

Put every regulatory-perimeter determination in a Trigger Register: **one row per condition**, with its status, anchor, evidence and where its consequence lands.

Tacit assessments fail exactly when they are tested — at inspection, at handover and when the configuration changes. **Name an owner in the quality system, seed the register from the RIA, define the review events that re-open it, and file it with its version history in the TMF.**

THE PICTURE Six fields make a determination defensible; without them it is opinion

Field	What it records	Example entry
Condition	The discrete regulatory fact being assessed, in plain terms	App computes a clinical risk score (possible MDSW)
Status	Whether it is met for the present configuration — and for whom	Met — sponsor & eCOA vendor; under review
Anchor	The regulation, guidance or standard the determination rests on	EU MDR Annex VIII Rule 11; MDCG 2019-11 Rev. 1 (June 2025)
Downstream artifact	Where the consequence lands: technical file, validation plan, contract	Technical file §3; validation plan VP-04
Evidence pointer	Where the supporting evidence can be found	RIA-2026-014; classification memo
Last review	When it was last assessed, and by whom	1 Jun 2026 — RA lead (illustrative)

One row per condition. Re-run on review events — protocol amendment, software or OS release, new country, vendor or role change, device substitution — not by the calendar. Entry is illustrative.

QOINTA'S POSITION Four positions that separate a controlled register from a spreadsheet

Explicit beats tacit, and the unit is the condition

Asking “is this phone, wearable or gateway a device?” conceals the multi-perimeter reality. Asking which discrete conditions are met, and recording each with its basis, makes the position auditable.

It is the risk management ICH E6(R3) already requires

The sponsor must identify, evaluate, control, communicate, review and report risks to critical-to-quality factors and document it (Annex 1, s.3.10.1). The register is that record.

A register is a living control; a checklist is filed once

Three governance properties set it apart: owned in the quality system, version-controlled so its history can be produced at inspection, and re-run on defined review events.

It earns its place by where its determinations land

Device consequences go to the technical file, GxP and data-integrity consequences scope the CSV validation plan, and the register itself is filed with its version history in the TMF.

FOUR STEPS, IN ORDER, STAND THE REGISTER UP AS A CONTROLLED INSTRUMENT

- 1 Assign a named owner** in the quality system; for a manufacturer, the person responsible for regulatory compliance (MDR Art. 15).
- 2 Seed it from the RIA** (QPP-00): one row per condition, each with status, anchor, evidence pointer and downstream artifact.
- 3 Make it event-driven** — re-run on amendments, releases, new countries, vendor or role changes and device substitutions.
- 4 Route each determination** to the technical file, validation plan or contract, and file the register with its history in the TMF.

6

fields per row: condition, status, anchor, artifact, evidence, last review

5

review events: amendment, release, new country, vendor change, device swap

3

ways informal tracking fails: not reviewable, not durable, not refreshed

3

destinations for determinations: technical file, validation plan, TMF

Read with care. No regulator prescribes a register by that name; that it is becoming an inspection expectation is qointa's assessment. The field case is an illustrative composite. The paper describes the instrument, not the catalog of conditions.

READ NEXT

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