CAHIR MEDTECH · COMPANION MANUAL

PCCP-to-QMSR Mapping Kit: companion guide

How to execute an FDA-authorized Predetermined Change Control Plan inside your QMSR quality system: mapping SaMD Pre-Specifications, the Algorithm Change Protocol and the impact assessment to ISO 13485:2016 design, risk, records, monitoring and CAPA clauses so every model update is inspection-ready.

Edition: November 6, 2026 · 9 min read



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

Online guide: https://medtech.cahir.ai/pccp-qmsr-mapping-guide

In this guide

1. Why a PCCP needs a quality-system home
2. The core crosswalk
3. Treat every update as a controlled design change
4. Link algorithm risk to the risk file
5. Close the loop with feedback and CAPA
6. Rehearse the inspection questions
7. Frequently asked questions

Why a PCCP needs a quality-system home

An authorized PCCP tells FDA what you will change and how. It does not, by itself, create the records that prove each change was made that way. Since February 2, 2026, those records live under the Quality Management System Regulation, which incorporates ISO 13485:2016 by reference.

FDA's final PCCP guidance expects modifications to be implemented in accordance with your quality system. This kit gives you the crosswalk: which clause owns each PCCP element, what the record must show, and who owns it.

This Cahir MedTech workbook is an illustrative planning aid, not an FDA-endorsed mapping. It pairs with the AI/ML PCCP Suite, which helps you build the PCCP itself.

The core crosswalk

PCCP element	ISO 13485:2016 clause	Record that proves it
SPS modification description	7.3.3 Design inputs	Controlled input with performance bounds
ACP performance evaluation	7.3.6 / 7.3.7 Verification and validation	Locked-test-set results vs acceptance criteria
ACP update procedures	7.3.8 Transfer, 7.5.1	Release, deployment and rollback records
Impact assessment	7.1 and ISO 14971	Updated risk management file
Executed modification	7.3.9 Design changes	Change review, approval and DHF update
Monitoring and stop conditions	8.2.1, 8.4, 8.5.2	Trend analysis, nonconformance and CAPA

The workbook's Clause Crosswalk tab expands this to twelve rows with status, record ID and owner columns.

Treat every update as a controlled design change

Clause 7.3.9 requires design changes to be reviewed, verified, validated and approved before implementation. A PCCP pre-authorizes the regulatory side; it does not waive the design-change record.

The Modification Execution Log captures, for each change: the SPS item it falls under, the evaluation that confirms it stayed inside the boundary, the V&V record, the DHF update and the approval. If a change falls outside the PCCP, the same evaluation documents why a new submission is needed.

Link algorithm risk to the risk file

Drift thresholds and stop conditions are risk controls. The Risk Linkage tab ties each algorithm failure mode to its SPS item, control, threshold and ISO 14971 risk file reference, so a reviewer can see why a threshold was set where it was.

Close the loop with feedback and CAPA

Real-world performance monitoring is QMSR feedback (8.2.1) and data analysis (8.4). When a metric breaches a stop condition, the Monitoring and CAPA tab routes it to nonconformance (8.3) and CAPA (8.5.2) and records the deployment hold or rollback.

Rehearse the inspection questions

Under Compliance Program 7382.850 an investigator may ask you to walk from a deployed model version back to the authorized PCCP. The Inspection Checklist tab lists six likely questions and where the evidence should live, so your team can rehearse retrieval before anyone asks.

Frequently asked questions

Does a PCCP replace design change control?

No. A PCCP removes the need for a new marketing submission for planned changes, but each change is still a controlled design change under ISO 13485 clause 7.3.9.

Is this mapping endorsed by FDA?

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

Do I need the AI/ML PCCP Suite too?

Only if you are still building the PCCP. This kit assumes you have, or are drafting, an authorized PCCP and need to run it inside your QMS.

What does it cost?

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