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E-LEARNING

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Commissioning and Installation Qualification

This module provides an introduction to the requirements of performing commissioning and Installation Qualification (IQ).

Objectives:

- Define commissioning and installation qualification activities and scope
- Explain the purposes of and differences between commissioning and qualification
- Determine qualification requirements based on an impact/risk assessment
- Prepare and execute an IQ protocol
- Prepare and approve an IQ report

Course Outline

INTRODUCTION TO IQ
- o Welcome
- o Outcomes
- o First Class Pharmaceuticals
- o Meet the V Team
- o The new line
- o Regulatory definitions
- o Guidance documents
- o V model approach
- o Summary

DEFINITIONS
- o Introduction
- o Common interfaces
- o Commissioning/IQ timeline
- o Purpose of commissioning
- o Purpose of IQ
- o Comparisons
- o Review I
- o FAT and SAT
- o Responsibilities
- o Vendor responsibilities
- o Commissioning reports
- o Summary
- o Review II

IMPACT ASSESSMENTS
- o Introduction
- o Levels of impact
- o System boundaries I
- o System boundaries II
- o The impact assessment
- o Criticality assessment
- o Determining criticality
- o Assessment flowchart
- o Review I
- o The scope of activity
- o Summary
- o Review II

SCOPE OF IQ
- o Introduction
- o Essential IQ items
- o Test requirements
- o IQ protocol
- o Protocol test sheets
- o Calibration requirements
- o Review I
- o Summary
- o Review II

IQ DOCUMENTATION
- o IQ protocols
- o Conducting the IQ
- o Approval of IQ report
- o Documentation
- o Summary
- o Review

CONCLUSION
- o Summary

GLOSSARY/RESOURCES
- o Glossary
- o Resources

Contact us for more information

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