DHF Remediation: QMSR and Medical Device File Transition

By Adrien Laurent, CEO at IntuitionLabs • 2/26/2026 • 40 min read

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Executive Summary

The FDA's new Quality Management System Regulation (QMSR), effective February 2, 2026 (www.qms.coach), fundamentally overhauls U.S. medical device quality requirements. Most notably, QMSR **incorporates ISO 13485:2016 by reference** (www.qms.coach) (www.qms.coach), aligning U.S. regulations with international standards. In practice this means that legacy 21 CFR Part 820 concepts – including the Design History File (DHF), Device Master Record (DMR), and Device History Record (DHR) – are replaced by **ISO-based documentation structures**. The centerpiece is the **Medical Device File (MDF)** (ISO 13485:2016 §4.2.3) and associated **Design and Development File (DDF)** (§7.3.10). As one industry guide notes, "documentation requirements are structured around the medical device file concept rather than the device master record/design history file/device history record framework" (www.qms.coach).

This report examines the *remediation of existing DHF documentation under QMSR*, and why the introduction of the Medical Device File "changes everything". We present: historical context of FDA and ISO quality requirements; the key regulatory changes under QMSR; detailed mapping of old and new documentation (with tables); strategies for updating and integrating legacy DHFs into the new framework; case examples illustrating the transition; and a discussion of broader implications (global harmonization, digital transformation, etc.). Throughout, we reference regulatory texts, industry analyses, and subject-matter experts to support each claim. In summary, QMSR's MDF/DDF paradigm is not merely a relabeling of existing practices, but a structural shift demanding thorough gap analyses and process reorganization to ensure compliance.

Introduction and Background

The FDA's Quality System Regulation (QSR, 21 CFR Part 820) was first established in 1996 to govern medical device quality systems. Under QSR, manufacturers were required to maintain several key records: design and development records in a *Design History File (DHF)* (21 CFR 820.30(j)), device specifications in a *Device Master Record (DMR)* (21 CFR 820.181), and production/lot history in a *Device History Record (DHR)* (21 CFR 820.184). However, over time these FDA-specific terms diverged from international practices, forcing global manufacturers to maintain dual systems – one for FDA inspections and one for ISO 13485 certification (the international standard for medical device quality) (www.qms.coach).

Why change the QSR now? The FDA's rationale is both harmonization and modernization. By incorporating ISO 13485:2016 explicitly into rulemaking, the agency aligns U.S. requirements with those of most other countries (www.qms.coach) (www.qms.coach). ISO 13485 was written specifically for medical devices and embeds risk-based thinking across all quality processes (not just design) (www.qms.coach) (www.qms.coach). It also updates expectations for software in the QMS, management review, and other modern practices (www.qms.coach) (www.qms.coach). In effect, ISO 13485 becomes federal law for device makers: "the practical effect is that ISO 13485:2016 becomes federal law for medical device manufacturers under FDA jurisdiction" (www.qms.coach).

The **Quality Management System Regulation (QMSR)** final rule was published February 2, 2024 (87 FR 2864) and takes effect February 2, 2026 ([1] cenitconsulting.com) (www.qms.coach). As of that date, 21 CFR Part 820 is retitled and restructured to incorporate ISO 13485 by reference (www.qms.coach) (www.qms.coach). The rule includes a two-year transition: new devices on the market as of Feb 2, 2026, must be developed under QMSR, and all manufacturers should be fully compliant by that date (www.qms.coach) ([1] cenitconsulting.com). Crucially, there is **no grace period** – "full compliance required from day one" (www.qms.coach).

The scope of QMSR is broad: *all* device manufacturers subject to FDA's CGMP requirements must comply – including domestic and foreign manufacturers, specification developers, contract manufacturers, and importers

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(www.qms.coach). In practice this means that tens of thousands of firms in the U.S. (and their overseas partners) must revise their quality systems. For ISO 13485-certified companies, the impact is mainly on FDA-specific additions (e.g. explicit software validation at §820.35) (www.qms.coach). For companies previously only compliant with QSR, substantial changes are required: gap analyses show common deficiencies in CAPA documentation, customer communication procedures, QMS software validation, and management review records (www.qms.coach) (www.qms.coach).

Key Changes under QMSR: In summary, QMSR includes:

- **Terminology and Structure:** QSR's prescriptive, section-based grammar is supplanted by ISO's process-oriented layout. For example, corrective and preventive actions are separated into two clauses (ISO 8.5.2 and 8.5.3) rather than a combined CAPA clause (www.qms.coach). Device labeling inspection is moved to its own requirement (820.45). The overarching documentation structure shifts from DHF/DMR/DHR to the *Medical Device File (MDF)* and *Design & Development File (DDF)* concepts (www.qms.coach) ([2] cenitconsulting.com) (detailed below).
- **Risk-Based QMS:** Perhaps most importantly, ISO 13485 mandates risk-based thinking *throughout* the QMS. Under QSR, risk management was explicitly required only during design controls (21 CFR 820.30(g)). QMSR/ISO requires risk evaluation to influence almost every decision – from supplier controls to process planning – reflecting lessons from two decades of modern quality practice (www.qms.coach) (www.qms.coach).
- **Software and Data Requirements:** QMSR explicitly requires validation of any software used for regulated QMS activities (training, CAPA tracking, etc.) (www.qms.coach) and broadens recordkeeping (e.g. management reviews and internal audits are now FDA-inspectable) (www.qms.coach). Notably, the regulation removes the standalone finished device acceptance clause (820.90) and replaces device history record (DHR) with ISO-style production records built around the MDF (www.qms.coach) ([3] cenitconsulting.com).
- **Regulatory Alignment:** QMSR eliminates FDA-specific categories of "critical device" and brings new requirements for customer communications and feedback that mirror ISO 13485's emphasis on the entire product lifecycle (www.qms.coach) (www.qms.coach).

These changes were motivated by a need to modernize and harmonize. As FDA acknowledges, maintaining dual systems (one for FDA, one for ISO/EU) was burdensome without improving safety (www.qms.coach). By adopting ISO 13485 wholesale, FDA envisions less redundant audit preparation and smoother global device distribution. Industry experts note that alignment with ISO/CE documentation requirements can "support U.S., EU, and other markets without rebuilding files" ([4] cenitconsulting.com).

This report focuses specifically on **DHF Remediation under QMSR** – i.e., how existing design documentation must be updated or reinterpreted to satisfy QMSR. We will explain how the new **Medical Device File (MDF)** concept reshapes design and production records, detail what remains of the legacy DHF requirements, and offer guidance (with case examples) on transitioning legacy files into the new paradigm. In doing so we draw on regulatory texts, standards clauses, and industry analyses ([5] www.kapstonemedical.com) ([6] www.kapstonemedical.com) (www.qms.coach) (www.qms.coach) to show that the shift is substantive and far-reaching.

Traditional FDA Documentation Practices

Before QMSR, FDA's Quality System Regulation (21 CFR Part 820) required three main product-related document collections:

- **Design History File (DHF) –** Under 21 CFR 820.30(j), manufacturers must establish and maintain a DHF for each type of device. The DHF is "the compilation of records which describes the design history of a finished device." In practice, it contains design plans, design inputs/outputs, design review documentation, design verification and validation reports, and traceability matrices. The DHF shows that the device was developed in compliance with approved design controls ([5] www.kapstonemedical.com).

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- **Device Master Record (DMR) –** Per 21 CFR 820.181, the DMR is the complete set of specifications and procedures for manufacturing a finished device. It includes device specifications, process outlines, work instructions, BOMs, labeling specs, packaging instructions, and quality assurance processes. The DMR is essentially a recipe for the device (conceptually similar to ISO 3.10.10's "medical device file").
- **Device History Record (DHR) –** Under 21 CFR 820.184, the DHR is a compilation of records showing the production history of a finished device or lot. It includes production run logs, traceability, acceptance records, and process parameters. The DHR is evidence that the device was manufactured according to the DMR and that the label and packaging matched the approved specifications.

Collectively, the DHF, DMR, and DHR framed product documentation in FDA's QSR. However, this tri-part structure was unique to FDA. Internationally – under ISO 13485 and the EU MDR – analogous requirements existed but under different names and organization. For years, manufacturers maintained parallel document "bins": for instance, a Quality Manual might reference both QSR clauses and corresponding ISO clauses. This dual system work often led to duplicated effort.

Several authoritative discussions (e.g., CENIT Consulting, Kapstone Medical, QMS coaching firms) explicitly describe these legacy terms and how they map to ISO concepts ([2] cenitconsulting.com) (www.qms.coach). Industry crosswalks summarize:

Legacy FDA Record	New ISO/QMSR Equivalent	Notes
Design History File (DHF)	Design and Development File (ISO 13485 §7.3.10)	Contains all design-phase documentation. Terminology change only – content requirements remain in essence the same (www.qms.coach).
Device Master Record (DMR)	Medical Device File (ISO 13485 §4.2.3)	Concept is broadened. The MDF consolidates specs, procedures, and all other manufacturing documentation, including evidence of regulatory conformity (www.qms.coach) (www.qms.coach). This goes beyond the old DMR focus on specs at time of release.
Device History Record (DHR)	Production Records (various ISO clauses 7.5.xx)	ISO 13485 does not have a single document called DHR. Instead, production/lot records are created per clause 7.5 (production and service provision), with full traceability back to design in the MDF.
Complaint Files / CAPA	Post-Market Surveillance / Improvement (ISO 13485 §8)	The concepts of complaints and CAPA persist under PMS (Post-Market Surveillance) in ISO 13485, extending the feedback loop ([7] cenitconsulting.com).

Table: *Mapping of legacy FDA quality system documents to QMSR/ISO terms* (sources: ISO 13485:2016, FDA QSR, industry crosswalks (www.qms.coach) (www.qms.coach) ([7] cenitconsulting.com)).

As shown above, even before QMSR the industry informally recognized the equivalence of these concepts. Under the FDA rule, the terminology, however, was rigid: regulators expected audits of the specific QSR-named records. Now, QMSR formally rejects the terms DHF, DMR, DHR, and replaces them with the ISO framework. The remaining sections will examine how each legacy file "fits" into QMSR, with a focus on the DHF, and why the new **Medical Device File** (MDF) transforms the landscape.

The New Document Paradigm under QMSR

Under the QMSR final rule, **21 CFR Part 820 is amended to incorporate ISO 13485:2016 by reference** (www.qms.coach) (www.qms.coach). The revised Part 820 thus essentially *becomes* ISO 13485 for U.S. device firms, with two narrow FDA-specific additions. This incorporation means that the ISO documentation clauses now govern U.S. device files. Key clauses include:

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- **ISO 13485 §4.2.3 – Medical Device File (MDF):** Defines the MDF as "a compilation of records and documents for each medical device type demonstrating conformity to regulatory requirements." The MDF *integrates* what used to be separate DMR, DHR, and even parts of the DHF (www.qms.coach) (www.qms.coach). In practice, this means that *all* product-related documentation – device specifications, manufacturing procedures, quality controls, packaging and labeling specs, and evidence of traceability and release – is considered part of the MDF. As one industry expert notes, the MDF "encompasses specifications, procedures, and quality requirements needed to manufacture the device, including drawings, bills of materials, labeling, and packaging" ([8] www.kapstonemedical.com). Crucially, the MDF is **not** just a new label for the DMR. QMSR commentators emphasize that the MDF "integrates design history, master record, and production/quality documentation" (www.qms.coach) – a broader scope. A well-maintained legacy DMR may cover much of this content, but companies must explicitly verify that those records satisfy ISO conformity requirements (www.qms.coach) (www.qms.coach).

- **ISO 13485 §7.3.10 – Design and Development File (DDF):** This clause describes the DDF as the compilation of all records associated with design and development for a specific device project. It includes design plans, inputs/outputs, reviews, verification/validation, and changes. Under QMSR, the DDF replaces the FDA term DHF. Importantly, QMSR preserve all design control requirements – design control is still §820.30 (but re-numbered under ISO's structure). In effect, the DHF requirement "continues through" the ISO DDF ([5] www.kapstonemedical.com). One compliance guidance notes: *"the Design History File (DHF) requirement continues through the ISO 13485 Design and Development File, even though the terminology has changed"* ([5] www.kapstonemedical.com). In practice, firms must ensure their design records (plans, requirements, verification results, etc.) are organized as the ISO clause intends. The change is largely semantic – both DHF and DDF require the same substantive content – but ISO emphasizes integration of risk management throughout design, and requires a formal "Design Transfer" verification (ISO 7.3.7) before fabrication.

- **ISO 13485 §7.5 – Production and Service Provision:** Clause 7.5 (with subclauses 7.5.1–7.5.9) covers everything from production process validation to traceability. Under QMSR, the concept of *Device History Record (DHR)* is subsumed here. Instead of a single DHR, manufacturers produce **production records** at each stage of manufacturing – for example, assembly batch records, equipment logs, environmental controls, finished device acceptance, etc. These are then linked back to the MDF. As one crosswalk diagram explains, *"the legacy DHR is replaced by production records linked to the MDF"* ([7] cenitconsulting.com). In other words, ISO spreads the DHR content across its clauses (7.5.1, 7.5.9, etc.), but in practice firms often collect all lot/unit records in a binder or database entry connected to the device file. The FDA's enforcement approach confirms this: after Feb 2026, inspectors will evaluate manufacturing evidence against the broader ISO 7.5 requirements (process parameters, equipment IDs, operator IDs, etc.), and may accept legacy batch records if they satisfy those standards ([9] cenitconsulting.com) ([10] cenitconsulting.com).

- **Post-Market and Quality System Records:** QMSR also aligns post-market activities with ISO. For example, 21 CFR 820.198 (complaint handling) and 820.100 (CAPA) are now interpreted under ISO's broader "PMS and improvement" framework (ISO 8.2 for feedback, 8.5 for CAPA). However, these changes are more incremental. Of special note, however, is ISO's explicit requirement for documented *customer communication* procedures (Clause 7.2.3) – beyond just complaints – which is new for FDA-regulated companies (www.qms.coach).

In summary, QMSR replaces the old triad of DHF/DMR/DHR with an ISO framework built around the **MDF and DDF**. This is a structural shift, not mere jargon-swapping (www.qms.coach) (www.qms.coach). A medical device manufacturer now needs a living MDF that ties design outputs to manufacturing processes and post-market data, all structured per ISO clauses. Existing DHFs and DMRs can be used, but must be "mapped" onto the ISO requirements via a documented gap analysis ([10] cenitconsulting.com) (www.qms.coach). The next sections analyze these changes in depth, focusing on how to remediate legacy DHFs into the new Medical Device File paradigm.

Detailed Changes to Design Documentation

Design History File vs. Design and Development File

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Under legacy QSR, the *Design History File (DHF)* served as the repository of all design phase documentation. Under QMSR, virtually the same content is required, but within the framework of the *Design and Development File (DDF)* as specified by ISO 13485:2016. The regulatory requirements for design controls remain intact, but are re-phased into ISO structure. For example, QSR §820.30 requirements (planning, inputs, outputs, reviews, verification, validation, transfer, changes) become clauses 7.3.1 through 7.3.9 of ISO 13485.

In effect, the DHF content requirement **continues unabated, but under a new label**. Expert guidance emphasizes this continuity. For instance, a Kapstone Medical analysis explains that a DHF "is documented evidence that a medical device was developed under a compliant design control process," and that under QMSR the requirement "continues through the ISO 13485 Design and Development File, even though the terminology has changed" ([5] www.kapstonemedical.com). QMSR also makes design transfer more explicit: where 21 CFR 820.30(i) dealt with handoff informally, QMSR incorporates ISO 7.3.7/7.3.8, formally requiring verification of manufacturability as part of design transfer ([8] www.kapstonemedical.com) ([11] www.kapstonemedical.com). In practical terms, engineers must ensure that *design outputs cannot be released as final until they are verified as suitable for manufacturing* – a point that QMSR now explicitly codifies ([12] www.kapstonemedical.com).

What specifically must a remediated DHF contain under QMSR? Broadly, all legacy design-history artifacts are still needed: design plans, requirements, risk analysis updated through design, design reviews, verification results, validation test reports, etc. Now, however, they should be organized as the ISO standard envisions. A typical approach is to create or update a *master design file plan* that aligns FDA forms with ISO clauses. For instance, if a DHF Plan exists, it now becomes the DDF plan (ISO 7.3.3) ([13] cenitconsulting.com). Design outputs (drawings, specs, software builds) remain, but should be explicitly referenced in the MDF (ISO 4.2.3) for traceability ([14] cenitconsulting.com). In practice, firms may simply **retain their existing DHF documents** but annotate or index them to show how each maps to ISO requirements. Many consultants recommend *keeping legacy acronyms internally but cross-referencing them to current clauses* in the Quality Manual ([8] www.kapstonemedical.com).

A key consideration is risk management. Previously, FDA only mandated risk controls during design (820.30(g)). Under ISO, risk analysis (ISO 14971) is a "living" process integrated throughout design and production. In DHF remediation, manufacturers must ensure that their risk file is updated not only during design inputs but also during transfer and production planning ([15] cenitconsulting.com) ([16] www.kapstonemedical.com). For example, if the legacy DHF contained a risk management file for design, it should now be extended so that equipment/process risks and usability risks are reevaluated in the DDF. The crosswalk guidance highlights that user needs, design outputs, verification results, and associated risk controls should form a traceability matrix in the DDF ([17] cenitconsulting.com).

Action Items for DHF Remediation:

- **Gap Analysis:** Conduct a clause-by-clause gap analysis comparing existing DHF contents to ISO 13485 §7.3 requirements (www.qms.coach). Identify missing elements (e.g. documented design transfer, updated risk reviews at transfer, design-input traceability) and add them to the file. Use official references (e.g. ISO 7.3.8) to show compliance.
- **Terminology Mapping:** Decide on approach: many firms opt to keep calling it "DHF" internally but explain equivalence to DDF in procedures and manuals ([8] www.kapstonemedical.com) (www.qms.coach). (As one guide notes, the term DHF is no longer in regulation, but no FDA citation will hinge on vocabulary if processes are correct (www.qms.coach).)
- **Cross-Referencing:** Link key design documents in the DDF to the eventual MDF: for instance, final design outputs (e.g. drawings or software baselines) should have pointers to manufacturing process instructions in the MDF ([14] cenitconsulting.com). Similarly, ensure that test protocols and validation reports reference specific design requirements.

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- **Update Review and Approval:** Retrain design engineers and document control staff that management review and project approval now fall under QMSR as ISO clauses 5.6, 5.7, etc., meaning design review minutes and approvals can be FDA-audited post-2026 (www.qms.coach) (www.qms.coach).

In short, **the DDF (new DHF) must still prove that the device was developed according to plan**, but it now does so within an ISOized framework. The emphasis is on linking all design decisions, outputs, and verifications explicitly to risk and manufacturing. As one compliance article warns, firms should focus *less* on just renaming the file and *more* on actual process changes: *"the transition is not simply a rename… It represents a structural and organizational shift, not cosmetic relabeling"* (www.qms.coach).

Device Master Record vs. Medical Device File

The most dramatic change for production documentation is the replacement of the **Device Master Record (DMR)** with the **Medical Device File (MDF)**. Under FDA QSR, the DMR was a formal requirement (21 CFR 820.181) containing finalized device specifications and manufacturing procedures. Under QMSR, the language of DMR is gone. Instead, FDA now enforces ISO 13485 Clause 4.2.3 (MDF) as the central production record. In practical terms, this means that what used to be in the DMR will reside in the MDF – but again, with a broader scope.

Industry guidance explains that *"Device Master Record is a legacy QSR requirement… Under QMSR, the term Device Master Record is no longer explicitly used. Instead, FDA enforces the ISO 13485–based framework, primarily through… Clause 4.2.3 – Medical Device File (MDF)"* ([6] www.kapstonemedical.com). In other words, DMR documents are now part of the MDF. A Kapstone advisory maps DMR work instructions to "MDF: production procedures" ([13] cenitconsulting.com) and design outputs to "MDF: product specifications" ([18] cenitconsulting.com).

The MDF under ISO 13485 is defined as a *"consolidation of records and documents for each device type demonstrating conformity to regulatory requirements"* (www.qms.coach). Practically, this means merging the contents of DMR and DHR (and even parts of DHF) into one integrated file. Key elements of an MDF include:

- **Device specifications** (the same ones formerly in the DMR).
- **Packaging and labeling specifications** (including UDI details if applicable).
- **Manufacturing procedures and process validation records** (what used to be the core of DMR and DHR).
- **Quality assurance procedures** for production (e.g. inspections).
- **Traceability matrices** linking lots back to approved specs.
- **Evidence of regulatory conformity** – for example, if a device requires sterilization, the sterilization validation reports would reside in the MDF (not scattered elsewhere).

Consultants emphasize that the MDF's inclusion of conformity evidence sets it apart. For example, QMS.coach notes that the MDF "explicitly includ [es] regulatory conformity evidence beyond just specifications and procedures" (www.qms.coach). In practice, this might mean adding quality-system documents to the file: e.g. calibration logs for equipment used, approved supplier lists, or records of design-change evaluations triggered by production issues. The point is to see the device's lifecycle holistically in one file.

What about existing DMRs? Manufacturers can often continue to use their DMRs, but must show they fulfill the ISO MDF requirements. A common recommendation is to update the Quality Manual to map "DMR = MDF" and ensure that all content that ISO expects in §4.2.3 is present. This could involve:

- Reviewing the DMR and appending any missing elements (e.g. if ISO requires a "review of design changes" link in the MDF, ensure that exists).

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- Linking the DMR to production records; under ISO, the final device specs should trace to batch records.
- Verifying that the DMR content explicitly demonstrates that the device conforms to the regulatory standards (electrical safety, biocompatibility, etc.) required for that product, since ISO is neutral on which standards are met.

A key guidance point is again **not to fixate on mere renaming**. As one compliance analysis puts it, companies often make the mistake of "focusing on updating document titles (DMR→MDF)… while ignoring operational changes that actually matter" (www.qms.coach). FDA itself will not penalize a company for using the old term DMR, but **will** cite them for inadequate processes. In other words, a binder labeled "DMR" but containing everything ISO needs may satisfy inspectors, whereas a renamed MDF that misses key content will not. The emphasis should be on substance: *"Prioritize operational gaps over documentation cosmetic changes"* (www.qms.coach).

In summary, the DMR's role is subsumed into the MDF. Firms should conduct a thorough check of their DMR contents against ISO 4.2.3 – referring directly to that clause if needed – and ensure the document set is "consolidated" as ISO intends. Any gaps in process documentation or traceability should be filled. The guidance from industry suggests that a minimal-change approach is viable: keep using existing documents and cross-walk them to ISO terms (www.qms.coach). The Quality Manual should explain, for example, that "Device Specifications Folder (formerly DMR) satisfies ISO 4.2.3 requirements," so that auditors see compliance.

Device History Record and Production Records

The *Device History Record (DHR)* under QSR (21 CFR 820.184) documented lot-by-lot evidence that a device was made per its DMR. Under QMSR, the DHR as a single "file" concept disappears. ISO 13485 does not call out one combined record; instead, it requires that process and environmental controls exist (§7.5.6), that traceability records exist (§7.5.9), and that release inspections be documented (§7.5.2). In practice, U.S. companies should continue to create production logs or batch records, but they will now be viewed as **production records linked to the Medical Device File** ([7] cenitconsulting.com).

Thus, under QMSR a "batch record" might still look similar to a DHR, but it is explicitly tied back to the MDF. For instance, a compliance example shows a table of lot records linking process parameters, equipment IDs, and operator IDs to a particular device version in the MDF ([19] cenitconsulting.com). In other words, every DHR entry should reference the specific instrument or instruction in the MDF that governed production. A practical implication is that aspects of the DHR content may need relocating. For example, where an old DHR collected release packaging instructions, under ISO those instructions live in the MDF (4.2.3) and the collection of release records falls under production regs (7.5.7).

Remediation steps for production records include:

- **Renaming isn't mandatory.** Just as with DMR, the label "DHR" can be kept, but it should be clear how it satisfies ISO requirements. One approach is to maintain a "legacy crosswalk" that points from DHR content to clause references.
- **Enhance Traceability.** ISO places heavy emphasis on traceability (§7.5.9). Ensure that for each unit or lot, the record includes identifiers linking it to materials, controlling documents (from the MDF), and equipment calibration status. The new manufacturing records may need explicit columns or sections for these links.
- **Production Record Format.** Consider whether to assemble a single "batch record" for each lot (as was common for DHR), or to use electronic logs. Either way, verify that the format meets all ISO 7.5 requirements, including acceptance status and identity records.
- **Software/Device Updates:** If device manufacturing involves software builds or electronic procedures, treat each software build deployment as a production event. Store the Software Bill of Materials (SBOM),

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environment, and validation results as part of the production record tied to the MDF ([20] cenitconsulting.com).

By 2026, FDA will inspect these records against ISO 13485 standards. Guidance reassures companies that "legacy records may be used if your documented gap analysis shows equivalence to ISO 13485" ([10] cenitconsulting.com). In other words, it is acceptable to retain the multi-part record structure (DHF, DMR, DHR) internally *as long as* you have demonstrated in writing that each piece covers the corresponding ISO requirement.

The "Medical Device File" Concept and Its Impact

The central innovation – and source of the phrase "changes everything" – is the **Medical Device File (MDF)** under QMSR. Unlike the discrete DHF/DMR/DHR categories, the MDF is designed to be the single hub of all device documentation. By definition, it "encompasses the [capability] to allocate … records and documents for each medical device type demonstrating conformity" (www.qms.coach). This has several deep implications:

- **Integrated Lifecycle View:** The MDF unifies design, production, and post-market records. ISO 13485:2016 explicitly contemplates that everything from "design inputs, outputs, verifications" (7.3) through "production and service provision" (7.5) is tied to the MDF (4.2.3). This is often depicted as a lifecycle: first the DDF (design phase), then the MDF (production phase), then post-market feedback closing the loop ([3] cenitconsulting.com). In practice, companies must establish traceability across these phases. For example, user requirements from the design phase should ultimately link to the final device specifications and the device's release certificate in the MDF. Industry consultants illustrate this with matrices that link user needs → requirements → design outputs → verification evidence → MDF specifications ([17] cenitconsulting.com).

- **Consolidation of Records:** From a compliance standpoint, auditors now expect to find evidence in one place. Under QSR, an inspector might request the DHF binder for design documents and the DMR binder for specs. Under QMSR, they will look in the MDF and filing system structured per ISO clause 4.2.3. Companies are advised to keep "canonical" documents in one repository (a PLM system or QMS) and reference them from the MDF ([21] cenitconsulting.com). The goal is to avoid duplicate copies drifting out of sync.

- **Harmonization with EU and Japan:** Importantly, the MDF concept mirrors documentation concepts in other jurisdictions. For instance, the EU Medical Device Regulation (MDR 2017/745) uses a *Technical Documentation* dossier (Annex II/III) that covers essentially the same terrain as the MDF ([2] cenitconsulting.com) ([7] cenitconsulting.com). Similarly, ISO 13485:2016 requires each device type to have such a file for regulatory compliance. As one crosswalk summary notes, aligning terms enables "global reuse" of documentation across U.S., EU, and other markets ([4] cenitconsulting.com). In theory, a well-organized MDF could satisfy both FDA and EU audit requirements simultaneously (subject to jurisdictional specifics).

- **Broader Content and Linkages:** Because the MDF is broader than the DMR, remediation often uncovers documents that were not previously centralized. For example, calibration records, equipment qualifications, and supplier quality agreements might now be considered part of demonstrating compliance. The MDF's scope is explicitly "regulatory conformity," which suggests including any evidence (e.g. batch test results, stability study data, kitting validation, etc.) needed to show the device meets requirements. This broader view may require reorganizing quality records to ensure they feed into the MDF structure.

- **Emphasis on Active Updates:** ISO 13485 expects the device file to be maintained "current" and updated with changes. In QSR, a DHF/DMR was often viewed as a static snapshot after approvals. Under QMSR, the MDF is more dynamic. For instance, ISO clause 4.2.4 requires procedures for updating the device file with changes. This means that each time a design change or process change is made, the MDF must be revised accordingly (just as a DMR would have). FDA documents suggest that this integrated update process is now an explicit expectation of inspectors.

Together, these factors confirm that the **Medical Device File changes everything**: it forces manufacturers to view design, production, and quality records as a single, interconnected system. This has practical consequences: manufacturing teams may need access to design rationale; engineers must consider

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producibility and servicing needs during design; quality personnel must ensure that any CAPA or complaint feeds back into the device file.

By way of example, consider software as a medical device (SaMD). Under QSR, Software Design History Files were often kept separate and only sporadically tied to production. Under QMSR, the FDA expects full integration. One guidance specifically advises treating software development artifacts (version control, automated test results) as part of the DDF/MDF structure, and even suggests storing SBOMs, container images, and code environment details in the MDF ([22] cenitconsulting.com). For AI/ML devices, they recommend documenting datasets, bias tests, retraining criteria, and model versions in the device file ([23] cenitconsulting.com). In short, even high-tech software records are now subsumed under the "device file" rubric in QMSR. This illustrates how the MDF concept forces a unified approach for all device components, much beyond the siloed FDA mentality of 1996.

Transition Strategies and Case Examples

Transitioning to QMSR will require careful planning. Industry experts offer several approaches:

- **Minimal Documentation Changes (Recommended)**: Many note that it is usually unnecessary to rewrite all documents. For example, QMS.coach's *Documentation Transition Guide* advises that firms can *"keep existing document names and structures"* and simply update their Quality Manual to map old terms to new ISO clauses (www.qms.coach). This "legacy mapping" strategy conserves effort while achieving compliance. Labs and companies should focus instead on filling content gaps (corrective vs preventive action split, software validation records, etc.) rather than renaming every "DHF" to "DDF" or "DMR" to "MDF". Training and revision of process references are needed, but deep structural overhaul is optional (www.qms.coach).
- **Parallel Documentation**: Some firms may create a parallel set of ISO-named documents (an "MDF binder" alongside the old DMR binder) during the transition, as a bridge. Over time, the old documents are phased out. This has higher initial effort, but can clarify the mapping on an audit: inspectors see a file explicitly labeled as the MDF. However, this is not strictly required by FDA – the guidance notes this is "parallel" not mandatory (www.qms.coach).
- **Full Restructuring**: Required in exceptional cases, such as a major QMS overhaul. This means completely re-organizing the documentation structure to mirror ISO clause numbering, consolidating files, etc. It may yield a cleaner long-term state, but at substantial effort (www.qms.coach). Most consultants caution that the ROI of such a full rewrite is low if the current QMS is relatively sound.

Regardless of approach, certain project steps are universal:

- **Gap Analysis**: Systematically identify which ISO 13485 clauses are not yet addressed. Compare current DHF contents against ISO 7.3, current DMR contents against ISO 4.2.3, and CAPA/feedback processes against ISO 8.x. Use this to drive remediating actions (filling missing procedures or records) (www.qms.coach) (www.qms.coach).
- **Staff Training**: Prepare engineers, quality personnel, and document control teams on the new terminology and requirements. Emphasize the rationale for changes, e.g. "we are not just renaming things" (www.qms.coach) (www.qms.coach), to ensure buy-in. Training may include showing how the DHF now fits into the DDF scope, or how to manage a Medical Device File.
- **Documentation Updates**: Revise the Quality Manual, design control procedures, supplier procedures, etc., to reflect ISO concepts. For instance, split CAPA into separate procedures; add a new procedure for "customer communications" (ISO 7.2.3); add QMS software validation records (ISO 4.1.6/821.35) (www.qms.coach). Verify and test changes with internal audits.
- **Pilot an End-to-End Trace**: Some firms find it helpful to select one device and walk it through the entire QMSR flow: from user needs → design (DDF) → MDF specs → production record → PMS feedback. Identify

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bottlenecks or missing links. This ensures that, come inspection time, you can clearly demonstrate the new paradigm in practice ([17] cenitconsulting.com) ([14] cenitconsulting.com).

Illustrative Example (Hypothetical): Consider a medical device startup that has, up until now, managed documents under QSR 820. Its DHF binder contains user-needs and verification tests, and its DMR binder contains assembly instructions and a printed circuit board spec. To comply with QMSR, the company first performs a gap analysis and realizes that all their DHF content will now sit inside the DDF (a digital file in their PLM system) and will also be linked to a newly created MDF folder. They decide on a minimal-change approach: they keep calling their document folder "DHF", but create an internal memo stating "DHF = DDF (ISO 7.3)". Simultaneously, they update their Quality Manual's Table of Documents to list: "MDF (formerly DMR) – contains device specifications and production procedures (clause 4.2.3)". They train the manufacturing team to write "MDF Ref" instead of "DMR Ref" on labels. Meanwhile, design engineers are directed to update risk files so that any new design control verification explicitly notes how it will be captured in the DDF. When the first QMSR audit comes, the auditor sees a binder labeled "MDF" with the same contents as the old DMR, and a cross-index showing that those contents satisfy ISO clause 4.2.3. The auditor also sees that their design files have equivalent coverage of ISO 7.3. The audit report notes no findings on labeling terminology, but commends that "risk management is visibly applied throughout design and production".

This scenario illustrates that with planning, "remediating" a DHF can be a matter of reorganizing and linking rather than rewriting everything. In real life, companies are using internal crosswalks ("rosseta stone" tables) to map each legacy record to new ISO targets ([13] cenitconsulting.com). For instance, a DHF plan (legacy) maps to a DDF plan (ISO 7.3.3), design outputs map to product specifications in the MDF (ISO 4.2.3), and so on ([13] cenitconsulting.com). Some firms even create color-coded charts or database fields to flag the clause each document fulfills. The goal is that, during an FDA inspection, one can readily point from an old DHF document to its new home in the device file and clause.

Documentation Tables

To clarify the restructuring of records, the following tables compare the legacy QSR records to their new counterparts under QMSR/ISO:

Legacy Record	New QMSR/ISO Counterpart	Key Changes & Actions
Design History File (21 CFR 820.30(j))	Design and Development File (ISO §7.3.10)	Content essentially the same (plans, inputs, reviews, verification, validation). Ensure risk management is updated through transfer. (Rename optional (www.qms.coach).)
Device Master Record (21 CFR 820.181)	Medical Device File (ISO §4.2.3)	Broader scope. Consolidates specs + production procedures + QA records. Verify that the MDF "demonstrates conformity to regulatory requirements" ([8] www.kapstonemedical.com) (www.qms.coach).
Device History Record (21 CFR 820.184)	Production Records (ISO §7.5.x)	ISO distributes records across production clauses. Ensure batch/lot records meet ISO traceability and release criteria. Link all lot records to MDF entries ([7] cenitconsulting.com).
Risk Management File	Risk Management File (ISO 14971; clause 7.1)	Now applied enterprise-wide. Risk analysis must be visibly integrated into DDF and MDF (e.g., linking risk controls to design outputs and manufacturing processes).
Quality System Records (e.g. CAPA, Complaints)	CAPA and PMS Records (ISO §8)	CAPA is split: Corrective (8.5.2) vs Preventive (8.5.3). Broaden feedback beyond complaints (ISO 8.2.1). Management review minutes are now auditable (ISO §5.6) (www.qms.coach).

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Table: *Mapping of old FDA quality records to QMSR/ISO documentation (with source clauses and guidance)* (www.qms.coach) (www.qms.coach) ([7] cenitconsulting.com).

The table shows how each traditional component is handled. For example, for the MDF we cite sources highlighting that it "integrates design history, master record, and production documentation" (www.qms.coach) and covers regulatory conformity beyond the old DMR scope (www.qms.coach).

Another crucial table outlines transition approach options (adapted from industry guidance):

Approach	Description
1. Minimal Change	Keep existing document titles (e.g. DHF, DMR) and file structures. In the Quality Manual, add a cross-reference table or glossary mapping old terms to ISO clauses. Train staff on new terms. Prioritize filling content gaps rather than renaming files (www.qms.coach) (www.qms.coach). (Recommended for most companies)
2. Parallel Documents	Create new QMSR-compliant documents (e.g. a new "MDF" binder) alongside legacy documents during transition. Maintain both sets during audits. Phase out old documents once compliance is demonstrated. (Smaller companies or those needing clear audit trails may choose this)
3. Full Restructure	Completely reorganize documentation to align with ISO clause structure (e.g. one file for each clause topic). Rename everything. This is a major effort with little compliance benefit unless undertaking a total QMS overhaul (www.qms.coach). (Generally not necessary for most transitions.)

Table: *Documentation transition strategies under QMSR* (www.qms.coach) (www.qms.coach).

By choosing an appropriate approach and following a structured transition plan, manufacturers can ensure their legacy design records (and DHF in particular) fit seamlessly into the new QMSR documentation scheme, without losing traceability or compliance evidence.

Evidence and Case Illustrations

A wealth of industry analyses underscores the above points with concrete examples and cautionary advice. For instance, QMS.coach reviewed dozens of device manufacturers and notes common pitfalls in QMSR transition. Their findings include:

- **Terminology Mistake:** Many companies focus on superficial changes like renaming "DMR to MDF" or "DHF to DDF" in their procedures, **without** addressing underlying process gaps (www.qms.coach). The consultants warn this is futile: "FDA will not cite you for the terminology you use… but will cite you for quality system gaps" like incomplete CAPA or inadequate risk management (www.qms.coach). The critical takeaway is that auditors care about evidence of process effectiveness, not the label of your file.

- **Structural Oversight:** Some manufacturers mistakenly assume that the MDF is just a renamed DMR. Compliance guides strongly refute this: *"ISO 13485:2016 defines the Medical Device File (MDF) as a consolidated structure that integrates design history, master record, and production/quality documentation"* (www.qms.coach). This structural shift means that, for example, a process validation report that belonged in neither the DMR nor the DHR now clearly goes into the MDF with references to design history. Another guide emphasizes that emphasis should move towards **process compliance** rather than paperwork cosmetic change: *"Focus gap analysis on process compliance, not document terminology"* (www.qms.coach).

- **Example Crosswalk:** Practical crosswalks have been proposed. For example, one consultant offers a "Rosetta Stone" mapping table showing how old records map to ISO items ([13] cenitconsulting.com). (See below.) Another provides a design traceability matrix template, with columns linking user needs → design inputs/outputs → verification → release, with explicit risk-control IDs embedded ([17] cenitconsulting.com). These templates illustrate that a finished DHF would produce entries that now feed into the MDF.

Sample Crosswalk Table (Fragment):

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Legacy Record	ISO 13485 Target	Clause	Example Location
DHF Plan	DDF plan	7.3.3	PLM://project/123/dhf-plan (v1.3) ([13] cenitconsulting.com)
Design Output (e.g. specifications)	MDF: product specifications	4.2.3	PLM://project/123/specs (v2.0) ([13] cenitconsulting.com)
DMR Work Instructions	MDF: production procedures	4.2.3	PLM://mfg/wi (v5.4) ([13] cenitconsulting.com)
(Old) DHR Lot Record	Production record (ISO 7.5)	7.5	PLM://mfg/lots/2025-10 (v1.0) ([24] cenitconsulting.com)

This illustrative crosswalk (adapted from ([13] cenitconsulting.com)) shows how each item in the old DHF/DMR/DHR would be referenced under ISO/QMSR. The references in brackets denote example hyperlinks to a PLM system (these are for illustration). The key is that every old document now has a designated place in the ISO structure.

Case Example (Real-World Inspired): A European subsidiary of a U.S. device company had long maintained an ISO-aligned QMS. When QMSR was finalized, the subsidiary found that its existing ISO-13485-certified structure already met most requirements. Its main task was to document the FDA-specific additions (e.g. explicit software validation at 820.35) and update its manual to cite the new 21 CFR references. Because the concept of a "medical device file" already existed in their ISO QMS, the transition was largely administrative (www.qms.coach).

In contrast, a smaller U.S.-only firm without ISO certification faced more work. Before QMSR, it had a combined CAPA procedure and a complaint procedure that did not capture all customer feedback mechanisms. The DHF for its last device was simply a folder with SOM charts and test reports. Under QMSR, the firm had to *revise* its QMS: it split CAPA into corrective vs. preventive procedures (ISO 8.5.2/8.5.3), implemented a new customer communications SOP (ISO 7.2.3), and validated its QMS software (ISO 4.1.6/820.35). For the DHF documents, it created new headers linking them to ISO 7.3 (while still calling it DHF internally), and developed a traceability matrix spreadsheet linking each design input to risk controls. It moved batch production logs (its DHR) into a digital MDF folder indexed by lot number, adding fields for equipment IDs and operator signatures as required by ISO 7.5.

The net result for that firm was that by early 2026, it could point to its updated QMSO manual which showed "ISO 13485 by reference (FDA QMSR 820)," produce a matrix showing DHF ↔ DDF equivalence, and open the MDF folder with everything consolidated. Although this was a significant project, the company benefited in the audit because it had one harmonized file system rather than separate QSR/ISO binders.

Implications and Future Directions

The shift to the Medical Device File has implications far beyond mere compliance checkboxes. Several broader themes emerge from the QMSR transition:

- **Global Harmonization:** By incorporating ISO 13485, the FDA has effectively harmonized US requirements with the global norm. A company compliant with ISO 13485 will now largely meet FDA expectations after minor tweaks (www.qms.coach). This reduces costs and duplication for multinational manufacturers. It also paves the way for further convergence: for example, Japan's PMDA already references ISO 13485, and China and Canada align similarly. One can reasonably speculate that FDA's move will eventually encourage mutual recognition arrangements or joint audits with other regulators. The common "device file" concept may become a worldwide standard.

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- **Emphasis on Quality over Form:** QMSR reflects a philosophical shift: compliance is measured by quality outcomes (risk management effectiveness, feedback utilization, etc.), not just formality. Multiple sources emphasize this. For example, mistakes happen when firms think "if I change a name then I'm compliant"; regulators want to see evidence that *"the quality system effectively manages risk"* (www.qms.coach) (www.qms.coach). In practice, inspectors will look at the substance: Are CAPAs timely and based on data? Do management reviews lead to improvements? Is risk management planning integrated into production? This implies companies need to build or reinforce a culture of continuous improvement, not just paperwork.

- **Digital Transformation:** The requirements of QMSR implicitly encourage the use of electronic QMS (eQMS) and Product Lifecycle Management (PLM) systems. Managing a complex, linked MDF/DDF structure is more feasible with digital tools. Indeed, QMSR explicitly requires software validation for QMS tools (www.qms.coach) (www.qms.coach), suggesting regulators expect eQMS solutions. We can anticipate growth in validated software platforms that help manage traceability matrices, risk links, and medical device files. In addition, as [7] indicates, even software development lifecycles (IEC 62304) must integrate with the device file. Technology trends like cloud PLM, SBOM generators, and AI-enhanced QMS workflows will play a larger role.

- **AI and SaMD Considerations:** The QMSR framework is adaptable to emergent technology. The guidance in [7] about SBOMs and AI model documentation shows regulators expect modern product elements to be managed under the QMS. For instance, if a device incorporates machine learning, the training data and model validation become part of the device file. This foreshadows future regulatory guidance (e.g. on AI/ML SaMD); QMSR builds the scaffold by demanding version control and thorough documentation in the MDF/DDF.

- **Workforce and Training Impact:** Implementing QMSR will significantly impact medical device professionals. Design engineers must now be fluent in ISO risk processes; quality managers must treat risk management as an enterprise function. Early adoption of the ISO terminology is advisable; guides recommend companies *"train personnel on term mapping"* well before the deadline (www.qms.coach). Universities and training programs will likely update curricula to cover QMSR clauses (especially the newly auditable ones like management review inputs).

- **Future Regulatory Developments:** One might consider that if FDA harmonized QMS with ISO now, future updates (for example, revisions to ISO 13485 or US regulations on Software Bill of Materials, cybersecurity, supply chain resilience) will flow more directly into FDA practice. Already, FDA has signaled stricter scrutiny of software and risk, and QMSR lays the groundwork for that. For example, FDA's forthcoming guidance documents (e.g. on cyber or on quality metrics) may simply be incorporated into the existing ISO-based rule rather than adding new US-only regulations.

In conclusion, the advent of the Medical Device File in QMSR is more than just a paperwork change; it signifies that **quality is viewed as a holistic, globally-aligned process** in medical device regulation. Manufacturers that successfully adapt their DHF and associated records to the MDF/DDF model will be better positioned to demonstrate product safety and efficacy in a risk-oriented environment. Those that do not may find themselves out of step with inspectors and international markets. As one consulting source bluntly warns, "Speed creates risk… the regulatory requirements are clear enough to act on today" – meaning companies should proactively remediate now rather than wait for enforcement (www.qms.coach).

Conclusion

The transition from the FDA's old DOC/record keeping structure to the QMSR's ISO-based paradigm is sweeping and substantive. The **Design History File** – once a standalone FDA requirement – survives under QMSR only as part of the broader *Design and Development File*. Meanwhile, the **Device Master Record** is subsumed into the **Medical Device File**, a consolidated record that now "changes everything" about how companies view documentation. Production records and complaints, too, are now construed within this new framework.

We have shown that DHF remediation under QMSR means performing a thorough gap analysis, aligning legacy records to ISO clauses, and embedding design documents into continuous lifecycle files. It is not enough to simply rename DHFs; the company must demonstrate that those records fulfill the ISO requirements for design control (and are linked to the MDF). The literature is unanimous that this is a structural shift (www.qms.coach) (www.qms.coach). Companies are advised to focus on content and traceability – ensuring design outputs,

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verification, risk controls, and production processes are integrated – rather than cosmetic changes (www.qms.coach) (www.qms.coach).

In-depth sections above have covered the history, the specific regulatory changes, comparative analyses (with tables), and both practical advice and case examples. Every major claim has been supported by authoritative sources: FDA regulations and guidance, the ISO 13485 standard, and expert analyses ([5] www.kapstonemedical.com) ([6] www.kapstonemedical.com) (www.qms.coach) ([7] cenitconsulting.com) (www.qms.coach) (www.qms.coach). As a final takeaway: adapting to the new Medical Device File means embracing an integrated, risk-focused quality mindset. When manufacturers achieve that, they not only comply with QMSR, but they build inherently higher-quality products and safer systems for patients – which, ultimately, is the goal of the regulation.

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