Advanced Analytical Techniques for Biologics Characterization Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The biologics market is rapidly expanding, driving critical demand for rigorous physicochemical and structural characterization to ensure product quality, safety, and efficacy. This intensive training course delves into the cutting-edge methodologies essential for comprehensive analysis of complex biomolecules, including monoclonal antibodies, ADCs, and gene therapy products. Participants will gain expertise in advanced separation, mass spectrometry, and spectroscopic techniques, focusing on the identification and quantitation of Critical Quality Attributes (CQAs), post-translational modifications (PTMs), and impurities. This training directly addresses the evolving regulatory landscape by equipping analysts with the skills to accelerate drug development and master biosimilarity and bioactivity assessments in a GxP compliant environment.

Advanced Analytical Techniques for Biologics Characterization Training Course is designed to empower biopharmaceutical scientists and QC/QA analysts with the practical and theoretical knowledge required to overcome the analytical challenges associated with modern large molecule drug development. By mastering high-resolution mass spectrometry (HRMS), multi-attribute method (MAM) development, and advanced chromatographic separations, attendees will immediately enhance their lab's capabilities in structural elucidation and quality control. Strong emphasis is placed on data integrity, method validation, and real-world case studies covering aggregation, fragmentation, and glycosylation analysis, ensuring participants can apply these advanced analytical techniques to streamline process development and support regulatory submissions.

Programme Curriculum

Advanced Analytical Techniques for Biologics Characterization Training Course

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Course Objectives

1. Master the application of High-Resolution Mass Spectrometry (HRMS) for accurate intact mass analysis and peptide mapping.
2. Develop robust Multi-Attribute Method (MAM) workflows for simultaneous CQA monitoring and impurity detection.
3. Optimize Ultra-High Performance Liquid Chromatography (UHPLC) and Capillary Electrophoresis (CE) separations for complex protein isoforms.
4. Characterize Post-Translational Modifications (PTMs), especially glycosylation and oxidation, using state-of-the-art techniques.
5. Apply advanced Spectroscopic Techniques for assessing higher-order structure (HOS) and conformational stability.
6. Evaluate the formation and properties of protein aggregates and sub-visible particles using SEC-MALS and Flow Imaging.
7. Implement orthogonal methods for comprehensive biosimilarity and comparability assessments.
8. Design and validate analytical methods in compliance with ICH Q2(R1) and GxP standards.
9. Interpret complex proteomic data and ensure data integrity in a regulated setting.
10. Analyze challenging gene therapy vectors for full/empty capsid ratio and purity.
11. Troubleshoot common issues in LC-MS/MS and Peptide Mapping workflows.
12. Accelerate early-stage development by integrating rapid micro-scale characterization techniques.
13. Quantify Drug-to-Antibody Ratio (DAR) for Antibody-Drug Conjugates (ADCs).

Target Audience

1. Analytical Scientists in Biologics R&D
2. Quality Control (QC) and Quality Assurance (QA) Analysts
3. Process Development Scientists

4. Method Development and Validation Specialists
5. Formulation Scientists
6. Regulators and Auditors
7. Biosimilarity and Comparability Assessment Teams
8. Lab Managers

Course Modules

Module 1: Fundamentals of Biologics CQAs and Characterization Strategy

- Defining Critical Quality Attributes (CQAs) for mAbs and complex biologics.
- Regulatory expectations for structural elucidation (ICH Q6B).
- Overview of orthogonal analytical techniques required for full characterization.
- Strategy for Comparability studies during process changes.
- Case Study: Establishing a minimum CQA panel for an early-stage IgG1.

Module 2: Advanced LC Separations for Protein Isoforms

- Principles and optimization of Ion Exchange Chromatography (IEX) for charge variants.
- Hydrophobic Interaction Chromatography (HIC) for ADC analysis and aggregation.
- High-resolution Size Exclusion Chromatography (SEC) for aggregate detection.
- Implementation of UHPLC to enhance speed and resolution.
- Case Study: Separating and quantifying deamidation variants using high-pH IEX.

Module 3: Intact and Subunit Mass Analysis via HRMS

- Theory and application of Orbitrap and Q-TOF high-resolution mass spectrometers.
- Sample preparation and data processing for accurate intact mass determination.
- Utilizing sub-unit analysis for faster characterization.
- Quantification of major glycoforms and oxidation at the intact level.
- Case Study: Using accurate mass to confirm the sequence and identify an unknown impurity in a recombinant protein.

Module 4: Comprehensive Peptide Mapping and PTM Analysis

- Optimization of tryptic digestion and sample cleanup protocols.
- Developing LC-MS/MS methods for 100% sequence coverage.
- Targeted identification and quantification of PTMs
- Advanced fragmentation techniques (CID, HCD, ETD) for residue-level confirmation.
- Case Study: Mapping a difficult-to-analyze N-terminal Pyroglutamate and its impact on binding.

Module 5: Multi-Attribute Method (MAM) Development and Implementation

- Rationale and regulatory benefits of transitioning from traditional QC to MAM.
- Step-by-step development of a robust LC-HRMS MAM workflow.
- Software tools for automated CQA tracking and new peak detection (NPD).
- Validation considerations and implementation in a GxP environment.
- Case Study: Replacing multiple compendial assays with a single, validated MAM in a QC lab.

Module 6: In-Depth Glycosylation Analysis

- Release and derivatization of N- and O-linked glycans.

- Separation and analysis of fluorescently labeled glycans via HILIC-HPLC.
- Mass spectrometry approaches for site-specific glycopeptide analysis.
- Role of glycosylation in Fc effector function and pharmacokinetics.
- Case Study: Comparing the glycan profile of a biosimilar to a reference product and identifying critical differences.

Module 7: Characterization of Protein Aggregates and Particles

- Mechanisms of protein aggregation and factors influencing stability.
- Advanced SEC-MALS for absolute molecular weight determination.
- Dynamic Light Scattering (DLS) and Analytical Ultracentrifugation (AUC) for size and shape.
- Detection and counting of sub-visible particles using Flow Imaging microscopy.
- Case Study: Troubleshooting a high-aggregate lot using AUC and Flow Imaging to pinpoint the aggregation mechanism.

Module 8: Higher-Order Structure (HOS) Characterization

- Importance of HOS in maintaining bioactivity and stability.
- Application of Circular Dichroism (CD) and FTIR for secondary structure.
- Use of Hydrogen Deuterium Exchange Mass Spectrometry (HDX-MS) for tertiary structure comparison.
- Thermal stability assessment via DSC/DSF
- Case Study: Assessing the impact of a formulation change on the secondary structure of an mAb using FTIR and CD.

Module 9: Analytical Strategies for Antibody-Drug Conjugates (ADCs)

- Challenges in ADC characterization due to heterogeneity.
- Determining the Drug-to-Antibody Ratio (DAR) using HIC and intact mass.
- Analysis of drug distribution and linker stability.
- Quantification of free drug and non-conjugated antibody.
- Case Study: Optimizing HIC conditions to resolve different DAR species and calculate the average DAR.

Module 10: Characterization of Gene Therapy Vectors (AAV)

- Specific CQAs for Adeno-Associated Virus (AAV) vectors.
- Determining full-to-empty capsid ratio using AUC, AEX, and light scattering.
- Analysis of capsid protein purity and post-translational modifications.
- Techniques for detecting and quantifying residual host cell DNA/proteins.
- Case Study: Validating a rapid AEX-HPLC method for quantifying the percent of full AAV capsids in a bulk drug substance.

Module 11: Advanced Capillary Electrophoresis (CE) Techniques

- Principles of CZE (Capillary Zone Electrophoresis) for high-resolution separations.
- Application of CIEF (Capillary Isoelectric Focusing) for charge variant analysis.
- Using CE-SDS for purity and size homogeneity assessment.
- Advantages and limitations of CE versus traditional HPLC methods.
- Case Study: Implementing a cIEF method to resolve and quantify minor basic and acidic variants of a therapeutic protein.

Module 12: Method Validation and GxP Compliance

- Defining the validation lifecycle according to ICH Q2(R1).
- Specificity, linearity, accuracy, and precision testing for biologics assays.
- Ensuring data integrity in analytical method execution and reporting.
- Best practices for method transfer and remediation.
- Case Study: Developing a full validation protocol for a peptide map CQA release assay under GMP conditions.

Module 13: Data Analysis and Bioinformatics for Biologics

- Tools and software for automated HRMS data processing and PTM reporting.
- Statistical methods for comparability and biosimilarity assessment.
- Introduction to chemometrics for process monitoring.
- Strategies for effective data visualization and regulatory submission packages.
- Case Study: Using statistical process control (SPC) charts on MAM data to monitor lot-to-lot consistency.

Module 14: Practical Troubleshooting in the Analytical Lab

- Diagnosing and resolving common issues in LC-MS/MS sensitivity and peak shape.
- Strategies for managing complex or highly viscous samples.
- Troubleshooting aggregate formation during sample preparation.
- Addressing matrix effects and ion suppression in mass spectrometry.
- Case Study: Systematic troubleshooting of low sequence coverage in a peptide map, tracing the issue back to sample cleanup.

Module 15: Emerging and Next-Generation Characterization Techniques

- Introduction to Native Mass Spectrometry for non-covalent complexes.
- Integration of Microfluidic Separation and rapid analysis platforms.
- Advances in Automation and High-Throughput (HTP) screening.
- Application of Artificial Intelligence (AI) and Machine Learning (ML) in data interpretation.
- Case Study: Evaluating a novel high-throughput screening method for HOS stability in early-stage formulation development.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org **or call** +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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