TRAINING COURSE

How to Improve Data Integrity in the Pharma Lab

This course focusses on improving laboratory data integrity and associated quality management systems by review of laboratory processes to identify data integrity risk, and implementation of appropriate solutions, paying particular attention to deficiencies that are commonly cited by regulatory authorities.

Learning Objectives

The learner will be able to:

1. Understand why data integrity has become a 'hot' topic for regulatory authorities and be aware of the currently available guidance.
2. Define the key terms related to data integrity.
3. Review laboratory processes and identify data integrity risks using process mapping tools and application of ALCOA+ principles.
4. Implement appropriate solutions for commonly observed data integrity problems in the pharma laboratory.

For more details on the contents of this course, refer to page 2 for the course outline.

This course is suitable for:

Everyone associated with the data generated in the pharma laboratory, e.g., analysts, reviewers, supervisors, managers, etc.

Included in the course fees:

- Comprehensive course hand-outs;
- Certificate of Attendance;
- Access to training resources via e-MTS;
- Optional post training assessment (leading to Certificate of Training);
- Post training support.

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Course Outline

How to Improve Data Integrity in the Pharma Lab

Reasons for current regulatory focus on the topic of data integrity, to include:

- Why has data integrity become a 'hot' topic for regulatory authorities?
- Available data integrity specific guidance, e.g., from MHRA & FDA.

Data integrity principles and definitions, to include:

- Data governance.
- ALCOA+
- Meaning of: data, raw data, metadata, audit trail, etc.
- Computerised systems

Common data integrity deficiencies cited by regulatory authorities, to include:

- Access to electronic systems
- Integration for chromatographic techniques
- Audit trails
- Use of 'trial' injections in HPLC
- Analytical records, paper and electronic.

Review of laboratory processes to identify data integrity risk, to include:

- Identification of laboratory processes.
- Use of process mapping to identify risks.
- Implementing solutions to eliminate or reduce risk.

Review of key messages.

TRAINING COURSE

Introduction to Laboratory Data Integrity

cGMP in the Pharma Lab Integrity

This course introduces the fundamental concepts of laboratory data integrity in the context of working within a quality management system and as such this course also acts as an introduction/refresher to laboratory cGMP.

Learning Objectives

The learner will be able to:

1. Understand the background to data integrity and how it applies to the laboratory.
2. Understand the purpose of the laboratory quality management system and its role in ensuring data integrity.
3. Interpret the relevant parts of Good Manufacturing Practice (GMP) regulations (primarily EU and US) and be aware of other available regulatory guidance.
4. Describe the essential components of an effective laboratory quality management system.

This course is suitable for:

Everyone associated with the data generated in the pharma laboratory, e.g., analysts, reviewers, supervisors, managers, etc.

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Course Outline

Introduction to Laboratory Data Integrity; cGMP in the Pharma Lab

Background to laboratory data integrity, to include:

- What does the pharma lab do?
- Why is data integrity so important?
- What is a quality management system?

Review of Good Manufacturing Practice (GMP) and other relevant regulatory guidance, to include:

- EU, Eudralex volume 4.
- FDA, 21 CFR.
- ICH
- Pharmacopeia
- Review of recent updates.

Components of Laboratory Quality Management Systems (QMS), to include:

- Laboratory documentation: Specifications, standard operating procedures (SOPs), analytical records, etc.
- Sampling.
- Equipment qualification, calibration and maintenance.
- Analytical methods development, validation, verification and transfer.
- Stability testing.
- Management of reference standards and reagents.
- Investigation of out of specification (OOS), out of trend (OOT) and out of expectation (OOE) results.
- Competence and training records.

Review of key messages.

TRAINING COURSE

Applying Data Integrity in the Laboratory

Minimising Analytical Error

This course deals with the effects of analytical errors on laboratory data integrity. This involves building an understanding of the nature and sources of analytical errors so that their effects can be minimised during testing, leading to high standards of data integrity and reduced numbers of OOS/OOE results due to laboratory errors.

Learning Objectives

The learner will be able to:

1. Understand the significance of analytical error and how it relates to laboratory data integrity.
2. Understand the concept of inherent measurement uncertainty and the types of analytical error, namely systematic and random, together with the potential sources of error in the pharma lab.
3. Identify potential sources of human error that may contribute to a lack of data integrity and potentially the generation of out of specification (OOS) and out of expectation (OOE) results.
4. Minimise inherent analytical error and eliminate human error in analytical testing to obtain high standards of data integrity and reduced numbers of OOS/OOE results due to laboratory error.

This course is suitable for:

Everyone associated with the data generated in the pharma laboratory, e.g., analysts, reviewers, supervisors, managers, etc.

Included in the course fees:

- Comprehensive course hand-outs;
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Course Outline

Applying Data Integrity in the Laboratory; Minimising Analytical Error

Analytical error and data integrity, to include:

- What is analytical error?
- Types of error - systematic and random.
- Potential sources of error in a pharma laboratory.
- How does it relate to data integrity?

Uncertainty in Analytical Measurement, to include:

- Definition of measurement uncertainty.
- Quantification of measurement uncertainty.
- Approaches to reduce uncertainty in analytical methods, e.g., replicate analysis, etc.
- Rounding and significant figures in reporting analytical results.

Identifying potential sources of human error in analytical testing, to include:

- What could go wrong?
- Common human error examples.
- Consequences of human error – may not be noticed or may cause an out of specification (OOS) or out of expectation (OOE) result.

Minimising error in analytical testing, to include:

- Best practice for basic analytical skills.
- Interpretation of analytical methods.
- Ways of working.
- Competence assessment and training records.

Review of key messages.