Innopharma education

INTRODUCTION TO EQUIPMENT VALIDATION FOR THE (BIO) PHARMACEUTICAL INDUSTRY

A focused introduction to the principles and practices of equipment validation within the (bio) pharmaceutical industry, by examining the core stages of equipment qualification—Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).

Aims and Objectives

The aim of this course is to provide participants with a foundational understanding of equipment validation concepts and practices specific to the (bio)pharmaceutical industry.

Participants will learn about the purposes for undertaking thorough validation processes, as they relate to the manufacture of highly regulated medicinal products. The course will focus on key guidelines and standards at each stage of qualification and validation activities, using practical examples to illustrate concepts.

PROGRAMME DELIVERY
1 day, online delivery

PROGRAMME CERTIFICATION
Innopharma Education Certificate of Completion

WHO IS THIS PROGRAMME FOR?
This programme is aimed at employees in all life-sciences manufacturing sectors, or those seeking employment in the industry, who wish to upskill, learn, or refresh their knowledge in the area of process validation.

ENTRY REQUIREMENT
To be eligible for this programme you must be in current employment.

Innopharma education

CHANGE DIRECTION, ADVANCE YOUR CAREER

Learning Outcomes

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

- Describe the distinction between the terms “qualification” and “validation”
- Demonstrate a clear understanding of the structured V-Model of Validation approach.
- Understand the importance of User Requirement Specifications (URS), including testable criteria, for designing and procuring equipment
- Demonstrate knowledge of the process of planning and executing Installation Qualification (IQ) and Operational Qualification (OQ) tests, and Performance Qualification (PQ), including identifying the testing requirements and executing the necessary protocols.
- Recognise the importance of requalification and be able to explain why periodic requalification is essential for maintaining product quality and safety

Course Content (Topics)

- The Validation regulatory landscape
- The V-Model of Validation
- Documentation requirements (GDP & Data Integrity)
- Design Qualification processes, from URS to FAT
- Commissioning of Equipment, from IQ to PQ
- Introduction to P&IDs
- Requalification and Change Management

A PROFILE OF IRELAND’S ADVANCED MANUFACTURING SECTOR

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 excellence

For more information on this course contact Pauline Flusk (Programme Lead) on:
T: +353 (0) 1 264 5570 e-mail: fluskp@innopharmalabs.com Visit our website on www.innopharmaeducation.com