

Overview

This course is designed for scientists who already understand the basic principles of bioassays and wish to see how they are applied in real-world biopharmaceutical development, manufacturing and control. It places bioassays firmly in their CMC context, exploring their use as release assays and stability-indicating assays, and their role in preclinical and clinical development. The training explains the distinction between potency assays, and content assays, as well as their use cases. All content delivered falls within the latest ICH (Q14) guidelines.

Course Structure

Module	Subject Area
Module 1	Bioassays in CMC and clinical context – their role in release testing, stability and comparability, and how they support mechanism-of-action claims and dose selection
Module 2	Potency vs content assays in practice: why both may be needed and how they complement each other
Module 3	Advanced statistical analysis – 4-parameter vs 5-parameter logistic models, parallel-line analysis, parallelism (EMA) and equivalence testing (FDA)
Module 4	Qualification versus validation, assay validity criteria, system suitability and run acceptance, and phase-appropriate assay adjustments
Module 5	Industrial challenges and troubleshooting: assay variability, cell banking, cell line stability, long-term reproducibility and common QC lab issues
Module 6	Lifecycle management – alignment with ICH Q14, managing reference standards and assay bridging. Includes case studies.

Audience

This course is designed for scientists who currently understand the basic principles of bioassays and are ready to explore their real-world application in CMC, preclinical and clinical development. It is best suited to those with prior bioassay exposure, such as completion of the Foundation course, who want to deepen their knowledge of assay lifecycle management, advanced data analysis and regulatory alignment.

Duration and Delivery

This is a one-day, six module course that can be delivered either in person or remotely. The content can be tailored to the client's specific bioassay platforms, products or areas of interest if requested. This often pairs with the foundation version of this course.