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Online GMP Training

GMP11 | Data Integrity

This course introduces you to the concept of Data Integrity; why it's important, how failures can occur and what can be done to protect it.

OBJECTIVES

- Understand what Data Integrity means
- Understand why Data Integrity is a hot topic
- Understand data criticality and data risk
- Understand how Data Integrity problems arise
- Understand who can contribute to good Data Integrity
- Understand how to protect your Data Integrity

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CONTENT

Introduction
- What is Data Integrity (DI)?
- Objectives
- Reviews and assessment

Overview
- Data integrity is not new
- Data integrity as part of FDA, EU and PIC/S GMPs
- GMPs for electronic records and computerised systems
- Regulators' perspectives
- Industry guidance

Risk management and controls
- Raw data and metadata
- Manual and electronic data
- What if the data are unreliable?
- Understanding risk to data integrity
- Good Documentation Practices
- ALCOA+
- Logical design

Scenarios
- Scenario 1 (digital reading on a pH meter)
- Scenario 2 (Operator is completing a logbook)
- Scenario 3 (Analyst calculates and records assay results in their workbook)
- Scenario 4 (automated chromatography instruments)

Human error
- Human error and DI
- Human behaviours that help protect data integrity
- Doing the wrong thing for the right reason
- Quality culture
- Controls for paper-based records

Computer systems
- Errors relating to computer systems
- Leverage audit trails

Conclusion
- Summary