

Aims

This course aims to provide participants with a foundational understanding of the types of water used in biopharmaceutical manufacturing, including the methods of purification and the applications of water and steam in the industry.

Objectives

The programme will cover key aspects of water systems, including:

- 1. Definition and specifications of different water types
- 2. The regulatory standards governing water quality
- 3. The processes used in the removal and identification of water impurities
- 4. The principles of water system design, with a focus on the Water for Injection (WFI) generation, storage and distribution.

PROGRAMME DELIVERY

1-day, live-online, daytime delivery

PROGRAMME CERTIFICATION

Innopharma Education Certificate of Completion

ENTRY REQUIREMENT

To be eligible for this programme you must be in current employment. Not on any other government funded course.

WHO IS THIS PROGRAMME FOR?

This course would be suitable for candidates from an Engineering, Quality or Production background who wish to gain a good understanding of the technical aspects of the production and control of purified water systems for Pharma, Medical Device and Manufacturing (e.g. Electronic Engineering sector) applications.











Learning Outcomes

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

- Understand the importance of water in biopharmaceutical manufacturing and the regulatory expectations for water quality (USP, EP, FDA) governing the use and standards of water.
- Differentiate the grades of pharmaceutical water and the specifications / limits for each grade.
- Explain the fundamentals of water system component and system design principles including material selection, compatibility, design considerations for preventing microbial contamination, risk assessment and mitigation strategies.

- Identify the different methods for generating WFI including the features and benefits of the following methods - Multiple-Effect Distillation (MED), Vapor Compression Distillation (VC), Reverse Osmosis (RO) and Distillation
- Identify key sources of microbial contamination and describe monitoring and testing methods,
- Explain Biofilm prevention

 control, and cleaning,
 sanitization and contaminant
 removal processes.
- Describe the approaches for WFI generation, storage, and distribution, including cold systems and hot systems.

Course Content

- Definition and specification of the different grades of water used in pharmaceutical manufacturing operations.
- Regulatory standards governing water quality in pharma manufacturing.
- Types of impurities and contaminants, and contaminant removal process.
- Water system design and design principles.
- Different types of WFI generation processes, multiple effects, vapor compression and reverse osmosis.

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

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

