uncountable

QMS

Close the loop from deviation to CAPA

Deviation, CAPA, change control, and audit trails on the same platform as your R&D and QC data. Built in, not bolted on.

Uncountable's AI end-to-end platform is deployed by

Dow · DuPont · SunChemical a member of the DIC group · Sika · Clariant · Mondelēz International · Beiersdorf

THE OLD WAY

Where quality breaks down

An out-of-spec result kicks off a hunt across systems, and the deviation, CAPA, and audit trail get stitched together after the fact.

Events live apart

Deviations sit in a separate tracker from the data that explains them.

Cross-system hunts

An out-of-spec result means chasing evidence across tools.

Stitched after the fact

The audit trail gets assembled later, by hand.

THE UNCOUNTABLE WAY

One quality system, every module built in

Every module on one governed system, connected to the same data as your R&D and QC.

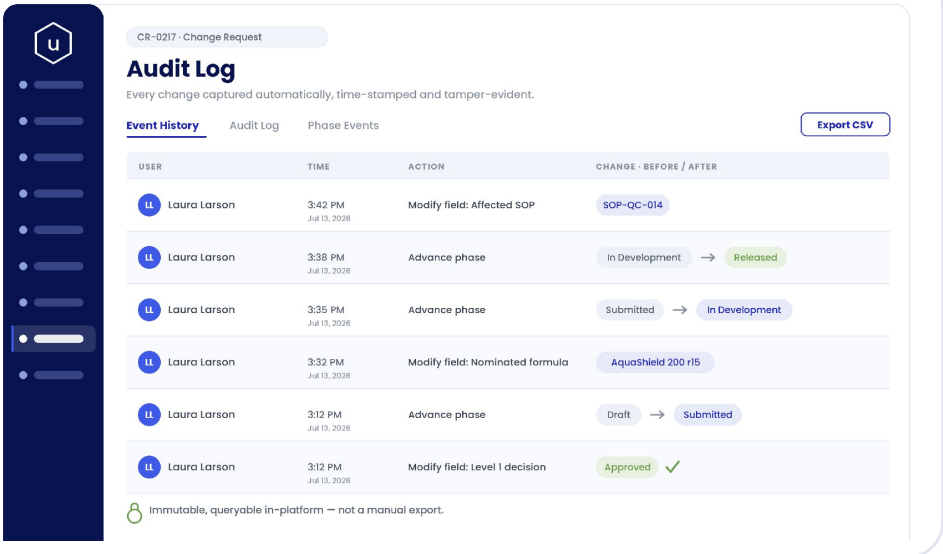
- **Audit** — Findings tracked to closure.
- **Complaint** — Routed straight into investigation.
- **Supplier** — Qualification, criticality, SCARs.
- **Training** — Auto-retrain on SOP change.
- **CAPA** — Root cause to verified fix.
- **Document** — Everyone on the current version.
- **Change** — Impact review, multi-level e-sig.
- **Equipment** — Calibration and maintenance dates.
- **Quality Event** — Fast containment and disposition.
- **Risk** — FMEA, risk matrix, or HACCP.

From out-of-spec to spec change

1. **Out of spec** — clear coat batch fails
2. **Deviation opens** — tied to batch + lot
3. **Root cause + CAPA** — resin lot identified
4. **Spec updated** — supplier incoming spec

One record, from deviation to CAPA

An out-of-spec clear coat batch opens a deviation automatically, and the CAPA updates the supplier's incoming spec, all in one system.



- OOS result opens a deviation automatically
- Tied to the batch record and raw-material lot
- Traced to a high molecular-weight resin lot
- CAPA opens; incoming inspection spec updated
- One system, no document hunt, no re-entry

The difference, Side by Side

Before Uncountable

- ✕ Quality events live apart from the data
- ✕ CAPA and change control on separate trackers
- ✕ Manual, night-before audit prep
- ✕ OOS handled separately from deviations
- ✕ Each site runs its own quality process

With Uncountable

- ✓ Every event linked to formulation, batch, and test
- ✓ CAPA, change control, and docs in one system
- ✓ Automatic audit trails and e-signatures (21 CFR Part 11)
- ✓ An OOS result can auto-generate a deviation
- ✓ Global harmonization, governed site variation

FDA 21 CFR PART 11 · EU ANNEX 11 · SOC 2 TYPE II · ISO 27001 · GxP · HIPAA · GDPR

The CAPA executes the spec change.
One action, one system, zero handoffs.

See it on your own data

Book a personalized demo and we'll show you how Uncountable applies to your lab.

uncountable®