GreyRigge Associates

Biopharmaceutical Analytical Validation, Transfer & Control ICH Q2

Overview

This course provides a practical, statistically grounded introduction to the analytical life cycle management of test methods used in biopharmaceutical development and manufacturing. Building on the foundations of analytical method development, the course trains the participants on the latest ICH Q2 guideline that includes: validating an analytical procedure, transferring a validated procedure between laboratories, and monitoring and controlling that procedure once it is in routine use through statistical process control (SPC). Throughout, concepts are illustrated with worked so that participants can both interpret and apply the underlying statistics.

Course Structure

Module	Subject Area
Module 1	**Method Validation** — establishing that an analytical procedure is fit for its intended purpose. Covers specificity, accuracy, precision, linearity, limit of detection/quantitation, range and robustness.
Module 2	**Analytical Method Transfer** — Covers transfer strategies, protocol design, and statistical approaches to acceptance criteria, including equivalence testing & TOST.
Module 3	**Statistical Process Control** — monitoring and controlling a validated, transferred method throughout routine use. It also covers the origins and principles of SPC, control chart construction, interpretation and process capability.

Audience

This course is designed for analytical scientists, quality control and quality assurance personnel as well as statisticians or data reviewers supporting them, within biopharmaceutical development, manufacturing or contract testing organizations. A basic familiarity with laboratory analytical techniques is assumed; prior statistical training is not required, with core concepts introduced from first principles.

Duration and Delivery

This 1-day course can be delivered either in person or remotely. This training content builds upon the course: "Biopharmaceutical Analytical Development & Method Optimisation ICH Q14"

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