

## **IQ/OQ for Laboratory Equipment**

This module covers the requirements for the qualification of laboratory instruments, including IQ, OQ, and PQ. The relationships between vendors, user requirements specifications and qualification are explained. The different approaches to simple and complex instruments are addressed, and specifications and calibration requirements for spectrophotometers, chromatographic systems and dissolution apparatus are reviewed.

### Objectives:

- Describe the steps involved in IQ and OQ of instruments
- State the requirements for software qualification
- List chromatography instrument calibration requirements and frequency
- List general lab instrument calibration requirements and frequency
- State the QC expectations for instrument logbooks

# Course Outline

## INTRODUCTION

- o Welcome
- o Objectives
- o Introduction
- o Instrument calibration
- o Useful definitions
- o Good QC laboratory data
- o The V model
- o Applying the V model
- o Simple vs complex instruments
- o Qualification phases
- o Vendors
- o Lab instrument specialist
- o Review

## INSTRUMENT QUALIFICATION

- o Introduction
- o Instrument URS
- o IQ: USP definition
- o IQ approach
- o IQ steps
- o OQ: USP definition
- o OQ phase
- o HPLC OQ
- o PQ: USP definition
- o PQ Phase
- o HPLC PQ
- o System suitability testing
- o SST acceptance criteria
- o Qualification protocols
- o Protocol execution
- o Summary
- o Review

## CALIBRATION RECORDS

- o Introduction
- o Calibration and performance checks
- o Precision and accuracy
- o GLP identification rules
- o Scope of calibration
- o Calibration rules
- o Schedules
- o Calibration records
- o Review

Contact us for more information

## LABORATORY SOFTWARE QUALIFICATION

- o Introduction
- o Software categories
- o Software qualification rules
- o Software examples
- o Qualifying spreadsheets
- o Review I
- o Review II

## CHROMATOGRAPHY

- o Introduction
- o HPLC/GC
- o HPLC components
- o Typical specifications
- o Column maintenance
- o Mobile phase
- o SST

## SPECTROPHOTOMETRY

- o Introduction
- o Types of systems
- o Operation principles
- o Typical specifications
- o Cell specifications
- o Calibration tasks I
- o Calibration tasks II

## DISSOLUTION APPARATUS

- o Introduction
- o Dissolution apparatus
- o Performance parameters
- o Typical specifications
- o Calibration tasks
- o Review

## INSTRUMENT LOGBOOKS AND EQUIPMENT HISTORY

- o Introduction
- o Purpose
- o What to record
- o Review

## CONCLUSION

- o Summary