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E-LEARNING

G(QC)LP

2

QC in a Regulated Laboratory

This module introduces you to the basic concepts and requirements of QC in a regulated pharmaceutical laboratory. The issues that laboratory auditors focus on will also be discussed. Specific pharmaceutical regulatory requirements will be presented including requirements for investigation and handling out-of-specification conditions.

Objectives:

- Recognise the importance and implications of regulations on day-to-day laboratory operations
- Identify QC rules for testing samples
- Recognise some basic requirements for handling automatic laboratory information
- Identify QC rules for completing laboratory notebooks, reporting, and altering laboratory data
- Recognise the essential requirements for evaluating laboratory out-of-specification (OOS) conditions
- Recognise why audits are necessary and what the laboratory needs to do to prepare for one

Course Outline

INTRODUCTION
- Welcome
- Overview
- Reviews and assessments
- Laboratory regulatory standards

INTERPRETING REGULATIONS
- What do you think?
- QC solution
- Overview
- Role of the laboratory
- Some important QC compliance requirements
- Laboratory equipment and instruments
- Laboratory documentation
- Personnel
- Test methods
- Test method reliability
- Sampling plans and procedures
- Review

PRODUCT STANDARDS
- What do you think?
- QC solution
- Overview
- Specifications
- Pharmacopoeias
- Reference standards
- Control over laboratory standards
- Preparing reagents
- Regulatory citations
- Review

COMPLETING LAB RECORDS
- What do you think?
- QC solution
- Overview
- Completing records
- Checking calculations
- Altering laboratory records
- Significant figures
- Archiving rules for records
- Regulatory citations
- Review

LAB E-RECORDS
- What do you think?
- QC solution
- Overview
- Standards and guidelines
- ERES rules
- Recording raw data
- Storing raw data
- Storing electronic data

MANAGING OOS EVENTS
- What do you think?
- QC solution
- Overview
- Origin of OOS events
- Initial investigation
- Formal investigation
- OOS documentation
- Retesting and resampling
- Averaging of final results
- Regulatory citations
- Review

INTERNAL LAB AUDITS
- What do you think?
- QC solution
- Overview
- Audits and preparation

CONCLUSION
- Summary

Contact us for more information

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