GreyRigge Associates

Bioanalytical Assays

Overview

This programme provides a practically grounded introduction to the assays used in the preclinical & clinical testing of biologics and other advanced therapeutics. Based upon the latest guidance, from ICH M10, this course guides you through the assay life cycle from development, qualification, validation, routine analysis, troubleshooting, cell banking as well as the use of quality by design (QbD) and design of experiments (DoE). Pivotal assays such as PK, ADA and biomarkers are also included.

Course Structure

Module	Subject Area
Module 1	(pre)clinical development of biologics and advanced therapies, the concept of PK and immunogenicity
Module 2	Overview of bioassays: definition, purpose, requirements
Module 3	Bioassays in (pre)clinical development: critical parameters in development of ligand binding assays and bioassays
Module 4	Biostatistics: curve fitting, weighing the curves, 4/5 PL fits
Module 5	Qualification vs validation including assay validity criteria, system suitability and run acceptance criteria
Module 6	Preclinical and Clinical Biomarkers
Module 7	Managing reference standards and critical reagents
Module 8	Design of experiments (DoE) and Quality by design (QbD)
Module 9	A focus on advanced therapeutics and their needs such as gene & cell-based therapies as well as viral vectors

Audience

This programme is suited to those working in preclinical and clinical biopharmaceutical environment as well as those at clinical sites. Modalities would include vaccines, proteins, mAbs and cell and gene therapies (ATMPs). Both those individuals working at innovator companies as well as at CROs will also benefit from this training.

Duration and Delivery

This course is delivered over 2 days and can be face-to-face or remotely. Course content and duration can be tailored to the specific needs of the requesting organisation, with individual modules offered as standalone sessions.

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