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DHF Remediation: QMSR and Medical Device File Transition

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Executive Summary

The FDA's Quality Management System Regulation (QMSR) is effective as of February 2, 2026, and incorporates ISO 13485:2016 by reference. FDA now uses Compliance Program 7382.850 for device-manufacturer inspections. [FDA's QMSR overview](#)

DHF remediation is a content and record-indexing exercise, rather than a mandatory merger of legacy files. The Medical Device File (MDF, clause 4.2.3) contains or references current manufacturing procedures and specifications; the Design and Development File (DDF, clause 7.3.10) contains or references design evidence; and device or batch records are addressed under clause 7.5.1. FDA describes the recordkeeping requirements as substantively similar to the former QSR requirements. [FDA final rule, response to Comment 31](#)

This article examines the legacy records, the current requirements, and practical steps for assessing gaps and locating compliance evidence. A unified repository is an optional implementation choice; it must preserve the distinct requirements for each record set.

Introduction and Background

The FDA's revised Quality System Regulation (QSR) was published on October 7, 1996, and became effective June 1, 1997. QMSR incorporates ISO 13485:2016 to harmonize and modernize that framework. [FDA's regulatory history and QMSR overview](#)

The transition changes regulatory terminology and clause references. It calls for an assessment of applicable requirements and the records that demonstrate compliance.

The **QMSR final rule** was published on February 2, 2024, at **89 FR 7496**, pages 7496–7525. It became effective on February 2, 2026. Current compliance work should assess the effective requirements, rather than treat that date as an approaching deadline. [Official FDA final rule](#) [FDA's current QMSR FAQ](#)

QMSR applies to finished-device manufacturers, including foreign manufacturers and entities whose activities meet the manufacturer definition. Importing alone does not establish the same obligations: FDA separately identifies initial importers' registration, reporting, corrections/removals, and applicable tracking duties. An importer that also performs manufacturing activities must assess the requirements for those activities. [21 CFR 820.1 and 820.3 FDA's importer guidance](#)

Design and development requirements apply to Class II, Class III, and the specified Class I devices in §820.10(c). Some devices have CGMP exemptions, but FDA states that these do not exempt finished-device manufacturers from complaint-file and general record requirements under §820.35. [Design applicability in §820.10\(c\) FDA's CGMP exemption explanation](#)

ISO certification does not remove the need for an FDA-specific gap assessment. QMS software validation is addressed by incorporated ISO 13485 clause 4.1.6, with validation and revalidation activities proportionate to software-use risk. Section 820.35 addresses supplemental records requirements. [FDA computer software assurance guidance Current Part 820](#)

Key changes relevant to remediation:

- **Record references:** Map design records to clause 7.3.10, current production specifications and procedures to clause 4.2.3, and device or batch records to clause 7.5.1. Keep the records identifiable even if they share a repository. [FDA's final-rule recordkeeping explanation](#)
- **Risk and software:** Assess QMS software under clause 4.1.6 using an approach proportionate to its use-related risk. [FDA software assurance guidance](#)
- **Acceptance and nonconforming product:** Legacy finished-device acceptance was governed by §820.80(d), while §820.90 governed nonconforming product. These controls continue through the incorporated standard: FDA's current crosswalk identifies product monitoring and measurement at clause 8.2.6 and nonconforming-product control at clause 8.3. [Historical Part 820 FDA inspection crosswalk, Attachment A](#)
- **Inspection access:** FDA may inspect management review, quality audit, and supplier audit reports; the former §820.180(c) exceptions are not retained. [FDA QMSR FAQ](#)

The following sections focus on how to assess and index existing DHF, DMR, and DHR content against these requirements.

Traditional FDA Documentation Practices

Before QMSR, the QSR used three main product-related record collections:

- **Design History File (DHF):** For devices subject to legacy design controls, §820.30(j) required a DHF containing or referencing evidence that the design was developed in accordance with the approved plan and applicable requirements. Design plans, inputs and outputs, reviews, verification, validation, transfer, and changes were addressed under §820.30.
- **Device Master Record (DMR):** Section 820.181 addressed the specifications and procedures for a finished device, including manufacturing, quality assurance, labeling, packaging, installation, maintenance, and servicing information.

- **Device History Record (DHR):** Section 820.184 addressed evidence of production history, including manufacture dates, quantities, acceptance records, labeling, and device identification.

These historical references help locate legacy records; they are not current Part 820 section numbers.

[Historical Part 820, February 2, 2025](#)

The following crosswalk keeps the three record sets distinct. FDA's final-rule response to Comment 31 explains their continuity, and its inspection program identifies the current clauses. [FDA final rule FDA inspection program, Attachment A](#)

Legacy record or activity	Current requirement	Remediation focus
DHF	Design and Development File, 7.3.10	Contain or reference design compliance records and changes.
DMR	Medical Device File, 4.2.3	Contain or reference current production specifications and procedures.
DHR	Device or batch record, 7.5.1	Assess production evidence against the current requirement.
Design planning	7.3.2	Index the plan and applicable planning records.
Design inputs	7.3.3	Index approved requirements and supporting records.
Design review	7.3.5	Locate review results and actions.
Design validation	7.3.7	Locate validation evidence.
Design transfer	7.3.8	Locate transfer procedures and evidence of manufacturing suitability.
Product monitoring and measurement	8.2.6	Assess acceptance and release evidence.
Management review	5.6	Locate management review records.

FDA's design-development transcript confirms that planning is 7.3.2, inputs are 7.3.3, and design review is 7.3.5. [FDA design-development transcript](#)

The New Document Paradigm under QMSR

Under §820.10, manufacturers must document a QMS that complies with applicable ISO 13485 requirements and the other applicable requirements of Part 820. The FDA-specific assessment includes applicable UDI, tracking, medical device reporting, and corrections/removals requirements. Section 820.10(c) sets design applicability, and §820.10(d) addresses additional traceability for specified life-supporting or life-sustaining devices. [Current §820.10](#)

The documentation requirements remain distinct: MDF specifications and procedures under clause 4.2.3; design evidence in or referenced by the DDF under clause 7.3.10; and device or batch records under clause 7.5.1. They do not create a requirement to put every product record into one MDF. [FDA final rule, response to Comment 31](#)

Section 820.35 supplements ISO record control with provisions for complaint records, servicing records, recording UDI for each device or batch, and marking confidential records. Section 820.45 supplements labeling and packaging controls. These provisions must be assessed alongside other applicable FDA requirements. [Current §§820.35 and 820.45](#)

Software validation for QMS applications is addressed by ISO 13485 clause 4.1.6, rather than §820.35. [FDA software assurance guidance](#)

Detailed Changes to Design Documentation

Design History File vs. Design and Development File

For devices within §820.10(c), design and development requirements are incorporated into ISO 13485 clause 7.3. Current §§820.20–820.30 are reserved. [Current Part 820](#)

The DHF's purpose continues through clause 7.3.10: the DDF contains or references records demonstrating compliance with design and development requirements. Existing design records should be assessed for coverage, rather than assumed to need wholesale relocation. [FDA final rule, response to Comment 31](#)

Legacy design transfer was a documented procedure requirement under §820.30(h); §820.30(i) addressed design changes. Under the incorporated standard, transfer is clause 7.3.8, while 7.3.7 concerns validation. Transfer procedures address whether design outputs are suitable for manufacturing before they become final production specifications. [Historical Part 820 FDA design-development presentation, slides 24–27](#)

Action items for DHF remediation:

- **Gap analysis:** Compare existing design evidence with the applicable clause 7.3 requirements; record missing evidence and assign remediation owners.
- **Planning and inputs:** Map the design plan to 7.3.2 and design inputs to 7.3.3. A change in file name does not establish coverage.
- **Traceability:** Check that design inputs, outputs, verification and validation evidence, and risk controls can be located and connected. Preserve links between final design outputs and current production specifications.
- **Review and approval:** Distinguish design review under 7.3.5 from management review under 5.6. Train staff on the correct references and record locations. [FDA design-development transcript FDA inspection crosswalk](#)

Use the crosswalk above to index evidence and explain the retained legacy terminology in procedures.

Device Master Record vs. Medical Device File

The MDF under ISO 13485 clause 4.2.3 contains or references procedures and specifications current on the manufacturing floor. FDA explains that final design output, maintained or referenced in the DDF, forms the starting point for the MDF. Former DMR content—including manufacturing, measuring, monitoring, servicing, and installation information—maps to the MDF. [FDA final rule, response to Comment 31](#)

Remediation should focus on the content and retrieval of the existing specification set:

- Review device, packaging, and labeling specifications and relevant procedures for completeness and current revision status.
- Check that manufacturing teams can locate the approved specifications that govern production.
- Maintain references between the specification set, design evidence, and device or batch records.
- Document gaps and update the index when controlled documents change.

A centralized document repository can help avoid duplicate copies, but it is an implementation choice. Design evidence and batch records retain their respective requirements; they do not all have to be moved into the MDF.

Device History Record and Production Records

FDA maps much of the former DHR content to the medical device or batch record described in ISO 13485 clause 7.5.1. It is therefore misleading to say that the standard has no combined device or batch record requirement. [FDA final rule, response to Comment 31](#)

Use the correct requirements when reviewing production records: product monitoring and measurement, including acceptance/release controls, is addressed under 8.2.6; work environment and contamination control under 6.4; process validation under 7.5.6; cleanliness under 7.5.2; and sterilization and sterile-barrier process validation under 7.5.7. Apply the relevant identification and traceability requirements rather than treating these clauses as interchangeable. [FDA inspection crosswalk, Attachment A](#)

Remediation steps include checking each selected unit or lot record against its governing specifications, locating acceptance and release evidence, and documenting missing records or links. A legacy DHR format can be assessed for continued use without assuming that relocation into an MDF folder establishes compliance.

FDA investigators may review QMS records created before February 2, 2026. A comparative analysis can help demonstrate that legacy records meet current requirements. [FDA QMSR FAQ](#)

The Medical Device File and Record Access

The MDF's role is to contain or reference current production procedures and specifications. Design evidence and device or batch evidence remain subject to their separate requirements. FDA's response to Comment 31 describes this continuity explicitly. [FDA final rule](#)

For remediation, the practical objective is reliable access to the right approved record. An organization may use linked folders, an electronic QMS, a PLM system, or a shared repository. A unified repository is an optional implementation choice, rather than a new requirement that inspectors find every record inside the MDF.

A useful index identifies the device or family, document owner, record location, revision, and applicable requirement. References can connect the final design output to current manufacturing specifications and the corresponding production evidence. When a controlled document changes, review the index and dependent references for accuracy.

For software devices, apply the relevant design, production, and cybersecurity requirements to the device and its records. Do not infer a blanket MDF-storage mandate for source code, SBOMs, container images, or AI datasets from the file terminology alone.

Transition Strategies and Case Examples

Current remediation work should begin with evidence of compliance. FDA notes that a comparative analysis can help demonstrate whether records created before the QMSR effective date meet its requirements. [FDA QMSR FAQ](#)

Documentation approaches are implementation choices:

- **Minimal changes:** Retain useful existing documents and names, add an index or crosswalk, and address identified content gaps.
- **Parallel documentation:** Use a temporary parallel index if it helps locate records, with clear controls over which version governs.
- **Restructuring:** Reorganize files when the existing arrangement impedes retrieval or control. Evaluate the effort and the risk of introducing duplicate or obsolete records.

Regardless of approach, a practical workflow is:

1. **Assess applicability:** Identify the manufacturer's activities, device classifications, exemptions, and applicable FDA requirements before defining the project scope.
2. **Inventory and map records:** Use the corrected crosswalk above to locate the design file, current specification set, and device or batch records. Record gaps, owners, and target actions.
3. **Update procedures:** Correct regulatory references and address demonstrated process gaps. Assess QMS software validation under ISO 13485 clause 4.1.6 using activities proportionate to software-use risk; assess §820.35 supplemental records requirements separately. [FDA software assurance guidance Current Part 820](#)
4. **Train staff:** Explain the applicable requirements, term mapping, record locations, and responsibilities.
5. **Pilot an end-to-end trace:** Select a device and trace requirements through design evidence, approved specifications, production evidence, and relevant feedback. Use the exercise to test retrieval and identify missing links.
6. **Verify remediation:** Review completed actions and whether the revised procedures and record index support the intended evidence trail.

Illustrative example (hypothetical): A startup retains its DHF and DMR folders and creates an index mapping their contents to current requirements. The team checks the design plan against 7.3.2 and indexes current manufacturing specifications under the MDF entry. It reviews a selected batch record separately, rather than moving every record into the MDF. The exercise could identify missing evidence or broken references; it does not predict a successful audit. [FDA planning and design-input clause explanation](#)

Documentation Approach Options

The corrected crosswalk above is the article's single regulatory mapping table. The options below describe ways to organize remediation; none establishes compliance on its own.

Approach	Description
Minimal change	Keep useful document titles and file structures. Add a cross-reference index and train staff. Prioritize filling content gaps.
Parallel documentation	Create a temporary parallel index or document set when needed for retrieval. Control versions and prevent conflicting governing copies.
Full restructure	Reorganize documentation when justified by the condition of the existing QMS. Assess the effort, retrieval benefit, and change-control implications.

Manufacturers can assess retained legacy records through a comparative analysis against current requirements. [FDA QMSR FAQ](#)

Evidence and Case Illustrations

FDA's final rule provides the regulatory basis for the record mapping. Consulting templates can illustrate indexing practices, but they do not establish a mandatory merger of design, specification, and production evidence. [FDA final rule, response to Comment 31](#)

A practical index can record the artifact identifier, applicable requirement, controlling revision, location, and owner. For example, a design plan can be indexed under 7.3.2 and its approved inputs under 7.3.3; the index should point to the actual controlled records rather than example PLM links. [FDA design-development transcript](#)

Use a retrieval exercise to verify that the index reaches current specifications, design evidence, and the selected device or batch record. A renamed folder is not evidence that missing records or process gaps have been remedied.

Case scenarios (hypothetical): These examples do not describe identified companies or observed audit results.

An ISO-aligned European subsidiary could begin with a comparative analysis of its existing records, then assess applicable FDA requirements and update its regulatory references and record index. ISO certification would not determine its FDA compliance or exempt it from inspection. [FDA QMSR FAQ](#)

A smaller U.S. manufacturer could identify gaps in its design evidence, software-validation records, or feedback processes. It could retain useful DHF and DMR records, map them to the current requirements, and index its device or batch evidence separately. If it uses QMS software, validation and revalidation activities should be proportionate to software-use risk under clause 4.1.6. [FDA software assurance guidance](#)

A successful retrieval exercise could help either organization identify missing evidence. No inspection outcome or benefit is asserted.

Implications and Future Directions

- **Global harmonization:** ISO 13485 provides a common framework, but applicable FDA requirements still need a separate assessment. FDA does not require or issue ISO 13485 certificates, and certification does not exempt a manufacturer from inspection. [FDA QMSR FAQ](#)
- **Evidence and record access:** The remediation objective is to demonstrate coverage of the applicable requirements with retrievable records. A comparative analysis can help assess legacy evidence. [FDA QMSR FAQ](#)
- **Digital tools:** An electronic index or repository may support retrieval and revision control. Treat the choice of tools as an implementation decision. Assess QMS software validation using the risk-proportionate approach under clause 4.1.6. [FDA software assurance guidance](#)
- **Software and cybersecurity:** FDA's final cybersecurity guidance, issued in February 2026, addresses device design, labeling, and documentation recommended for premarket submissions for devices with cybersecurity risk. It also addresses section 524B recommendations for cyber devices. Assess the guidance's scope and the requirements applicable to the device. [FDA's current cybersecurity guidance](#)
- **Training:** Update personnel training around the requirements applicable to their work, correct clause references, and the locations of controlled records.
- **Future changes:** Future ISO revisions do not automatically alter QMSR. FDA will evaluate revisions and, where appropriate, implement amendments through rulemaking. [FDA QMSR FAQ](#)

Conclusion

DHF remediation under QMSR should focus on applicable requirements, missing evidence, and a usable record index. FDA describes the recordkeeping requirements as substantively similar to the former QSR requirements. The MDF contains or references current production procedures and specifications, the DDF contains or references design evidence, and device or batch records are addressed under clause 7.5.1. [FDA final rule, response to Comment 31](#)

Use the corrected crosswalk, document the gap assessment, assign remediation owners, update affected procedures, and test retrieval with a selected device and batch. A common repository may support that work, but consolidating every record into an MDF is not the regulatory objective.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
2. <https://www.govinfo.gov/content/pkg/FR-2024-02-02/html/2024-01709.htm>
3. <https://www.fda.gov/medical-devices/quality-management-system-regulation-qmsr/quality-management-system-regulation-frequently-asked-questions>
4. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820>
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