

Three quality systems govern one DHT trial; each is complete within its own scope, and **none of them governs the handoffs** between them.

A control that exists in two systems but is owned by neither at the boundary is covered by neither — and an inspector follows one control end to end. **Map the systems, name every seam, assign one owner on each side in a written quality or technical agreement, and evidence each transfer in the Trigger Register.**

THE PICTURE Five seams carry the control, and each needs a named owner on both sides

Seam	Failure mode if unowned	Evidence of successful handoff
1 · Manufacturer → sponsor (change)	An update disturbs the validated state with no one assessing it	Dated change notice in the Trigger Register, with impact assessment
2 · Vendor → sponsor (issue)	A defect never reaches the sponsor's issue management	Vendor defect record traceable to the sponsor's issue record
3 · Sponsor → vendor (risk)	The vendor validates to its own scope, not the trial's risks	Validation plan references the trial risk assessment
4 · Vendor ↔ manufacturer (interface)	Neither party owns a fault that lives between them	One accountable party named in the quality or technical agreement
5 · All → Trigger Register	Changes accumulate with no single controlled record	A Trigger Register entry per change, linked to its disposition

A seam is closed by a written agreement, a named owner and a dated record. Worked example: a compliant firmware update changed sensor scaling; Seam 1 was unowned, so weeks of endpoint data ran on a configuration nobody revalidated — three compliant systems, one missing handoff, one finding.

QOINTA'S POSITION Obligations stack at the seam, and the sponsor owns the structure that carries them

No quality system reaches past its own scope

Sponsor GCP under ICH E6(R3), the manufacturer's system under MDR Art. 10(9) and the FDA QMSR, and vendor software validation each govern a part; DHT control depends on actions that cross them.

Only one of the three systems is a certificate

No certificate exists for a sponsor's GCP quality system, and an ISO 13485 certificate is not evidence of US quality-regulation compliance. The quality agreement is what connects the systems.

Integration is not oversight, and the sponsor stays responsible

Qualifying a vendor (QPP-12) is necessary but different from designing how systems interlock. ICH E6(R3) s.3.6.6 keeps ultimate responsibility for data reliability with the sponsor.

Four processes must be reconciled, not merged

Change control, issue management, validation and risk management recur in all three systems; each party keeps its own, but an event in one must trigger the right response in the others.

FIVE STEPS, FROM MAPPING THE SYSTEMS TO AN END-TO-END TRACE AN INSPECTOR CAN FOLLOW

- 1 Map the quality systems** in play — sponsor GCP, manufacturer QMS, vendor validation controls — and what each governs.
- 2 Find the seams** — every point where control passes between systems: validation evidence, change notification, deviation handling.
- 3 Assign seam ownership** explicitly, in a written quality or technical agreement, with how conformance is evidenced across it.
- 4 Reconcile the four processes** — change control, issue and CAPA handling, validation, risk management — so they connect, not collide.
- 5 Evidence end to end** so an inspector can follow a control from sponsor accountability through to vendor execution without a gap.

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quality systems govern one DHT trial — GCP, regulated manufacturer QMS, vendor software validation

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seams between them, none governed by any of the three systems on its own

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cross-cutting processes to reconcile: change control, issue management, validation, risk management

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FDA Quality Management System Regulation in force, incorporating ISO 13485:2016 by reference

Read with care. Which systems are in play depends on whether the DHT software is a medical device and which parties are engaged; a CRO, MDM or connectivity provider adds further seams, and an investigational DHT adds ISO 14155:2020 as a fourth regime. The seam-failure example is an illustrative composite.

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Summary of QPP-24 1.0 — the full paper, with sources and figures, is published at qointa.com.

ICH E6(R3) s.3.6.6, s.3.10, s.4.3.4 and Annex 2 · MDR Art. 10(9) · 21 CFR Part 820 (QMSR) · ISO 13485:2016 · IEC 62304:2006 + A1:2015 · ISO 14971:2019 · ISO 14155:2020 · EMA/INS/GCP/112288/2023 Annex 2 · MDSAP

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