



Global Regulatory Enablement for Digital Health Technologies (DHTs) in Decentralized and Hybrid Clinical Trials

Ensuring Ongoing Compliance for Life Sciences Systems

Decentralized and hybrid trials increasingly rely on Digital Health Technologies (DHTs)—including wearables, Software as a Medical Device (SaMD), and Point-of-Care (POC) devices—to collect endpoints, support monitoring, and enable remote participation. However, each device introduces jurisdiction-specific regulatory responsibilities that must be proactively identified, documented, and defended.

qointa DeviceReg is a turnkey regulatory enablement solution that ensures DHTs—regardless of whether they are investigational or non-investigational—are properly classified, justified, and documented for use in clinical research across all global markets.

Why DeviceReg Matters

Even commercially available or consumer-grade DHTs can trigger regulatory oversight when:

- Used to collect endpoint data or safety signals
- Embedded into workflows governed by Good Clinical Practice (GCP)
- Subject to device software updates or geographic expansion

Failure to manage this oversight can lead to:

- IRB or EC rejection
- Inspection findings (e.g., lack of CE/DoC, UDI)
- Regulatory hold, customs delay, or FSCA exposure

DeviceReg prevents these issues by aligning with:

- FDA 21 CFR 812, 820, 11
- EU MDR 2017/745 (Annex VIII, Articles 10, 13–16, 22)
- MDSAP, SOR/98-282 (Canada), UK MDR, PMDA, NMPA
- ISO 13485, ISO 14971, IMDRF SaMD & AI frameworks

Have you validated whether your non-investigational devices need to be classified under EU MDR, FDA, or PMDA—even if they're commercially available?

Can you confidently map the importer, distributor, and manufacturer roles for your devices across the EU, UK, China, and Japan?"

How are you documenting regulatory impact when you change a device, update software, or add a new trial country mid-study?

When firmware or software updates are pushed, do you initiate regulatory impact assessments and change control updates? Are they inspection-ready for ethics boards and authorities?

If a regulator asked you to justify why a consumer device like a smartwatch was appropriate for your primary endpoint, how would you respond?

Have you assessed whether your DHT requires classification under MDR Rule 11, FDA SaMD guidance, or PMDA device registration?

Can you trace the legal manufacturer, importer, distributor, and system producer roles for your DHTs in the EU, UK, Japan, China, and Canada?

Do you have centralized records of UDI, CE/DoC, and risk classification for each device used in your study?"

Risks we mitigate:

Risk

- Misclassification of devices
- Lack of CE/FDA documentation
- Unmapped importer roles
- Device/software updates
- Incomplete audit records

Regulatory Impact

- Ethics board rejection; customs delays
- Non-approval by IRB/EC; failed audits
- EU MDR Article 13 noncompliance
- Requires new validation and RIA
- CAPA-triggering regulatory findings

Our Comprehensive Services

1. Global Regulatory Classification & Documentation

- Classify devices by jurisdiction (EU MDR, FDA, PMDA, NMPA, etc.)
- Prepare CE certificate/510(k)/PMDA listing verifications
- Build risk classification rationale using ISO 14971
- Align documentation with MDR Annex I, GSPR, and labeling/UDI requirements

2. Regulatory Strategy & Submission Support

- Generate statements of non-investigational use for IRBs/ethics boards
- Prepare trial-specific device documentation bundles
- Provide investigational justification support for studies requiring investigational use designation under FDA's IDE process (21 CFR 812) or under MDR Article 62 for clinical investigations, if needed

3. Study-Specific Regulatory Impact Assessments (RIA)

- Analyze impact of device changes, new geographies, or software updates
- Use standardized RIA templates aligned with MDR Article 22, FDA guidance, EU AI Act, etc.
- Score discount/reuse eligibility per validated frameworks (e.g., maintenance or reuse tiers)

4. Economic Operator Role Mapping

- Assign and document economic operator roles (Manufacturer, Importer, Distributor)
- Ensure compliance with EU MDR Articles 13–16
- Support national registrations and IOR documentation (EUDAMED, GUDID, MDALL, NMPA DB)

5. Vendor Qualification & Audit Readiness

- Assess manufacturer and logistics vendor compliance with ISO 13485:2016
- Review FSCA/recall history, complaint logs, and audit trails
- Prepare centralized QARA binders per study—aligned with FDA, EMA, MHRA, PMDA standards

6. Change Control & Version Management

- Review the regulatory impact of device substitutions, software updates, or country expansion
- Maintain version control logs and validation histories
- Participate in study or enterprise-level Change Control Boards (CCBs)

7. Cybersecurity & Data Privacy Oversight

- Verify SaMD or connected device security per ISO 27001/27701, MDR Annex I, and FDA cybersecurity guidance
- Ensure GDPR/CCPA/HIPAA compliance for data collection, processing, and transmission

8. Regulatory Intelligence & Governance

- Monitor evolving regulations (FDA PCCP, EU AI Act, MDCG guidance, IVDR updates)
- Advise sponsors on upcoming compliance risks and policy shifts
- Maintain centralized QMS alignment (ISO 13485, FDA QSR, MDSAP, IMDRF)

01 Regulatory Mastery

We excel in understanding and navigating complex regulatory requirements, ensuring compliance and product approval.

02 Quality Excellence

qointa is committed to helping you maintain the highest standards of quality throughout your operations.

03 Customized Solutions

We tailor our services to your specific needs, ensuring a personalized and effective approach.

04 Global Expertise

Our team has extensive experience in dealing with regulatory standards and compliance across the globe.

05 Holistic Approach

Our services cover every aspect of quality and regulatory support, offering a one-stop solution for your needs.

For Sponsors, CROs, and DCT platforms that want to deploy validated, regulatorily aligned devices across multiple countries—without risking trial delays.

DeviceReg = Regulatory Confidence at Scale

With DeviceReg, sponsors reduce risk, accelerate approvals, and stay audit-ready. From ethics boards to regulators, you have the classification, documentation, and role mapping to defend every DHT in your trial.

Don't let one device derail your trial.

Let DeviceReg build your regulatory foundation, globally.



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