

Course Outline

Bioprocessing Validation

Hello and welcome to this course Bioprocessing Validation. In this course, we will explore the principles of validation and how validation methodologies are applied within biotechnology and bioprocessing environments. Validation is an essential part of ensuring that processes, equipment and systems are capable of consistently achieving their intended results and meeting defined requirements. Throughout the course, we will begin by looking at biotechnology and bioprocessing before progressing through the different types and stages of validation.

This course is divided into eight lessons:

Lesson 1 – Types of Biotechnology

Lesson 2 – Validation

Lesson 3 – Product or Process Validation

Lesson 4 – Process Validation Protocol

Lesson 5 – Bioprocessing

Lesson 6 – Bioprocess Sequence

Lesson 7 – Fermentation Systems

Lesson 8 – Downstream Processing.

Types of Biotechnology

We begin with Lesson 1 – Types of Biotechnology. Biotechnology is a broad and diverse field, and in this lesson we will introduce the different forms of biotechnology and the areas in which they are applied. We will look at bioinformatics, blue biotechnology, green biotechnology, red biotechnology and white biotechnology. We will also introduce the concept of multi-coloured biotechnology and consider the role of biopharmaceuticals. This lesson provides an important foundation for understanding the wider biotechnology environment and the processes that will be explored throughout the remainder of the course.

In this lesson, we will introduce biotechnology and explore the different forms of biotechnology, including bioinformatics, blue biotechnology, green biotechnology, red biotechnology and white biotechnology. We will also look at multi-coloured biotechnology and biopharmaceuticals.

Validation

In Lesson 2, we focus on Validation. We begin by defining validation and examining the activities that form part of a validation programme. We will look at process validation, cleaning validation and analytical methods validation. An important consideration in validation is when validation should take place. Therefore, we will examine retrospective validation, prospective validation and concurrent validation. Understanding these different approaches will help us to appreciate how validation can be applied at different stages in the life of a process or system.

Validation Activities & Timing

In this lesson, we will introduce the principles of validation. We will look at validation activities, including process validation, cleaning validation and analytical methods validation. We will also examine retrospective, prospective and concurrent validation.

Product or Process Validation

Lesson 3 looks at Product or Process Validation. We will examine the different stages involved in validation and consider the importance of process validation and documentation. A key document introduced in this lesson is the Validation Master Plan, commonly referred to as the VMP. We will also examine Risk Assessment, or RA, and its role within the validation process. Together, these elements provide a structured approach to planning, documenting and managing validation activities.

Process Validation Protocol

In Lesson 4, we examine the Process Validation Protocol. We begin with Design Qualification, or DQ. As part of Design Qualification, we will examine the User Requirement Specification, or URS, and the Functional Design Specification, or FDS. We will then consider the development of the DQ protocol. Following Design Qualification, we will introduce Commissioning, before progressing through Installation Qualification, Operational Qualification and Performance Qualification. Installation Qualification, or IQ, focuses on verification, checks, calibration and testing. Operational Qualification, or OQ, examines key operating parameters, their effective operating ranges, functionality testing and associated checks. Performance Qualification, or PQ, considers repeatability runs used to verify system capability and consistency over time, together with sampling plans and product testing.

Qualification Stages

In this lesson, we will examine the Process Validation Protocol and the different stages of qualification. These include Design Qualification, or DQ, Commissioning, Installation Qualification, or IQ, Operational Qualification, or OQ, and Performance Qualification, or PQ.

Bioprocessing

In Lesson 5, we introduce Bioprocessing. We will begin with an introduction to bioprocessing and examine the role of mammalian cells and proteins. We will also look at biological drugs and consider how biotechnological processes can be operated at commercial scale. This lesson provides the process background required to understand how validation principles are applied within a bioprocessing environment.

Key Bioprocessing Concepts

This lesson introduces bioprocessing, including mammalian cells and proteins, biological drugs and the operation of biotechnological processes at commercial scale.

Bioprocess Sequence

Lesson 6 focuses on the Bioprocess Sequence. We will examine the overall bioprocess sequence and introduce the typical upstream processing sequence. We will then consider fermentation and its position within the overall bioprocess. Understanding the sequence of bioprocessing activities is important because validation must consider the individual processes and systems that contribute to the final product.

Fermentation Systems

In Lesson 7, we examine Fermentation Systems. We will look at several different approaches to fermentation. These include Solid State Fermentation, or SSF; Batch Fermentation; Fed-Batch Fermentation; Cell Recycle Batch Fermentation; and Continuous Fermentation. Understanding these different systems provides important context for the equipment, parameters and controls that may be subject to validation.

Types of Fermentation

This lesson focuses on the different types of fermentation systems. These include Solid State Fermentation, Batch Fermentation, Fed-Batch Fermentation, Cell Recycle Batch Fermentation and Continuous Fermentation.

Downstream Processing

Our final lesson is Lesson 8 – Downstream Processing. We will introduce the downstream process and examine the key activities involved in processing the product following the upstream stages. These activities include harvesting, isolation and purification. We will then look at the different sections of downstream processing, including preparation, capture, purification and polishing. The lesson will also introduce a number of important downstream processing technologies. These include Tangential Flow Filtration, or TFF; Affinity Chromatography; Size Exclusion Chromatography; Ion-Exchange Chromatography; and Hydrophobic Interaction Chromatography, or HIC.

Downstream Processing Stages

In the final lesson, we will examine downstream processing, including harvesting, isolation and purification. We will also introduce preparation, capture, purification and polishing, together with technologies such as Tangential Flow Filtration, Affinity Chromatography, Size Exclusion Chromatography, Ion-Exchange Chromatography and Hydrophobic Interaction Chromatography.

Key Downstream Technologies

The lesson will introduce a number of important downstream processing technologies. These include Tangential Flow Filtration, or TFF; Affinity Chromatography; Size Exclusion Chromatography; Ion-Exchange Chromatography; and Hydrophobic Interaction Chromatography, or HIC.

– Bringing It All Together

Throughout this course, we will move from the fundamentals of biotechnology and bioprocessing into the principles and practical application of validation. We will examine how validation is planned, documented and carried out, and how the different qualification stages demonstrate that systems and processes are suitable for their intended purpose. We will also explore the upstream and downstream stages of bioprocessing and the different systems and technologies used within these processes. By bringing these areas together, the course will provide you with a clear understanding of validation methodologies in relation to bioprocessing.

Slide 19 – Course Learning Outcomes

By the end of this course, you will have a clear understanding of the different forms of biotechnology, the principles and activities of validation, the stages of process validation and associated documentation, the qualification stages within the Process Validation Protocol, and the upstream and downstream stages of bioprocessing.

Slide 20 – Let's Begin

Let's begin with Lesson 1 – Types of Biotechnology.