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CAP INSPECTION READINESS TOOLKIT

Tools and templates to help your laboratory respond effectively to CAP inspection findings.

- READINESS CHECKLIST
- 90-DAY PREPARATION TIMELINE
- DOCUMENT REVIEW CHECKLIST
- STAFF READINESS CHECKLIST

ALP CAP Inspection Readiness Toolkit

Practical guide for preparing teams, records, and sites for inspection readiness

AUDIT READY | COMPLIANCE TOOLKIT | QUALITY SYSTEM

ABOUT THIS TOOLKIT

This toolkit is designed to equip ALP CAP teams with structured, practical resources to achieve and sustain inspection readiness at all times. It covers the full inspection lifecycle, from pre-inspection preparation through to post-inspection CAPA closure, ensuring every team member understands their role and responsibilities.

- Framework and Pillars
- Checklists and Playbooks
- CAPA and Quick Tools

SECTION 01

Purpose and Scope

What is Inspection Readiness?

Inspection readiness is an ongoing state of preparedness ensuring compliance with regulatory and quality standards at any time, not just during audits. It reflects a continuous quality culture rather than a reactive response.

Who Should Use This Toolkit?

This toolkit is designed for all personnel involved in ALP CAP operations, including:

- **Leadership & Directors:** Responsible for governance and accountability
- **Quality & Compliance:** Managing documentation and audit trails
- **Managers & Supervisors:** Overseeing day-to-day operational controls
- **Frontline Staff:** Executing procedures and maintaining records

Key Objectives

Establish Readiness Culture
Embed inspection readiness as a daily habit, not a reactive exercise.

Strengthen Documentation
Keep records, SOPs, and evidence current and rapidly retrievable.

Build Team Competency
Ensure staff are trained, qualified, and confident in their roles.

Drive Continuous Improvement
Use self-assessments and CAPAs to proactively close gaps.

EXPECTED OUTCOMES

Teams applying this toolkit will ensure consistent compliance, minimize findings, host audits with confidence, and sustain a verifiable quality record.

SECTION 02

Inspection Readiness Framework

The ALP CAP Readiness Framework is built on five core pillars. Each pillar represents a critical dimension of compliance that must be maintained continuously.

01 Governance and Accountability

Leadership ownership of quality and compliance outcomes

Clear ownership structures, defined escalation pathways, and monthly governance reviews ensure accountability.

02 Documentation and Records

Complete, current, and retrievable records at all times

All SOPs, batch records, and audit trails are maintained in controlled systems for rapid retrieval.

03 Training and Competency

Verified skills and current qualifications across all roles

Training records and competency assessments are documented to ensure staff operate within qualified scope.

04 Site and Operational Controls

Physical environment, equipment, and process integrity

Sites are maintained to GMP and GCP standards with calibrated equipment and organized workspaces.

05 CAPA and Follow-Up Discipline

Systematic closure of findings and prevention of recurrence

Corrective and preventive actions are documented, tracked, and verified monthly to prevent recurrence.

SECTION 04

Pre-Inspection Checklist

Complete this checklist 4 weeks before a scheduled inspection and use it as a rolling readiness verification tool throughout the year.

Documents and SOPs

- SOPs reviewed and approved within 2 years
- Master document list is current and accessible
- Obsolete documents archived or removed
- Document control log is fully up to date
- Version history maintained for key files
- Regulatory submissions and approvals filed

Training Records

- Training matrix complete for active staff
- No overdue training for any team member
- Competency assessments signed and dated
- New staff onboarding records complete
- Annual refresher training documented
- Role-specific qualifications verified

Deviations and CAPAs

- Open deviations have owners and timelines
- No overdue CAPAs in the tracking system
- Effectiveness checks completed for CAPAs
- Deviation trends analyzed quarterly
- Root cause documentation is complete
- Repeat deviations have escalated actions

Equipment and Facilities

- Calibration current for all instruments
- Preventive maintenance up to date
- Equipment qualifications available
- Out-of-service units clearly labelled
- Environmental monitoring complete
- Housekeeping logs signed and current

Evidence Preparation

- Inspection binder prepared with key files
- Subject matter experts briefed on roles
- Mock inspection done within 6 weeks
- Inspection room set up with access
- Record retrieval process tested and timed
- Communication tree and contacts ready

READINESS STATUS

Score each category: Green (ready), Amber (1-2 gaps), or Red (3+ gaps). Red requires immediate escalation to Quality leadership.

Ready | Gaps | Critical

SECTION 05

During-Inspection Playbook

How to host inspectors professionally, manage requests, and maintain control throughout the inspection process.

Hosting Inspectors

Greet inspectors with the Quality lead and site director. Provide a brief opening meeting under 30 minutes covering site overview and logistics. Assign a dedicated escort for each inspector at all times. Ensure a quiet, well-equipped room is available with water and Wi-Fi access.

Answering Questions and Retrieving Records

Answer questions directly and concisely. If you do not know the answer, say so and commit to a specific retrieval time. Log all record requests immediately. Retrieve requested documents within 30 minutes. Never provide unreviewed or draft documents.

DO

- Remain calm and professional
- Answer concisely and directly
- Log every request immediately
- Escort inspectors at all times
- Escalate concerns to Quality lead
- Conduct daily team debriefs

DO NOT

- Speculate or guess on answers
- Provide unreviewed documents
- Allow unescorted roaming
- Make unlogged verbal promises
- Discuss findings with staff
- Argue with inspector observations

Escalation Protocol

1	2	3
Escalate flags & concern to Quality lead within 5 minutes	Quality lead assesses and notifies site director	Leadership resolves and documents in real time

SECTION 06

Post-Inspection Response and CAPA

Structured actions during the first 24–72 hours following inspection closure, combined with a disciplined Corrective and Preventive Action (CAPA) process to address all findings.

Immediate Actions (Within 24 Hours)

STEP 1
Close-Out Meeting
Debrief with Quality lead and site director to review observations.

STEP 2
Document Findings
Log every observation and commitment in the Finding Register.

STEP 3
Notify Stakeholders
Inform senior leadership of outcomes within 24 hours.

CAPA Process for Inspection Findings

Finding Priority	Response Timeline	Owner	Verification Method
Critical	Within 15 days	Quality Director	Independent audit re-check
Major	Within 15 days	Site Quality Manager	Quality review and sign-off
Minor	Within 30 days	Department Lead	Manager verification

Communication and Closure

Submit formal CAPA responses within 15 to 30 days. Include root cause analysis, corrective actions, and implementation evidence. Track all commitments in the CAPA register and report progress during monthly reviews.

EFFECTIVENESS VERIFICATION
Verify closed CAPAs 60 to 90 days post-implementation to ensure the root cause is eliminated. Failed checks must be re-escalated.

SECTION 07

Quick-Reference Tools

Readiness Scorecard

Pillar	Score (1-5)	Status
Governance	___	___
Documentation	___	___
Training	___	___
Site Controls	___	___
CAPA Discipline	___	___

Score 1 for critical gaps to 5 for fully ready. Target score of 4 or higher for all pillars before inspection.

Critical Evidence to Maintain

- SOP list and training matrix
- CAPA and deviation registers
- Calibration and maintenance logs
- Internal audit reports
- Regulatory correspondence
- Environmental monitoring logs
- Governance meeting minutes
- Change control approvals

Meeting Cadence

WEEKLY QA status huddle

MONTHLY Governance review

QUARTERLY Mock inspection

ANNUALLY Full assessment

Key Contacts During Inspection

Quality Director: First escalation

Site Director: Executive decisions

Compliance Lead: Regulatory queries

Legal Counsel: Formal notices

Maintaining Continuous Readiness

Inspection readiness is a permanent operational discipline. Use this toolkit as a living reference, update it continuously, and embed quality habits into daily routines. Always ready means never caught off guard.

CLOSING - CALL TO ACTION

Let's Build a Stronger Laboratory Together

At Accreditation Lab Partners, we believe the best inspections are the result of strong quality systems, not last-minute preparation. Whether your goal is achieving CAP accreditation, strengthening CLIA compliance, improving operational performance, or building a culture of continuous quality improvement, our team is ready to help.

Contact Accreditation Lab Partners

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