by six feet, with a landscape orientation. This large format allowed for a sufficient level of detail while maintaining readability. The source of data is cited for each section within the process map using a superscript number.
RESULTS/DISCUSSION

The finished process map is shown in Appendix A. Because the initial layout was large, individual sections are also included in figures 2 to 15. These have been given in the best order suitable, starting from the top left hand corner of the chart and ending in the bottom right.

Limitations

Limitations have been discussed in the introduction section to this paper. The process used to collect data was potentially misrepresentative of the different paths and processes, and the importance of each. The total time of each process was noted whenever possible, but the final product does not have an accurate representation of the flow of time through the entire process.

There was an unexpected level of difficulty in assuring accuracy in a process that is, as a whole, somewhat informal and malleable. It was difficult to determine which processes were concrete, and which were just an author’s suggestions or general descriptions.

Also, the changing nature of regulatory requirements as technology increases may prove problematic to the accuracy of a process map over time, and therefore the usefulness of mapping such a broad process. For example, if a process is conceived at the beginning of a ten-year development phase, new legislation may be introduced within that time frame. There may have been better way of dealing with the requirements in a timely manner, if they were known beforehand. This may be a necessary limitation of trying to understand medical device development. A useful process map in this scenario must be able to convey that there are different possibilities, not just one set path.

There are also clear limitations in expressing the magnitude of other resources involved. Because this process may change, and is based upon different devices with different levels of complexity,

Each process map was pieced together using a number of resources. Because each map was abstracted from a number of sources, the processes may vary. The map is inherently vague, as there is no systematic way to evaluate the entire system. There was also a limited amount of information on certain processes.
CONCLUSIONS

Process mapping has potential to be used in understanding the medical device development process. The map created in this project gives a basic understanding of the broader development process. However, the medical device development cycle, on a broad scope, is not well defined. The lack of a universal language with which to describe this process has made it difficult to understand and communicate. The level of detail and accuracy of the process map created here is also limited by the time and cost of process mapping. There are several things that have been identified that can be improved in order for the data to be more useful:

1. Developing a better understanding of the innovation process holistically
2. Development of a common language used to describe this process
3. Further investment in process mapping to provide more detailed results

These improvements can come from various sources. For example, terminology may need to be invented to describe this whole process. There is no term that describes the entire cycle of research, innovation, development, regulatory control, and marketing. The term used throughout this paper was “development”, which also indicated a smaller subprocess within this process.

This paper supports that a process-based approach may be used to understand the terrain of the biomedical industry holistically, and that understanding the diverse range of processes and cross-organizational relationships is essential to this approach. There are clear improvements that can be made with further involvement and research. Process mapping tools can ultimately be used to improve efficiency and eliminate waste within this system.

This project has provided evidence that process mapping can be used in other more abstract, long-term applications in which the initial conditions are not explicitly known. It reinforces the idea that mapping a process promotes an understanding of the underlying scenario.
REFERENCES


APPENDICES

Appendix A. Final Process Map

Figure 1: Process Map for Medical Device Development
Figure 2: Regulatory Paths

Regulatory Path: Routes to Market

Classification: 21 CFR 860

Class I

510 (k) Exempt Devices
See section 9 of 21 CFR parts 862-892

Premarket Notification 510(k) Devices
To prove substantial equivalence to an existing device

Class II

Premarket Approval (PMA) Devices
Individual license for marketing a new device, or for a device designed to support or sustain human life.

Class III

Humanitarian Use Devices (HUD): Humanitarian Device Exemption (HDE)
For treating conditions that affect less than 4000 people/year in the U.S. Similar to PMA, without the requirement of proving the effectiveness of the device.
Figure 3: Grant Application Process
Figure 4: Basic Research Knowledge Transfer
Figure 5: Development Process: Funding & Concept Phases

- Seek Funding From Applicable Sources
- Draft Rough Schedules, Resources, and Budgets
- Anticipate Regulatory Approval
- Understand IP Landscape
- Understand Market Potential
- Identify Clinical Need

Funding Phase

- Funding Approved?

Concept Phase

- Update Regulatory Roadmap, Financial Strategy, Marketing Plans
- Draft First Version of Production Plans
- Draft First Edition of Risk Analysis
- Draft First Edition of Specifications, Marketing, and Product Requirements
Figure 6: Development Process: Development Phase
Figure 7: Development Process: Design Controls

“Waterfall” Model: Design stage is an iterative process, starting with user needs and ending with specifications.
Figure 8: Development Process: Verification & Validation Phase, Production Phase
Figure 9: Development Process: Market Phase & Post Market Requirements
Figure 10: Regulatory Process: Routes to Market
Figure 11: Regulatory Process: Investigational Device Exemption (IDE)
Figure 12: Regulatory Process: Institutional Review Board (IRB) Process
Figure 13: Regulatory Process: Clinical Testing Phases

**Pilot Phase**
- To establish safety and to with design of the pivotal trial
- Clinical Trials: a few centers, usually <100 patients
- Major Milestone: First clinical use

**Pivotal Phase**
- To develop data used to determine which users and for what use the device is safe and effective
- First in class require large randomized controlled studies
- Most studies carefully document product performance

Funding: this stage represents largest commercial risk

To 510(k)

OR

To PMA (if required)
Figure 14: Regulatory Process: Premarket Notification 510(k) Process
Figure 15: Regulatory Process: Premarket Approval (PMA) Process
Appendix B. Hand-Drawn Process Map Examples

Figure 16: Example of Notes for Hand-Drawn Flowchart

Premarket Notification 510(k) process

- file a 510(k) application 90 days before anticipated marketing
  - post-arrival class I & II devices
    - substantially equivalent to a pre. class III device

Review process
  - no time limit for FDA
    - FDA requests info
      - firm must submit within 30 days (unless extension is obtained)

End review
  - FDA issues "substantially equivalent letter" "not"
  - device may be marketed immediately

Within 30 days FDA issues summary of device
  - safety & effectiveness

Submit PMA
  - file reclassification petition
  - appeal
Figure 17: Example of Hand-Drawn Flowchart
Appendix C. Project Organization

Figure 18: Project Gantt Chart