

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21 CFR Part 11, EU GMP Annex 11, and GAMP 5, informed by ICH Q9 (R1) and the FDA CSA draft guidance.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



### Audit management

Walk-the-lab checklists; findings tracked to closure.

## 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.

- |                                              |                                          |
|----------------------------------------------|------------------------------------------|
| ✓ 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 what Uncountable can do in your workflow.

