

VAL



Computer System Validation

Part I

This module provides an introduction to Computer Systems Validation (CSV), as required by GxP regulations.

Objectives:

- Define some important computer systems validation terms
- List the benefits of performing computer systems validation
- Describe the planning phase in the Computer Systems Lifecycle

Course Outline

INTRODUCTION

- o Welcome
- o Outcomes
- o First Class Pharmaceutical
- o Meet the V team
- o Introduction
- o Validation project
- o Definition I
- o Definition II
- o What requires validation?
- o Review I
- o Benefits
- o Qualification
- o Risk management
- o Industry guidelines
- o GAMP
- o GAMP review
- o Data Integrity
- o Summary
- o Review II

PLANNING PHASE

- o Introduction
- o Computer Systems Lifecycle
- o Planning Phase
- o URS
- o Traceability matrix

VALIDATION STRATEGY AND PLAN

- o Validation strategy
- o Regulation assessment
- o ERES I
- o ERES II
- o ERES assessment
- o Supplier audits
- o Audit questionnaire
- o Risk assessment
- o Risk management
- o Validation strategy
- o Validation plan
- o Change management
- o Summary
- o Review

CONCLUSION

- o Summary

GLOSSARY/RESOURCES

- o Glossary
- o Resources