Quality Management System Regulation (QMSR) - Design and Development

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Hello, my name is Joseph Tartal, and I am the Acting Director in the Division of Industry and Consumer Education or DICE. I'll be presenting on the Quality Management System Regulation requirements for medical device design and development. It is important to start things off the right way, and good design and development does that, and I am pleased to provide this important information.

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Design and development is a regulatory requirement and can impact many things. You and your customers do not want recalls, adverse events, or complaints. We all want medical devices on the market to work as intended and be safe and effective. One of the ways to ensure this is good design and development.

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In this module we are going to cover the requirements for design and development in the Quality Management System Regulation or QMSR. First, we will look at the history of medical device design and development. Then I will outline the regulatory requirements and provide a hypothetical example of how this could look. In addition to looking at the requirements I will identify and describe how the different stages of design and development interact with one another.

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To begin, let's look at some history and understand the concept of design and development.

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What is design and development? The International Standard Organization, ISO, defines it as a set of processes that transform requirements for an object into more detailed requirements for that object. Processes are a set of interrelated or interacting activities that use inputs to deliver an intended result, and requirements are the needs or expectations that are stated, generally implied or obligatory. The ISO definition further states that the terms design and development are synonymous with one another and can be used interchangeably.

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Here are important studies that show the impact of design and development. FDA over the years have performed multiple studies investigating the causes of recalls, first in the mid-1980s and again in the mid-2000s. Both studies identified poor design as one of the causes of voluntary recalls. What this tells

us is that design and development requirements have an important and direct real-world impact on device quality, safety, and effectiveness.

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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. After 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. Design and development further persist in the 2024 Quality Management System Regulation effective February 2, 2026.

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Now let's talk about Quality Management System Regulation requirements and walk through a hypothetical example for design and development.

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Design and development is codified in the Code of Federal Regulation, or CFR, 820. FDA uses a risk-based approach for the application of design and development in 820.10(c). They apply to all Class II and Class III medical devices and to a small number of Class I medical devices listed below. These are medical devices automated with computer software, tracheobronchial suction catheters, non-powdered surgeon gloves, protective restraints, manual radionuclide applicator systems and sources for radionuclide teletherapy.

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The definitions for design and development as well as the specific requirements for it are incorporated by reference in ISO 9000:2015 QMS Fundamentals and Vocabulary, Clause 3 and ISO 13485:2016. The QMSR further states in 21 CFR 820.10(a) that manufactures are required to document a quality management system that complies with the applicable requirements in ISO 13485:2016. Note for this presentation the use of clause X.X refers to a clause in ISO 13485:2016.

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Now that we know what medical devices require design and development, and where to find the requirements, the question is now when should they begin? Organizations should document the flow of the design and development process so that it is clear where research ends and design and

development begins. They are not intended to apply to feasibility studies or proof of concept. They are required prior to any Investigational Device Exemption and are premarket such as before submitting a 510(k), De Novo or other premarket submission. They are also used when design and development changes are made to the device. Last, they are not intended to be retroactive.

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There are multiple stages to design and development, and a good place to start is looking at risk, more on it in the next slide. The stages generally flow from planning, to input, to output, to review with verification and validation performed within those stages and then transfer to manufacturing. When changes are made to the device design these are feed back into the stages. Please be aware there are times these stages may overlap and have multiple iterations, however for the purpose of this presentation I will go through them in this order.

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This brings us to where to start and the beginning of requirements incorporated by reference in ISO 13485. In planning of product realization, design and development activities are included with risk management. The organization documents one or more processes for risk management and maintains records of risk management activity. Therefore, you start by looking at risk. Please reference the CDRH Learn modules on risk and risk management activities, including risk management in the QMSR for more information.

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Continuing with requirements, you must have documented procedures for design and development. Then we move to design and development planning. Planning is important as both a requirement and a practical tool to control the design and development process. Document the progress of the design and development activities to keep track of all requirements, their status at appropriate stages and the completion of reviews and activities. Identify, describe, and define interfaces, responsibilities, and resources that impact the device design and development. Note who has what roles and responsibility and the authority to make decisions. Ensure the plan has methodology to trace design and development outputs to inputs. Determine the resources needed, including any competencies of personnel. Last maintain and update the plans as they evolve. The plan provides a road map of where you are in device design and development and where it is going and helps to make it an efficient and effective process.

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Once there is a plan then start design inputs. These are the functional, performance, usability, and safety requirements of the device for its intended use that are used as a basis for the device's design and development. These include applicable regulatory, and standards requirements and they account for pertinent risk management outputs. Some questions to consider are who are the users? What are the user needs? In what environment is the device intended to be used and what other kinds of devices will it be used with? Also, you shall use as appropriate information derived from previous similar designs and other requirements essential for design and development of the product or processes. The inputs must be complete, unambiguous, and not conflict. These inputs shall be reviewed for adequacy and approved.

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Now let's use a hypothetical example to further illustrate design input. We can take a use need such as portable and further narrow it down that a first responder must carry the device. To define this aspect of portable into measurable specifications we can use criteria such as dimensions and weight. We can make the design input for a weight specification be three 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 three pounds plus or minus one kilogram. The measurable specification must use a single unit of measure, for example pounds. The design input is now a specification of three pounds plus or minus one pound.

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Design outputs, and their records are the results of the design and development effort at each stage and at the end of the total effort. They must be suitable to show the inputs meet the outputs, as confirmed during design verification, and be approved prior to the release. They provide information for purchasing, production, and service of the device as appropriate, contain or reference acceptance criteria and specify essential characteristics for the proper use and safety of the device. Last, you must maintain records for design outputs.

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Continuing with our example of portable. The approved specification from the input as three pounds plus or minus one pound is weighed on a calibrated scale. The design output is the specification meeting the input requirements, as confirmed during the verification of weighing it on the scale. The approved

specification, the finished device itself, the records, and documents for the device and how to manufacture it to specification are all design outputs.

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Using an appropriate team, including representatives of functions concerned with the design and development stage being reviewed, as well as other specialists, plan and conduct formal documented design reviews of the design results at suitable stages. Design reviews are not ad-hoc meetings. They are documented, comprehensive and systematic. Evaluate the adequacy of the results and the capability of the design to meet requirements. Identify and propose necessary actions. Document the results and actions from the design review.

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Going back to our example, a review team made up of representatives from sales, research, quality and regulatory reviewed the design per the planned schedule. During a review meeting among other identified items, it was determined the weight output needs to be considered in addition to other equipment in the use environment. The review team noted this as an action item to determine how this device and other equipment is carried by these users.

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In addition, the design review team also updated the risk traceability matrix for the hypothetical device. Noting that the device must be carried with other items to be readily available and needs storage protection from the environment. This led to a new input being identified, that the device needs to fit and be included in a specified emergency bag.

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Design verification is confirmation by objective evidence that design outputs meet design inputs. Organizations must perform verification per documented plans and procedures, and the plans need to include the methods, acceptance criteria and statistical techniques used. Additionally, any connections or interfaces with other devices or systems are also confirmed when connected. Last, record the results and conclusions of the verification and any necessary actions.

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Next using our example, during the review it was identified that portable includes weight, three pounds, with users being first responders and the ocean as a use environment. This caused further iteration in

the design input to output and after referencing our risk matrix new information was learned and included. Therefore, to understand how the device will fit in with other equipment a coast guard health service technician was contacted for assistance. They provided information as well as samples of a standard coast guard emergency bag. The team then verified that the device with a dimension of three by two by one fits into the packed bag adding three pounds plus or minus one pound.

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Following verification is validation. Design and development validation confirms, by objective evidence, that the device can meet the requirement for its specified application or intended use. Organizations must perform validation per documented plans and procedures that include the methods used, acceptance criteria and statistical techniques. Connections or interfaces are also confirmed, and it must be performed with representative product, representative product includes initial production units or their equivalent. The organization must document the rational for the choice. Any clinical evaluations must meet their applicable regulatory requirements and in the case of FDA that would include 21 CFR 812 Investigational Device Exemption or IDE. The validation shall be completed prior to release to customers. A medical device used for clinical evaluation is not considered to be released for use to the customer.

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I think about verification and validation in this way. Verification does the design output meet the input requirements. The design output, using our example, meets the requirement, measured on a scale weighs three pounds plus or minus one pound as noted in the design input. I made the product correctly.

For design validation, where the three pound device is put into the actual use environment with intended users and meets its requirement for the intended use. I made the correct product. Both are important to the design process.

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Returning to our hypothetical example, we have actual production units of the device that are three pounds with dimensions of three by two by one, both inputs and outputs verified, under an IDE, placed in standard emergency bags used by coast guard personnel. As part of the study, overseen by an institutional review board, devices were monitored and users reported back on the weight of the bag as negligible, so acceptable for intended use, and the devices availability and inclusion in the emergency

bag as needed by users. Please note this example is only to illustrate at a high level how design and development might look for a hypothetical device and how the different stages may interact. It is not intended to be inclusive.

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Now that the design team has done a great job, and the verification and validation activities are completed and reviewed, are we done? No, the organization must document procedures for the transfer of the outputs to manufacturing. These procedures need to ensure the outputs are verified as suitable for manufacturing before becoming final production specification. That production capability can meet device requirements. There could be a need to address production scale up, remaining process validation protocols, finalization of purchasing controls, training, and qualifying manufacturing personnel among other transfer considerations. For me a worst-case scenario is to have an effectively designed device not manufactured correctly.

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We have the approved output for the device's weight and dimensions and all the procedures and validated process are in place to consistently manufacture the device to meet all requirements. The production is controlled per our quality management system and meets all other regulatory requirements. It is good to go.

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Now at some point and time things will change and next I will discuss the continual role design and development must play with changes. Organizations must document procedures to control design and development changes. They must determine the significance of the change, and these could be changes in function, performance, usability, safety, or regulatory requirements for the device or its intended use.

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Design changes must be identified and reviewed, and verified or validated as appropriate and approved before the change is implemented. Also, an evaluation or review of the impact of the change must be included, and it could consist of changes on constituent parts, product in process or product already delivered, and inputs or outputs of risk management and product realization processes. That covers a large umbrella of changes to consider as part of design and development.

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For example, and this is a quick hypothetical, the change we are going to look at, is a new fit size of the device. One that after meeting all the other design and development requirements, including verification and validation activities, in that its weight and dimensions fit into a specific standard life vest used by end users. Production units are used, and an IDE study is completed, and all design and development activities are completed, then it can now go to market with this change to the device. Be aware for some design and development changes they may require a new regulatory submission.

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Last, let's talk design and development file. This is the full history of the device type or family and needs to include or reference records that demonstrate conformity to the design and development requirements, including changes. This file is extremely valuable in understanding your device, and its iterations and evolution.

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In summary, design and development is important to medical device quality and safety. The Quality Management System Regulation provides FDA requirements for design and development and integrates risk management throughout the design and development process. The QMSR incorporates by reference ISO 13485:2016 and incorporates by reference ISO 9000:2015(E) Clause 3.

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Linked here are referenced resources available to help you understand the foundational aspects of design and development in the QMSR. Use these and other educational materials such as those on CDRH Learn, for example the QMSR overview module to understand the FDA requirements for your medical device.

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This presentation and other educational resources can be found on CDRH Learn. For text-based information including how to bring a medical device to market please visit Device Advice. For additional questions on this or any other general medical device regulatory topic please email or call us at the Division of Industry and Consumer Education.

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Your call to action. Implement regulatory requirements for design and development per 21 CFR 820.7 and 21 CFR 820.10 by February 2, 2026. Ensure design and development addresses the devices intended uses and defines and meets all appropriate requirements. Use design and development to build quality, safety, and effectiveness into your medical device.

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Thank you.

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