honeyman
TRAINING

Biotechnology

Principles in Practice®

Biotechnology Principles in Practice®

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2 Days Virtual Training

Who Should Attend?

Ideal for anyone new to the industry or processes, as well as being a good refresher for those more experienced individuals.

The course would be suitable for different functional groups within the organisation including:

- Operations
- Quality Assurance
- Engineering
- Validation

This course provides a comprehensive overview of biotechnology ideology and practice, historically, as we are now, and expected developments in the future.

The course is spread over two days to allow interaction between the lecturer and attendees.

The presentations will be supplemented with workshops that will be used to verify understanding and look at the biotechnology industry and its future. This course itself will encourage discussion and participation which will lead to greater understanding of the current status of biotechnology and the future of the industry.

Course Objectives & Learning Outcomes

- To gain an understanding of the different types of biotechnology processes.
- Current and future GMP requirements for biotechnology.
- Typical product lifecycle phases and regulatory requirements.
- Steps involved in the manufacture of clinical batches including scale up, product characterisation, and control of process inputs and outputs.
- How the product can influence facility design and the use of disposable technologies.
- Differences between the production of a variety of cell substrates e.g. mammalian, bacterial, viral and plant cell products.
- Upstream processing including cell culture, fermentation, harvest.
- Downstream processing including typical purification techniques.
- Analytical techniques employed to verify final product purity.
- Fill Finish activities, storage and distribution of product.
- Principles of process and equipment validation.

“Very good overview of Biotech, exactly what I needed to put into context what we are planning for our new R&D facility”
CEO, EirGen Pharma

Course Programme

DAY ONE

- cGMP in Biotechnology
- Regulations and Standards
- Biotech Products, Licensing, Development
- Clinical Batches, Scale-up, Raw Materials
- Control of Plant, Animal, Viral and Bacterial Derived Products
- Facility Structure and Organisation for Biotech Production
- Disposable Technology

DAY TWO

- Upstream Processing:
  Crude Biotech Products Prior to Purification
- Downstream Processing:
  Production, Primary and Secondary Purification Requirements, Techniques and In-process Activities
- Analytical Techniques: Absence of Viruses, DNA and Plasmid Confirmation, Purity and Stability, Final Product Purity and Definition
- Fill-finish and Storage/Distribution: Formulation, Fill/Finish, Final Containers, Controls Required, Storage and Distribution of Final Product, Including Hospital or Clinic Requirements

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