

A Validated Platform, Every Quarter

Uncountable ships a complete vendor validation kit with every quarterly release, so regulated teams inherit the evidence, not the effort. A GAMP 5 Category 4 ELN/LIMS, aligned to 21 CFR Part 11 and EU GMP Annex 11.

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



GxP at a Glance



GAMP 5 Category 4

A configurable ELN/LIMS, validated out of the box by the vendor, with clear scope and exclusions.



Standards it aligns to

21 CFR Part 11, EU GMP Annex 11, and GAMP 5, informed by ICH Q9 (R1) and the FDA CSA draft guidance.



ALCOA+ data integrity

Attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, available.



Single-tenant AWS

A dedicated environment (us-west-2 or eu-central-1), with separate DEV, TEST, and PROD.



Quarterly validated releases

Feb, May, Aug, and Nov, each with an updated kit. You control release timing on single-tenant.



Independently audited

The validation kit is reviewed by an independent GxP auditor and aligns with common industry standards.

The Validation Kit: Shipped With Every Release

Our pre-executed OQ evidence feeds your IQ/PQ, so your team validates its own configurations, not the platform.

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| ✓ Validation Master Plan (VMP) | ✓ Requirements Traceability Matrix (RTM) |
| ✓ User & Functional Requirements (URS / FRS) | ✓ 21 CFR Part 11 actual results |
| ✓ FMEA risk assessment (RPN scoring) | ✓ EU Annex 11 actual results |
| ✓ Pre-executed, signed OQ test evidence | ✓ Validation Release Certificate |

Sharing Responsibility, the GAMP 5 Way

The vendor validation kit reduces your validation effort.

Uncountable

- Installation & Operational Qualification (IQ/OQ)
- Quarterly validation kit release
- 21 CFR Part 11 & Annex 11 compliance docs
- FMEA, RTM, and URS / FRS documentation
- Out-of-the-box change & release management
- AWS infrastructure security & backup
- Validation Release Certificate per release

Your team

- Review & leverage the vendor validation kit
- Validate your own configurations
- Validate custom integrations (API, LIMS, ERP)
- Performance Qualification / UAT
- User management & audit-trail review
- Periodic re-validation assessment
- Final acceptance & release for use

A stable, auditable baseline every quarter



Four validated releases a year, on Feb 1, May 1, Aug 1, and Nov 1. Each one arrives with a refreshed validation kit and a GxP impact assessment, so your validated state stays current

What Auditors Ask: Inspection-Ready by Design

Can you show every change to this record?



A complete audit trail captures user, timestamp, and before/after values automatically, time-stamped and tamper-evident.

Who approved this, and when?



Electronic signatures bind each approval to the user and the record, with full history retained.

How do you know access was controlled?



Role-based access with SSO and MFA, plus periodic access reviews, all logged.

Inherit the evidence, not the effort.



See It on Your Own Data

Book a walkthrough and we'll show you the full validation kit.

