Innopharma education

Introduction to Validation for the Pharmaceutical Industry

This programme provides participants with an overview of essential validation activities performed from the initial process design stage to the finished commercial product.

Focusing on key validation protocols and the validation life cycle, the programme outlines the importance of validation in ensuring all processes, and products manufactured meet the required quality standards.

Aims and Objectives

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

On completion of the programme learners will be able to demonstrate knowledge and understanding of key validation protocols related to Installation Qualification(IQ), Operational Qualification (OQ) and Performance Qualification (PQ). Participants will also gain knowledge of validation documentation and the validation lifecycle.

Learning Outcomes

On completion of this programme the learner should be able to:

- Develop an understanding of the validation lifecycle
- Demonstrate knowledge and competence related to the V model for equipment qualification

PROGRAMME DELIVERY

2 day online delivery.

PROGRAMME CERTIFICATION

Innopharma Education Certificate of Completion & Digital Badge.

WHO IS THIS PROGRAMME FOR?

This programme is aimed at employees working in a manufacturing setting, or those wishing to up skill and gain essential knowledge of validation in a pharmaceutical context.

ENTRY REQUIREMENT

Courses are fully funded to both employed and unemployed applicants who are either living or working in the Midlands region (Longford, Laois, Offaly or Westmeath).

ReSHAPE Regional Skills Horizon And Pathways to Employment
Rialtas na hÉireann Government of Ireland
Arna chomhchistiú ag an Aontas Eorpach Co-funded by the European Union
Tionól Réigiúnach an Oirthir agus Lár Tíre Eastern and Midland Regional Assembly
pobal government supporting communities

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CHANGE DIRECTION, ADVANCE YOUR CAREER

- Demonstrate an awareness of the regulatory responsibility of a manufacturing organisation in relation to validation
- Understand the CAPA process in relation to validation studies

Course Content

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

Other courses options include

- Introduction to Technical Writing for the Manufacturing Sector
- Advanced Technical Writing for the Manufacturing Sector
- Introduction to cGMP for the Bio-Pharmaceutical Industry
- Introduction to Clinical Trials for the Pharmaceutical Sector
- Introduction to Quality Control for Bio-Pharmaceutical Manufacturing
- Certificate in Supply Chain (Special Purpose Award/QQI Level 6 20 credits)
- Certificate in Operational Excellence (Special Purpose Award/ QQI Level 6 25 credits)

A PROFILE OF IRELAND'S ADVANCED MANUFACTURING

Advanced Manufacturing accounts for

36.7%

of GDP in Ireland

The sector employs

231,000

direct employees

9

out of the worlds top 10 STEM companies have a presence in Ireland

Ireland is the world's

3rd

largest exporter of pharmaceuticals

Ireland's life sciences sector has a **global reputation** for operational and innovation

For more information on this course contact Innopharma Admissions on: T: +353 (0) 1 485 3346 e-mail: admissions@innopharmalabs.com Visit our website on www.innopharmaeducation.com

learning works