

A sponsor can transfer all the work of building and running a DHT; ICH E6(R3) s.3.6.6 keeps ultimate responsibility for data reliability with the sponsor.

A vendor's certifications describe the vendor; they do not discharge that duty for this study — and a DHT vendor changes during the study. **Qualify for this use before reliance, set a risk-proportionate monitoring cadence, contract for notification, flow-down, audit and exit, and record every re-assessment.**

THE PICTURE Oversight reaches six areas, and each needs its own evidence over time

Area	What oversight checks	Evidence / monitoring method
Validation	Validated for this intended use, not "validated" in the abstract	Use-specific validation report; re-review on material change
Data integrity	Audit trail, access control and device-side integrity	Audit-trail review; periodic access-control and integrity checks
Security	Security posture and incident handling for the trial data held	Security assessment review; incident-notification clause and log
Change control	How releases and updates affecting the validated state are managed	Release notes and change log; impact assessment per release (QPP-07)
Subcontractors and sub-processors	The vendor's own connectivity, hosting and analytics suppliers	Sub-processor list in contract; flow-down evidence (GDPR Art. 28(4))
Continuity	Data export, retention and what happens if the relationship ends	Export / retention terms and a tested exit plan

Oversight is a cadence, not a selection gate: qualify for this use, monitor on a risk basis (E6(R3) s.3.10), re-assess when a trigger fires. Distinct from who is manufacturer, importer or distributor.

QOINTA'S POSITION Four positions that separate "certified" from "overseen"

Delegation moves the work, not the accountability

E6(R3) s.3.6.6 keeps ultimate responsibility with the sponsor; ss.3.6.7–3.6.8 require suitability assessment and access to procedures and metrics; 21 CFR 312.52 retains the rest.

Oversight reaches the subcontracted chain

E6(R3) s.3.6.9 extends oversight to activities the provider subcontracts further; GDPR Art. 28(2) and 28(4) require written authorization and flow-down. Annex 2 repeats the duty for DCTs.

Certification is evidence about the vendor, not this study

A certificate shows general capability, not that this system, configured for this protocol, is fit for purpose or stays so. At inspection, "the vendor handled that" is not an answer.

DHT vendors break the classic service-provider model

In qointa's assessment, the "validated once" fallacy, OS dependency on uncontracted platform vendors, hosting and connectivity sub-vendors and release pace mean a one-time check misses all four.

SIX ACTIONS THAT TURN A SELECTION GATE INTO CONTINUOUS OVERSIGHT

- 1 Qualify for the use before reliance** — validation, data integrity, security, change control, sub-processors and continuity.
- 2 Set a monitoring cadence proportionate to criticality** — event-driven on releases, OS or connectivity changes, sub-processor moves.
- 3 Put oversight into the contract** — release and sub-processor notification, flow-down (GDPR Art. 28(4)), audit rights, export and exit.
- 4 Run an impact assessment on each relevant release** (QPP-07) and specify and monitor the device / OS range.
- 5 Test the exit plan before it is needed** where the vendor holds the only copy of source data.
- 6 Record each qualification and re-assessment in the Trigger Register** (QPP-08); file the evidence in the quality system and TMF.

6

areas oversight must reach, each with its own evidence method

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deployment facts that raise the oversight weight and feed the RIA

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ways DHT vendors break the classic service-provider oversight model

15 Jan 2027

EU effective date of ICH E6(R3) Annex 2 (Step 4, 3 June 2026)

Read with care. The worked example is an illustrative composite. GAMP 5 is industry practice, not binding; EU GMP Annex 11 is an analog, not the source of the GCP duty. AI Act dates (2 Dec 2027; 2 Aug 2028 per Reg. (EU) 2026/1744) as stated.

READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-03 Economic-Operator Roles · QPP-04 AI/ML Overlay · QPP-05 Cybersecurity · QPP-07 Change Control · QPP-08 Trigger Register



Summary of QPP-12 1.0 — the full paper, with sources and figures, is published at qointa.com.

ICH E6(R3) ss.3.6.6–3.6.9, 3.10 and Annex 2 · EMA/INS/GCP/112288/2023 (Annex 1, A2.1) · GAMP 5 (second edition) · GDPR Art. 28(2), 28(4) · 21 CFR 312.52 · FDA DHT guidance · EU AI Act · Regulation (EU) 2026/1744 · NIS2

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