Bispecific and Multispecific Antibody Engineering 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 undergoing a revolutionary transformation, with Bispecific Antibodies (BsAbs) and Multispecific Antibodies (MsAbs) emerging as next-generation therapeutics that overcome the limitations of traditional monoclonal antibodies (mAbs). These engineered molecules, capable of simultaneously engaging multiple targets, unlock potent, novel mechanisms of action (MoAs) essential for tackling complex diseases like solid tumors, hematologic malignancies, and autoimmune disorders. Key innovations such as T-cell Engagers (TCEs), which redirect cytotoxic T cells to tumor cells, and formats designed for enhanced half-life and tumor penetration, are reshaping the clinical landscape. Bispecific and Multispecific Antibody Engineering Training Course provides a deep, practical dive into the rational design, advanced protein engineering, and developability assessment required to successfully advance these complex, multi-chain molecules from discovery through to GMP manufacturing.

The complexity inherent in designing molecules that ensure correct chain pairing, high stability, and optimal pharmacokinetics (PK) while mitigating critical risks like cytokine release syndrome (CRS) demands specialized expertise. Our intensive training is focused on equipping biopharma professionals with the latest tools, including AI/Machine Learning (AI/ML) applications for in silico drug design, high-throughput screening technologies (HTS), and proprietary engineering platforms like Knobs-into-Holes (KIH) and SEED. Participants will master the end-to-end lifecycle, from target selection and format optimization to quality control (QC) and navigating the intricate regulatory pathways for BsAb and MsAb products, ensuring they remain at the forefront of next-generation immunotherapeutics.

Programme Curriculum

Bispecific and Multispecific Antibody Engineering Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Master the fundamental Antibody Engineering principles for rational design of asymmetric heterodimeric constructs.
2. Evaluate the full spectrum of Bispecific Antibody Formats and their distinct mechanisms of action (MoA).
3. Design and optimize T-cell Engagers (TCEs) and NK-cell Engagers (NKEs) for enhanced tumor targeting and a wider therapeutic index.
4. Apply current genetic and protein engineering platforms (KIH, SEED, CrossMab) to maximize heavy/light chain pairing efficiency.
5. Proactively Address critical Developability Challenges, including aggregation, chemical degradation, and formulation stability.
6. Analyze the Pharmacokinetics (PK) and Pharmacodynamics (PD) of MsAbs for improved half-life and tissue distribution.
7. Implement High-Throughput Screening (HTS) and quantitative biophysical assays for candidate selection and rapid characterization.
8. Leverage Artificial Intelligence (AI) and Computational Protein Design tools for in silico lead optimization.
9. Develop robust strategies for risk mitigation of format-specific toxicities, notably Cytokine Release Syndrome (CRS).
10. Assess the Immunogenicity risk profile and apply advanced deimmunization strategies for humanization.
11. Understand the Process Development and CMC (Chemistry, Manufacturing, and Controls) complexities for scalable GMP manufacturing.
12. Explore the expansion of MsAbs beyond oncology into Autoimmune Diseases and Infectious Disease applications.
13. Interpret regulatory and Intellectual Property (IP) landscapes for novel Multispecific Antibody formats.

Target Audience

1. Biopharmaceutical R&D Scientists.
2. Protein and Antibody Engineers.
3. Process Development (PD) Scientists.
4. Analytical & Quality Control (QC) Specialists.
5. CMC and Regulatory Affairs Professionals.
6. Translational and Clinical Scientists.
7. Academic Researchers and Post-Docs.
8. Project/Portfolio Managers.

Course Modules

Module 1: Foundational Concepts & Market Landscape

- Overview of IgG structure and function.
- Rationale for multispecificity.
- Approved BsAbs (Blinatumomab, Teclistamab, Epcoritamab) and clinical pipeline analysis.
- T-cell redirection, receptor cross-linking, and co-stimulatory engagement.
- Case Study: Analysis of Blinatumomab (CD19/CD3).

Module 2: Bispecific Antibody Formats and Architecture

- IgG-like and Non-IgG-like
- Detailed review of symmetric and asymmetric formats.
- Valency, geometry, and molecular size.
- Impact of format choice on PK, manufacturability, and tissue penetration.
- Case Study: Comparing the design rationale and clinical performance of IgG-like and Fragment-based T-cell engagers.

Module 3: Genetic and Protein Engineering Platforms

- Knobs-into-Holes and its variants for engineered heavy-chain heterodimerization.
- Electrostatic steering and domain exchange technologies
- Strategies for solving light-chain mispairing
- Optimization of linker design for flexibility, stability, and function in fragment formats.
- Case Study: Implementation of CrossMab technology to ensure correct chain pairing and enhanced stability for a VEGF/Ang2 dual-targeting bispecific.

Module 4: Target Selection and Combinatorial MoA

- Principles of pairing two or more targets for synergistic therapeutic effect.
- Strategies for targeting the Tumor Microenvironment
- Multi-antigen targeting to overcome tumor heterogeneity and antigen escape.
- Co-stimulatory molecule engagement to boost T-cell activation.
- Case Study: Rationale for a PD-1/CTLA-4 or PD-L1/4-1BB bispecific: achieving superior anti-tumor activity compared to monotherapy.

Module 5: Upstream Process Development and Expression

- Selection of the optimal host cell line for multispecific expression.
- Transient and stable cell line generation for production scale-up.

- Optimization of gene transfection and heavy/light chain ratio to maximize correct assembly yield.
- Bioreactor process optimization.
- Case Study: Troubleshooting a low yield issue in a Quadroma system vs. a high-titer KIH-based recombinant expression process.

Module 6: Downstream Purification and Manufacturing

- Advanced chromatography techniques
- Effective strategies for separating desired heterodimer product from homodimers and variants.
- Viral clearance/inactivation and GMP compliance for complex biologics.
- Process validation, robustness, and successful technology transfer to CMC.
- Case Study: Using a Multi-Column Chromatography approach for high-resolution separation of a trispecific antibody with multiple isoforms.

Module 7: Biophysical and Analytical Characterization

- High-resolution methods for purity and structural analysis.
- Assessment of structural integrity, chemical modifications, and aggregation via SEC-HPLC.
- Biophysical stability assessment
- Characterization of glycosylation profiles and other Post-Translational Modifications (PTMs).
- Case Study: Identifying and resolving an issue of agitation-induced aggregation in a bispecific via sequence and surface engineering.

Module 8: Functional Assays and In Vitro Potency

- Assays for simultaneous dual-antigen binding and affinity measurement.
- Cell-based functional assays.
- Quantifying T-cell redirection and activation via cytokine release and cell killing assays.
- Developing and validating robust potency assays for product release and stability.
- Case Study: Designing a co-culture assay to demonstrate the in vitro T-cell retargeting efficacy of a CD20/CD3 bispecific.

Module 9: Developability Assessment and Risk Mitigation

- Early-stage developability scoring and high-throughput screening for drug-like properties.
- Predictive modeling for solubility, stability, and propensity for aggregation/fragmentation.
- Sequence engineering to minimize immunogenicity hotspots and chemical liability sites.
- Formulation development strategies for high-concentration and long-term stability.
- Case Study: Benchmarking a panel of multispecific antibody candidates against predefined developability thresholds to select the optimal lead molecule.

Module 10: Pharmacokinetics (PK) and Bioavailability

- Understanding the structural factors that influence serum half-life
- Strategies for half-life extension.
- Comparative PK/PD modeling for traditional mAbs versus fragment-based BsAbs.
- Impact of multispecificity on tissue distribution and on-target binding/clearance.
- Case Study: Analysis of how Fc-silencing and half-life extension were engineered into a therapeutic bispecific to optimize its dosing regimen.

Module 11: Immunogenicity and Safety

- Risk factors for Anti-Drug Antibody (ADA) generation in multispecific formats.
- In silico and in vitro tools for T-cell epitope prediction and deimmunization.
- Strategies to mitigate and manage on-target, off-tumor toxicity.
- Detailed review of Cytokine Release Syndrome (CRS), neurotoxicity (ICANS), and on-target hematological toxicity.
- Case Study: Consensus guidelines for the monitoring and clinical management of CRS associated with approved BCMA/CD3 bispecifics in Multiple Myeloma.

Module 12: Computational Design and AI/ML

- Introduction to Computational Protein Design and molecular modeling for in silico lead generation.
- Leveraging Machine Learning (ML) for predicting biophysical properties and optimizing antibody sequences.
- Using computational tools to guide epitope selection and binding interface design.
- The role of AI in exploring the vast combinatorial space of multispecific formats.
- Case Study: Application of AlphaFold/Rosetta-based algorithms to de novo design novel antibody folds for improved stability.

Module 13: Multispecifics in Immuno-Oncology

- Deep dive into T-cell redirection for solid tumors and overcoming the TME.
- Trispecific Antibodies (TsAbs) and higher-order multispecifics for enhanced cell engagement.
- MsAbs in conjunction with checkpoint inhibitors or chemotherapy.
- Targeting tumor vasculature and the use of conditionally active or protease-cleavable designs.
- Case Study: The clinical development and success of Tarlatamab (DLL3/CD3) in Small Cell Lung Cancer (SCLC) and its unique toxicity profile.

Module 14: Non-Oncology Applications

- MsAbs for Autoimmune and Inflammatory Diseases
- Bispecifics in Infectious Disease.
- Applications for penetrating the Blood-Brain Barrier via receptor-mediated transcytosis.
- Development of multispecific fusion proteins and Antibody-Drug Conjugates
- Case Study: Engineering a Transferrin Receptor/BACE1 bispecific for enhanced drug delivery across the BBB to treat Alzheimer's disease.

Module 15: Regulatory and IP Strategies

- Current FDA/EMA guidelines and expectations for CMC data packages for multispecifics.
- Strategies for effective Investigational New Drug application submission.
- Patenting novel bispecific formats, chain pairing technologies, and MoAs.
- Navigating the landscape of platform licensing and freedom-to-operate analysis.
- Case Study: Review of the regulatory pathway and patent strategies employed for a commercially successful proprietary bispecific platform

Training Methodology

The course employs an Interactive Blended Learning Approach combining theoretical instruction with practical, real-world application.

- Expert-Led Lectures.
- Hands-on Workshops

- In-depth Case Studies.
- Group Problem-Solving.
- Q&A/Expert Panels.

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

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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