Mass Spectrometry 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

Mass Spectrometry (MS) is an indispensable analytical technique that plays a crucial role in the characterization of biologics, enabling high-throughput and precise analysis of proteins, peptides, and complex biomolecules. In biopharmaceuticals and biotechnology industries, the demand for cutting-edge techniques to characterize biologic drugs, particularly monoclonal antibodies (mAbs), recombinant proteins, and other biologic entities, has risen sharply. Mass Spectrometry for Biologics Characterization Training Course equips professionals with essential skills to utilize MS in biologic drug development, ensuring higher accuracy and speed in characterization processes, crucial for regulatory compliance and product quality.

This advanced training covers the principles, applications, and technologies behind mass spectrometry in biologics characterization, offering both theoretical understanding and hands-on experience. With a focus on bioanalytical techniques such as high-resolution mass spectrometry and proteomics, participants will learn how to interpret data, troubleshoot problems, and implement MS methodologies across different biologic platforms. The course is designed for both newcomers and experienced professionals seeking to enhance their analytical skills with state-of-the-art mass spectrometry techniques.

Programme Curriculum

Mass Spectrometry for Biologics Characterization Training Course

Introduction

Mass Spectrometry (MS) is an indispensable analytical technique that plays a crucial role in the characterization of biologics, enabling high-throughput and precise analysis of proteins, peptides, and complex biomolecules. In biopharmaceuticals and biotechnology industries, the demand for cutting-edge techniques to

characterize biologic drugs, particularly monoclonal antibodies (mAbs), recombinant proteins, and other biologic entities, has risen sharply. Mass Spectrometry for Biologics Characterization Training Course equips professionals with essential skills to utilize MS in biologic drug development, ensuring higher accuracy and speed in characterization processes, crucial for regulatory compliance and product quality.

This advanced training covers the principles, applications, and technologies behind mass spectrometry in biologics characterization, offering both theoretical understanding and hands-on experience. With a focus on bioanalytical techniques such as high-resolution mass spectrometry and proteomics, participants will learn how to interpret data, troubleshoot problems, and implement MS methodologies across different biologic platforms. The course is designed for both newcomers and experienced professionals seeking to enhance their analytical skills with state-of-the-art mass spectrometry techniques.

Course Duration

10 days

Course Objectives

1. Gain an in-depth understanding of mass spectrometry techniques and their application in biologics.
2. Master the use of high-resolution mass spectrometry in the analysis of monoclonal antibodies and proteins.
3. Learn to analyze the protein structure and post-translational modifications (PTMs) using mass spectrometry.
4. Understand peptide mapping techniques and how they aid in biologics characterization.
5. Develop skills in quantitative analysis and interpretation of biologic drug data.
6. Implement proteomic analysis to characterize complex biologics.
7. Study the role of MS in stability studies of biologic molecules.
8. Familiarize with sample preparation techniques critical for biologics MS analysis.
9. Explore MS's role in drug development and its integration with other analytical techniques like chromatography.
10. Discover regulatory aspects of mass spectrometry in biologics characterization for FDA and EMA compliance.
11. Learn the latest MS technologies such as Orbitrap and QTOF for biologics characterization.
12. Understand how MS data is used in biomarker discovery and validation for biologic products.
13. Apply MS for biopharmaceutical manufacturing and troubleshooting during product development.

Target Audience

1. Biopharmaceutical Scientists
2. Analytical Chemists
3. Biotechnology Researchers
4. Drug Development Managers
5. Quality Control Professionals
6. Regulatory Affairs Specialists
7. Laboratory Technicians
8. Postgraduate Students in Bioanalytics

Course Outline

Module 1: Introduction to Mass Spectrometry in Biologics

- Overview of mass spectrometry principles.
- Evolution of MS in biopharmaceuticals.
- MS as a bioanalytical tool in biologics characterization.
- Differences between MS and traditional characterization methods.
- Case study: Applications in biopharma and biotechnology.

Module 2: Sample Preparation for Biologics MS Analysis

- Protein extraction techniques.
- Digestion protocols for peptide mapping.
- Impact of sample purity on MS results.
- Automation in sample prep workflows.
- Case study: Challenges in sample preparation for biologics.

Module 3: Peptide Mapping and Sequence Analysis

- Peptide mapping principles and techniques.
- Sequence analysis using MS.
- Enzyme digestion strategies.
- Advanced peptide identification techniques.
- Case study: Peptide mapping of monoclonal antibodies.

Module 4: Post-translational Modifications (PTMs)

- PTM types and their importance in biologics.
- MS techniques for PTM identification.
- Quantification of PTMs in biologics.
- Role of MS in glycosylation and phosphorylation analysis.
- Case study: Glycosylation analysis in mAbs.

Module 5: Mass Spectrometry Data Analysis

- Tools and software for MS data analysis.
- Interpreting mass spectra and chromatograms.
- Data quality control and validation techniques.
- Common MS data analysis pitfalls and solutions.
- Case study: Data interpretation for biologics stability.

Module 6: Quantitative Analysis of Biologics

- Principles of quantitative mass spectrometry.
- Techniques for concentration determination.
- Calibration and validation of quantitative assays.
- Applications in biomarker discovery.
- Case study: Quantification of recombinant proteins.

Module 7: High-Resolution Mass Spectrometry Technologies

- Overview of high-resolution MS systems (Orbitrap, QTOF).
- Sensitivity and resolution in biologics analysis.
- Advantages of high-resolution MS in large biomolecules.
- Limitations and troubleshooting.

?? Case study: Using Orbitrap for antibody characterization.

Module 8: MS in Stability Studies of Biologics

- Role of MS in analyzing protein stability.
- Thermal and chemical stability studies using MS.
- Application in protein aggregation studies.
- Data interpretation for stability testing.
- Case study: Stability analysis of a biopharmaceutical product.

Module 9: MS for Biopharmaceutical Manufacturing

- MS applications in manufacturing settings.
- Process optimization using MS.
- In-line MS for real-time monitoring.
- Quality control in biologics production.
- Case study: MS in bioprocess monitoring.

Module 10: MS for Biologics Purity and Contamination Analysis

- Impurity detection using MS.
- Identifying contaminants and degradation products.
- Purity assessment methods.
- MS in batch-to-batch consistency studies.
- Case study: Purity analysis of recombinant protein.

Module 11: Regulatory Aspects of MS in Biologics

- Understanding FDA, EMA, and ICH guidelines.
- MS as part of regulatory submission dossiers.
- Compliance challenges and solutions.
- Case study: Regulatory approval of a biologic drug using MS data.
- Data management and traceability for audits.

Module 12: Advances in MS Technology for Biologics Characterization

- Emerging technologies in MS
- MS coupled with other analytical platforms.
- Future trends in biologics MS.
- MS for next-generation biologics.
- Case study: Novel MS techniques in protein therapeutics.

Module 13: Troubleshooting MS Analysis for Biologics

- Common issues encountered in MS analysis.
- Troubleshooting MS data interpretation.
- Optimizing MS settings for biologics.
- Resolving protein aggregation issues.
- Case study: Troubleshooting in protein characterization.

Module 14: Case Studies and Applications

- Real-world case studies of MS in biologics characterization.

- Applications in monoclonal antibody development.
- MS in biosimilar characterization.
- Case study: MS applications in vaccine development.
- Collaborative case study discussions.

Module 15: Future of Mass Spectrometry in Biologics

- Emerging research in MS for biologics.
- Novel applications of MS in biotechnology.
- MS in personalized medicine.
- Integrating MS into AI-driven drug discovery.
- Case study: MS in CRISPR technology.

Training Methodology

- Interactive Lectures: Instructor-led sessions combined with multimedia presentations.
- Hands-On Workshops: Practical experience with mass spectrometry instruments and data analysis.
- Case Study Discussions: Real-world applications of mass spectrometry in biologics.
- Group Activities: Collaborative problem-solving and troubleshooting exercises.
- Q&A Sessions: Expert-led discussions and query resolution.

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

Ready to enroll or request a customized program? Book online or contact us:

Register Online Now

Email: info@fineskilltrainingcenter.com | Website: www.fineskilltrainingcenter.com