Advanced Biologics: Monoclonal Antibodies and Beyond 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 field of biologics is rapidly transforming modern medicine, with Monoclonal Antibodies standing as the most significant and commercially successful class of therapeutic agents. These highly specific targeted therapies are at the forefront of treating complex diseases like cancer, autoimmune disorders, and infectious diseases. Advanced Biologics: Monoclonal Antibodies and Beyond Training Course dives deep into the entire mAb lifecycle, from discovery and engineering to clinical development and commercial-scale manufacturing. Participants will master the critical quality attributes and regulatory landscape essential for bringing these innovative therapies to patients, ensuring they are prepared for the next wave of drug development.

While mAbs remain central, the future of biopharma is expanding into next-generation biologics. This course extends beyond conventional antibodies to explore emerging modalities such as bispecific antibodies, antibody-drug conjugates, and cell and gene therapies providing a holistic view of the advanced biologics pipeline. We will dissect the technical challenges in process development, formulation, and analytical characterization for these complex molecules. By focusing on quality by design principles and navigating global regulatory submissions, this program equips professionals with the cutting-edge knowledge and bioprocessing expertise needed to drive innovation in the biopharmaceutical industry

Programme Curriculum

Advanced Biologics: Monoclonal Antibodies and Beyond Training Course

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Course Objectives

Upon completion of this course, participants will be able to:

1. Analyze the molecular mechanisms and therapeutic potential of different mAb classes
2. Evaluate state-of-the-art antibody discovery techniques, including phage display and B-cell sorting.
3. Design and engineer novel bispecific and trispecific antibodies for enhanced efficacy.
4. Master the principles and practical application of Antibody-Drug Conjugates, including linker and payload selection.
5. Assess the impact of glycosylation and other Post-Translational Modifications on mAb stability and function.
6. Apply Quality by Design and Process Analytical Technology to bioprocess development.
7. Optimize upstream bioprocessing for high titer and productivity.
8. Develop robust downstream purification strategies for high-purity mAbs.
9. Characterize biologics using advanced bioanalytical techniques
10. Formulate stable and patient-friendly drug products for various delivery routes.
11. Interpret the current FDA and EMA regulatory requirements for biologics registration
12. Address the challenges and opportunities in biosimilar development and comparability studies.
13. Explore the integration of AI/Machine Learning in biologics R&D and manufacturing.

Target Audience

1. R&D Scientists
2. Process Development Engineers
3. Analytical Scientists and QC/QA Specialists
4. Formulation Scientists
5. Regulatory Affairs Professionals
6. Biomanufacturing/Operations Staff
7. Project Managers in Biopharma
8. Technology Transfer Specialists

Course Modules

Module 1: Fundamentals of Biologics and mAb Structure

- Introduction to biologics: scope, history, and market impact.
- Detailed structure, nomenclature, and function of different IgG subclasses.
- Molecular mechanisms of action: ADCC, CDC, immune checkpoint blockade.
- Overview of therapeutic areas: oncology, autoimmunity, infectious disease.
- Case Study: The clinical success and mechanism of action of Rituximab

Module 2: Monoclonal Antibody Discovery and Optimization

- Hybridoma technology versus modern recombinant techniques
- Humanization and chimerization to reduce immunogenicity.
- Techniques for affinity maturation and half-life extension
- High-throughput screening and primary cell-based assays.
- Case Study: The discovery process of Adalimumab and its optimization from a murine source.

Module 3: Next-Generation Antibody Formats

- Design and applications of bispecific and trispecific antibodies
- Small antibody fragments
- Non-antibody scaffolds and alternative protein therapeutics.
- Considerations for multi-specific antibody manufacturing and stability.
- Case Study: The clinical impact and T-cell engagement mechanism of the first approved BiTE therapeutic.

Module 4: Antibody-Drug Conjugates (ADCs): Design and Development

- Critical components of an ADC.
- Site-specific conjugation methods versus conventional random conjugation.
- Toxicity, bystander effect, and therapeutic index optimization.
- Quality control for Drug-to-Antibody Ratio (DAR) and aggregation.
- Case Study: Analysis of Trastuzumab Emtansine (Kadcyla) lessons in linker stability and payload efficacy.

Module 5: Cell Line Development and Upstream Processing (USP)

- Selection and engineering of mammalian expression systems
- Process intensification: perfusion vs. fed-batch strategies.
- Media optimization, feeding strategies, and control of CQAs in bioreactors.
- Scale-up principles and tech transfer from bench to clinical scale.
- Case Study: Implementing a high-titer fed-batch strategy to reduce Cost of Goods Sold

Module 6: Downstream Processing (DSP) and Purification

- Primary capture steps.
- Intermediate purification
- Virus clearance/inactivation strategies
- Non-chromatographic purification and continuous processing concepts.
- Case Study: Designing a three-column purification train to meet purity and recovery goals.

Module 7: Analytical Characterization and Bioassays

- Advanced techniques for structural analysis.
- Physicochemical characterization: SEC-HPLC, CE-SDS, and DSC.
- Potency assays and mechanism-of-action bioassays
- Assessment of charge variants and host cell proteins
- Case Study: Using Peptide Mapping and LC-MS/MS to identify a critical deamidation site.

Module 8: Glycosylation and Post-Translational Modifications (PTMs)

- The critical role of glycosylation on mAb function, PK/PD, and immunogenicity.
- Analysis and control of PTMs.
- Strategies for engineering afucosylated and other custom glycoforms.
- Impact of process parameters on PTM profile
- Case Study: Modifying CHO cell culture to control the level of sialylation for an enhanced therapeutic.

Module 9: Formulation and Drug Product Development

- Excipient selection.
- Mechanisms of protein degradation.
- Development of high-concentration subcutaneous formulations.
- Container/closure selection and device considerations
- Case Study: Overcoming high viscosity challenges in a 150 mg/mL mAb formulation.

Module 10: Quality by Design (QbD) in Biologics Development

- Defining the Target Product Profile and Critical Quality Attributes
- Risk assessment: FMEA and identifying Critical Process Parameters
- Defining the Design Space and control strategy for biomanufacturing.
- Implementation of Process Analytical Technology tools.
- Case Study: Applying QbD principles to define the chromatography loading range for a stable process.

Module 11: Regulatory Strategy and Submissions (IND/BLA)

- Global regulatory landscape: FDA, EMA, and ICH guidelines.
- Structure and content of Investigational New Drug (IND) applications.
- Preparing the Chemistry, Manufacturing, and Controls (CMC) section for a Biologics License Application (BLA).
- Comparability protocols and post-approval changes.
- Case Study: Navigating an FDA deficiency letter related to HCP validation data in the CMC section.

Module 12: Biosimilars and Comparability Studies

- Definition, regulatory pathways, and global acceptance of biosimilars.
- Designing and executing comprehensive comparability studies
- The concept of totality of the evidence for demonstrating biosimilarity.
- Immunogenicity risk and anti-drug antibody (ADA) testing.
- Case Study: A successful biosimilar program demonstrating analytical and clinical equivalence to the reference product.

Module 13: Facility Design and cGMP Manufacturing

- Principles of Good Manufacturing Practice in a biologics facility.
- Facility design.
- Aseptic processing and contamination control strategies.
- Validation of equipment, cleaning, and sterile filters.
- Case Study: Transitioning a traditional multi-product stainless steel facility to a flexible single-use bioprocess platform.

Module 14: Emerging Trends and Digital Biologics

- Introduction to Cell and Gene Therapy (CGT) manufacturing challenges
- In silico tools, AI, and Machine Learning for antibody design and process modeling.
- Continuous bioprocessing and integrated manufacturing platforms.
- Personalized medicine and point-of-care biomanufacturing.
- Case Study: Utilizing Predictive Modeling to optimize cell culture feeding schedules.

Module 15: Commercialization and Supply Chain

- The economics of biologics manufacturing: COGS analysis and cost drivers.
- Global supply chain logistics and cold chain management for biologics.
- Intellectual property and patent considerations for novel biologics.
- Outsourcing strategies
- Case Study: Managing the global distribution and temperature excursion risks for a commercial mAb product.

Training Methodology

The course employs a highly interactive and practical methodology designed for professionals:

- Interactive Lectures & Discussions.
- In-Depth Case Studies.
- Group Problem-Solving.
- Industry Expert Insights.

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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