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MDM
LAB CONSULTING

CAP & CLIA INSPECTION PREP

A PRACTICAL GUIDE TO PASSING YOUR NEXT INSPECTION WITH CONFIDENCE

Helping laboratories build inspection-ready quality systems.

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BONUS RESOURCE

01 WHY LABORATORIES FAIL INSPECTIONS

Most inspection deficiencies are not caused by a lack of knowledge — they're caused by breakdowns in processes, documentation, and consistency.

Inspectors are not looking for perfect laboratories; they are looking for evidence that your laboratory follows its own procedures every day.

COMMON ROOT CAUSES:

- Poor documentation practices
- Incomplete records
- Lack of staff training or competency
- Inconsistent quality management
- Waiting until the last minute to prepare

02 UNDERSTANDING WHAT INSPECTORS ARE LOOKING FOR

CAP and CLIA inspections focus on whether your laboratory is following regulations and standards that ensure accurate, reliable, and patient-safe testing.

Inspectors evaluate both your written procedures and the evidence that these procedures are consistently followed.

> If it is not documented, it did not happen.

- **COMPLIANCE** WITH REGULATIONS
- **DOCUMENTATION** AND RECORDS
- **STAFF COMPETENCY** AND TRAINING
- **QUALITY MANAGEMENT SYSTEM**
- **EQUIPMENT** AND FACILITIES
- **PATIENT SAFETY** AND RISK MANAGEMENT

03 THE INSPECTION READINESS MINDSET

Inspection readiness is not an event — it's a habit. Laboratories that are always ready for an inspection have systems that support quality every day.

KEY PRINCIPLES

- ✓ Maintain organized, complete documentation
- ✓ Train and empower your team
- ✓ Monitor quality indicators regularly
- ✓ Address issues early
- ✓ Continuously improve your processes
- ✓ Prepare all year, not just before an inspection

04 ESSENTIAL DOCUMENTS EVERY LABORATORY SHOULD HAVE

Inspectors will review documents to verify that your laboratory has established processes and is following them.

SOPs	Validation Plans & Reports	Training Records
Competency Assessments	Quality Control Records	Proficiency Testing Records
Equipment Maintenance	Temperature Logs	CAPA Records
Internal Audit Reports	Risk Assessments	Policy & Procedure Approvals

05 PREPARING YOUR TEAM

Your team is your greatest asset during an inspection. Inspectors will speak with staff to understand how work is performed daily.

Make sure your team is confident, informed, and prepared.

FOCUS AREAS

- ✓ Ensure staff understand their roles
- ✓ Review key procedures and processes
- ✓ Conduct mock interviews
- ✓ Verify competencies are current
- ✓ Encourage open communication
- ✓ Provide feedback and reinforcement

06 THE INSPECTION DAY CHECKLIST

A well-prepared day sets the tone for a successful inspection.

BEFORE INSPECTORS ARRIVE

- ☐ Conference room ready
- ☐ Essential documents organized
- ☐ Staff informed of roles
- ☐ QC results reviewed
- ☐ Equipment functioning
- ☐ Leadership point of contact assigned

DURING THE INSPECTION

- ☐ Be honest and professional
- ☐ Provide requested information
- ☐ Do not guess—find the answer
- ☐ Take notes
- ☐ Escalate issues if needed

AFTER THE INSPECTORS LEAVE

- ☐ Thank the inspectors
- ☐ Debrief with your team
- ☐ Review any concerns or comments
- ☐ Create an action plan if needed

07 COMMON DEFICIENCIES (AND HOW TO PREVENT THEM)

Many deficiencies are preventable with attention to detail and strong quality practices.

COMMON DEFICIENCY	HOW TO PREVENT IT
Missing signatures	Review and sign all records in real time
Outdated SOPs	Review SOPs annually and update as needed
Incomplete competencies	Track and complete competencies on time
Validation gaps	Follow a documented validation plan
Missing maintenance docs	Keep maintenance current and documented
Temperature excursions	Monitor daily and document all excursions
Poor document control	Use version control and approval tracking
Incomplete QC review	Review QC daily and document findings

08 BUILDING A SUSTAINABLE QUALITY SYSTEM

A strong quality system reduces risk and supports long-term success.

INTERNAL AUDITS
Identify gaps and drive improvement

KEY PERFORMANCE INDICATORS (KPIs)
Track what matters

QUALITY INDICATORS
Monitor performance and trends

MANAGEMENT REVIEW
Ensure leadership oversight

CONTINUOUS IMPROVEMENT
Build a culture of quality

09 INSPECTION READINESS CHECKLIST

Use this checklist to perform a quick self-assessment.

- ☐ Documentation
- ☐ Personnel
- ☐ Equipment
- ☐ Validation
- ☐ Quality Control
- ☐ Proficiency Testing
- ☐ Safety
- ☐ Facilities
- ☐ Corrective Actions
- ☐ Management Review

If you can confidently check all boxes, you are on the right track!

10 NEXT STEPS

Inspection preparedness doesn't have to be overwhelming.

With the right support, your laboratory can build a strong quality system and face inspections with confidence.

If your laboratory is preparing for a CAP or CLIA inspection—or simply wants confidence that your quality system is inspection-ready—MDM Lab Consulting provides practical support tailored to your workflow.

From document reviews to mock inspections and quality system development, we're here to help your team succeed.