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A Basic Understanding of Design Controls

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Introduction

This report is meant to simplify Subpart C of the Quality System Regulations. Within this report each section of Design Control Subpart C is dissected and explained. It is important for engineers to note that design controls are an integral part of making any device; if done correctly, design controls can save companies and designers last minute redesign and possible recall. Design control consists of eight parts: general requirements, planning for design and development, design input, design output, design review, design verification, design validation, design transfer, design changes, and the design history file; all which will be reviewed in this report.

Purpose of Design Control

To protect patients and users from flaws in design which could have been prevented through thorough documentation and vigilance.

Why Design Control

The purpose of design control is to make sure that a plan has been made to be implemented by the company and manufacturer that ensures that all final requirements of the design are met during the process and development. By doing this the FDA had a better control over development, review and documentation which, when lacking, could lead to patient risk. Design control includes:

1. General
2. Planning for design and development
3. Design input
4. Design output
5. Design review
6. Design verification
7. Design validation
8. Design transfer
9. Design Changes
10. Design history file (DHF)

These steps can be applied using a design process as can be depicted in figure 1.

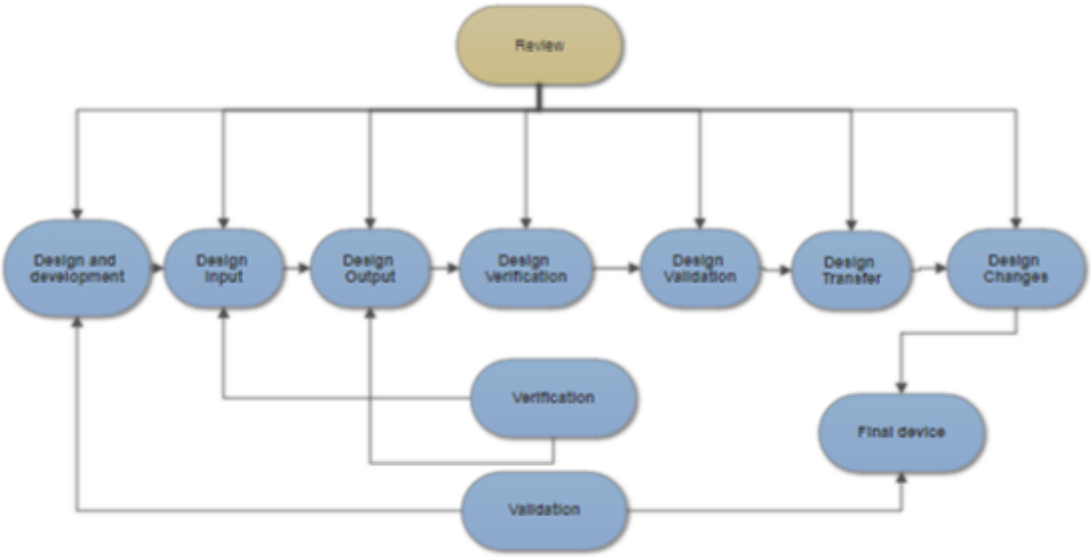

Figure 1. Design Control Flow Chart

Design control must include all activities involved in designing the product and must apply responsibility to each aspect of the implementation of the design. According to the Quality System Regulations(QSR) a design control is necessary for all type II and III devices. Design control is also necessary for all devices which are automated by a software, and for some type I devices. Each part of design control is integral in keeping patient and user risk low as well as to ensure that the best product is manufactured.

What Influences design control?

Design control has many contributing factors which can influence design control such as type of device, software, materials, and manufacturing. However, design control mainly falls in line with its design input and output.

Design Input

The design input is the most important part of Subpart C of the QSR. In this section the designer must essentially define all product and market specifications. A market specification should be what speaks for the customer. This component focuses specifically on the needs of the market and the effects of each aspect of the product, down to the size of the font on the package. To ensure that all market specifications have been analyzed and for poka- yoke (inadvertent error prevention) it is advised that a flowchart be made to trace the use of product by the consumer. Both patient and user needs, as well as applicable standards and guidance documents, must be evaluated, and a procedure must be made to ensure that these needs are attended to through the product specification to the final device. The product specification should quantify the market specification and interpret needs numerically through a quantitative analysis. Within these, aspects like materials, safety regulations, cost to patient and user interface must be considered as well as outputs of risk management and information taken from older designs. The input section must also take into consideration certain requirements that may be vague, with efforts made to make them quantifiable / measurable, but most importantly it must prioritize the needs of the user and patient.

Design Output

The design output should fundamentally be a manuscript of all components that are used in the medical device including but not limited to: drawings, schematics, specifications, and anything else which could also be placed in the Design Master Record. Design output must be tested for conformity when being compared to the design input, and as such should be produced with the design inputs in mind. While all design outputs are important, it is essential that the outputs which are indispensable to function be identified thoroughly.

According to ISO 13485:2014 7.3.3 all outputs shall:

a) meet the input requirements for design and development

b) provide appropriate information for purchasing, production, and for service provision

c) contain or reference product acceptance criteria

d) specify the characteristics of the product that are essential for its safe and proper use.

The design output should include every physical and numerical aspect of the design, and should be recorded in the Device Master Record.

What falls under Design Controls?

The General step as well as Planning for design development are the preambles of outputs and inputs. These step of design controls sets the pace for the remainder of the project, they define the project. In the General step a basic procedure of how the design control process will occur is made. Questions that can be asked during this step are: how is this defined? How will this be documented? How will this be implemented? During planning, logistical coordination, responsibilities for team members, contractors, and other contributors, are solidified. A timeline can be created to set the project pace, review teams can be hired and future activities can be planned. As a result of this thorough planning, communication within the project can be optimized and any policy or regulation can be addressed ahead of time. The following activities should be dissected and explained to the entire team for the best possible results and to ensure everyone is held liable for their actions or lack thereof:

- The time involved for each major task
- The resources and personnel required
- The allocation of responsibilities for completing each major task
- The prerequisite information necessary to start each major task and the interrelationship between tasks
- The form of each task output or deliverable constraints, such as applicable codes, standards, and regulations

[1]

With thorough development of design input and output, device requirements are defined and the potential for a strong foundation is possible.

Design Review

The process of developing a design review is simple, yet necessary for product approval. These design reviews are made specifically for each stage of the product development. They should include a variety of experts for every part of the design stage, including experts on:

1. Materials
2. Techniques for construct
3. Software
4. Specialized medicine pertaining to the device
5. Electronics
6. Pneumatics

And any other experts deemed necessary, one of which should be neutral to the review outcomes.

These design reviews aim to keep project focus, critique the designer on potential issues, and act as a checkpoint before pursuing the project further. While tedious, performing these reviews early and often

lowers the risk of redesign later in development where cost may be higher. These reviews also correct problems which may have occurred in previous iterations of the project. It is especially important for design reviews to be documented so designers have the power to say every resource was sought to ensure the best product. In this stage it is also important for designers to be able to explain all decisions made within their design. Thoroughness is necessary in order to mitigate any further need for correction later in the project timeline. During design review the designer must be open to feedback and change to their design and should ensure that a plan for corrective action is set in place with the help of the reviewers.

When looking at figure 1. it can be noted that almost every step of design control falls under design review. From the beginning of the project to the delivery of the product, all aspects must be looked at, critiqued, and corrected to the best possible standard. While this occurs, design verification and validation can be done simultaneously.

Design Verification

Simply put, design verification allows designers to demonstrate that the device meets the product specifications. As stated in the QSR, “Design verification shall confirm that the design output meets the design input requirements.” [2] Verification is used by designers to quantitatively measure the output which was initially required. The approaches which can make up design verification include tests, inspections, and analyses. Types of analyses broadly used include:

- Fault Tree Analysis of process or design
- Failure modes and effects analysis
- Package integrity tests
- Biocompatibility testing
- Product comparison

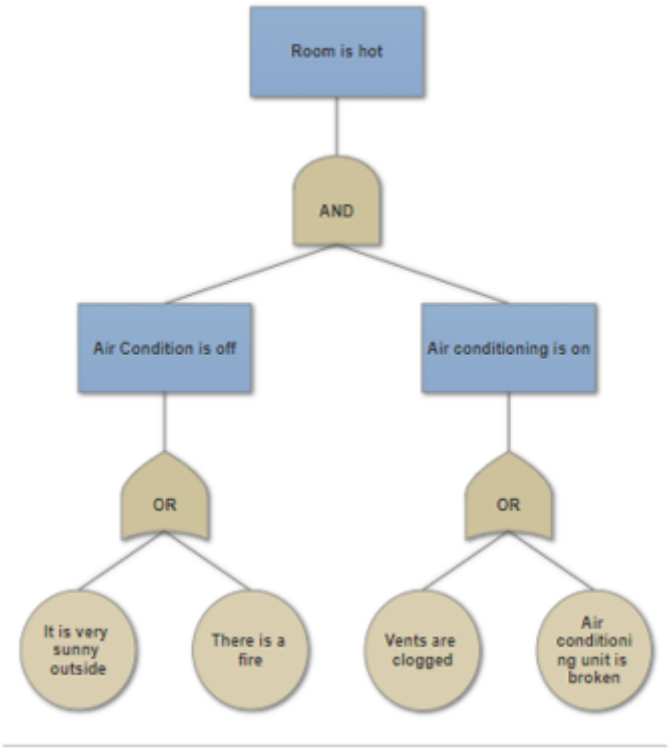

Figure 2. Failure Tree Analysis Example

When considering which test or analysis to run a few things should be kept under consideration. First, does your test cover your device when in good and fault conditions, and do you care? What kind of packaging do you have and what kind of test does that package require? Where will this device be placed and how can you ensure that all the materials will not cause adverse side effects in vivo? Lastly, is there a device out there that

meets the requirements needed, if so, how alike are the devices?

Design Verification and validation always go hand in hand however it is necessary to see the difference between them. Verification focuses heavily on the product specification while validation focuses more on market specifications like user needs, standards, guidance documents, etc.

Design Validation

Design validation looks at the market specification to ensure it has been met. Many responsibilities fall in this section, because it is what ensures the customer is getting what was asked for. The requirements of validation as stated in Subpart C [2] are as follows:

- Each manufacturer shall establish and maintain procedures for validating the device design.
- Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents.
- Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.
- Design validation shall include software validation and risk analysis, where appropriate.
- The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the Design History File.

There are two kinds of validation; Process validation and design Validation. In process validation what is looked at is that the process gives consistent results regarding the values that had been specified. With design validation it can be said through testing and observation that the device specifications do meet the needs of the user and patient. Validation has various parts, with the first being planning. Validation planning should be done well ahead of time. The points which are being looked at, the party which will validate, the methods and acceptance criteria are all things which can be established during design development planning. Making a schedule ahead of time to ensure validation activities get done within the timeline can facilitate dealing with negative findings during validation in a timely manner.

As stated previously, many things fall under design review, one of which is validation review. Here what is being reviewed are the original needs and uses of the device. Does the specified need fulfill what is being asked for? Will the intended use suffice? Early validation review can save designers from carrying out a project which will not bring financial gain due to its inefficiency to solve the need at hand. A critical part of validation review includes making sure the validation methods are up to par. Validation must always include clinical evaluations which should be done while device is in use, either in a simulation or in an actual environment. When performing evaluations all processes must be the same as what will be expected to be used during actual production. Within validation methods, literature searches, inspection, comparison to similar designs and clinical trials can also be done [1]. Within validation, packaging and labeling must be looked at. Again, a simulation or actual testing conditions must be ensured in order to verify that packaging can withstand things like humidity, vibrations, pressure changes, shock, temperature and more. Before documentation, the last element which should be looked at are all the people which will come in contact with the device, not just its daily users. During packaging validation, every single movement of the package must be foreseen to ensure that appropriate measures can be taken so the device can arrive to its destination in its best shape. Once validation is done and the product is ready for production a plan must be made to execute proper mass manufacturing. This step in design control is called design transfer.

Design Transfer

When the device is ready for production, it must be guaranteed that proper instructions are given so that the device may be produced through maximization of lessons learned in this process. These instructions are the last step in order for individual manufacturers to provide a reliable product. This step in the process greatly varies across projects, but must be given equal care as it is essential in the successful rollout of the product.

Many factors are the cause for such variation, the biggest being the skill and knowledge of the specific manufacturer and the specificity of the device. For an appropriate design transfer, certain production specifications must be made that encompass all instructions needed to carry out each step in the manufacturing process. This can include: documentation, training, and computer programs. To avoid mishap, all instruction should be as clear and thorough as possible to confirm that in the future any unforeseen change in personnel or machinery is dealt with within the instructions.

Design Changes

Design changes have the potential to be a smooth part in this process. They must be controlled through two different elements: document control and change control. Document control is simple in that all document updates which include pictures, files, or any design are checked for their latest updates. Change control looks at the number of mistakes and corrections that had to be made due to any review or verification. When making changes to the design, they must be documented and executed. When a change is completed, it is expected to have fixed the problem and any problem that may have stemmed from it.

Design History File

The design history file is the culmination of design controls. Its main purpose is to show that the design plan was followed and all requirements were fulfilled. It is mandatory in the United States in accordance to the QSR, and in the EU per ISO 13485:2014, 7.3 Design and development planning, which lists the same 10 DC elements and must document all sections of design control as extensively as possible.

References

1. FDA, Design control guidance for medical device manufacturers (Santa Monica, CA, 1997).
2. FDA “CFR - Code of Federal Regulations Title 21.” Accessdata.fda.gov, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.30.

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