CAHIR MEDTECH · COMPANION MANUAL

21 CFR to ISO 13485 Regulatory Requirements Mapping Kit: companion guide

How US manufacturers identify which FDA 21 CFR requirements fill the "applicable regulatory requirements" references in ISO 13485:2016, now that the QMSR incorporates the standard, and where MDR, corrections and removals, registration, UDI and Part 11 need their own procedures.

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Workbook + guide · $199 USD one-time · Applicable taxes may apply

Online guide: https://medtech.cahir.ai/cfr-iso-13485-mapping-guide

In this guide

1. Why "regulatory requirements" needs a US answer
2. Sample crosswalk rows
3. Start from the regulation, too
4. US-only additions
5. Turn gaps into an owned plan
6. Rehearse the inspection questions
7. Frequently asked questions

Why "regulatory requirements" needs a US answer

ISO 13485:2016 refers to "applicable regulatory requirements" in dozens of clauses but never says which ones. Since February 2, 2026, FDA's Quality Management System Regulation incorporates ISO 13485 by reference, so for a US manufacturer those references point to Title 21 of the Code of Federal Regulations.

This kit is a crosswalk for US industry: for each clause that mentions regulatory requirements, it lists the 21 CFR Parts that typically apply, what your QMS should address and which record proves it.

This Cahir MedTech workbook is an illustrative planning aid, not an FDA-endorsed mapping or legal advice. ISO clauses are referenced by number and title only; obtain the standard from ISO.

Sample crosswalk rows

ISO 13485:2016 clause	21 CFR requirement(s)	What to address
4.1.1 General	820.10; Part 807	Document your US role(s) and applicable Parts
4.2.3 Medical device file	801, 830; 807 / 814	Labeling, UDI and marketing authorization basis
7.2.3 Communication	803, 806; Part 7	MDR, correction/removal and recall communications
7.3.9 Design changes	807.81(a)(3); 814.39	Documented new-510(k) or PMA-supplement decision
7.5.8 Identification	Part 830	UDI on labels and GUDID data
8.2.2 Complaint handling	803	MDR reportability evaluated for every complaint

The Clause Crosswalk tab expands this to about thirty rows with status, procedure ID, owner and target date columns.

Start from the regulation, too

The Reverse Map tab works the other way: it starts from each 21 CFR Part and shows the ISO 13485 clauses it touches and whether ISO wording alone creates the US procedure. For Part 803 MDR, Part 806 corrections and removals, and Part 807 registration and 510(k), the answer is no: you need dedicated procedures.

US-only additions

The US-Only Additions tab lists the procedures most ISO-certified companies still need to add for FDA: MDR procedures (803.17), correction and removal reports (806.10), annual registration and listing, 510(k) change decisions, UDI and GUDID data (830.300), recall management under Part 7, and Part 11 electronic records.

Turn gaps into an owned plan

The Procedure Register records which SOP holds each requirement, and the Gap Action Plan assigns priority, owner and due date. Overlays for Class I, Class II 510(k), Class III PMA, software and combination products add the items specific to each.

Rehearse the inspection questions

Under Compliance Program 7382.850 an investigator may ask how your QMS identifies US regulatory requirements. The Inspection Checklist lists seven likely questions and where the evidence should live.

Frequently asked questions

Does ISO 13485 certification meet FDA requirements?

Not on its own. The QMSR incorporates ISO 13485, but FDA requirements such as MDR, corrections and removals, registration and UDI still need their own procedures and records.

Is this mapping endorsed by FDA?

No. It is an illustrative crosswalk prepared from 21 CFR and FDA's QMSR materials. Confirm it with qualified quality and regulatory reviewers for your device.

Does the kit include ISO 13485 text?

No. Clauses are referenced by number and title only.

What does it cost?

$199 USD one-time per company workspace. Applicable taxes may apply.