Quality Management System Regulation (QMSR) - Design and Development

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Design and Development can impact…

Reset Form

FDA

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
FORM 3500A

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291
Expires: 6-30-2025
See PRA statement on page 6.

FDA USE ONLY
Mfr report #
UF/Importer Report #
Exemption/Variance #

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-JAN-1900

A. PATIENT INFORMATION

1. **Patient Identifier** *(In confidence)*

2. Age ☐ Year(s) ☐ Week(s) ☐ Month(s) ☐ Day(s)

or Date of Birth *(e.g., 01-Jan-1900)*

3a. **Sex:** Enter the patient's sex at birth *(the sex that a person has or was assigned to at birth).*
☐ Male ☐ Undifferentiated
☐ Female ☐ Decline to answer

3b. **Gender:** Enter the patient's current gender *(how the patient thinks of themself).*
☐ Cisgender man/boy (gender corresponds with birth sex)
☐ Cisgender woman/girl (gender corresponds with birth sex)
☐ Transgender man/trans man/ female-to-male (FTM)
☐ Transgender woman/trans woman/ male-to-female (MTF)
☐ Other gender category; please specify:
☐ Decline to answer

4. **Weight** ☐ lb ☐ kg

5. **Ethnicity** *(Check one)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

6. **Race** *(check all that apply)*
☐ American Indian/Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian/ Other Pacific Islander
☐ White

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. **Type of Report** *(check all that apply)*
☐ Adverse Event
☐ Product Problem *(e.g., defects/malfunctions)*

2. **Outcome Attributed to Adverse Event** *(check all that apply)*
☐ Death – Date of death *(01-JAN-1900):*
☐ Life-threatening
☐ Hospitalization (initial or prolonged)
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

Learning Objectives

- Review the history of design and development in medical device quality regulations
- Outline QMSR requirements for design and development
- Identify different design stages and how they interact with one another

The History of Design and Development in Medical Devices

What is Design and Development

- A set of *processes* that transform *requirements* for an object into more detailed requirements for that object
- The terms “design” and “development” and “design and development” are sometimes synonymous and used interchangeably

Important Studies Show Impact

- The most frequent causes for recalls are related to Design, Software, and Non-Conforming Materials/Components

  Source: "Medical Recall Report FY2003 to FY2012" (CDRH Office of Compliance, Division of Analysis and Program Operations)

- 44% of voluntary recalls from October 1983 through September 1989 may have been prevented by adequate design controls

  Source: ''Device Recalls: A Study of Quality Problems'' (see 55 FR 21108, May 22, 1990) and "QS Regulations (Final Rule)" (see 61 FR 52602, October 07, 1996)

How Did It Become a Requirement

- 1990 – The Safe Medical Device Act authorized FDA to add Design Controls to the current Good Manufacturing Practice (cGMP) requirements for medical devices
- 1997 – The Quality System (QS) Regulation with design controls became effective
- 2026 – The Quality Management System Regulation (QMSR) incorporates by reference ISO 13485:2016, 7.3 Design and development, and is effective February 2, 2026

QMSR Requirements for Design and Development

21 CFR 820.10 (c)
Design and Development

QMSR Design and development requirements apply to manufacturers of:

- *All* **Class II** and **Class III** medical devices
- These **Class I** medical devices:
  - Devices automated with computer software
  - Tracheobronchial suction catheters
  - Non-powdered surgeon's gloves
  - Protective restraints
  - Manual radionuclide applicator system
  - Radionuclide teletherapy source

Incorporation by Reference

- 21 CFR 820.7 Certain material is incorporated by reference;
  - ISO 9000:2015(E), QMS Fundamentals and Vocabulary, Clause 3 - Terms and definitions.
  - ISO 13485:2016, Medical Device QMS

- 21 CFR 820.10(a) Document a QMS that complies with the applicable requirements in ISO 13485:2016
  - Note: In this presentation the use of “Clause X.X” refers to a clause in ISO 13485:2016.

When to Start Design and Development

Recommended:

- When research is ending
- After Feasibility/“Proof of Concept”

Required:

- Prior to the start of a clinical evaluation such as an Investigation Device Exemption (21 CFR 812)
- Submitting to FDA, a 510(k), De Novo, Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) *NOTE this list is not all inclusive.

Design and Development Stages

- Planning – starting with RISK
- Input
- Output
- Review
- Verification
- Validation
- Transfer
- Changes

Clause 7.1 Planning of Product Realization

Risk Management – this includes design and development activities

- The organization documents one or more processes for risk management
- And maintain records of risk management activities

Clause 7.3 Requirements

General: Organizations shall document procedures for design and development

Design and Development Planning:

- Plan and control the design and development of the device
- Document the progress of the design and development, as appropriate, identify stages, reviews and activities
- Note roles and responsibilities, traceability methods, and resources needed

Clause 7.3.3 Inputs

Determine inputs related to product requirements and maintain records. These include functional, performance, usability and safety requirements according to the intended use, AND…

- Contain any applicable regulatory and standard requirements
- Account for all pertinent risk management outputs
- And they must be complete, unambiguous, able to be verified or validated, and not in conflict with each other

Input: Example

Example: “**Portable**”

- Firm develops device intended to be carried by user
- Consider weight and device dimensions
- Drilling down to weight, determine measurement
  - ❖ Identified conflicting requirement, different units of measure
    3 **lb** ± 1 **kg**
  - ❖ Resolved discrepancy, recorded device design input as
    3 **lb** ± 1 **lb**

Clause 7.3.4 Outputs

Design and development outputs shall:

- Meet the input requirements
- Provide information for the purchasing, manufacturing, and servicing of the device as appropriate
- Contain or reference acceptance criteria
- Specify any essential characteristics for the proper use and safety of the device

Output: Example

Device is designed to be "**Portable.**" Firm design input is

3 **lb ± 1 lb**

- Measure the weight of the device on a calibrated scale
- The recorded weight of 3.2 lb, the device itself and documents to manufacturer the device for that weight are all outputs

Clause 7.3.5 Review Requirements

Use an appropriate team to systematically review the design and development of the device at suitable stages

- Evaluate the ability of design and development results to meet requirements
- Identify and propose necessary actions
- Record the results and actions from the review

Review: Example

Review: “**Portable**”, Output **3 lb ± 1 lb**

- During review the team identifies a new primary use environment, the ocean, and users including lifeguards, beach patrol, and Coast Guard. The 3 lb output needs to be considered in addition to other carried equipment.
- Action item for team, to determine how equipment is carried by these users.

Identified Risk and New Input Example

- During review, updates were made to the risk traceability matrix of the device, for example:
  - Must be carried with other items to be readily available
  - Needs storage protection from the environment.
- A new input was identified that the device needs to fit and be included in a specified emergency bag.

Clause 7.3.6 Verification

- Need to be performed per documented plans and procedures to ensure outputs meet inputs
- The verification plans, including methods, acceptance criteria, and statistical techniques must be documented
- Any connections or interfaces with other devices or systems must also be confirmed when connected

Verification: Example

"**Portable**" for first responders at the ocean,

Output **3 lb ± 1 lb**

- An additional portable input to output is that the device size fits in and is part of the weight of a known standard Coast Guard emergency bag.
- Samples of the bag were acquired and the team verified that the device, dimensions 3"x2"x1", fits in the packed bag and adds an additional 2 to 4 lbs.

Clause 7.3.7 Validation

- Shall be performed per documented plans and procedures to ensure the device meets its intended use
- The plans, including methods, acceptance criteria, and statistical techniques must be documented
- Any connections or interfaces must be confirmed
- Need to be conducted on representative product
- Clinical evaluations need to meet applicable regulatory requirements
- Must be completed prior to release

Verification vs. Validation

- **Design and Development Verification**
  - Output meets Input requirements
  - I made the device correctly
- **Design and Development Validation**
  - Device meets the requirements for the intended use
  - I made the correct device

Validation: Example

"**Portable**", Output **3 lb ± 1 lb** and fits in bag,

- Production units of the device were placed in emergency bags used by Coast Guard personnel at multiple locations.
- Devices were monitored and personnel reported back on the weight of the bag. The weight was rated as negligible, and the device's availability in the bag as necessary and important.

Clause 7.3.8 Transfer

- Document procedures for the transfer of the outputs to manufacturing
- Procedures ensure the outputs are verified as suitable for manufacturing before becoming final production specifications
- Production capability can meet device requirements

Transfer: Example

Output **3 lb ± 1 lb** with dimensions of 3”x2”x1”.

- Production units of the device can be manufactured to meet the weight, dimensions, and all other output requirements.
- Device production is controlled and meets all other device and regulatory requirements.

Clause 7.3.9 Changes

- Document procedures to control design and development changes
- Determine the significance of the change. These could be changes in function, performance, usability, safety or regulatory requirements for the device and/or its intended use

Clause 7.3.9 Changes Continued

- The design changes shall be identified, and before implemented:
  - Reviewed
  - Verified, or Validated as appropriate
  - Approved
- And include evaluation of the impact of that change on constituent parts and the product

Change: Example

Input: “**Portable**”, change to **fits in issued life vest pocket**.

Output: Specifications and drawings to meet weight and dimension requirements of input including pocket fit.

- Verification: Production units are used to verify they are within specification and fit in the vests.
- Validation: Same units are used as part of the life vest package in real world conditions, as appropriate.
- Devices were monitored and personnel reported on results.
- The new vest model meets all design and development change requirements.

Clause 7.3.10 Design and Development File

- Organizations must maintain a design and development file for each medical device type or medical device family
- The file needs to include or reference records that demonstrate conformity to the design and development requirements, including changes

Summary

- Design and Development is important to medical device quality and safety
- The Quality Management System Regulation (QMSR) 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 ISO 9000:2015(E) Clause 3

Resources

Slide Number	Cited Resource	URL
5	ISO 9000:2015 Quality Management Systems – Fundamentals and Vocabulary	ibr.ansi.org/
7	Part 820 - Quality Management System Regulation	www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments
10	Where to view only (read) ISO 13485 and ISO 9000 standards	ibr.ansi.org/standards/iso1.aspx
10	Where to purchase a copy of the ISO 13485 and ISO 9000 standards	ibr.ansi.org/

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1-800-638-2041 or (301) 796-7100 (9 am – 12:30 pm; 1 – 4:30 pm ET)

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 intended use(s) 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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