

INTRODUCTION TO PROCESS VALIDATION FOR THE (BIO) PHARMACEUTICAL INDUSTRY

A focused introduction to the principles and practices of process validation within the (bio) pharmaceutical industry, by examining the 3-stage cyclical approach, including Process Design (PD), Process Qualification (PQ), and Continued Process Verification (CPV).

Aims and Objectives

This aim of this training is to provide participants with a foundational understanding of process validation in the biopharmaceutical industry, including its importance, regulatory requirements, and key concepts.

Participants will learn about the purposes for undertaking thorough validation processes, as they relate to the manufacturing process of highly regulated medicinal products. The course will focus on key guidelines and standards at each stage of 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.

CHANGE DIRECTION, ADVANCE YOUR CAREER

Learning Outcomes

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

- Understand the importance of process validation in the (bio) pharmaceutical industry.
- Demonstrate an understanding of the regulatory requirements and guidelines related to process validation, including the three stages of process validation, and how to apply them.
- Identify the critical quality attributes (CQAs) and process parameters (CPP) of a biopharmaceutical product, and how this contributes to process validation
- Outline the meaning of “design space”, as it relates to biopharmaceuticals and ensuring the quality and safety of the final product
- Understand the concept of designing process validation protocols and related documentation.
- Describe the need for deviation and change management during the process validation cycle.
- The FDA-approved 3-Stage Process Validation lifecycle
- Process Validation protocols and documentation
- Critical quality attributes (CQAs) vs Critical Process Parameters (CPPs)
- Sampling plans & Acceptance Criteria of Continued Process Verification
- Concurrent Validation, Prospective Validation and Retrospective Validation.
- Deviations and Change Management

Course Content (Topics)

- Definition of product quality
- The evolution of process validation approaches, in recent decades

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:
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