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Medical Device Design Process

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***Abstract* – The current design process is a combination of methods from engineering disciplines, government regulatory agencies (domestic and international) and independent certification and compliance companies. The goal of the processes that have been developed is to be certain that a new product meets the users expectations, is safe and effective in providing its claimed benefits. As products have become more complex and particularly with regard to software control it has become increasingly more difficult to determine the safety and efficacy of a product by inspection or after the fact testing alone. In order to improve the ability of designers and auditors to ascertain the safety and efficacy of a product, the use of design controls has been adopted that specify a method of evaluating the design process at several key stages. This paper will describe some of the methods that are used for design controls intending to give the reader an overview of these methods in the context of medical products.**

***Keywords* — Medical Products, Design Controls, Process,**

I. INTRODUCTION

Many of today's medical devices are truly miraculous life saving engineering marvels. However most are very complex and while they may be composed of very clever widgets, they require more than great engineering to get to the market. In part because software (which does not lend itself to examination to determine its quality) is such an integral part of many products it was determined that a design process was needed to insure quality products. This process is called "design controls" and must be implemented and followed throughout the design process. Design controls are a set of well-defined systematic procedures to be followed in a design process in order to insure that the resulting product is safe, effective and can be successful in a competitive marketplace. In this discussion the process will be considered in four parts:

1) The main phases of the process
2) The objectives of each phase in the design process
3) Key outside considerations
   a) Regulatory requirements
   b) Reimbursement

The process may be very detailed and formal in a large organization or more streamlined and informal in a small company. With fewer product lines and market segments smaller companies can coordinate the required resources with a less detailed process. Whether the company is large or small, the process intricate or streamlined, there are specific steps that must be taken and documented to ensure that the result is a desired product that is safe, effective and profitable...complies with regulatory design controls

II. THE PROCESS

The FDA has published a useful diagram shown in figure 1 that nicely summarizes the steps they require in a design-controlled process[1].

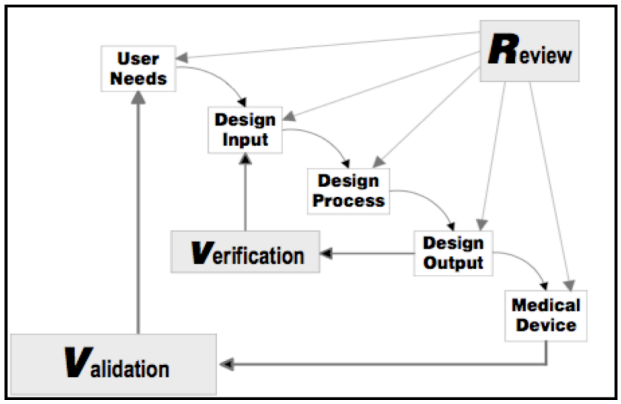

Fig. 1. Application of design controls to design process. Design review should be held and documented at each of the five milestones pictured. (From Fda "Design Control Guidance For Medical Device Manufacturers" relating to FDA 21 CFR 820.30)

In a small company the design process may be very simple and straightforward as shown as in figure 2. Close physical proximity and fewer individuals involved in the process can allow a simple process work, as long as the necessary steps are taken and documented.

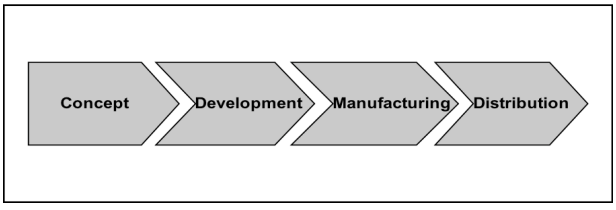

Fig. 2. Phases of a design process in its simplest

In contrast when many people and departments are involved such as in a large company with many product lines and market segments, a detailed process may be required such as that shown in figure 3.

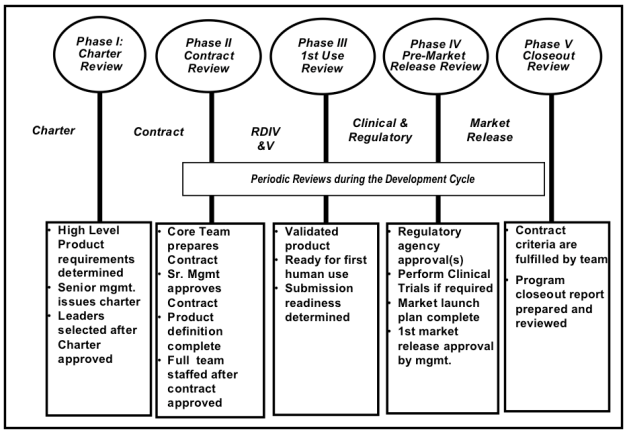

Fig. 3. Numerous phases and complexity such as shown in this diagram may be required for a large company.

While in some cases these phases may be broken down in to more detailed sub-phases, this discussion will focus on the simplified model of figure 2. Even though the diagram shows these phases to be quite distinct, there is in fact considerable overlap and revisiting of previous phases as additional information is gained throughout the design process.

II CONCEPT PHASE

The objective of the concept phase is to define and document the product to be designed so that all contributors to the design effort have an accurate perception of what is to be designed. Formal documentation of this step (as well as at several milestones throughout the process) is a fundamental aspect of design controls.

The concept phase usually starts with product planning, whether it may done formally in a designated product-planning department or by design engineers with knowledge of the market. In either case the issues to be considered are the same. One must determine the customers' requirements and document them.

For illustrative purposes the development of the SurVivaLink automated external defibrillator (AED) will be used in this manuscript. In the case of the SurVivaLink AED the Company's first identification of a need was articulated in an American Heart Association review article in which the authors explained the need for an small, inexpensive, easy to use, reliable defibrillator because so many victims of heart disease died before they reached the hospital[2].

The next step is to determine and document the customer needs. At the outset of this step it is critical to understand the specific need that is to be solved by the new product. This understanding must be acquired from someone who is frequently faced with this problem. In medical devices this is most often the physician specializing in this area. Speaking with physicians (or other end users of the intended product), observing their procedures and understanding the shortcomings of the current devices and methods are all important at this time.

At SurVivaLink, this was done by discussion first with a cardiologist who said talk to his wife, an emergency department nurse, who in turn recommended emergency department physicians who had been involved with a previous defibrillator company and in resuscitation research.

Finding and listening to the right experts is important. But equally critical is using one's own judgment in weighting and prioritizing the various opinions heard. Once the problem is well understood, reviewing ones' observations and conclusions with the specialist is very helpful. In the end in addition to providing a defibrillation shock the key requirements decided upon were that the AED be affordable, very easy to use, compact and reliable[3].

An initial description of specific features in the AED was reviewed with emergency department physicians and nurses as well as with Emergency Medical Technicians (EMTs) and paramedics. Again judgment was required to filter out the assertion of some professionals that a display of the cardiac rhythm was necessary. Remembering two key requirements that this defibrillator must be affordable and easy to use it was determined that a rhythm display was not only a expensive and unnecessary feature, it was a detriment to the required simplicity of the product. (The Company later discovered that the only people unable to use the device properly with no training were those who were too timid to try.) The absence of a display makes this a much more user-friendly device.

In addition to user interviews one must search the literature and existing competitive products to have a complete knowledge of the current product sector and what are the unresolved problems and unmet needs.

In the case of the AED a review of the literature revealed external defibrillators to have a very high failure rate and that poor maintenance (battery maintenance and electrode replacement) was a major cause of these failures. In response, the company focused on the user interface and period self-testing features to insure reliability.

As one concludes the Concept phase with an identified target problem or product there are key questions to be considered such as

1) Is it real?
2) Can it win?
3) Is it worth it?

If the answer to these questions is yes, it is time to proceed to the Development Phase. The documentation of the Concept phase is the Customer Requirements Specification (CRS). This is a controlled document and is intended to specify in

detail the necessary and sufficient features of the potential product to make it successful.

III DEVELOPMENT PHASE

The Development Phase can begin once the CRS has been reviewed and signed off by the appropriate department representatives usually including marketing, sales, design, clinical affairs, regulatory affairs, reimbursement, manufacturing and quality.

The primary work in the Development Phase is done by engineering, but must also include planning for subsequent critical tasks in the areas of:

1) Clinical testing required
2) The regulatory or governmental clearances required of medical devices
3) The reimbursement strategy

Working from the CRS, another controlled document called the Product Requirements Specification is developed. This is a living document that specifies the detail needed to build the product. This document is as important to the design controls as are the detailed schematics and drawings of the physical design.

In the case of the SurVivaLink AED the requirement of small size required significant engineering, bread boarding and testing of a unique high-energy capacitor and switching circuit, in the early days with the resultant odor of burned epoxy. Similarly, a single button human interface was designed and evaluated in many tests with naïve users.

The clinical testing required will have a major impact on the overall project schedule and effect the critical market launch date. Careful design choices can sometimes make the difference between obtaining FDA clearance in the US via a "substantially equivalence" 510(k) pathway or the more laborious IDE/PMA pathway.

For the AED, previous, but more complex defibrillators had been cleared for market release by the FDA through a "data supported" 510(k) process. Which meant that safety and efficacy proven by *in vitro* and preclinical testing would be accepted.

The regulatory pathway through which the product will be cleared by the FDA in the US and the plans for complying with ISO requirements and obtaining a CE Mark for much of the rest of the world must be considered early in the Development Phase. By considering this task early in the design, one can identify the standards which must be met and facilitate the approval process.

Knowledge of the ISO regulations was required for a medical device of this type of medical device at the outset. This enabled SurVivaLink engineers to incorporate the shielding and circuit protection needed to comply with the requirements for electromagnetic emissions and susceptibility.

Particularly in the US, obtaining reimbursement has become important and perhaps even more demanding than obtaining FDA clearance. Without reimbursement it is extremely difficult for a medical product in the US to be profitable. With careful planning and some luck a product may be designed to fit into an existing reimbursement code. In such a case the additional work required for reimbursement may be quite minimal. On the other hand an entirely new product or mode of treatment may require its own unique reimbursement code. If that is the case substantial clinical efficacy studies must be conducted and usually two or more peer-reviewed publications are required.

Close communication among the clinical, regulatory and reimbursement representatives can result in properly designed clinical studies that serve the needs of engineering for efficacy of the product, regulatory affairs for showing safety and efficacy and for the reimbursement to show the value of the product. While the objectives of these departments may seem much the same, the coordination among them will insure that the specific requirements of all can be met with the minimum amount of testing.

During the development phase as the product takes shape, prototypes are built, evaluated and modified and improved, the Engineering Product Requirements Specification is updated from time to time so that it contains the latest and best design of the intended product. Frequent review and updating of the Engineering Product Requirements specification is an important aspect of a good design controls system.

A manufacturing engineer's involvement at this time can improve manufacturability with suggestions making the product fit more smoothly into existing processes, use parts and processes in common with existing products, or to be compatible with existing equipment. As the design nears completion, subassemblies and subsystems are tested individually and finally as a complete assembly.

Clinical testing may begin at this point by using prototypes in some case or may be required to wait until production units are available. This may depend on the FDA classification of the product; or the caliber of the prototyping facility, the controls under which the prototype was produce and the quality of the product.

Throughout this process a verification test plan is being developed that will be thorough enough insure that a device that passes all aspects of the test plan will meet the Engineering Product Requirements. The passing of the verification test plan marks the formal end of the Development Phase and results in a complete documentation package from which the manufacturing department can build the new product. This package includes:

1) Final Engineering Product Requirements
2) Verification Test Plan
3) Verification Test Report

IV. MANUFACTURING PHASE

The Manufacturing Phase formally begins at this point so that the product can be reliably produced in the quantities planned for in the sales forecast. Close work of the design engineer with manufacturing is required during the transition to insure that the mass-produced product meets the requirements of the Engineering Product Requirements and is comparable to the carefully built prototypes and preproduction units. At the end of the transition, manufacturing should be able to produce the required volume of product reliably. In order to document this milestone a Product Validation Test Plan is developed such that passage of the Validation Test Plan insures that the final product meets the Customer Requirements Specification. Passage of the Product Validation Test Plan is documented in the Product Validation Test Report and marks the end of the transition and the beginning of the formal Manufacturing Phase. Throughout the Manufacturing Phase involvement of design engineering is valuable in order consider design and part tradeoffs that may make the product easier and/or cheaper to manufacture.

V. MARKETING PHASE

The Marketing Phase planning begins when the product development planning begins. However, the implementation of the marketing plan can begin only after the successful completion of the milestones discussed above and FDA clearance is obtained. In an ideally planned and executed project, the regulatory clearance and reimbursement approval coincide with the availability of the first lot of product from manufacturing. At that time the Market Launch can take place signaling the completion of the product development process.

The shipment of the first SurVivaLink AED was not only a milestone for the development team but for the startup company as this was its first product.

VI. CONCLUSION

Medical device design processes whether simple or complex are characterized by a disciplined pathway by in which the progress of the development is formally reviewed at several key milestones. This review ensures that the perspective of the all the interested parties is considered and adjustments if necessary, can be made at an earlier stage in the process than might otherwise be the case. By following the a systematic process in for the entire development life cycle the likelihood of producing a reliable product that meets the needs of the customer and is successful in the market place is optimized

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