

Every app, OS, permission or model update that reaches a live trial is a **regulated event**, and its materiality must be assessed and recorded — either way.

“Just an update” is the assumption that no perimeter was crossed; where nobody checked, the next inspection will. **Separate the change you release from the change the platform pushes, set written materiality criteria before the next release, bound foreseeable change in a PCCP-style plan, and monitor a device / OS range.**

THE PICTURE Five kinds of change cross perimeters — and each has its own control

Kind of change	Why it is a regulated event	Example control
New app feature	Can move the software into medical-device territory mid-study	Materiality determination before release; re-assess classification
OS / firmware upgrade	Can alter the measurement and break comparability with prior data	Specified device / OS range; compatibility test; hold or re-validate
Permission / SDK change	Can change the data-flow and privacy position	Permission review; SBOM and data-flow check before deployment
Model retrain	Changes device behavior; engages change-control obligations	Predetermined change control plan (PCCP; QPP-16); bounded retraining
Config / MDM change	Can change the managed-platform and routing position	Change request through MDM governance; re-baseline the configuration

Each kind is a trigger for the RIA (QPP-00) and the Trigger Register (QPP-08). Every change moves the system off its validated state; the assess–re-validate–record loop returns it.

QOINTA'S POSITION Four positions that turn maintenance into a controlled, regulated event

Every change moves the system off its validated state

Validation is a snapshot of a configuration. 21 CFR Part 11, EMA/INS/GCP/112288/2023, ICH E6(R3) and GAMP 5 require change to be assessed, re-validated where material and recorded.

The trial rules decide materiality first

FDA's DHT guidance expects a record of every DHT update and continued fitness for purpose; an EU change with substantial impact on safety or data reliability is a substantial modification.

Marketed-device tests apply only if the software is a device

510(k) software-change logic and MDR Annex IX s.4.10 approval or s.2.4 notification bind only a marketed device; the Art. 120(3c)(b) test belongs to legacy devices.

Uncontrollable change alters the duty's shape, not its size

OS and firmware upgrades arrive on the vendor's timetable and cannot be held back on BYOD. The sponsor still detects, assesses and acts; a monitored device / OS range makes that possible.

SIX ACTIONS THAT MAKE CHANGE DETECTABLE, ASSESSABLE AND DEFENSIBLE

- 1 Map controllable vs uncontrollable change** — separate what you release from what the platform pushes, and assign detection to each.
- 2 Set the materiality criteria** — define and document what counts as a significant change before the next release, not after.
- 3 Bound foreseeable change** in a PCCP-style change plan (QPP-16) for the app and model change you can anticipate.
- 4 Specify and monitor the device / OS range** so an uncontrollable upgrade becomes a detectable, assessable event.
- 5 Wire change triggers into the RIA** (QPP-00) and keep the Trigger Register (QPP-08) live.
- 6 Assess every release with the eight materiality questions** and record the answer, with rationale, material or not.

5

kinds of change: feature, OS / firmware, permission / SDK, model, config / MDM

8

questions decide materiality before a release ships

5 days

working-day notice for qualifying IDE changes under 21 CFR 812.35

1 week

to notify a substantial-impact modification under MDR Art. 75

Read with care. The composite case is illustrative, not a specific study. FDA's PCCP guidance for all device software (Aug 2024) and AI lifecycle guidance (Jan 2025) remain drafts; the MDR has no AI Act Art. 43(4) equivalent (qointa's view).

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-01 Endpoint Validation · QPP-04 AI/ML Overlay · QPP-06 Inspection-Readiness · QPP-08 Trigger Register · QPP-16 PCCP



Summary of QPP-07 1.0 — the full paper, with sources and figures, is published at qointa.com.

FDA DHT guidance · 21 CFR Part 11 and Part 11 Q&A · 21 CFR 812.35 · EMA/INS/GCP/112288/2023 · ICH E6(R3) · GAMP 5 · EU MDR Art. 75, Annex IX, Art. 120(3c)(b) · FDA 510(k) software-change and PCCP guidance · EU AI Act
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