Innopharma education

Introduction to Validation for the Pharmaceutical Industry

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

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

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 regulatory responsibility of a manufacturing organization in relation to validation
- Understand the CAPA process with regard 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, performance qualification (IQ,OQ PQ)
- V Model for Validation
- Validation Master Plan
- Validation Documentation
- Corrective Actions and Preventative Actions (CAPA)

Programme Duration

2 day blended learning programme

AMTCE Ionad Oiliúna Barr Feabhais Ard-Déantúsaíochta Advanced Manufacturing Training Centre of Excellence

SOLAS learning works

lmetb Bord Oideachais agus Oiliúna Lú agus na Mí Louth and Meath Education and Training Board

Learner Certifcation

Innopharma Education Certificate of Completion (Digital badge)