



MLKC CONSULTING, LLC

Life Science Quality and Regulatory Experts

FDA Compliance Pitfalls Checklist

This checklist highlights common FDA compliance pitfalls and provides steps to avoid them. By addressing these risks proactively, companies can reduce regulatory violations and maintain FDA compliance.

Use this checklist to:

- Identify and correct common FDA compliance issues
- Improve documentation practices and regulatory adherence
- Strengthen supplier qualification and raw material testing
- Implement robust CAPA and internal audit programs
- Train employees on FDA expectations and compliance best practices

1. Documentation & Record-Keeping

- Ensure batch records, CAPA reports, and complaint logs are complete.
- Follow Good Documentation Practices (GDPs) to maintain data accuracy.
- Use electronic record-keeping systems that comply with FDA 21 CFR Part 11.

2. Supplier Qualification & Raw Material Testing

- Verify suppliers are GMP-compliant before purchasing raw materials.
- Require Certificates of Analysis (CoA) for all raw materials.
- Test each batch for contamination, potency, and identity.

3. Corrective and Preventive Action (CAPA) System

- Conduct root cause analysis (RCA) for all quality issues.
- Implement corrective actions that address the underlying problem.
- Follow up on CAPAs to verify effectiveness and prevent recurrence.

4. Internal Audits & FDA Readiness

- Conduct internal audits at least every 6-12 months.
- Simulate FDA inspections with mock audits to identify compliance gaps.

- Ensure all audit findings result in corrective actions and follow-ups.

5. Employee Training on FDA Regulations

- Provide annual GMP, GDP, and FDA compliance training.
- Maintain detailed training logs for regulatory inspections.
- Ensure employees know how to properly respond to FDA inspector questions.

6. Data Integrity & Electronic Record Compliance

- Ensure electronic systems comply with FDA 21 CFR Part 11.
- Use unique login credentials for all employees (no shared accounts).
- Maintain tamper-proof audit trails for all electronic records.

7. Complaint Handling & Adverse Event Reporting

- Document and investigate all customer complaints.
- Submit FDA-mandated Adverse Event Reports (AERs) when necessary.
- Analyze complaint trends to identify potential product quality issues.

8. Labeling & Marketing Compliance

- Ensure product labeling complies with FDA regulations (21 CFR 101, 201, 801, etc.).
- Do not make unsubstantiated health claims in marketing materials.
- Verify that labeling matches the approved product formulation.

Pro Tip: How to Stay FDA Compliant

- * Maintain a proactive compliance program with routine self-audits.
- * Ensure employees are trained in FDA expectations and compliance protocols.
- * Keep supplier and raw material testing records up to date.
- * Stay informed on FDA regulatory changes and enforcement trends.

Need Expert Support for FDA Compliance?

MLKC Consulting, LLC specializes in FDA compliance audits, training, CAPA development, and regulatory assessments. Contact us for expert guidance!

Contact us today for a Consultation!

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