

# The evidence an inspector asks for in a digital trial is contemporaneous: it is generated while the trial runs or not at all.

The standard is written down — 21 CFR Part 11 and FDA's Part 11 Q&A, the EMA computerized-systems guideline, ICH E6(R3) — so a sponsor can build to it before the first request. **QA / GCP compliance owns a readiness pack, scoped in the RIA before enrollment and kept current through the Trigger Register; the sponsor signs it off.**

## THE PICTURE

**The inspection baseline is knowable in advance: six evidence areas, each anchored in a published provision**

| Area                            | What is examined                                                                                     | Grounding                                                     |
|---------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| <b>Audit trail</b>              | Who did what and when, on the device and at the device–system boundary                               | 21 CFR 11.10(e); EMA guideline 6.2.1–6.2.2; Part 11 Q&A Q22   |
| <b>Timestamps</b>               | Time used for windowed assessments; protection against user-settable clocks                          | EMA guideline 5.5; Part 11 Q&A Q14; drift monitoring (qointa) |
| <b>Electronic signature</b>     | Binding of eConsent and other signatures to person and record                                        | 21 CFR 11.50, 11.70; EMA guideline 4.8, Annex 5 A5.3          |
| <b>Validation</b>               | System and specific device configuration validated for their use                                     | EMA guideline Annex 2; ICH E6(R3) 3.9; Part 11 Q&A Q7         |
| <b>Change control</b>           | How app and OS updates during the study were assessed                                                | EMA guideline A2.10; Part 11 Q&A Q7; FDA DHT guidance IV.H.4  |
| <b>Source data &amp; access</b> | FDA: the durable repository, devices not inspected. EU: first permanent record, device-side controls | Part 11 Q&A Q23; EMA guideline 4.4, Annex 3, Annex 5 A5.1     |

The US and EU diverge on the device only. qointa's assessment: design to the EU standard in every trial — the device-side controls the EU expects are what make the US repository record trustworthy.

## QOINTA'S POSITION Four positions: readiness is a property the trial has by inspection day, or does not

### The expectations are written down, not inspector whim

Audit trail, time, signatures, validation and change control are grounded in Regulation (EU) 536/2014, 21 CFR Part 11, ICH E6(R3), the EMA guideline and FDA's Part 11 Q&A. EU GMP Annex 11 is not a GCP instrument.

### Inspectors ask for evidence, not assurances

"We believed it was fine" is the weakest answer; documented assessment and validation are the strongest. Records not kept during the trial cannot be produced on request.

### The first inspection sets a baseline that follows the sponsor

In qointa's experience the level of control demonstrated becomes the de facto standard for the study and for later digital trials. A weak showing is harder to walk back than to meet.

### BYOD does not lower the bar

Sponsor accountability for data reliability and oversight of service providers persists where the participant owns the device (ICH E6(R3) 3.6; EMA guideline Annex 5, A5.1). Recurring findings cluster here.

## SIX DEPLOYMENT FACTS THAT RAISE EXPOSURE — AND HOW THE RIA CLOSES EACH BEFORE THE TRIAL RUNS

- 1 Define the electronic source and the capture-to-repository path** in the RIA; set audit-trail, timestamp and access controls up front.
- 2 Bring BYOD inside the validated perimeter**; record the device / OS range and its assessment.
- 3 Lock device date, time and time zone** (EMA guideline 5.5); use trusted server time; monitor device–server drift; flag user-settable clocks in the Trigger Register.
- 4 Validate the signature-to-identity-to-record binding** for eConsent and retain the binding evidence.
- 5 Log every app or OS update and its assessment** under change control (QPP-07) and the Trigger Register (QPP-08).
- 6 Assemble and index the readiness pack** before any request, and run a mock inspection to test retrieval.

**Read with care.** The recurring findings and the baseline effect reflect qointa's experience, not published inspection statistics. The paper does not predict the outcome of any inspection; practice varies by authority and over time. Not legal advice.

### READ NEXT

QPP-00 Regulatory Impact Assessment · QPP-07 Change Control · QPP-08 Trigger Register · QPP-10 Data Integrity



Summary of QPP-06 1.0 — the full paper, with sources and figures, is published at qointa.com.

21 CFR Part 11 · FDA Part 11 Q&A (Oct 2024) · FDA BIMO process guidance (Dec 2025) · FDA DHT guidance IV.H.4 · EMA/INS/GCP/112288/2023 · ICH E6(R3) incl. Annex 2 (Step 4, 3 June 2026) · Regulation (EU) 536/2014 · MHRA GCP guidance (ALCOA)

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