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E-LEARNING

VAL 2

Validation Master Plans and Documentation

This module provides an introduction to the requirements of a Validation Master Plan (VMP) and other important documents.

Objectives:

- Explain why a VMP is important to validation management
- Determine the scope and content of a VMP
- Prepare validation schedules and a responsibility matrix
- Develop and publish validation documentation
- Apply the change control program to maintain items in a validated state

Course Outline

INTRODUCTION TO VMP
- o Welcome
- o Outcomes
- o First Class Pharmaceuticals
- o Introduction
- o Definitions and standards
- o The new line
- o Glossary of terms
- o VMP Structure
- o Importance of VMP
- o VMP and responsibilities
- o Regulatory requirements
- o VMP sections
- o VMP content
- o Summary
- o Review

SCOPE OF THE VMP
- o Introduction
- o Using risk assessment
- o Defining risk
- o Critical vs non-critical
- o Risk assessment approach
- o Validation strategy
- o Validation policies
- o Qualification phases
- o Equipment qualification
- o Developing a plan
- o Summary
- o Review

VALIDATION DOCUMENTS
- o Introduction
- o Documentation overview
- o Document relationships
- o Reference documents
- o Authorising validation
- o Organising validation
- o Using protocol templates
- o Change control
- o Required procedures
- o Handling deviations
- o Validation data
- o Tracking and cataloguing
- o Archiving and retrieving
- o Report and certification
- o Summary
- o Review

RESPONSIBILITIES, SCHEDULES, RESOURCING
- o Introduction
- o Validation responsibilties
- o Validation schedules
- o Resource planning
- o Summary
- o Review

CHANGE CONTROL
- o Introduction
- o Change management
- o Reporting rules
- o Summary
- o Review
- o

CONCLUSION
- o Summary

GLOSSARY/RESOURCES
- o Glossary
- o Resources

Contact us for more information

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