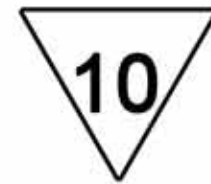


VAL



Computer System Validation Part II

This module builds on VAL 9 (Computer Systems Validation Part I) looking at the Design/Development/Installation, Validation and Operation/Maintenance phases of CSV.

Objectives:

- Describe each of the phases in the Computer Systems Lifecycle
- Describe which systems to validate
- Determine the amount of validation required, and the strategy to use
- Describe legacy systems and a suitable validation approach

Course Outline

INTRODUCTION

- o Welcome
- o Outcomes
- o First Class Pharmaceuticals
- o Introduction
- o The validation project
- o Computer Systems Lifecycle

DESIGN/DEVELOP/INSTALL

- o Introduction
- o Deliverables
- o Design specifications
- o Development testing
- o Test plans
- o Test cases and scripts
- o Good testing practices
- o Test documents
- o Change management
- o Summary
- o Review

VALIDATION PHASE

- o Introduction
- o Deliverables
- o Computerised systems
- o Timeline
- o Platform qualification
- o Application IQ
- o OQ
- o PQ
- o Change management
- o Validation report
- o Test scripts
- o Summary
- o Review

OPERATION/MAINTENANCE PHASE

- o Introduction
- o Deliverables
- o Operational lifecycle
- o Change control
- o Summary
- o Review

LEGACY SYSTEMS

- o Legacy systems

CONCLUSION

- o Summary

GLOSSARY/RESOURCES

- o Glossary
- o Resources