

VAL



Operational and Performance Qualification

This module provides an introduction to Operational Qualification (OQ) and Performance Qualification (PQ).

Objectives:

- Define OQ and PQ scope
- Identify and explain the scope of OQ and PQ
- Identify and explain the activities to be carried out during OQ and PQ
- Identify and explain the responsibilities of OQ and PQ
- Summarise the key differences between OQ and PQ
- Prepare, approve, and execute an OQ protocol
- Compile an OQ and a PQ report

Course Outline

INTRODUCTION TO OQ/PQ

- o Welcome
- o Outcomes
- o First Class Pharmaceuticals
- o The new line
- o Definitions

OQ PHASE

- o The scope of OQ
- o OQ responsibilities
- o Vendor responsibilities
- o Definitions
- o OQ protocol design
- o OQ activities
- o OQ tests
- o Test requirements
- o Executing the OQ
- o Final OQ report
- o Review

PQ PHASE

- o The scope of PQ
- o PQ responsibilities
- o PQ steps
- o PQ activities
- o Microbial monitoring
- o Other considerations
- o Executing PQ I
- o Executing PQ II
- o OQ/PQ comparison
- o Documentation requirements
- o Final PQ report
- o Review

CONCLUSION

- o Summary

GLOSSARY/RESOURCES

- o Glossary
- o Resources