

VAL



# Validation Principles and International Regulations



Validation

This module provides an introduction to the international regulations and principles behind effective qualification and validation.

Objectives:

- Define some important validation terms
- Describe the development of validation and regulatory control
- State the reasons for validation
- Describe the difference between critical and non-critical equipment, in terms of validation activities
- Describe the roles of a validation team
- List the scope of validation
- Describe the V model approach to validation

# Course Outline

## INTRODUCTION

- o Welcome
- o Outcomes
- o First Class Pharmaceuticals
- o Introductions
- o New liquids line
- o Definition of validation
- o Equipment qualification
- o Process validation
- o Process control
- o Glossary of terms
- o USA and Canada GMPs
- o EU and PIC/S GMPs
- o Summary
- o Review

## OVERVIEW

- o Introduction
- o History of validation
- o Origins
- o Current trends
- o Applying risk assessment
- o Assessing risk
- o Summary
- o Review

## WHAT TO VALIDATE?

- o Introduction
- o Developing the scope
- o Other consideration
- o Critical vs non-critical
- o Services and utilities
- o Computerised systems
- o Selecting process steps
- o Cleaning validation
- o Cleaning validation II
- o Laboratory test methods
- o What not to validate?
- o Summary
- o Review

## STAGES OF VALIDATION

- o Introduction
- o V Model
- o The URS document
- o FAT and SAT
- o Qualification & commissioning
- o IQ phase
- o OQ phase
- o PQ phase
- o Process validation
- o Validation & SOPs
- o Review of sequences
- o Summary
- o Review

## DOCUMENTATION

- o Introduction
- o Validation Master plans
- o Protocols and reports
- o Document linkage
- o Documentation flowchart
- o Managing deviations
- o Summary
- o Review

## CHANGE CONTROL

- o Introduction
- o Importance
- o Types of changes
- o Summary
- o Review

## CONCLUSION

- o Summary

## GLOSSARY/RESOURCES

- o Glossary
- o Resources

Contact us for more information