



Global Logistics, Labeling & Compliance for Digital Health Technologies (DHTs) in Decentralized Clinical Trials

Decentralized trials depend on more than the right devices—they depend on getting those devices to the right place, on time, and in full compliance with local and global regulations.

qointa DeviceOps delivers end-to-end operational enablement for Digital Health Technologies (DHTs), including POC devices, wearables, and SaMD kits. From procurement to provisioning, labeling, customs, and reuse, DeviceOps ensures readiness at scale across geographies, integrated with regulations such as **EU MDR**, **FDA 21 CFR**, **ISO 13485**, **GDP/GSP**, **PMDA**, and **NMPA**.

Why DeviceOps Is Mission-Critical

Operational risks in DHT logistics cause regulatory delays, ethics rejections, and patient safety issues. DeviceOps solves this by embedding regulatory-grade oversight into the physical movement and handling of every device.

Common pitfalls it addresses:

- Missing or incorrect labeling
- Delayed customs clearance
- Lack of reuse tracking
- Incomplete importer documentation
- Ethics board pushback on device readiness

“Can you prove each device in your trial was shipped, labeled, and handled in compliance with local laws and GDP standards?”

“Do you have validated SOPs for reuse, chain-of-custody, and triggered actions like FSQA?”

“How are you ensuring that every device shipped—across all countries—is labeled, documented, and registered in compliance with local regulations like EU MDR, FDA, PMDA, and NMPA?”

“What systems are you using to track device inventory, usage history, and chain of custody—especially when reusing devices across patients or studies?”

“Have you experienced delays in customs clearance due to missing documentation, importer of record (IOR) confusion, or UDI/labeling issues?”

“How are you validating Good Distribution Practice (GDP) and storage conditions for temperature-sensitive or high-risk POC devices?”

“If a regulator asked for proof that your devices were delivered, handled, and reused according to documented SOPs, could you provide that within 24 hours?”

Risks Addressed

Operational Risk

- Noncompliant labeling or documentation
- Cold chain or transport issues
- Inadequate importer records
- Reuse without validated SOP
- Supplier without CE/FDA clearance

Potential Impact

- Customs delays; ethics rejection
- Device failures; invalid endpoint data
- Regulatory nonconformity
- Patient safety risk; protocol deviation
- Ethics board challenge or audit finding

What DeviceOps Delivers

1. Global Procurement & Logistics Coordination

- Coordinate sourcing, inventory, and warehousing across regions
- Plan and execute kit assembly, device configuration, and trial-specific packaging
- Support Direct-to-Patient (DTP) and site-based deployment models

2. Regulatory Import/Export Compliance

- Align with EU MDR Article 13, FDA import requirements, NMPA, PMDA, and more
- Prepare compliant customs documentation (shipping labels, CE/DoC, declarations)
- Coordinate with Importers of Record (IORs) to ensure timely and lawful device movement

3. Labeling, UDI, and Localization

- Ensure compliance with regional labeling rules (EUDAMED, GUDID, UKCA, etc.)
- Customize Instructions for Use (IFUs) and safety information in local languages
- Apply risk-based labeling aligned with MDR Annex I and GSPR requirements

4. Device Tracking, Reuse & Sustainability

- Track devices by serial/lot number, version, and usage lifecycle
- Manage device returns, refurbishment, and validated reuse
- Maintain traceability records for 10+ years in line with EU MDR Article 10(8)

5. Good Distribution & Storage Practice Oversight

- Monitor distribution under GDP/GSP standards
- Perform checks for shipping conditions (temperature, humidity, handling)
- Align with ICH GCP and ISO 13485:2016 distribution expectations

6. Supplier & Vendor Qualification

- Audit and qualify manufacturers, importers, and logistics vendors
- Review credentials including CE marking, 510(k), QMS certificates, and FSCA history
- Maintain onboarding logs, CAPA records, and regulatory checklists

7. Triggered Event Management

- Respond to Field Safety Corrective Actions (FSCAs), recalls, urgent labeling updates, or regulatory holds
- Coordinate documentation, traceability, and health authority notifications in partnership with QARA

8. Study Enablement & Milestone Integration

- Plan logistics milestones alongside study timelines
- Track readiness for deployment by country, site, and patient kit
- Feed logistics status into centralized PMO dashboards and readiness trackers

9. Operational SOPs & Training

- Develop SOPs and quick reference guides for internal teams, sites, and vendors
- Train stakeholders on chain-of-custody, handling procedures, and compliance triggers

Who Benefits from DeviceOps

01 Sponsors

conducting global decentralized or hybrid trials

04 DCT Platforms

requiring country-level readiness and provisioning oversight

02 CROs

managing logistics and regulatory compliance

05 Logistic Providers

Shipping devices to clinical sites and patients

03 MedTech companies

acting as importers or distributors

DeviceOps = Operational Confidence, Global Readiness

With quinta DeviceOps, your devices are not just shipped—they're **validated, traceable, and regulator-ready (compliant)**.

You eliminate the friction that slows down DCTs and replace it with control, transparency, and speed.

Let DeviceOps power your device strategy—so your clinical trial never waits for logistics.



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