

Quality Control Training Curriculum

— Lectures
— Practicals

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 Assays
Mass Spectrometry
Titration and Karl Fischer
Intro to Polarimetry, Refractography & Viscosity
Intro to Spectroscopy (UV, IR, Raman)
Future Strategies in the Analysis of ATMPs
PCR
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 (IEF - Slab Gel)
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

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