



MLKC CONSULTING, LLC

Life Science Quality and Regulatory Experts

Data Integrity Compliance Checklist

This checklist outlines best practices for ensuring data integrity in FDA-regulated industries. Maintaining accurate, reliable, and traceable data is essential for regulatory compliance and product quality.

Use this checklist to:

- Ensure compliance with FDA data integrity regulations
- Implement ALCOA+ principles for accurate and secure data
- Validate electronic record systems and enforce access controls
- Train employees on Good Documentation Practices (GDPs)
- Conduct routine audits to identify and correct compliance risks

1. Implement ALCOA+ Principles

- Ensure data is Attributable, Legible, Contemporaneous, Original, and Accurate.
- Ensure data is Complete, Consistent, Enduring, and Available.
- Train employees to follow ALCOA+ principles in documentation and electronic records.

2. Validate Electronic Record Systems

- Ensure compliance with FDA 21 CFR Part 11 for electronic records and signatures.
- Implement audit trails that track all changes and modifications.
- Perform system validation and security testing for data protection.

3. Train Employees on Data Integrity & GDPs

- Provide annual training on Good Documentation Practices (GDPs).
- Ensure employees understand how to properly document manufacturing and quality control data.
- Conduct knowledge checks and refresher training sessions.

4. Establish Role-Based Access & Security Controls

- Restrict access to electronic records based on user roles.
- Require unique logins and multi-factor authentication for sensitive data.

- Monitor system access logs for unauthorized changes.

5. Implement Data Backup & Disaster Recovery Plans

- Ensure automated data backups are performed regularly.
- Test data recovery procedures to confirm data integrity.
- Encrypt sensitive data to prevent unauthorized access.

6. Conduct Routine Data Integrity Audits

- Perform internal audits to verify compliance with data integrity requirements.
- Review batch records, laboratory data, and audit trails for inconsistencies.
- Investigate and document any deviations related to data integrity.

Pro Tip: Strengthening Data Integrity Compliance

- * Ensure all employees understand and follow ALCOA+ principles.
- * Validate all electronic systems used for GMP data management.
- * Conduct periodic audits to detect and address data integrity risks.
- * Implement data security measures to prevent unauthorized access and modifications.

Need Expert Support for Data Integrity Compliance?

MLKC Consulting, LLC specializes in data integrity compliance, FDA 21 CFR Part 11 validation, and electronic record management strategies. Contact us for expert guidance!

Contact us today for a Consultation!

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