CAHIR MEDTECH · COMPANION MANUAL

AI/ML PCCP Suite: companion guide

A practical, section-by-section workflow for building a Predetermined Change Control Plan for an AI/ML-enabled device: deciding which modifications belong inside the plan, drafting the SaMD Pre-Specifications and Algorithm Change Protocol, planning verification and validation, and monitoring performance after each authorized update.

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Workbook + guide · $399 USD one-time · Applicable taxes may apply

Online guide: https://medtech.cahir.ai/ai-ml-pccp-guide

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Start here: authorization to improve, not permission to drift

A Predetermined Change Control Plan (PCCP) is the mechanism Congress gave FDA in section 515C of the FD&C Act (added by FDORA in 2022) to let a manufacturer make specific, planned modifications to a device — most often an AI/ML-enabled device software function — without filing a new marketing submission each time. FDA's final PCCP guidance (December 2024) is the rulebook this suite operationalizes.

The mental model matters: a PCCP is not a license to change whatever you want. It is a bounded contract. You describe exactly which modifications you anticipate, exactly how you will develop and validate them, and exactly how you will know they worked. Anything outside that boundary still needs a new submission.

This Cahir MedTech workbook is your company's preparation aid, not an official FDA form. It pairs with the free AI/ML Diagnostics PCCP & Evidence Planner, which helps you inventory evidence; this suite is the full build-out for teams ready to put a PCCP in front of FDA.

Deciding what belongs inside the boundary

The single most consequential decision is scope. FDA is explicit that modifications changing the intended use or indications for use do not belong in a PCCP. The workbook's Modification Inventory tab forces the discipline: list every change you anticipate over the lifecycle, classify it, and defend why it stays inside or outside the plan.

Modification	Inside a PCCP?	Why
Periodic retraining on newly collected data	Usually yes	Same intended use; bounded by acceptance criteria
Expanding the input data sources or acquisition devices	Often yes	If validation covers the new inputs
Tuning an operating threshold within a claimed range	Usually yes	Performance trade-off stays within labeling
New architecture or model class	Rarely	Hard to pre-specify validation FDA will accept
New patient population or clinical indication	No	Changes indications for use — new submission
New hardware sensor feeding the model	Usually no	Beyond software function boundary

If you are unsure where a modification lands, that uncertainty is itself a strong reason to discuss PCCP scope with FDA in a Pre-Submission meeting before you file.

The two pillars: SPS and ACP

FDA's guidance structures a PCCP around two components, and the Update Protocol Builder tab walks through both:

SaMD Pre-Specifications (SPS) — what you intend to change. Each modification is described precisely: the trigger, the boundary, and the rationale. Vague scope statements are the fastest route to a deficiency letter; 'periodic performance improvements' is not a specification.

Algorithm Change Protocol (ACP) — how you will change it. This is the methodology: data management and train/tune/test separation, retraining procedures, performance evaluation with pre-specified acceptance criteria, deployment and rollback procedures, and how users are informed.

A useful test from the Good Machine Learning Practice principles: if an independent team could execute your ACP and reach the same validation outcome, the protocol is specific enough. Our article on PCCP

implementation in 2026 walks through how authorized PCCPs describe these elements in practice.

Verification and validation: pre-specify or renegotiate

Every modification inside the PCCP needs a validation package defined in advance — the V&V Matrix tab maps modification types to evidence. Three rules keep the matrix honest:

1. **Locked test sets stay locked.** Retraining data must never contaminate the test set used for acceptance. Data provenance and leakage controls belong in the ACP, not in a slide deck.
2. **Acceptance criteria are numerical.** 'Non-inferior to baseline on the primary metric within a pre-specified margin' is a criterion; 'maintains performance' is not.
3. **Subgroups are pre-planned.** If your labeling claims performance across sites, demographics or acquisition devices, the V&V plan must evaluate those subgroups for every update — a lesson reinforced by FDA's AI-enabled device lifecycle draft guidance (January 2025).

For diagnostics teams, our AI/ML diagnostics evidence article covers matrix and comparator considerations that feed directly into this tab.

After authorization: monitoring is part of the plan

A PCCP does not reduce postmarket obligations — it formalizes them. The Monitoring Tracker tab logs each deployed version, the metrics you watch, and the drift signals that trigger investigation or rollback. FDA expects the plan to name stop conditions: the performance thresholds at which you halt further modifications and, if necessary, revert.

Keep the tracker connected to your QMS. Under the QMSR, design changes — including PCCP-executed changes — are documented in the design history file, and complaint and monitoring data feed the next modification cycle. Teams building that connective tissue should also review our QMSR for AI/ML devices article.

FDA's public AI-Enabled Medical Device List is worth studying: it shows how authorized devices describe their AI functions and, increasingly, their PCCPs.

Putting the PCCP in the submission

The Submission Planner tab back-plans the work. Practical sequence:

1. Decide to pursue a PCCP before protocol lock — retrofitting one after validation is designed is expensive.
2. Draft the SPS and ACP alongside the main submission, not after it.
3. Discuss scope in a Pre-Sub. FDA's guidance encourages early interaction, and a Q-Sub that resolves boundary questions protects the pivotal validation budget.
4. Integrate the PCCP into the eSTAR or traditional submission as a clearly identified section.
5. After authorization, execute modifications strictly per the ACP and file the documentation in the DHF.

The FDA Q-Sub Master Pack covers step 3 in depth if a pre-submission meeting is part of your plan.

How to use the workbook

The suite contains ten tabs:

- **Universal Baseline** — fourteen readiness criteria to confirm before you include a PCCP in a submission.
- **Modification Inventory** — every anticipated change, classified, with an inside/outside-the-PCCP decision and rationale.

- **Update Protocol Builder** — the SPS and ACP drafted section by section.
- **V&V Matrix** — verification and validation activities, test data requirements and acceptance criteria per modification type.
- **Monitoring Tracker** — deployed versions, monitored metrics, drift signals and actions.
- **Submission Planner** — milestones from the internal PCCP decision through the first authorized update.
- **Category overlays** — additional items for SaMD, IVD, implantable, capital equipment and consumable portfolios.

Status columns carry dropdowns (Not started / In progress / Complete / N/A), and every row records evidence by controlled document ID and revision so the workbook stays audit-ready. White cells are editable; the layout and branding are protected.

Frequently asked questions

Does a PCCP let us change the intended use of our device?

No. FDA is explicit that modifications changing the intended use or indications for use cannot be included in a PCCP. Those changes always require a new marketing submission. The PCCP boundary covers planned modifications that keep the device within its authorized intended use.

Which pathways can include a PCCP?

Section 515C of the FD&C Act covers devices cleared through 510(k), authorized through De Novo, or approved through PMA. The PCCP is submitted as part of the marketing submission and, once authorized, applies to that device.

Do we still need to validate every update?

Yes. A PCCP pre-authorizes the validation plan, not the outcome. Each modification must be executed and validated exactly as the Algorithm Change Protocol describes, with the documentation filed in your design history file. Updates that fail the pre-specified acceptance criteria cannot be deployed under the PCCP.

Should we discuss our PCCP with FDA before filing?

FDA encourages it, and for most teams a Pre-Submission meeting is the cheapest way to resolve scope questions before the pivotal validation budget is spent. The Q-Sub Master Pack covers that interaction in depth.

Does a PCCP reduce our postmarket obligations?

No. Monitoring, complaint handling and QMSR design-change documentation still apply. The PCCP formalizes how you watch performance and what triggers a stop or rollback — it does not replace those obligations.

Sources and scope

Primary references: FDA PCCP final guidance (December 2024); AI-enabled device software functions lifecycle draft guidance (January 2025); GMLP guiding principles; AI-Enabled Medical Device List.

This guide and workbook are planning aids, not legal or regulatory advice. Confirm PCCP scope, validation strategy and submission content for your specific device with qualified regulatory reviewers. Edition: November 5, 2026.