Design Controls – Joe Tartal

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Hello. Design controls are important. In my experience, I have found that how things start are how they go, and this is also true when bringing a medical device to market. If you begin with effective design controls, you dramatically increase your ability to meet user needs and ensure your device will be safe and effective. My name is Joseph Tartal and I'm the Postmarket and Consumer branch chief in the Division of Industry and Consumer Education. I have designed medical devices while working in industry and I understand the difficulties of bringing a medical device to market. Having worked at FDA, I understand the importance of design controls in ensuring that all medical devices are safe and effective. When design controls are established correctly, we all share in the benefits that the right medical device was brought to market and that it meets user needs, its specifications, and it works as intended.

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By the time I'm finished, I want you to know the following learning objectives: understand the importance of design controls in device quality and in the quality system regulation; know the Quality System Regulation requirements for design controls and learn how its sections interact with one another and the rest of the quality system; and finally, understand the continual role that design controls play in both premarket and postmarket device development.

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Design controls are a set of quality practices and procedures incorporated into the design and development process. They are a systematic way to assure that medical devices meet user needs, intended use needs and all specified requirements, thereby ensuring the medical device is safe and effective. They are a directed controlled action, something you do. They are not retrospective. Properly established design controls can improve your medical device and prevent foreseeable issues and problems, both in the device and in device manufacturing.

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Why were design controls added to the quality system regulation when the current good manufacturing practices were revised? From the fiscal year 1983 to the fiscal year 1989, FDA conducted a six year study to determine the causes of voluntary recalls. What the study found was that forty four percent of all voluntary recalls could have been prevented if adequate design controls were used. Basically, poor design was a leading cause of voluntary recalls.

Forward to another study performed on recall data from fiscal year 2003 to fiscal year 2012, and design is still cited as one of the most frequent causes of recalls.

That tells us that design has an important and direct real world impact on device quality, safety and effectiveness. Many postmarket problems with medical devices can be traced back to poor design. As I noted earlier, how it starts is how it goes.

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After the recall study of the 1980s, there were discussions between the medical device industry, FDA and Congress about the inclusion of preproduction requirements in the current good manufacturing practices. Industry was concerned that such requirements would stifle research, while FDA wanted to ensure that once research entered into a development phase, the development would be defined and controlled. With the passage of the Safe Medical Device Act of 1990, FDA was given authorization by Congress to add design control requirements to medical devices. They were subsequently written into the 1996 Quality System Regulation, which became effective June 1, 1997. The preamble to the regulation provides a lot of useful information about industry's concerns at the time, FDA's intent, and the context for design control expectations.

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Design Controls are codified in the Code of Federal Regulation 820.30. FDA uses a risk-based approach with the application and requirement for design controls. Design Controls apply to all Class II and Class III medical devices. Design Controls also apply to a small number of Class I medical devices. They are medical devices automated with computer software, tracheobronchial suction catheters, surgeons' gloves, protective restraints, manual radionuclide applicator systems, and sources for radionuclide teletherapy.

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Now that we know what types of medical devices require design controls, when should they begin? Manufacturers should document the flow of the design process so that it's clear where research ends and design begins. Per the preamble, they are not intended to apply to development of concept and feasibility studies. A good rule of thumb is that design controls begin after feasibility and when the decision has been made to bring the medical device to market. They are required prior to any investigational device exemption, and are premarket. They are also used when design changes are made to the device. Again, design controls are not intended to be retroactive.

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Next, I will review the quality system regulatory requirements for design controls.

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Since we now know when, the question becomes where to start? I recommend starting with design planning. Planning is important as both a requirement and a practical tool to control the design process. Establish, which means define, document and implement the following--First, describe or reference design and development activities to keep track of all requirements, their status and completion.

Next, identify, describe, and define interfaces, responsibilities, functions and activities that impact the device design. I recommend using cross functional teams with appropriate representation from all parts of the organization. Define who has what responsibility and the authority to make decisions. Last, review, document, approve, and update the plans as development and design changes evolve. The plan will provide a road map of where the design is and where it's going, and help to make it an efficient and effective process.

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Once there's a plan, then start with design inputs. Design inputs are the physical and performance characteristics of a device that are used as a basis for the device design. Questions to consider at this stage are -- who are the users? What are the user needs? In what environment is the device intended to be used, and with what other kinds of devices will it be used? Manufacturers are required to establish and maintain procedures for design input to ensure requirements are appropriate by addressing user needs and intended uses in terms that are measurable. Also, any incomplete, ambiguous, or conflicting requirements must be addressed. Last - document, review, and approve all design input requirements.

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Next, let's use an example to further illustrate a design input. We can take a user need, such as "portable", and further narrow it down that the end user must hand carry the device. To define this aspect of "portable" into measureable specifications, we can use criteria such as dimensions and weight. We can have the design input for a weight specification be five pounds, plus or minus one kilogram. Next, we must address any incomplete, ambiguous, or conflicting requirements. For example, we cannot use a conflicting unit of measure, such as five pounds plus or minus one kilogram. The measureable specification must use a single unit of measure, for example, pounds. The design input is now a specification of five pounds, plus or minus one pound. Last, the design input is documented, reviewed, and approved.

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The design inputs should include human factors. Human factors are the study of the interactions between humans and the device, such as the interface end users and patients have with the device, and the subsequent design of that interface. This is important, since human factors can lead to improved ease-of-use, appropriate instructions for use, increased proper use, and decreased use error.

Also, human factors can help to increase the device reliability, durability and life, and decrease maintenance and repair. Last, taking human factors into consideration during design can lead to fewer adverse events and recalls.

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Design inputs can come from many sources, such as customers, standards, guidance documents, complaints, and adverse event reports to name a few. Examples of design inputs from these sources can include device functions, physical characteristics, performance, safety and reliability among those listed and others that are not. Spending enough time upfront capturing the right information to develop design inputs will help to get your design process off to a successful start.

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Design outputs are the results of a design effort at each design phase and at the end of the total design effort. In general, design outputs are the design specifications which must meet design input requirements, as confirmed during design verification and validation, and ensured during design review. The finished design output is the basis for the Device Master Record, or DMR. The total finished design output consists of the device, its packaging, labeling, and the Device Master Record. Also, manufacturers must identify design outputs essential for the proper functioning of the device. Using our previous design input example of a weight specification, one design output would be the physical hand held device itself that weighs five pounds, plus or minus one pound. Last, manufacturers are required to review, approve, and document design outputs before release. Design outputs are included as part of a premarket submission as device specifications. And a premarket submission, such as a 510(k) or Premarket Approval, could be included as a design output.

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Establish and maintain procedures for design reviews. Plan and conduct formal documented design reviews of the design results at appropriate stages. Design reviews are not ad-hoc meetings. They are documented, comprehensive and systematic. Manufacturers determine the frequency and stages for design review. For a more complex and higher risk device, more design reviews will be needed, while for a simple lower risk device, fewer or a single design review may be acceptable. At each design review, include representatives of all functions involved, specialists as needed, and at least one individual without direct responsibility for the stage being reviewed. During the review, evaluate the adequacy of the design requirements and the capability of the design to meet those requirements. Identify and correct any problems that need to be resolved. Document results of the design review in the Design History File, or DHF, and include the identification of the design, the date, and the names of the individuals performing the review.

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Design verification is confirmation by objective evidence that design output meets design input. Manufacturers are required to establish and maintain procedures for design verification. Continuing on with our example, I can use a calibrated scale to weigh the device from my design output, and using the measurement on the scale, I can verify that the device weighs five pounds, plus or minus one pound.

The design output meets the design input, and is verified and confirmed by measureable means. The verification is reviewed, approved and documented as part of the design history file.

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The next section that follows design verification is design validation. Design validation is establishing, again, by objective evidence, that specifications conform to user needs and intended uses. Manufacturers are required to establish and maintain procedures for design validation. These procedures must include performing the design validation under defined operating conditions, on initial production units or their equivalent, and under actual or simulated use conditions. If the plan is to use equivalent production units or simulated use conditions, then the manufacturer must also document how these units are equivalent to initial production units, and how the simulated use conditions are similar to the real world conditions.

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Think about verification and validation in this way. Design verification - does the design output meet the input? The design output - the device - is measured on a scale and weighs five pounds, plus or minus one pound, which is the specification as noted in the design input. I made the product correctly. This is in contrast to design validation, where the five pound device is put into the actual use environment with intended users, and they confirm that it is portable. Using the example, the intended users can carry the device by hand in the intended use environment. Therefore, the intended use and user need for portable are met. I made the correct product. Both are important to the design process.

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Continuing on with design validation, risk analysis is noted one time in the quality system regulation and it's in design validation. Risk is noted many times though out the preamble.

Design validation shall include software validation and risk analysis, where appropriate. Where appropriate means it is appropriate unless the manufacturer can document a justification for why it is not appropriate. It's almost always appropriate to perform risk analysis. It will likely take more effort to justify why it's not appropriate to perform a risk analysis than not doing so. Also, while risk analysis is noted in design validation, it's more practical to perform initial risk analysis earlier during design input. Then, as more information and data are gathered, the initial risk analysis is updated.

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That being said, what does FDA mean by "risk analysis"? Regardless of the risk analysis tool used, the preamble is clear that manufacturers are to identify possible hazards, including use errors. Evaluate and calculate the risk under both normal and fault device operating conditions. Determine the risk acceptability.

Reduce all unacceptable risks to acceptable levels and ensure those changes do not introduce new hazards. This is the expectation for risk analysis in order to meet the regulatory requirement.

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While risk analysis is the regulatory requirement, the current industry practice goes one step further and utilizes risk management. This slide shows two resources that will help you better understand risk management. The first is a guidance document, titled "Implementation of Risk Management Principles and Activities within a Quality Management System". It was written by the global harmonization task force, which has since been replaced by the international medical device regulator forum. And the second is ISO 14971, which is the standard for the application of risk management to medical devices. ISO 14971:2007 is a FDA recognized voluntary consensus standard.

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Now that the design team has done a great job and the verification and validation activities are completed can we just throw it over the wall to our manufacturing staff? No. Manufacturers are required to establish and maintain procedures to ensure that the correct design is transferred into production. From a practical standpoint, there's a real need to address production scale-up issues; the completion of process validation protocols; finalization of purchasing controls; and training and qualifying manufacturing personnel, among other transfer considerations. This is one area where design controls interact with other parts of the quality system, and a worst case scenario is to have an effectively designed device not manufactured correctly. And while design transfer should happen throughout the design process, frequently, there's a final stage of development intended to ensure all outputs are adequately transferred to production. The term I've heard used to stop the continuation of a design is a "design freeze".

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Over time, the one thing I can guarantee is that things will change. Next, I'll discuss the continual role design controls play in premarket and postmarket device development. This will also include the rest of the quality system regulatory requirements for design controls.

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Manufacturers are required to establish and maintain procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation. Make sure there is a system in place to enact future changes. As a device is improved, or more information becomes available after it's on the market, there has to be a system for change. Also, depending on its scope and impact, the change may require a premarket submission, such as a new 510(k), a new PMA, or a PMA supplement.

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Last, let's discuss the Design History File, or DHF. This is a compilation of records which describes the design history of a finished device. It's a record of all design actions, from start through transfer, including any changes. It's the totality of the entire design effort for the life of the device. Manufacturers are required to establish and maintain a design history file for each type of device. The DHF can be specific to a single device, or a family of devices. Include in the DHF the information necessary to demonstrate that the design was developed in accordance with the design plan and quality system requirements. It can be a single notebook, several books, or an index reference to other records. The design history file becomes very important as researchers, engineers, quality and regulatory personnel leave, and time goes by and activities completed years ago become a memory.

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Additional information on design control guidance and human factors can be found at the links on this slide.

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In concluding this presentation, I now ask you to take on the following call to action: Meet your regulatory requirements for design controls per 21 CFR 820.30. Use cross functional teams to design your device. Ensure your design controls address user needs and intended use, and define appropriate device specifications. And last, use design controls to build quality, safety, effectiveness and savings into your medical device.

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This presentation and other helpful videos and educational resources can be found at CDRH Learn. For text based information on premarket and post market topics, including how to bring a medical device to market, please visit Device Advice. For additional information on these or any other medical device regulatory topics, feel free to call us at the Division of Industry and Consumer Education Monday thru Friday from 9AM to 4:30PM eastern standard time.

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Thank You for watching.

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