

Program: Data Integrity

Duration: 7 hours

Training: in-house

Target group: Quality Assurance and IT, Quality Control and Pharmaceutical Production

Prerequisites: No prerequisites

Training accessible to people with disabilities

Pedagogical objectives

- Clarify the definition of this term and the expectations of regulatory authorities on this subject.
- Evaluate, through a case study, the different risks linked to "Data Integrity".
- Propose technical and human resources to control these risks.

Training content

- The number of inspection observations relating to "Data Integrity" is on the increase, and not just in emerging countries. These remarks highlight major shortcomings in the management of electronic or paper data, for which manufacturers need to have effective means of prevention at their disposal.
- The proposed training course will review the main regulatory requirements applicable to this subject and, through a case study of a laboratory system, will enable participants to discover the appropriate means of control on this subject and their possible application in the company.
 - o Definition(s) of "Data Integrity" and related terms: data life cycle...
 - o History and regulatory references,
 - o Examples of inspection feedback
 - o Risk assessment: criticality of data, processes/systems, risks associated with the data lifecycle, etc.
 - o Risk management methods for paper and computerized data: Behavioral, Organizational and Technical.

Training organization

Speaker(s): Jean-Louis JOUVE or Christophe Fagard

Teaching and technical resources

- Pre-training positioning questionnaire
- Training and regulatory documents.
- Theoretical input, case studies
- Participatory teaching
- Question-and-answer sessions

System for monitoring and evaluating training results

- Attendance sheets.

- Knowledge acquisition assessment test
- Training certificate.