PHARMATRAK UK LTD
AUDIT | COMPLIANCE | ASSURANCE

Supplier Audit Readiness Checklist

A practical self-assessment for API manufacturers and suppliers preparing for customer or third-party audits. Use it to review key areas before the audit date and to record where further action is needed.

1. Review the Audit Scope and Requirements

- ☐ The audit date, duration, agenda, and audit team.
- ☐ The API, manufacturing site, and activities included in the scope.
- ☐ The applicable GMP standards and customer-specific requirements.
- ☐ The departments, systems, and personnel likely to be involved.
- ☐ Any documents or records requested before the audit.
- ☐ The status of findings from previous customer or third-party audits.

2. Documentation and Record Readiness

- ☐ Site master file and relevant facility information.
- ☐ Standard operating procedures (SOPs).
- ☐ Batch manufacturing and packaging records, where applicable.
- ☐ Raw-material receipt, sampling, testing, and release records.
- ☐ Specifications, analytical methods, and certificates of analysis.
- ☐ Deviation investigations, CAPAs, and change-control records.
- ☐ Equipment qualification, calibration, and maintenance records.
- ☐ Cleaning records and cleaning-validation documentation, where applicable.
- ☐ Training records and personnel qualification evidence.
- ☐ Relevant validation, stability, and process-monitoring records.

3. Personnel Readiness and Training

- ☐ Confirm that required GMP and job-specific training is current.
- ☐ Review responsibilities for critical manufacturing and laboratory activities.
- ☐ Ensure relevant personnel are available for their assigned sessions.
- ☐ Explain the audit process and how documents and questions will be handled.
- ☐ Remind staff to answer honestly and within their area of knowledge.

4. Manufacturing Controls and Facility Readiness

- ☐ Material identification, status labelling, and traceability.
- ☐ Weighing, dispensing, and material handling controls.
- ☐ Equipment status, cleaning, maintenance, and calibration.
- ☐ Process parameters and in-process controls.
- ☐ Prevention of contamination and cross-contamination.
- ☐ Environmental and utility controls where relevant.
- ☐ Equipment and facility qualification status.
- ☐ Deviation handling and response to unexpected process results.
- ☐ Storage conditions and material segregation.

5. Laboratory Systems and Analytical Controls

- ☐ Approved specifications and analytical methods are available.
- ☐ Instruments are qualified or calibrated as required.
- ☐ Analysts are appropriately trained.
- ☐ Reference standards and reagents are controlled.
- ☐ Raw data and calculations are complete and traceable.
- ☐ Out-of-specification (OOS) and out-of-trend (OOT) results are investigated appropriately.
- ☐ Laboratory deviations and invalidated results have documented justifications.
- ☐ Data review and approval procedures are followed.
- ☐ Electronic laboratory systems have appropriate access and control mechanisms.

6. Data Integrity and Electronic Records

- ☐ Individual user accounts and role-based access.
- ☐ Audit-trail availability and review, where applicable.
- ☐ Electronic signatures and record controls.
- ☐ Backup, retention, and retrieval arrangements.
- ☐ Management of shared accounts and administrator privileges.
- ☐ Controls over spreadsheets and other tools used for GMP-related calculations.
- ☐ Procedures for recording, correcting, reviewing, and retaining data.
- ☐ The handling of missing, repeated, amended, or invalidated results.

7. Quality Management System Effectiveness

- [ ] Deviation and nonconformance management.
- [ ] Root-cause analysis and CAPA.
- [ ] Change control.
- [ ] Complaint and quality-defect handling, where applicable.
- [ ] Internal audits and management review.
- [ ] Supplier qualification and monitoring.
- [ ] Product quality review or other applicable periodic quality assessments.
- [ ] Training and continuous improvement.
- [ ] Escalation of significant quality risks.

8. Prepare an Audit Room and Document Retrieval Process

- [ ] Assign a coordinator to manage the agenda and requests.
- [ ] Identify subject-matter experts for each department.
- [ ] Establish controlled access to requested documents and records.
- [ ] Ensure documents are provided in their approved versions.
- [ ] Track each request and its response status.
- [ ] Record questions that require further investigation.
- [ ] Agree on a process for documenting and clarifying observations.

9. How to Handle Audit Findings

- [ ] Clarifying the observation and the evidence supporting it.
- [ ] Identifying the applicable procedure or requirement.
- [ ] Recording the issue through the appropriate process.
- [ ] Assessing the potential impact on product quality, patient safety, and compliance.
- [ ] Conducting a proportionate investigation and root-cause analysis.
- [ ] Defining corrective and preventive actions where required.
- [ ] Providing evidence of implementation and effectiveness as appropriate.

10. Final Pre-Audit Checklist

- ☐ Audit scope, agenda, and responsibilities are confirmed.
- ☐ Requested documents and relevant records are available.
- ☐ Previous audit findings and CAPA status have been reviewed.
- ☐ Personnel training and subject-matter expert availability are confirmed.
- ☐ Manufacturing, laboratory, and storage practices align with approved procedures.
- ☐ Equipment, qualification, calibration, and maintenance records are current as required.
- ☐ Data integrity controls and electronic records have been reviewed.
- ☐ Deviations, changes, and CAPAs are appropriately documented.
- ☐ Document retrieval and audit coordination arrangements are in place.
- ☐ Potential gaps have been assessed and managed through the quality system.

This checklist is for general guidance and does not guarantee a successful audit or inspection. Audit scope and expectations vary according to the applicable GMP requirements, the customer and the products involved. PharmaTrak provides independent, evidence-based GxP audits. Visit pharmatrakuk.com to discuss your audit requirements.