

No GCP rule binds an OS or firmware vendor: every duty your release creates belongs to the sponsor — and the sponsor cannot discharge it without facts that exist only on your side.

A single release can move sampling, sensor behavior, permissions or APIs, rolls out unevenly, and is announced as a build number — so the sponsor learns of it after the data has moved. **Publish a release calendar, state the behavioral delta, declare end-of-support against study timelines, and offer a defer-or-pin path.**

THE PICTURE Every duty in the table is the sponsor's, and every input is yours

Sponsor's duty	What your release does to it	Your disclosure
Change control (QPP-07)	Updates can break the validated state mid-study.	Publish a release calendar and change notices the sponsor can plan around.
Endpoint validation (QPP-01)	A sampling change can alter a sensor-derived measure.	Flag changes to sampling, sensors or signal processing in the release notes.
Security (QPP-05)	Patch cadence and end-of-support drive security exposure.	Declare patch cadence and end-of-support dates against study timelines.
PCCP (QPP-16)	A PCCP is held by the manufacturer of an AI-enabled device software function — not by you.	Say what you ship and when; do not expect a change plan to pre-authorize it.

FDA requires changes to a DHT during a study to be assessed for their effect on the data; the EMA computerized-systems guideline requires the change to be controlled and the system revalidated where the assessment requires it. Both are blind without a release note that says what actually changed.

QOINTA'S POSITION Four facts about your releases that a sponsor has to work around

Your update is the trial's change event

A routine OS push can alter a measure or a permission: a silent sensor or sampling change can shift a mobility or signal measure; a permission-model change alters what the app may access.

You are an uncontracted dependency

The sponsor relies on a party it never contracted with and cannot control your cadence; it can only plan around what it can see.

Behavioral changes are announced as build numbers

In qointa's experience, sampling, sensor and permission changes reach release notes as version strings, if at all — which is why the sponsor learns of them after the data has moved.

End-of-support forces a choice

Update and accept behavioral drift, or stay on an unsupported version and carry the security exposure — and a support window can close inside a study that is still recruiting.

FIVE MOVES TURN AN UNCONTRACTED DEPENDENCY INTO A PREDICTABLE ONE

- 1 Publish a release calendar** — give the study a forward view of your cadence and forced-update deadlines.
- 2 Flag behavioral deltas, not just build numbers** — call out changes to sampling, sensors, permissions or timing.
- 3 Declare end-of-support dates early** so support windows can be reconciled with study timelines.
- 4 Offer a defer-or-pin path** where your platform allows one — a way to delay an update or hold a version for the duration of a study.
- 5 Say what a change plan will not cover** — a PCCP sits with the manufacturer of an AI-enabled device software function, not with you.

Read with care. The defer-or-pin path is, in qointa's assessment, the single most valuable thing a vendor can offer a trial — a recommendation, not a legal requirement. Neither the FDA nor the EMA instrument binds an OS or firmware vendor.

READ NEXT

QPP-00 Regulatory Impact Assessment (Section 12) · QPP-07 Change Control · QPP-01 Endpoint Validation · QPP-05 Cybersecurity · QPP-16 PCCP · QPP-08 Trigger Register

