# **Quality Control Curriculum**

### **General QC Curriculum**

#### **Lectures**

- QC Testing of Biologics
- Sample Management
- GxP
- Quality Management Systems
- Lab Safety
- Introduction to Regulation of Medicines
- Method Qualification and Validation

## **Practicals**

- Water sampling with TOC
- Basic lab methods
- Weighing/balance overview
- Common lab calculations
- Lab safety

# **QC Analytics**

#### Lectures

- Introduction to Quality Control and Overview of QC Methods for Biologics
- Capillary Electrophoresis
- Gel Electrophoresis (SDS PAGE, IEF)
- Compendial methods (Conductivity, pH, Osmolality)
- HPLC/UPLC (Peptide Mapping, SEC)
- Immunoassays
- Bioassays
- Introduction to Glycobiology
- Glycan Analysis

- Protein Estimation Assays
- Introduction to Mass Spectrometry
- Karl Fischer Titration
- Introduction to Polarimetry, Refractometry & Viscometry
- Introduction to Spectroscopy (UV, IR, Raman)
- PCR
- Chromatography in the Analysis of Proteins
- Volumetric and Gravimetric Methods

#### **Practicals**

- Protein Stability
- Protein Estimation Assays (Bradford, A280, SoloVPE)
- SDS-PAGE
- Capillary Electrophoresis (CE)
- Size Exclusion Chromatography (SEC)
- Glycan Sample Prep and Analysis
- ELISA (Pro A, Competitive, HCP)
- Empower Data Analysis
- HPLC Instrumentation and Troubleshooting
- Cell-based Bioassay
- Karl Fischer Titration
- Common Lab Calculations
- qPCR

# **QC Microbiology**

#### Lectures

- 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

#### **Practicals**

- Microbial Identifications
- Bioburden Testing
- Support Testing Biological Indicators
- Support Testing (Growth Promotion & Bls)
- Water Sampling
- EM Location & Sampling
- Endotoxin Testing
- Sterility Testing
- Rapid Mycoplasma Testing