

INTRODUCTION TO VALIDATION FOR THE PHARMACEUTICAL INDUSTRY

The aim of this course is to provide learners with an understanding of the regulatory requirements related to validation practices and documentation, in order to ensure consistent high-quality pharmaceutical products.

The module will provide core foundational knowledge and understanding of the fundamental principles and concepts related to key protocols of IQ, OQ, and PQ. Learners will also gain knowledge related to validation documentation and the validation lifecycle.

Programme Learning Outcomes

- Develop an understanding of the validation lifecycle
- Demonstrate knowledge and competence related to the V model for equipment qualification
- Demonstrate an awareness of the regulatory responsibility of a manufacturing organisation in relation to validation
- Understand the CAPA process in relation to validation studies

Indicative Programme Content

- The lifecycle approach to drug development processes and validation
- Introduction to the key sets of protocols within equipment validation installation qualification, operational qualification and performance qualification (IQ, OQ, and PQ)
- V Model for Validation
- Validation Master Plan
- Validation Documentation
- Corrective Actions and Preventative Actions (CAPA)

PROGRAMME DURATION

2 day blended learning programme.

LEARNER CERTIFICATION

Innopharma Education Certificate of Completion (Digital badge).