

Bio
Pharma
Chem

Skillnet,

Introduction to Bioprocessing



Delivered by:



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Introduction

NIBRT is a global centre of excellence for training and research in bioprocessing located in a world class facility. This introduction to bioprocessing training course is a one day course designed to deliver training on the overall process of biopharmaceutical production and cleanroom operations. This technical course has been designed to deliver training on the overall process of biopharmaceutical production and the operations involved including upstream and downstream processing. The course involves theoretical sessions to offer trainees an introduction to all aspects of biopharmaceutical processing and the wide variety of roles and responsibilities required to maintain a successful biopharmaceutical facility. Trainees will then build on this knowledge with an interactive tour of the NIBRT facility which has been purpose built to replicate a modern bioprocessing plant with state of the art equipment.

The principal objective of this training course is to provide a thorough understanding of the principles of bioprocessing in a setting which provides hands-on learning in a safe and friendly manner. Participants will receive NIBRT certification upon completion of this course.

Training Overview

Safety Induction & Course Overview

This session includes a safety induction and an introduction to the course and gives an overview of the different training sessions.

Introduction to Biopharmaceuticals and Bioprocessing Lecture

The biopharmaceutical processing lecture will give an overview of the entire biopharmaceutical production process. This will introduce to the trainees the importance of each production step and the operations involved. By discussing the production process from upstream to downstream processing to final fill the trainees will understand where the product comes from and goes to throughout the batch and also get and understanding for the importance of aseptic processing and clean room behaviour throughout.

Learning Outcomes

Upon completion of this lecture the trainee will be able to:

- Compare traditional small molecule manufacture to large molecule manufacture.
- Outline the key operations in a typical biopharmaceutical production process.
- Understand the key steps involved in the upstream process of biopharmaceutical production
- Understand the key steps involved in the downstream process of biopharmaceutical production
- Explain the need for aseptic processing in bioprocessing and the regulatory demands around it.
- Future trends in manufacturing.

NIBRT Facilities Process Overview and Tour

Following on from the Bioprocessing lecture, the trainees will then go on a tour of the bioprocessing pilot plant with access to all production areas. This will give trainees a good understanding of the process flow and the equipment involved in manufacture of biologics.

Introduction to Quality Control and Analytics

This theory session aims to provide an overview the quality control discipline and its importance within industrial facilities. The role of the analyst will be discussed and the qualities require in personnel working within this discipline.

Learning Outcomes

Upon completion of this theory session the trainee will be able to:

- Understand the discipline of quality control (QC) in biopharmaceutical production
- Understand how quality, safety and efficacy are tested in biologic products and why this is crucial for patient safety.

Introduction to Good Manufacturing practice (GMP) and Quality Assurance

All regulated facilities within industry are mandated to have policies and procedures in place that are deemed to conform to the requirements of a good manufacturing process (GMP). This theory session will discuss the notion of GMP, how and where it is applied and extend into the wider disciplines constituting Quality Assurance (QA).

Learning Outcomes

Upon successful completion of this lecture the trainee will be able to:

- Understand what is meant by GMP and QA.
- Explain the qualities required from staff to work within GMP environments

This training is delivered on behalf of BioPharmaChem Skillnet by NIBRT Training. For further information please contact training@bpcskillnet.ie or phone 087 997 0848

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