LIMS FOR PHARMACEUTICAL QC LABS

Laboratory Information Management System (LIMS)

The QC lab's work in one module, from sample registration to the Certificate of Analysis — every result calculated by the system, checked against its limits as it is entered, and approved by electronic signature.

OVERVIEW

GAMP LIMS keeps that work in one system. Each result is calculated by the system and checked against its approved limit as it is entered, and recorded with the analyst, instrument and standard behind it.

WHY TEAMS CHOOSE GAMP LIMS

Every sample, tested to the approved version

Samples are registered and labelled at receipt and followed through to retention, and each one is tested against the specification and test procedure currently approved.

Checked the moment it is entered

Analysts work in electronic worksheets where the system does the arithmetic. Each result is compared with its limit at entry, so an OOS or OOT result is flagged before anyone moves on.

Reviewed with the full context

A second person approves the results by electronic signature, with the instrument, reagent and standard behind each test already on the record. The Certificate of Analysis is generated from the approved results.

The work that runs for days, or years

Stability studies run for years and microbiology plates wait days in the incubator. Both are scheduled in the system, with an alert before a pull or a read-out falls due.

WHAT IT COVERS

- ✓ Samples, from receipt to retention
- ✓ Analysis, results and review
- ✓ Stability studies
- ✓ Microbiology
- ✓ Specifications and test procedures
- ✓ Certificates of Analysis
- ✓ Instruments, reagents and standards

CAPABILITIES

- ✓ Sample registration, barcode labels and chain of custody, from receipt to retention
- ✓ Specifications and standard test procedures under version control
- ✓ Electronic worksheets, with calculations done by the system and formulas locked
- ✓ Results checked against specification limits as they are entered, with OOS and OOT flagged
- ✓ Second-person review, approval by electronic signature and the Certificate of Analysis
- ✓ Instruments, reagents and standards checked for calibration and expiry, and recorded against each test
- ✓ Stability protocols with pull schedules and due-date alerts
- ✓ Microbiology media, incubations and plate counts, with read-out reminders

ON THE LABONE PLATFORM

- Single sign-on across modules, managed through one administration layer
- Active Directory integration
- Audit trail, electronic signatures and role-based access
- Cloud, on-premises or hybrid deployment
- Built for 21 CFR Part 11 and EU Annex 11