



Pharmaceutical Laboratory Information Management System (LIMS) Audit Checklist 2026

System Administration and User Access Control

Verification of user roles, permission levels, password complexity requirements, and audit trail of administrative changes to ensure data integrity and security.

Audit Date

Auditor Name

System Access Level Audited

- ☐ Administrator
- ☐ Super User
- ☐ Laboratory Technician
- ☐ Quality Assurance Reviewer
- ☐ Read-Only User

Access Control Checks Performed

- ☐ Password Complexity Verification
- ☐ User Role/Permission Review
- ☐ Inactive Account Deactivation Check
- ☐ Unauthorized Access Attempt Review
- ☐ Segregation of Duties Verification

Observations and Discrepancies

Write something...

User Access List Evidence

 Upload File

Auditor Signature

Data Integrity and Audit Trail Review

Evaluation of the system's ability to capture time-stamped, unalterable records of all entries, modifications, and deletions in compliance with ALCOA+ principles.

Audit Trail Review Frequency

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ Per Batch/Lot

Audit Trail Verification Parameters

- ☐ User ID Identification
- ☐ Timestamp Accuracy
- ☐ Old Value vs New Value Comparison
- ☐ Reason for Change Documentation
- ☐ Data Deletion Attempts

Date of Audit Trail Review

Enter date...

Discrepancies or Anomalies Identified

Write something...

Supporting Audit Log Export

 Upload File

Auditor Verification Signature

Configuration Management and Validation

Assessment of the software installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) protocols and their alignment with 2026 regulatory standards.

Last Validation Date

Enter date...

Validation Status

- ☐ Validated
- ☐ In-Progress
- ☐ Failed
- ☐ Out of Date

Summary of Configuration Changes

Write something...

Upload IQ/OQ/PQ Documentation

 Upload File

Verified Parameters

- ☐ User Access Rights
- ☐ Workflow Logic
- ☐ Data Fields/Metadata
- ☐ Reporting Templates
- ☐ Audit Trail Configuration

Validator Signature

Sample Lifecycle Management

Audit of the end-to-end workflow including sample login, labeling, tracking, testing progress, and final result recording/disposition.

Sample Collection Date

Sample Identification/ID Number

Sample Type

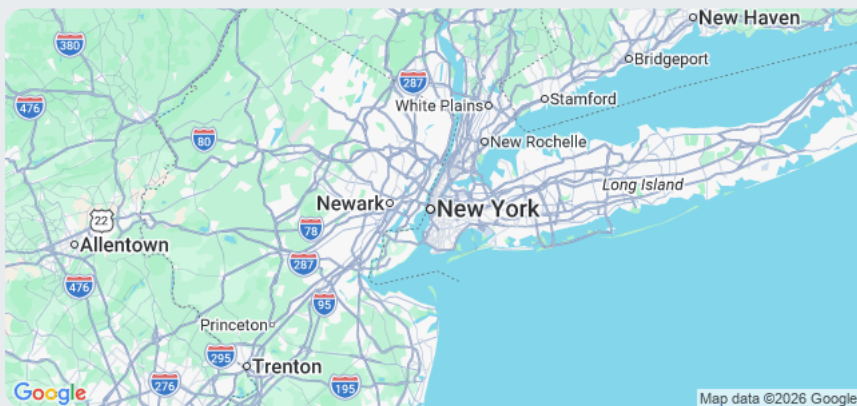
- ☐ Raw Material
- ☐ In-Process
- ☐ Finished Product
- ☐ Stability Sample

Required Testing Parameters

- ☐ pH Testing
- ☐ Dissolution
- ☐ Assay
- ☐ Impurity Profile
- ☐ Microbial Limit Test

Storage Location/Reference

 [Set My Current Location](#)



Initial Lab Notebook Entry/Scan

 [Upload File](#)

Analyst Verification Signature

Instrument Integration and Interoperability

Verification of seamless data transfer from laboratory instruments to the LIMS to prevent manual transcription errors and ensure automated data capture.

Instrument Connection Type

- ☐ Direct Interface (Automated)
- ☐ Manual Data Entry (LIMS Input)
- ☐ CSV/File Import
- ☐ Middleware Integration

Instrument ID/Asset Number

Data Transfer Methods Verified

- ☐ Auto-parsing of raw data
- ☐ Electronic signature capture
- ☐ Real-time status updates
- ☐ Error/Alert notification

Last Integration Testing Date

Enter date...

Interface Validation Protocol/Report



Upload File

Auditor Verification Signature

Reporting and Analytical Output

Review of the accuracy and reliability of automated certificates of analysis (CoA), stability reports, and management dashboards.

Report Type Audited

- ☐ Certificate of Analysis (CoA)
- ☐ Stability Summary Report
- ☐ Audit Trail Summary
- ☐ Inventory/Reagent Report

Verified Data Attributes

- ☐ Time-stamps
- ☐ User Identities
- ☐ Calculated Results
- ☐ Unit of Measure
- ☐ Approval Status

Report Generation Date

Enter date...

Report Reference Number

Write something...

Discrepancies Identified in Output

Write something...

Upload Sample Report for Review

 Upload File

Auditor Verification Signature

Backup, Recovery, and Disaster Management

Validation of data backup frequency, storage security, and the effectiveness of data restoration procedures in the event of system failure.

Last Backup Completion Date

Enter date...

Backup Frequency Compliance

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ As Required

Backup Storage Locations

- ☐ On-site Server
- ☐ Off-site Cloud Storage
- ☐ Secondary Data Center
- ☐ Encrypted Physical Media

Disaster Recovery Test Summary

Write something...

Backup Logs and Verification Report

 Upload File

Auditor Verification Signature

System Maintenance and Change Control

Review of documented procedures for software updates, patches, and any structural changes made to the LIMS configuration during the 2026 period.

Date of Change Implementation

Change Control Reference ID

Description of System Update or Patch

Impact Level of Change

- ☐ Minor
- ☐ Major
- ☐ Critical

Components Affected

- ☐ Database
- ☐ User Interface
- ☐ Instrument Interface
- ☐ Report Templates
- ☐ Security Permissions

Supporting Validation/Testing Documentation

 **Upload File**

Quality Assurance Approval Signature

Compliance with 21 CFR Part 11 and Annex 11

Specific audit of electronic signature authenticity, record retention policies, and compliance with global regulatory electronic record requirements.

Electronic Signature Verification Status

- ☐ Compliant
- ☐ Non-Compliant
- ☐ Not Applicable

Audit Trail Review Components

- ☐ User ID
- ☐ Timestamp
- ☐ Original Value
- ☐ New Value
- ☐ Reason for Change

Last Audit Trail Review Date

Enter date...

Description of Identified Discrepancies

Write something...

Evidence of Electronic Signature Validation Report

 Upload File

Auditor Authentication

User Training and Operational SOPs

Assessment of training records for all LIMS users and the availability of up-to-date Standard Operating Procedures (SOPs) governing system usage.

Last Training Session Date

Enter date...

Training Completion Status

- ☐ Completed
- ☐ In Progress
- ☐ Not Started
- ☐ Overdue

Training Modules Covered

- ☐ System Administration
- ☐ Sample Entry & Logging
- ☐ Data Analysis & Reporting
- ☐ Audit Trail Review
- ☐ Incident Management

Training Evidence/Certificate Upload

 Upload File

Training Gap Analysis & Corrective Actions

Write something...

Auditor Verification Signature

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✔ Finish

✎ Generate Sample Report