

Overview

This course provides biotech professionals with the essential, practical knowledge needed to design, develop and control a bioprocess that is capable of manufacturing complex biologic products, from initiation to commercial launch. Modalities include recombinant proteins, mAbs and viral vectors used for gene therapy & vaccines. The course draws on real, hands-on industry experience to illustrate the practicalities of process development and control as encountered on the manufacturing floor.

Course Structure

Module	Subject Area
Module 1: Development	An overview of the development of a bioprocess, from cell line selection through to bulk filling, covering the approaches used at each stage.
Module 2: Optimisation	General process streamlining, adjustment of parameters, and the implementation of new techniques and materials.
Module 3: Validation	The approaches required to validate a manufacturing process and the regulatory standards.
Module 4: Scale Up	How to scale up a process and distinguishing production models.
Module 5: Tech Transfer	Real-world examples of the problems encountered when tech transferring a process into a another manufacturing facility.
Module 6: Verification (CPV)	Continued process verification (CPV) and process capability & performance together with its impact on product quality.

Audience

This course is designed for biotechnology professionals involved in the design, development, and operation of bioprocesses for the manufacture of biologic products such as vaccines, viral vectors, and recombinant proteins produced via cell culture. It is well suited to those working in process development, process engineering, MSAT, quality, and technical operations roles who want a practical, applied understanding of the bioprocess lifecycle.

Duration and Delivery

This 4-day course can be delivered either in person or remotely. Course content and duration can be tailored to the specific needs of the requesting organisation, with individual modules offered as standalone sessions.