

An evolving on-device model is designed to change — bound the changes, fix the method and acceptance criteria, and assess the impact **before the study starts.**

Every retraining or re-thresholding can alter what an endpoint records or a safety alert fires on; skipping the plan does not make the change unregulated, it leaves it uncontrolled. **Design the envelope once, to the IMDRF / FDA three-component structure, and map it to each regime — do not assume a single global rule.**

THE PICTURE

Which rule governs a model change depends on what the DHT is — a plan is authorized only for a current or future marketed device

What the DHT is	Who authorizes the change plan	The rule
Trial-only DHT	No regulator — the sponsor's own change control	FDA DHT guidance: the DHT must remain fit-for-purpose so updates do not affect the measurements
Marketed AI-enabled device, US	FDA, via a PCCP in the marketing submission	FD&C Act s.515C; PCCP guidance final 4 Dec 2024, re-issued 18 Aug 2025
Device with a high-risk AI system, EU	Notified body, at conformity assessment	AI Act Art. 43(4) pre-determined changes (MDCG 2025-6, Q30); MDR PCCP proposed in COM(2025) 1023
Any market	Map onto the shared structure	IMDRF N90 (6 Aug 2026): description of modifications · modification protocol · impact assessment

A PCCP moves the control forward in time: envelope and method agreed once, conforming changes ship under change control, anything outside needs a new submission or conformity assessment.

QOINTA'S POSITION Four positions that turn unplanned change into planned change

An evolving model is a regulated artifact, not just code

Where the model is, or is a safety component of, a device, changing it changes the device; a marketed-device change affecting safety or effectiveness needs a new 510(k) or PMA supplement.

The envelope is the unit

What is pre-authorized is exactly what the plan describes; a change outside the envelope, or one that cannot meet the plan's criteria, still needs a new submission.

Authorization follows device status

A trial-only DHT runs its plan under the sponsor's change control; only a DHT that is, or will become, a marketed device can have the plan authorized by a regulator.

The dates are settled, not aligned

The US route is final; Regulation (EU) 2026/1744 moved the device-embedded high-risk obligations to 2 August 2028. A model across both markets sits under two change-control logics at once.

SIX QUESTIONS TO ANSWER BEFORE RELYING ON AN EVOLVING MODEL

- 1 Bound the envelope** — write down the foreseen modifications and their boundaries, and make what is out of scope explicit.
- 2 Fix the method** — a data-governance, training, testing and acceptance method every in-scope change must meet before deployment.
- 3 Assess the impact** of each change on safety, performance and any endpoint the model feeds, including its qualification.
- 4 Record device status in the RIA** — marketed or trial-only decides whether a regulator or the sponsor authorizes the plan.
- 5 Operate inside the envelope** — only conforming changes deploy, each logged in the Trigger Register; out-of-envelope change escalates.
- 6 Make the plan visible** — state the PCCP's existence and the changes made under it in labelling, as FDA's guidance recommends.

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PCCP components shared by FDA guidance and IMDRF N90: modifications, protocol, impact

2 Aug 2028

EU device-embedded high-risk AI obligations apply (Regulation (EU) 2026/1744)

4 Dec 2024

FDA PCCP guidance finalized; re-issued 18 Aug 2025 under FD&C Act s.515C

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FDA / Health Canada / MHRA guiding principles: bounded, risk-based, evidence-based, transparent, lifecycle

Read with care. Timelines reflect 1 September 2026 — Regulation (EU) 2026/1744 in force; COM(2025) 1023 a proposal, not law — and should be re-confirmed before reliance. The PCCP table is illustrative, not a regulatory determination.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-04 The AI/ML Overlay · QPP-05 Cybersecurity · QPP-07 Change Control · QPP-08 Trigger Register · QPP-15 Endpoint Qualification



Summary of QPP-16 1.0 — the full paper, with sources and figures, is published at qointa.com.

FDA PCCP guidance (Dec 2024, re-issued Aug 2025) · FD&C Act s.515C · FDA DHT guidance · 21 CFR 807.81(a)(3), 814.39 ·

IMDRF N90 (Aug 2026) · AI Act Art. 6(1), 43(4) · Reg. (EU) 2026/1744 · MDCG 2025-6 · COM(2025) 1023

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