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Quality Management System Information for Certain Premarket Submission Reviews

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

October 2025

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact Office of Regulatory Policy/Division of Submission Support at 301-796-5640 or CDRHPremarketProgramOperations@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD) at 800-835-4709 or 240-402-8010, or industry.biologics@fda.hhs.gov.

When final, this guidance will supersede "Quality System Information for Certain Premarket Application Reviews," issued February 3, 2003.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

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Quality Management System Information for Certain Premarket Submission Reviews

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA is issuing this draft document to provide guidance to industry and FDA staff about FDA expectations related to the Quality Management System Regulation (QMSR) [1] requirements and Quality Management System (QMS) information included in premarket approval applications (PMAs) and Humanitarian Device Exemption (HDE) applications.[2] When final, this guidance is intended to assist medical device manufacturers in preparing and maintaining a QMS and providing the information required to be included in marketing submissions regarding a QMS stemming from the QMSR.

Marketing submissions submitted under section 515(c)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), are required to include a number of informational components, as set forth in both section 515(c)(1)(C) of the Act and 21 CFR 814.20.[3] One component covers the current good manufacturing practice (CGMP) requirements included in the QMSR.

The medical device CGMP requirements have been amended to align more closely with global regulatory authorities by incorporating by reference the international consensus standard for

[1] When referring to 21 CFR part 820 as amended, effective on February 2, 2026, FDA uses the term "QMSR." When referring to the regulation at 21 CFR part 820 in effect before February 2, 2026, FDA uses the term "QS regulation."

[2] PMA and HDE submission types will be referenced as "marketing submission" throughout this draft guidance.

[3] See also 21 CFR 814.37 (PMA supplements), 21 CFR 814.39 (PMA amendments), and 21 CFR 814.108 (HDE supplements).

device QMS set by the International Organization for Standardization (ISO), ISO 13485:2016,[4] and Clause 3 of its normative reference ISO 9000:2015.[5] When finalized, this guidance will replace the guidance, "Quality System Information for Certain Premarket Application Reviews," issued on February 3, 2003.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

FDA has historically recognized the benefits of harmonization with other regulatory authorities and, over time, has taken a number of actions to promote consistency with its international regulatory counterparts.

The QS regulation included requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of devices intended for human use. These requirements have been effective in providing assurance that devices are safe and effective and otherwise in compliance with the Act.

In 1996, ISO issued the first version of ISO 13485, "Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001," as a voluntary consensus standard to specify, in conjunction with the application of ISO 9001, the QMS requirements for the design and development and, when relevant, installation and servicing of medical devices.

Over time, the requirements in ISO 13485 have become more closely aligned with the requirements set forth in FDA's QS regulation. This alignment and similarity are particularly true for the 2016 version of ISO 13485. Recognizing this progression, FDA realized an opportunity for regulatory harmonization by amending 21 CFR part 820 to incorporate by reference the QMS requirements of ISO 13485 (2016 edition) and, thereby, replace the QS regulation with the new QMSR. As such, the QMSR incorporated by reference the 2016 version of ISO 13485 and the 2015 version of Clause 3 of ISO 9000.[6] FDA finalized a rule entitled, Medical Devices; Quality System Regulation Amendments on February 2, 2024. Effective February 2, 2026, 21 CFR part 820, will be revised to the following sections:[7]

Subpart A—General Provisions
820.1 Scope.
820.3 Definitions.

[4] ISO 13485:2016 *Medical devices — Quality management systems — Requirements for regulatory purposes*.
[5] ISO 9000:2015 *Quality management systems — Fundamentals and vocabulary*.
[6] Any future revisions to these standards would need to be evaluated to determine the impact of any changes and whether it is appropriate to amend the QMSR.
[7] For more information on the 21 CFR part 820 revisions please see: https://www.regulations.gov/document/FDA-2021-N-0507-0083

820.5 [Reserved]
820.7 Incorporation by reference.
820.10 Requirements for a quality management system.
Subpart B—Supplemental Provisions
820.20–820.30 [Reserved]
820.35 Control of records.
820.40 [Reserved]
820.45 Device labeling and packaging controls.
Subparts C–O [Reserved]

FDA believes the global harmonization of medical device regulation can help provide safe, effective, and high-quality devices and contributes to public health through timelier patient access to such devices. Harmonizing regulations removes unnecessary duplicative regulatory requirements and impediments to market access and removes barriers to patient access.

III. Overview

This draft guidance document is intended to assist medical device manufacturers both to prepare and maintain a QMS and to provide the information required to be included in marketing submissions regarding a QMS, in line with the QMSR. In addition, this draft guidance is intended to make recommendations regarding information that may help FDA determine compliance with the QMSR.

The Act requires that certain marketing submissions contain a "full description" of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of such device.[8] This information needs to be in sufficient detail so that FDA can make a knowledgeable assessment of the quality controls used in producing the medical device. FDA shall deny approval of an application if, based upon the submission and any other information before FDA with respect to the device, FDA finds that the methods used in, or the facilities and/or controls used for, the manufacture, processing, and when relevant, packing or installation of the device do not conform to good manufacturing practices.[9]

In general, FDA recommends that submitters provide copies of written procedures, summaries, reports, or lists of items related to the QMSR as part of their FDA submissions. The QMSR requires firms to implement, establish, and maintain many of the items described in this draft guidance. Where the QMSR does not explicitly require such information to be documented, FDA considers the information to be the type that submitters are likely to create and maintain as part of the QMS, and as such recommends that it be included in a marketing submission that is the subject of this draft guidance. Including such information in the submission may reduce or eliminate the need for FDA to request additional information to determine compliance with the

[8] Section 515(c)(1)(C) and 520(m) of the Act, see 21 CFR 814.20(b)(4)(v); 21 CFR 814.104(b)(4).
[9] Section 515(d)(2)(C) of the Act; see 21 CFR 814.45(a); 21 CFR 814.118(a).

QMSR and can help FDA focus the preapproval inspection process.[10]

Generally, section 515(c)(1)(C) of the Act requires that a PMA contain a full description of the methods used in, and the facilities and controls used for, manufacturing, processing, and packing a device. A complete description must provide sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about an applicant's QMSR.[11] If FDA finds there has not been a demonstration that the methods used in, and the facilities and controls used for, manufacturing, processing, and packing a device conform to the QMSR, including because there is insufficient information submitted in the PMA, FDA is required to deny approval of the application under the Act.[12]

In this document, FDA describes the types of information that would be sufficient to comprise the full description required by the Act and its implementing regulations. As such, FDA recommends that a submitter provide the information described in this document to enable FDA to find that methods used in, and the facilities and controls used for, manufacturing, processing, and packing a device conform to the QMSR.

A submitter who chooses to meet marketing submission requirements related to the QMSR information in an alternative manner than that recommended in this guidance may wish to consult with the appropriate review office prior to the submission. FDA staff can help identify areas that might raise particular concerns for reviewers or investigators. FDA recommends reaching out to the appropriate review office to discuss this through the Q-Submission program. For additional information regarding the Q-Submission Program, please refer to the guidance titled, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

In developing the guidance, FDA carefully considered the relevant statutory criteria for Agency decision making. FDA also considered the burden that may be incurred in the submitters' efforts to comply with the regulation and address the issues that have been identified in this guidance. FDA has considered the least burdensome approach to resolving the issues presented in this guidance document. For further information on the least burdensome principles, please refer to the guidance titled, "The Least Burdensome Provisions: Concept and Principles."

IV. Scope

This draft guidance provides recommendations to industry and FDA staff about the QMSR information needed to be included in a marketing submission for a medical device. The recommendations provided in this draft guidance document are not intended to propose any changes to applicable statutory and regulatory standards.

This guidance, when finalized, is also not intended to supplant existing device-specific guidance

[10] FDA may obtain information through either correspondence or other communication with the manufacturer or through an inspection, as needed.
[11] See 21 CFR 814.20(b)(4)(v).
[12] See section 515(d)(2)(C) of the Act.

documents but may cover broader areas not addressed in device-specific guidance documents.

On and after February 2, 2026, FDA will be evaluating the documents and records included in marketing submissions to determine whether there is conformance with the requirements of the QMSR. A gap analysis or another type of comparative analysis may assist FDA in determining when documents and records created prior to the QMSR effective date are submitted to FDA. Additionally, on and after February 2, 2026, FDA inspections of device manufacturers that are evaluating CGMP, including PMA preapproval inspections, will evaluate compliance with QMSR requirements. In doing so, it may help FDA to make that determination by providing a gap analysis or a comparative assessment.

V. Quality Management System

A. General Information

(1) Format

The "Cover Letter" and the general information described below in "Content" may be submitted only once if all appropriate QMSR information is submitted at the same time. If the QMSR information is not all submitted at the same time, as permitted by programs such as the PMA modular review process,[13] the general information should be submitted with each submission. This will allow FDA reviewers to have ready access to this basic information with each submission under review and avoid possible delays. If submitting as an eCopy, FDA recommends including a cover letter with the information outlined in Section V.A.2 below.[14]

Alternatively, if using FDA's eSTAR template for PMAs, the submitter should ensure that the information included below is included in the responses to the eSTAR questions. For additional information on the eSTAR program see, FDA's webpage titled, eSTAR Program.

If submitting a modular PMA submission, FDA recommends that the QMSR information be submitted in a standalone module separate from other PMA modules.

When multiple facilities are involved in the manufacture, processing, packing or installation of the device, FDA recommends specifying the activities performed at each facility and submitting applicable QMSR information for each facility in separate volumes that clearly identify the facility to which it applies.

(2) Cover Letter

FDA recommends that submitters include a cover letter that includes the following information to help FDA manage the marketing submission and related documents more efficiently:

[13] For further information on the PMA review process please visit FDA's webpage PMA Review Process. For more information on the PMA and HDE application modular process, please reference the guidance titled, "Premarket Approval Application and Humanitarian Device Exemption Modular Review."

[14] See FDA's guidance, "eCopy Program for Medical Device Submissions."

- Identification elements:
  - Full name and street address (no P.O. Box number),
  - Telephone number,
  - FDA Facility Establishment Identifier (FEI) or registration number, and
  - Relationship of (each) manufacturing facility to submitter.[15]
- DUNS business number issued by Dun & Bradstreet (D&B).
- Contact person (and alternates) and the associated telephone number(s) and email addresses.
- The date the facility site(s) will be ready for inspection.

(3) Content

The initial volume for each facility should include the following information:

- A copy of the cover letter, as described above in Section V.A.2,
- A description of the subject device, including pictures, and where possible, the proprietary brand name, common name, version or model number(s), product code, previous Unique Device Identifier (UDI) (if applicable), UDI assignment and maintenance plan, and intended use,
- A description of how the device works, and
- The documentation described in Sections VI - IX of this draft guidance.

Note: If resubmitting information, FDA recommends the submitter verify that the information does not include any changes that would require a PMA or HDE amendment.[16]

VI. Establishing a Quality Management System

21 CFR part 820 directs manufacturers to establish and maintain a QMS that complies with the applicable provisions of ISO 13485. See 21 CFR 820.7 and 21 CFR 820.10(a). FDA is providing the following information to help submitters comply with those provisions in documenting their QMS. FDA also recommends providing the information outlined in Section VI of this draft guidance in the manufacturing portion of the marketing submission. Providing the information described in Section VI may enable FDA to make a knowledgeable assessment of the quality controls used in manufacturing the device.[17] If FDA finds there has not been a demonstration that the methods used in, and the facilities and controls used for, manufacturing, processing, and packing a device conform to the QMSR, including because there is insufficient information submitted in the PMA, FDA is required to deny approval of the application under the Act.[18]

[15] The location and affiliation information will help FDA determine the appropriate facilities to be inspected under the preapproval process.
[16] See 21 CFR 814.37, 21 CFR 814.106.
[17] See section 520 of the Act, and 21 CFR part 820.
[18] See section 515(d)(2)(C) of the Act.

A. Quality management system

ISO 13485 Clause 4 and its subclauses[19] describe the basic expectations for how an organization establishes its QMS and emphasizes that risk-based decision making is critical to implementing the requirements of ISO 13485. FDA expects that the documents described in Clause 4 and its subclauses will provide a full description of the QMS and will enable FDA to evaluate a manufacturer's ability to comply with the QMSR.

(1) Basic expectations for establishing a QMS

ISO 13485 Subclause 4.1 establishes the general requirements for a QMS. Subclauses 4.1.1-4.1.6 set forth the basic elements that a manufacturer must document in its QMS. A full description of a QMS in a marketing submission will address how the manufacturer meets those requirements. FDA recommends that a submitter include the following information in its marketing submissions:

- A summary of the risk-based approach(es) used to control the processes that make up the organization's QMS. This summary should explain how the submitter addresses the following:
    - The risk-based approach(es) used to control the appropriate processes that make up the organization's QMS, as described in Subclause 4.1.2(b),
    - The organization's documented methods for monitoring and ensuring control over outsourced processes that affect product conformity to requirements. As described in Subclause 4.1.5, the controls should be proportionate to the risk involved and the ability of the external party to meet the requirements, and
    - The risk-based approach and activities the organization uses for initial validation and revalidation after QMS software changes, as described in Subclause 4.1.6.

(2) General QMS Documentation

ISO 13485 Subclause 4.2 requires an organization to document certain general QMS information and processes. FDA expects that a full description of that documentation and the processes that maintain the documents in a marketing submission will include:

- Documented statements of its quality policy and quality objectives,
- A quality manual, which should address the scope of the QMS, describe documented or referenced QMS procedures, provide a description of the interactions between QMS processes, and include an outline of the QMS documentation structure,
- Medical device files, and
- A full description of the document and record control processes that maintain the documentation described in Subclause 4.2.

Note: 21 CFR 820.35 sets forth additional requirements for the content of specific records. Please see Section VIII of this draft guidance.

[19] References to clauses and subclauses in this draft guidance are to clauses and subclauses of ISO 13485:2016, unless otherwise specified.

B. Management responsibility

(1) Responsibilities of Top Management

Top management is a person or group of people who directs and controls an organization.[20] ISO 13485 Clause 5 describes the responsibilities of top management in developing, implementing, and documenting the organization's QMS. ISO 13485 requires an organization to document and maintain certain information described in Clause 5 and its subclauses. A marketing submission containing a full description of the documentation described in Clause 5 should:

- Identify the management representative(s) with the responsibility and authority to ensure documentation of the QMS processes, who reports to top management on the effectiveness of the QMS and any need for improvement and who ensures the promotion of awareness of applicable regulatory and QMS requirements throughout the organization, as described in Subclause 5.5.2.
- Document the organization's management review procedure, as described in Subclause 5.6.
- So that FDA can evaluate how top management complied with the requirements of ISO 13485 Clause 5 for the subject device, FDA recommends that the submitter include a summary of the management review inputs and outputs for the subject device.

C. Resource management

(1) Infrastructure Requirements

ISO 13485 Subclause 6.3 sets forth the organization's infrastructure requirements needed to achieve product conformity, prevent product mix-up, and ensure orderly handling of the product. As such, a submission containing a full description of the documentation required by Subclause 6.3 should contain the following information to enable FDA to make a knowledgeable assessment about that system:

- A diagram of the facility(ies), demonstrating that the facility(ies) has sufficient space to:
  - ensure orderly handling of product, and
  - prevent mixing between incoming material, in-process batches, material scrapped, re-worked, modified or repaired, any other nonconforming material, medical devices, manufacturing equipment, inspection aids, documents and drawings.
- The procedure(s) or summary that explains how risk management is used to determine the interval for performing the maintenance activities, and when such maintenance activities, or lack thereof, can affect product quality for equipment used in production, the control of the work environment and monitoring and measurement.

  Note: if this involves many procedures, FDA intends to consider a sample of the most relevant procedures supporting the subject device to be sufficient.

[20] See ISO 9000, Subclause 3.1.1.

(2) Work Environment and Contamination Control

ISO 13485 Subclause 6.4 and its subclauses set forth an organization's responsibilities for documenting the work environment needed to achieve conformity to product requirements and contamination control processes.

The controls for the work environment and contamination control may vary depending on the type of product, the associated manufacturing processes, sterility status, and with consideration to the extent to which the product contact with the environment may adversely impact product cleanliness.

For example, for an implanted device, the final cleanliness of the implant surface affects medical safety performance and is crucial for that device to perform as intended. For other devices, such as electronically controlled medical devices, protections in the work environment against electrostatic discharge, or other sources of damage or contamination of the electronic components may be crucial to the device. For many devices, controls for (1) the production environment for air cleanliness, including particulate and bioburden, may be applied in the form of a defined "cleanroom" or controlled environment and classification, and (2) personnel (such as gowning, gloves, personal hygiene) may apply, because preventing contamination with microorganisms or particulate matter may prevent contamination of the product. Therefore, as for other sections of this draft guidance, the risk management documentation should clearly define the type and extent of controls to be exercised for the subject device.

As such, a marketing submission containing a full description of the documentation required by Subclause 6.4 should contain the following information:

- Documents that identify the requirements for the work environment needed to achieve conformity to the product requirements, as described in Subclause 6.4.1.
- Documents that describe the plan, procedures, and arrangements to control contaminated or potentially contaminated product, including control of contamination with microorganisms or particulate matter, to prevent conditions that could adversely affect the device, consistent with Subclause 6.4.2.
- The overarching (main or top level) documents that apply to the device, if there are multiple applicable procedures. Additionally, submitters should identify (list) the others (i.e., next document tier or layer down). FDA may interactively request select examples of next layer/tier documents, where appropriate, to complete/facilitate its review.
- Either within this section, or under Subclauses 7.5.6 and 7.5.7, as discussed in this draft guidance, the related validation plan, associated validation protocol and report to represent an example[21] of the environmental and/or contamination control systems/processes (e.g., cleaning process, cleanroom qualification) applicable for the subject device.

[21] For purposes of the review, one related validation plan, associated validation protocol and report should be sufficient. However, FDA may request additional information during the course of the review, if needed.

- The risk-based approach for the submitter's choice of cleanliness criteria (e.g. cleanroom classification).

D. Product Realization

(1) Product Realization Development Processes

ISO 13485 Subclause 7.1 requires the organization to plan and develop processes needed for product realization, including one or more risk management processes used in product realization and for records of these risk management activities to be maintained. A marketing submission containing a full description of the documentation required by Subclause 7.1 should contain the following information:

- The report or other output that documents the result of planning for product realization for the device.
- A procedure(s) or detailed summary of each risk management process used in product realization and where in product realization it is used for the device.
- The summary results of the risk management activities for the device. This summary should document the links between the identified potential hazards, hazardous situations and associated possible harm, device failure modes, risk estimation, risk control measures and activities for verification of the implementation and effectiveness of risk control measures.

(2) Design and Development Requirements

ISO 13485 Subclause 7.3 and its subclauses describe the requirements for design and development controls. Because Subclause 7.3.10 requires a manufacturer to maintain its design and development files, FDA expects that those files will contain the necessary information to provide a full description of the design and development controls that are part of the QMS. In particular, and to the extent the information does not appear elsewhere in the application but is maintained as part of the manufacturer's QMS in accordance with Subclause 7.3, FDA recommends that submitters provide the following information as part of the manufacturer's full description of its QMS in the marketing submission:

- The design and development plan(s) that includes all of the documented elements specified under Subclause 7.3.2. A full description would generally include the following:
    - Any traceability matrix (tracing design and development inputs to design and development outputs); subsequent portions of the description may refer back to this matrix.
    - Where a manufacturer uses multiple plans for design and development (for example, for complex processes), each of those design and development plans.
    - Records of planning document approvals and, as applicable, associated version numbering and dates.

- All of the design and development inputs described under Subclause 7.3.3. A full description would generally include:
  - Identification of the process to address any potential and/or emerging risks and how the submitter plans to manage such risks.
  - Identification of each input, including which of them were derived from risk management outputs.
  - The documented reviews for determining that the inputs are complete, unambiguous, able to be verified or validated, and not in conflict, including the responsible person(s) and dates.
  - Any appropriate cross-references to traceability matrices, for example, a design traceability matrix provided for Subclause 7.3.2 and/or a risk management trace matrix.
- All of the design and development outputs described under Subclause 7.3.4. A full description would generally include:
  - Identification of each output, in a form suitable for verification against the inputs.
  - The resulting appropriate information for purchasing, production, and service provision (see also ISO 13485 Subclauses 7.4 and 7.5).
  - Product[22] acceptance criteria or a reference to the acceptance criteria.
  - Identification of the characteristics of the device that are essential for its safe and effective use.
  - Records of approvals of design outputs prior to release.
  - Any appropriate cross-reference to a traceability matrix, for example, a design traceability matrix provided for Subclause 7.3.2.
- The documented plan for and results of design and development reviews as described in Subclause 7.3.5. A full description would generally include:
  - The documented evaluation that the results of design and development meet identified requirements.
  - Results of design and development reviews at various stages, which may be, for example, any point(s) at which the submitter evaluated the product design in order to adjust and/or change the design plan, or at the end of other predefined design and development phases.
  - Identification of the need for further action, proposals for such action, and any adjustments made based on the reviews.
  - Identification of the participants in such reviews, including relevant expertise or role, and the dates of such reviews.
- The plan for, and results of, the verification activities for design and development described in Subclause 7.3.6. A full description would generally include:
  - A list of verification activities conducted and associated reports of results (these may be cross-references to other reports provided elsewhere in the application).
  - Any test methods, protocols, acceptance criteria, and as appropriate, statistical techniques with sample descriptions/sizes and supporting rationale.

[22] Note that, for purposes of the QMSR, "product" has a distinct definition (see ISO 13485 Subclause 3.15). "Product" so defined can refer to something besides the final finished device or device constituent part.

- A clear statement of limitations on the scope of the verification activities, for example, in cases where the verification was limited to a specific component.
- When a device is intended to be used as part of a system or with another device, the verification activities for the system or with the other device(s).
- Any other appropriate cross-references to information provided elsewhere in the application.

- The plan for, and results of, the validation activities for design and development as described in Subclause 7.3.7. A full description would generally include:
  - A list of validation activities conducted and associated reports of results (these may be cross-references to other reports provided elsewhere in the application).
  - Documentation that the design and development results will meet the requirements for the specified application or intended use(s).
  - Documentation of validation plans that include methods, acceptance criteria, and as appropriate, statistical techniques with sample size/descriptions and supporting rationale.
  - The design validation on representative product, which includes initial production units/batches or their equivalents, with:
    - A rationale for the choice of product used for validation.
    - The differences, if any, between the product used for validation and the device under review.
  - A clear statement of limitations on the scope of the validation activities, for example, in cases where the validation was limited to a specific component.
  - When a device is intended to be used as part of a system or with another device, the validation activities for the system or with the other device(s).
  - Any other appropriate cross-references to information provided elsewhere in the application.
- The procedures for the transfer of design and development outputs to manufacturing under Subclause 7.3.8. A full description would generally include:
  - Procedures specific to the organizations responsible for each activity, including for in-house manufacturing and various contract manufacturers and component (or product) suppliers, as applicable, with:
    - An explanation for how to transfer information about manufacturing controls and requirements to the different organizations.
    - Procedures to ensure adequate transfer of design and development outputs that are essential to the safe and effective use of the device.
    - Records of verification and approval of design outputs prior to transfer.
  - Specifications for necessary infrastructure, equipment, personnel, and expertise.
  - Plans for, and records of, equipment qualification, process validation, personnel training, and other setup activities.
  - Sampling plans, equipment maintenance activities, cleaning procedures, and specifications for other ongoing/periodic quality control measures.
  - Records of any review(s) to determine if transfer was effective and complete.
  - Any appropriate checklists or trace matrices (or cross-references to information provided elsewhere in the application).

Note: Section VI.D.4 below recommends detailed information regarding the production flow for the device. If addressing any information recommended here in the response to the production flow information request in Section VI.D.4 below, submitters should indicate that in relation to Subclause 7.3.8.

- The procedures under Subclause 7.3.9 to control design and development changes. A full description would generally include:
    - Procedures to determine the significance of any change to function, performance, usability, safety, intended use, and applicable regulatory requirements.
    - Procedures for the review, verification, validation (as appropriate), and approval, with:
        - Procedures to review the effects on constituent parts, product in-process or already delivered, inputs or outputs of risk management, and product realization processes.
        - Information establishing any such review was completed before implementation of the change(s).
    - A detailed summary of all approved process and design and development changes.
        - Including changes to associated software that occurred after the initiation of manufacturing units for design and development verification and validation activities.
        - Changes should be grouped based on how a change impacts function, performance, usability, safety, and whether there are any changes to applicable regulatory requirements for the device and intended use due to these changes.
        - This summary should include a justification for why the changes do not impact the validity of the data collected during the design and development verification and validation activities, including any clinical data used to establish the safety and effectiveness of the subject device.
    - Records showing approvals of changes prior to implementation.
- Information describing the design and development files required to be maintained under Subclause 7.3.10. A full description would generally include:
    - A summary of the information contained in the design and development files.
    - Records (or references to records) generated to demonstrate conformity to the requirements for design and development.
    - Records for design and development changes.
    - Any records not specifically mentioned above about establishing, reviewing, approving, changing, verifying, or validating design and development activities or determinations, as applicable.

(3) Purchasing, Purchasing Process, Purchasing Information, and Verification of Purchased Product Requirements

ISO 13485 Subclause 7.4 describes the requirements for purchasing, purchasing process, purchasing information, and verifying product requirements. This information is particularly important if the organization uses a contract design service, contract manufacturer(s), or suppliers for the subject device. FDA expects that purchasing files will contain information to provide a full description of the organization's purchasing activities that are part of QMS. As such, a marketing submission containing a full description of the documentation required by Subclause 7.4 should contain the following information:

- The procedure(s) or other documents that ensure the purchased product conforms to specified purchasing information, which is described in Subclause 7.4.1. Those documents or procedures should:
    - Establish criteria for evaluation and selection of suppliers for the subject device, based on the supplier's ability to provide product that meets requirements, based on the supplier performance, based on the effect of the purchased product on the quality of the device, and proportionate to the risk associated with the device.
    - Plan for monitoring and re-evaluating suppliers for the subject device.
    - Provide an explanation of how non-fulfillment of purchasing requirements are addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.
- Procedures for verification of purchased product, as set forth in Subclause 7.4.3. FDA notes that if these procedures are voluminous, a submitter may provide FDA with a sample of the procedures focusing on higher risk purchasing activities. These procedures should:
    - Establish and implement inspection or other activities necessary for ensuring that purchased product meets purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.
    - Explain how the type of and extent of the verification activities are based on supplier evaluation results and proportionate to the risks associated with the purchased product.
    - Determine if any changes to purchased product affect the product realization process or the medical device.

In accordance with Subclause 7.3.4, to maintain a compliant QMS, a manufacturer is required to provide appropriate information for purchasing, production and service provision, and its design and development outputs must specify the characteristics of the product essential for its safe and proper use. To comply with that design and development requirement, FDA recommends that the manufacturer maintain a list of suppliers, vendors, contract manufacturers, and contract design and development firms that provide a component or service that is related to characteristics of the subject device that are essential for its safe and proper use. To demonstrate purchasing processes, and as required by Subclause 7.4.1, FDA recommends the submitter include that list as part of its full description of its QMS in its marketing submission. In addition, FDA

recommends that the submitter provide a summary of the purchasing processes applied to these suppliers, vendors, contract manufacturers, and contract design and development firms for the component or service provided.

(4) Implementation of Production and Service Provisions

ISO 13485 Subclause 7.5 sets forth the requirements for a QMS that plans, carries out, monitors, and controls the production processes and service provisions. FDA recognizes that such documents or records may be voluminous. Therefore, FDA recommends that a full description of that process, which may enable FDA to assess conformance with this requirement, include:

- A summary of the method(s) the organization uses to plan, carry out, monitor, and control production and service provision to ensure that the product conforms to its specifications, as described in Subclause 7.5.1. FDA recommends the submitter include an explanation of how risk management methods for production and service provision relate to the overall product realization risk management methods (in accordance with Subclause 7.1) and how they were used to implement Clause 7.
- A summary of the activities conducted to verify that product requirements have been met at applicable stages of the product realization process for the device. As part of this summary, FDA recommends the submitter include the location of the activity in the process and the acceptance criteria the manufacturer used.
- The production flow diagram for the subject device.
    - The production flow diagram schematically should identify how all the manufacturing processes, different manufacturing entities, and process controls fit together. The submitter should provide a production flow diagram that identifies the steps involved in the manufacture of the subject device and the responsible entity (when multiple facilities are involved) of each step. In the production flow diagram, FDA recommends that the submitter also provide process controls (e.g., when samples are taken, the parameters being tested, and the associated specification and/or acceptance criterion), if applicable. This information helps to show the important aspects of the production process and understand where and when the manufacturing process crosses facility lines and whether purchasing controls of the facility or contractor are needed.
- In accordance with Subclause 7.5.2, in its QMS, the manufacturer shall document requirements for product cleanliness or contamination control if one of the conditions identified in Subclause 7.5.2(a)-(e) is met. To fully describe how the submitter intends to address those conditions, the submitter should provide the documented requirements for cleanliness or contamination control for the subject device, when applicable.
- In accordance with Subclause 7.5.4, in its QMS, the manufacturer shall document servicing procedures, reference materials, and reference measurements, as necessary, when servicing a medical device is a specified requirement. A full description of a QMS should include the servicing procedure(s) for the subject device, when applicable.
- In accordance with Subclauses 7.5.6 and 7.5.7, in its QMS, the manufacturer shall validate any processes for production and service provision where the process cannot be

or is not fully verified. FDA recommends that a full description of those validation processes include:

- A list of all processes used in the production of the subject device. The list should indicate which processes are/will be validated and which processes are/will not be validated.
- The validation plans for each process identified as to be validated. The plan should contain or refer to the objective and measurable acceptance criteria; describe how appropriate statistical methods for data collection and analysis are used; and define the criteria for re-validation.

Note: Validation plans should be in place at the time of submission of the 21 CFR part 820 information. Although all process validations do not have to be completed at the time of submission, FDA encourages sponsors to complete process validations, if possible, and include two or three relevant process validation reports from those that have been completed by the time of submission. This will help FDA conduct a thorough evaluation of the submitter's QMS. However, all process validations should be completed prior to the preapproval inspection and prior to distribution of any finished devices.

Note: For the manufacture/processing, packaging and sterilization of medical devices/combination products, where there is an additional need to consider the controls for effectively inactivating the causative agents of spongiform encephalopathies, such as scrapie, bovine spongiform encephalopathy (BSE), and Creutzfeldt-Jakob disease, the submitter should define the relevant procedures and processes, and provide the documentation establishing their control (e.g., validation).

- In accordance with Subclause 7.5.8, in its QMS, the manufacturer shall document procedures for product identification and identify product by suitable means throughout product realization. FDA recommends that a full description of those procedures include:
  - Product status with respect to monitoring and measuring requirements throughout product realization.
  - Product status throughout production, storage, installation and servicing of product to ensure only product meeting requirements is dispatched, used or installed.

Note: Section VII of this draft guidance includes a bullet related to ISO 13485 Subclause 7.5.8 and it addresses the requirements for identification associated with 21 CFR part 830. See Sections VII and VIII of this draft guidance for more on traceability/identification expectations.

(5) Control of Monitoring and Measuring Equipment

ISO 13485 Subclause 7.6 addresses the requirements for control of monitoring and measuring equipment that a manufacturer must meet. FDA recommends that a full description of a QMS, as it relates to Subclause 7.6, include:

- The control of monitoring and measurement equipment procedure(s) that provide for applicable routine calibration or verification, intervals, inspection and adjustment or readjustment, status, protection from damage during use and maintenance.
- The applicable provisions for assessing previous measurements, when such equipment is found to be nonconforming.
- Any applicable actions for such equipment and any affected product.

  Note: If this involves a large number of procedures, FDA recommends a sample of the most relevant procedures be provided.

- Additionally, the documentation of one or more processes for risk management in product realization is required throughout the implementation of ISO 13485 Subclause 7.1.

To help FDA evaluate a marketing submission, the submitter should provide a summary of how the risk management process(es) necessary to implement product realization is utilized to determine the monitoring and measurement activities for the device. FDA recommends the submitter include an example of a higher risk related to monitoring or measuring equipment/process, demonstrating how the provisions (extent of controls, etc.) of the procedures/process were implemented based on the risk(s) presented. The submitter should provide the procedure(s) for the validation and re-validation of the application of computer software used in the monitoring and measurement requirements for the device. The procedure(s) should address how the organization ensures that validation activities are proportionate to the risk associated with the use of the software.

E. Measurement, Analysis and Improvement

(1) Monitoring and Measurement

ISO 13485 Clause 8 addresses the requirements for planning and implementing the monitoring, measurement, analysis, and improvement processes in a QMS that demonstrates the product and the QMS are effective and in conformity with the requirements. In particular, FDA recommends that a full description of a QMS contain the following information in a marketing submission:

- As set forth in Subclause 8.2.1, a summary of the feedback process, which should address how the organization gathers and monitors feedback regarding whether the organization has met customer needs and how it gathers data from production and post-production activities. This summary should also address how the feedback process is utilized in the product realization and improvement processes.
- As set forth in Subclause 8.2.2, procedure(s) for the organization's complaint handling. ISO 13485 Subclause 8.2.2 explicitly ties the complaint handling process to "applicable regulatory requirements." Thus, submitters should provide a description of how the complaint handling procedure aligns with the medical device reporting (MDR) process set forth at 21 CFR part 803.

Note: Section VII of this draft guidance includes a bullet related to ISO 13485 Subclause 8.2.3 and it also addresses the requirements for MDR associated with 21 CFR 820.10 (b)(3). If applicable, the submitter may reference the information included in Section VII of this draft guidance.

Note: Section VII of this draft guidance includes a bullet related to ISO 13485 Subclauses 7.2.3, 8.2.3, and 8.3.3 and it address the requirements for corrections and removals associated with 21 CFR part 806. If applicable, the submitter may reference the information included in Section VII.

- Its internal audit procedure(s), as set forth in Subclause 8.2.4.
- A summary of the methods the organization applies to monitor and measure the QMS processes, as set forth in Subclause 8.2.5. The submitter should explain how the methods demonstrate the QMS processes achieve planned results, and when planned results are not achieved, the appropriate correction or corrective action that will be taken.
- As set forth in Subclause 8.2.6, a summary of the methods the organization applies to monitor and measure the product to verify that product requirements have been met at applicable stages of the product realizations process, in accordance with the planned documented arrangements and documented procedures.

(2) Control of Nonconforming Product

ISO 13485 Subclause 8.3 describes control of nonconforming product. A QMS must address the requirements outlined in Subclauses 8.3.1 to 8.3.4, and as these documents will be a part of its QMS, FDA recommends that a full description in a marketing submission include:

- A description of the necessary controls, responsibilities, and authorities to identify, control, document, quarantine, assess, and resolve the nonconforming product, as described in Subclause 8.3.1.
- A procedure to determine the need for an investigation and notification of the external parties responsible for the nonconformity, as described in Subclause 8.3.1.
- A procedure to ensure that acceptance of any nonconforming product is adequately justified, approved, and applicable regulatory requirements are met, as described in Subclause 8.3.2.

Note: Section VII of this draft guidance includes a bullet related to ISO 13485 Subclauses 7.2.3, 8.2.3, and 8.3.3, and it address the requirements for corrections and removals associated with 21 CFR part 806.

- A procedure to take appropriate action when nonconforming product has been identified after distribution/delivery and how the submitter issues advisory notices in accordance with applicable regulatory requirements, as described in Subclause 8.3.3.

Note: Section VII of this draft guidance includes a bullet related to ISO 13485 Subclauses 7.2.3, 8.2.3, and 8.3.3, and it addresses the requirements for reports of

corrections and removals associated with 21 CFR part 806. If applicable, the submitter may reference the information included in Section VII of this draft guidance.

- Rework procedure(s), as described in Subclause 8.3.4.

(3) Analysis of Data

ISO 13485 Subclause 8.4 describes requirements for analysis of data within a QMS. As such, the submitter should provide a full description of the procedure(s) in a marketing submission to determine, collect, and analyze data to demonstrate the suitability, adequacy, and effectiveness of the QMS, and the determination of appropriate methods and the extent of their use.

(4) Identifying and Implementing Necessary Changes

ISO 13485 Subclause 8.5 includes requirements for improvement activities within the QMS. Subclause 8.5.1 describes the organization's requirement for identifying and implementing any changes needed to ensure and maintain the continued suitability, adequacy, and effectiveness of the QMS. It also describes medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions, and management review. A full description of those processes in a marketing submission should include:

- The corrective action procedure(s) that ensure the corrective actions are proportionate to the effect of the nonconformity and that they meet all other requirements listed in Subclause 8.5.2.
- Additionally, FDA believes the risk management and/or risk-based decision making is necessary to ensure that the corrective actions taken are proportionate to the effect of the nonconformity and the risk. Therefore, the submitted procedure(s) should explain how risk management process(es) and/or risk-based decision making is incorporated into the corrective action process.
- In accordance with the requirements for a QMS set forth in Subclause 8.5.3, the submitter should provide preventive action procedures that ensure the preventive actions are proportionate to the effect of the nonconformity and meet all other requirements listed in Subclause 8.5.3.
- Additionally, FDA believes the risk management and/or risk-based decision making is necessary to ensure that the preventive actions taken are proportionate to the effect of the nonconformity. The submitted procedure(s) should explain how risk management process(es) and/or risk-based decision making is incorporated into the preventive action process.
- The procedure(s) must meet the requirements listed in Subclause 8.5.3 and should explain how risk management process(es) and/or risk-based decision making is incorporated into the preventive action process.

VII. 21 CFR 820.10 Applicable regulatory requirements

21 CFR 820.10(b) identifies a limited list of additional regulatory requirements needed to fully comply with the identified ISO 13485 citation. A full description of the QMS in a marketing submission should include:

- A summary of the system used to assign a UDI to the subject device and utilization of UDI to identify devices accurately from manufacturing through distribution to patient use, as required by Subclause 7.5.8. The submitter should also document a system to assign UDI to the medical device in accordance with the requirements of 21 CFR 820.10(b)(1) and 21 CFR part 830.
- Procedures for traceability in accordance with the requirements of 21 CFR 820.10(b)(2), 21 CFR part 821, and Subclause 7.5.9.1.
- The device tracking procedure(s) and explain how it is linked to the process(es) that implement the traceability requirements in Subclause 7.5.9.1.
- The process by which the submitter will notify FDA of complaints that meet the reporting criteria of 21 CFR 820.10(b)(3) and 21 CFR part 803, as set forth at Subclause 8.2.3.
- A summary of the MDR procedure(s) and explain how this process(es) is linked to the process(es) that implement the complaint handling requirements in Subclause 8.2.3.
- A description of how the submitter will handle advisory notices in accordance with the requirements of 21 CFR 820.10(b)(4), 21 CFR part 806, and Subclauses 7.2.3, 8.2.3, and 8.3.3.
- A summary of the process(es) implementing the requirements of 21 CFR 820.10(b)(4) and 21 CFR part 806, and explain how this process(es) is linked to those processes implementing ISO 13485 Subclauses 7.2.3, 8.2.3, and 8.3.3.

VIII. 21 CFR 820.35 Control of records

21 CFR 820.35 identifies additional record keeping requirements that must be fulfilled along with the records requirements identified in ISO 13485 Subclause 4.2.5. As such, to allow FDA to evaluate a full description of a submitter's QMS, FDA recommends the submitter include the following information in its marketing submission:

- Process regarding complaint handling records, and explain how the records fulfill the requirements outlined in 21 CFR 820.35(a) and how it is linked to ISO 13485 Subclause 8.2.2.
- Process regarding servicing activities records. The submitter should explain how the records fulfill the requirements outlined in 21 CFR 820.35(b) and how it is linked to Subclause 7.5.4.
- A sampling of UDIs and Global Unique Device Identification Database (GUDID) records. The submitter should explain how the records fulfill the requirements of 21 CFR 820.35(c), and how it is linked to ISO 13485 Subclauses 7.5.1, 7.5.8, and 7.5.9. These supplied records should be for the subject device whenever possible.

IX. 21 CFR 820.45 Device labeling and packaging controls

The QMSR describes device labeling and packaging controls required in addition to those noted in ISO 13485 Subclause 7.5.1 Control of production and service provision. More specifically, as set forth in ISO 13485, manufacturers shall document and maintain procedures that provide a detailed description of the activities to ensure the integrity, inspection, storage, and operations for labeling and packaging during the customary conditions of processing, storage, handling, distribution, and, as appropriate, use of the device. As such, in its marketing submission, the submitter should provide the procedure(s) that fulfill the requirements for device labeling and packaging control described in 21 CFR 820.45(a)-(c) for the subject device.

Guidance History[*]	Date	Description
Reissued as Level 1 Draft Guidance	October 2025	See Notice of Availability for more information.**
Level 1 Final Guidance	February 2003	See Notice of Availability for more information.**

*This table was implemented, beginning October 2025, and previous guidance history may not be captured in totality.

**The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage.