GreyRigge Associates

Biopharmaceutical Analytical Development & Optimisation ICH Q14

contactus@greyrigge.com

Overview

This course provides a foundation in the development and optimisation of analytical methods for biopharmaceutical products, structured around the analytical procedure lifecycle described in the latest ICH Q14. guidance. Participants are guided from the early stages of method development, the application of Quality by Design (QbD) principles, through to the statistical tools used to optimise and evaluate a method's accuracy, robustness, precision and linearity. The course assumes no prior background in this area and combines explanation of the underlying principles with worked statistical examples.

Course Structure

Module	Subject Area
Module 1	**Method Development** – the stages of analytical method development, the Analytical Target Profile (ATP), the assay lifecycle, the use of risk assessments for risk based approaches and an introduction to Design of Experiments (DoE).
Module 2	**Accuracy & Robustness** – the assessment of accuracy, sample stability, method parameter robustness, and the application of DoE to assess to optimise assay robustness.
Module 3	**Precision and Linearity** – the assessment of precision, including repeatability, intermediate precision and reproducibility. The use of DoE and Variance Component Analysis (VCA) for precision studies, and the assessment of linearity through the used of regression.

Audience

This course is aimed at analytical and QC scientists and quality professionals working in, or moving into, analytical method development and optimisation within a development environment. It assumes no prior statistical background and is suitable both as an introduction for those new to analytical method development or as a refresher for those wanting to consolidate their understanding of method development.

Duration and Delivery

This 1-day course can be delivered either in person or remotely. Course content supports the course "Biopharmaceutical Analytical Validation, Transfer & Control ICH Q2"