Quality Control Training Curriculum



General QC Curriculum

QC Testing of Biologics

Sample Management
GXP
Quality Management Systems
Lab Safety
Introduction to Regulation of Medicines
Method Qualification and Validation

Water Sampling with TOC testing
Basic Lab Methods
(Buffer preparation, Pipetting Skills,
Weigh Balance overview)
pH & Conductivity Measurement
Common Lab Calculations
Lab Safety

QC Bioanalytics

Introduction to QC Testing for Biopharmaceuticals
Biosimilars
Capillary Electrophoresis

Gel Electrophoresis (SDS PAGE, IEF)
Compendial methods (Conductivity, pH, Osmolality)

HPLC/UPLC (Peptide Mapping, SEC) Immunoassays

Bioassays

Introduction to Glycobiology
Glycoanalytics

Protein Estimation Assavs

Mass Spectrometry

Titration and Karl Fischer

Intro to Polarimetry, Refractography & Viscosity Intro to Spectroscopy (UV, IR, Raman) Future Strategies in the Analysis of ATMPs

Chromatography in the Analysis of Proteins Volumetric and Gravimetric Methods

Protein Stability

Compendial Methods (Conductivity, pH, Osmolality)
Protein Estimation Assays (Spectrophotometry,

SoloVPE)

SDS PAGE

Capillary Electrophoresis (CE)

Iso-electric Focusing

Size Exclusion Chromatography (SEC)

Glycan Sample Prep and Analysis

Peptide Mapping

ELISA (Pro A, Competitive, HCP)

Empower Data Analysis

HPLC Instrumentation, Troubleshooting & Maintenance

Cell-based Bioassay

Karl Fischer Titration

Common Lab Calculations

qPCR

QC Microbiology

Micro for Biopharma Environmental Monitoring Bioburden & Sterility Testing Endotoxin testing Lab Support Testing Viruses & Mycoplasma Testing Audits & Regulations for Micro Aseptic Processing & Biology Microbial Identifications

Bioburden Testing
Endotoxin Testing
Microbial Identifications
Growth Promotion & BI's
Environmental Monitoring
Water Sampling
Media Fill Vial Inspection
EM Trends & Deviation
Handling Workshop