GreyRigge Associates

Good Manufacturing Practices

Overview

This comprehensive training programme provides a practically grounded introduction to GMP as applied to the manufacture of sterile biological products, including vaccines, cell-based therapeutics and other complex biologics. Drawing on WHO GMP Guidelines, ISO 14644-1 and applicable national regulatory requirements, the course addresses the unique compliance challenges of biological manufacturing.

Course Structure

Module	Subject Area
Module 1	Overview – GMP Principles and the Pharmaceutical Quality System
Module 2	Personnel – Qualifications, Responsibilities, Training and Hygiene
Module 3	Premises – Design, Cleanrooms, Environmental Monitoring and Storage
Module 4	Equipment – Qualification, Maintenance, Calibration and Computerised Systems
Module 5	Materials – Starting Materials, Seed Lots, Cell Banks and Packaging Materials
Module 6	Production – Aseptic Processing, Contamination Control and Validation
Module 7	Documentation – Specifications, Batch Records, SOPs and Data Integrity
Module 8	Quality Control – Sampling, Testing, Stability and Batch Release
Module 9	Good Distribution Practices – Supply Chain Integrity and Cold Chain Management

Audience

This programme is suited to those interested in understanding GMP manufacturing of biopharmaceutical products such as vaccines, biologics, including mAbs and cell and gene therapies. Those individuals working at or working in clinical supply and MSAT, as well as those working in CMC regulatory affairs or Quality Assurance will find this course relevant.

Duration and Delivery

This course is delivered over one day and can be performed on-site 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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