Advanced Glycan Analysis of Biologics 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

Advanced Glycan Analysis of Biologics Training Course is designed for biopharmaceutical professionals to master the cutting-edge field of Advanced Glycan Analysis for therapeutic proteins. Glycosylation, a critical post-translational modification (PTM), is a major Critical Quality Attribute (CQA) for the safety, efficacy, and stability of biologics, particularly monoclonal antibodies (mAbs) and biosimilars. This course focuses on practical, high-resolution analytical techniques, including advanced Mass Spectrometry (MS) and Liquid Chromatography (LC) methods, providing the expertise necessary for robust glycoform profiling, structural elucidation, and quantitative analysis in a regulated environment.

The course bridges theoretical glycobiology principles with hands-on application of glycoanalytical workflows to ensure regulatory compliance and accelerate bioprocess development. Participants will gain troubleshooting proficiency and a deep understanding of how glycosylation impacts product function, including Fc effector function and immunogenicity. By emphasizing bioinformatics and data interpretation for complex glycan structures, this training empowers scientists to drive Quality by Design (QbD) initiatives, streamline biosimilar comparability studies, and secure the product quality of next-generation therapeutic glycoproteins.

Programme Curriculum

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Course Objectives

1. Master state-of-the-art Mass Spectrometry (MS) techniques for high-resolution glycan and glycopeptide structural elucidation.
2. Design and execute robust, validated glycoanalytical workflows for N-linked and O-linked glycosylation.
3. Evaluate the role of glycosylation as a Critical Quality Attribute (CQA) in the stability, efficacy, and immunogenicity of biologics.
4. Apply Hydrophilic Interaction Liquid Chromatography (HILIC) and other advanced LC methods for complex glycan separation and quantification.
5. Perform accurate, quantitative glycomics to determine glycan abundance and heterogeneity for process monitoring.
6. Interpret and manage large, complex glycomics data sets using current bioinformatics tools and software.
7. Understand the impact of Fc glycosylation on the Fc effector function of monoclonal antibodies
8. Navigate and ensure compliance with global Regulatory Guidelines for glycoprotein characterization.
9. Develop robust analytical methods to support Biosimilar Comparability Studies and quality control (QC).
10. Implement best practices for sample preparation including enzymatic release and fluorescent labeling of glycans.
11. Troubleshoot common analytical challenges in glycoform profiling and method optimization for reproducibility.
12. Analyze and characterize Post-Translational Modifications (PTMs) beyond glycosylation that affect biologic quality.
13. Integrate Quality by Design (QbD) principles into bioprocess development through analytical characterization.

Target Audience

1. Analytical Scientists and R&D Chemists.
2. Quality Control (QC) and Quality Assurance (QA) personnel.
3. Process Development and Bioprocess Engineers.
4. Biosimilar Development teams.
5. Senior Technicians and Lab Managers.
6. Regulatory Affairs Professionals.

7. Researchers in Glycobiology and academia.
8. Scientists involved in early-stage Drug Discovery and protein engineering.

Course Modules

Module 1: Fundamentals of Glycosylation in Biologics

- Glycan structures and nomenclature
- Role of glycosylation as a Post-Translational Modification (PTM).
- Impact on protein folding, stability, and therapeutic function.
- Biosynthesis pathways in host cells
- Defining glycosylation as a Critical Quality Attribute (CQA).
- Case Study: The relationship between Fc glycosylation and the Antibody-Dependent Cellular Cytotoxicity (ADCC) activity of a therapeutic mAb.

Module 2: Sample Preparation for Released Glycan Analysis

- Enzymatic release of N-glycans and O-glycan release methods.
- Fluorescent labeling techniques for detection and quantification.
- Solid Phase Extraction (SPE) and clean-up for complex matrices.
- Optimization of digestion and labeling for high-throughput workflows.
- Minimizing sample loss and handling artifacts.
- Case Study: Optimizing sample preparation to handle a heavily glycosylated fusion protein with challenging O-glycan release.

Module 3: Hydrophilic Interaction Liquid Chromatography (HILIC)

- Principles of HILIC for separating highly polar glycan structures.
- Method development for robust and reproducible separation.
- Fluorescence detection (FLD) and integration with Mass Spectrometry.
- Use of external standards and retention time normalization.
- Quantification and relative abundance determination of glycoforms.
- Case Study: Developing a HILIC-FLD method to achieve baseline separation for high-mannose and complex glycan structures in a biosimilar product.

Module 4: Advanced Mass Spectrometry (MS) for Glycans

- ESI and MALDI applications in glycan analysis.
- Mass analyzers: Orbitrap, QTOF, and triple quad for high resolution and accuracy.
- Principles of Tandem Mass Spectrometry (MS/MS) for structural elucidation.
- Accurate mass determination and mass defect analysis.
- Data acquisition strategies for maximizing glycan coverage.
- Case Study: Using High-Resolution MS to confirm the presence of low-abundance terminal??-Gal epitopes that are potential immunogens.

Module 5: N-linked Glycan Analysis Workflow

- Step-by-step workflow from release to structural assignment.
- Exoglycosidase array digestion for sequential structural confirmation.
- Software tools for matching experimental data to glycan databases.
- Relative and absolute quantification strategies.
- Interpreting glycan profile shifts in process development.

- Case Study: Investigating an unexpected shift in galactosylation during a change in cell culture feed media and determining the root cause.

Module 6: O-linked Glycan Analysis Challenges

- Unique challenges of O-glycan release and stability
- Analysis of mucin-type O-glycans and core structures.
- Site-specific O-glycosylation characterization using Glycopeptide Analysis.
- LC-MS methods for O-glycan profiling.
- Strategies for handling highly heterogeneous O-glycan populations.
- Case Study: Characterizing the O-glycosylation profile of a proprietary recombinant therapeutic enzyme and verifying its impact on in vivo half-life.

Module 7: Glycopeptide Analysis and Site-Specificity

- Enrichment techniques for isolating glycopeptides from tryptic digests.
- LC-MS/MS strategies for simultaneous peptide and glycan identification.
- Determining the exact glycosylation site.
- Using intact mass analysis of protein fragments.
- Interpretation of MS fragmentation data for structural assignment.
- Case Study: Determining the site-specific glycosylation of a multi-domain fusion protein to ensure the glycan doesn't interfere with the active site.

Module 8: Quantitative Glycomics

- Relative versus absolute quantification methodologies.
- Implementation of labeled internal standards for accuracy.
- Calibration curves and method validation for quantitative assays.
- Addressing challenges in quantifying low-abundance and complex mixtures.
- Statistical analysis of quantitative glycoform data.
- Case Study: Developing a validated quantitative assay for sialylation to monitor lot-to-lot consistency in a high-value glycoprotein.

Module 9: Data Processing and Bioinformatics Tools

- Software for raw MS data processing and peak picking.
- Algorithms for automated glycan composition and structural assignment.
- Data visualization and reporting of complex glycan profiles.
- Integration of HILIC and MS data for comprehensive characterization.
- Data management for regulatory submissions and long-term storage.
- Case Study: Utilizing bioinformatics to rapidly identify and confirm a novel, low-level glycan structure in a late-stage biologic product.

Module 10: Biosimilar Comparability Studies

- Regulatory requirements for demonstrating biosimilarity in glycosylation.
- Designing an effective analytical plan for comparative glycoform profiling.
- Statistical equivalence testing for critical glycan attributes.
- Risk-based approach to assessing glycosylation drift.
- Case studies of successful and challenging biosimilar submissions.

- Case Study: A comparative analysis of the G0?ÇïF and G2?ÇïF glycoforms in a proposed biosimilar versus the reference product to demonstrate comparability.

Module 11: Regulatory Compliance and Documentation

- Overview of ICH Q6B and other key guidelines for glycoprotein characterization.
- Defining reportable glycan attributes for regulatory filings.
- Method validation parameters.
- Good Documentation Practices (GDP) for analytical records.
- Preparing the Glycosylation section for an Investigational New Drug (IND) or Biologics License Application (BLA).
- Case Study: Auditing an existing in-house glycan analysis method against current regulatory expectations and proposing remediation strategies.

Module 12: Advanced Mass Spectrometry Techniques

- Ion Mobility Spectrometry (IMS) for separating glycan isomers.
- Native MS approaches for intact glycoprotein analysis.
- Electron-transfer dissociation (ETD) for sequencing glycopeptides.
- Multiplexed quantitative analysis using isobaric tags.
- Emerging MS technologies in the field of glycomics.
- Case Study: Using IMS-MS to distinguish between ??(1,3) and ??(1,6) linked fucose isomers that have different functional implications.

Module 13: Troubleshooting Glycoanalytical Workflows

- Diagnosing poor HILIC peak shape or resolution issues.
- Identifying and eliminating common MS interferences and contaminants.
- Root cause analysis for unexpected shifts in the glycan profile.
- Strategies for handling challenging, low-concentration samples.
- Quality control (QC) procedures and system suitability testing.
- Case Study: Diagnosing a systemic analytical failure and tracing the root cause back to a buffer issue in the HILIC system.

Module 14: Integrating Glycan Data into QbD

- Defining the Glycosylation Quality Target Product Profile (QTPP).
- Identifying and controlling Critical Process Parameters (CPPs) that influence glycosylation.
- Developing control strategies based on analytical characterization data.
- Using risk assessments to prioritize glycan testing.
- Implementation of process analytical technology (PAT) for monitoring.
- Case Study: Using glycan data to establish the design space for a fed-batch cell culture process to ensure target galactosylation levels.

Module 15: Impact on Immunogenicity and Efficacy

- The role of non-human glycans as immunogens.
- Impact of high-mannose and agalactosylated structures on clearance
- The function of sialylation on the anti-inflammatory activity of IgG.
- Glycoengineering strategies for optimized therapeutic function.
- Assessing the clinical significance of minor glycoform variations.

- Case Study: Analyzing a therapeutic protein lot associated with an immunogenic response and determining if an aberrant glycan profile was the contributing factor.

Training Methodology

The course employs a highly interactive and practical methodology, combining:

- Interactive Lectures.
- Hands-on Workshops.
- Case Study Analysis.
- Problem-Based Learning.
- Peer-to-Peer Discussion.

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

Start Date	End Date	Location	Price
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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