

INTRODUCTION TO CLEANING VALIDATION FOR THE (BIO) PHARMACEUTICAL INDUSTRY

A focused introduction to the principles and practices of cleaning validation within the (bio) pharmaceutical industry, by examining the process of designing and validating clean-in-place (CIP) and clean-out-of-place (COP) cycles of manufacturing equipment.

Aims and Objectives

This aim of this training is to provide participants with a foundational understanding of cleaning validation principles, methods, and regulatory requirements for cleaning validation in the (bio) pharmaceutical industry.

Participants will learn about the purposes for validating effective and thorough cleaning processes, as they relate to the control and qualification of equipment used in the manufacture of highly regulated medicinal products.

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:

- Demonstrate an understanding the fundamental principles of cleaning validation and the industry’s regulatory requirements for compliance and documentation
- Describe the different cleaning methods, such as manual cleaning, automated cleaning, and cleaning-in / out of- place (CIP/COP).
- Understand the product risk associated with non-compliance of cleaning validation standards and regulations, and the criticality of developing correct protocols, acceptance criteria, and processes.
- Identify critical cleaning parameters, including as cleaning agents, water usage, equipment, surfaces, and sampling methods.
- Understand the concept of deviations and change management in the context of cleaning validation.
- Visual Inspection & Coverage Testing
- Direct sampling (swabs) vs Indirect Sampling (rinse samples)
- Deviations during cleaning validation.
- Introduction to P&IDs

Course Content (Topics)

- Contamination & potential sources of contamination
- Manual Cleaning, Clean in place (CIP), Clean out of place (COP)
- Cleaning Validation Approach “worst case product”
- Dirty and Clean hold times

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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