Biosimilars and Biobetters Development Strategy 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 landscape is undergoing a profound and rapid transformation, driven primarily by the expiration of patents for blockbuster biologics and the escalating global demand for affordable, high-quality treatments. Biosimilars and Biobetters Development Strategy Training Course is spearheaded by biosimilars highly similar, lower-cost versions of approved reference products and a new generation of biobetters. Biosimilars represent the most significant structural shift since small-molecule generics, compelling the biopharmaceutical industry to radically rethink R&D pipelines, manufacturing excellence, and commercialization strategies. For organizations to capitalize on the projected $171+ billion market growth by 2033, they must master the complex scientific, regulatory, and intellectual property (IP) frameworks governing these products. This course is an essential investment for professionals seeking to lead in this new era of biological drug development.

The competitive pressure from biosimilars is simultaneously creating a strategic pivot: the development of biobetters. These are deliberately engineered molecules based on existing biologics but with demonstrable improvements in efficacy, safety profile, and patient convenience. Unlike biosimilars, biobetters require a full regulatory application and aim for a defensible, premium market position through next-generation innovation. Navigating this bifurcated market one focusing on comparability and access and the other on superiority and differentiation requires a deep, integrated understanding of both the regulatory pathways and cutting-edge CMC (Chemistry, Manufacturing, and Controls) science. This program provides the strategic blueprint to succeed, covering everything from analytical similarity and extrapolation of indications to lifecycle management and global market access.

Programme Curriculum

Biosimilars and Biobetters Development Strategy Training Course

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Course Duration

10 days

Course Objectives

1. Master the Global Regulatory Pathways for biosimilar and biobetter approval.
2. Design robust Analytical Comparability Studies to demonstrate physicochemical and functional similarity.
3. Evaluate the critical role of QbD (Quality by Design) in biopharmaceutical manufacturing consistency.
4. Formulate efficient, risk-based Clinical Development Plans for biosimilars, leveraging extrapolation.
5. Analyze the scientific basis and regulatory implications of Interchangeability and patient switching studies.
6. Develop sophisticated Intellectual Property (IP) Strategies, including the "patent dance" and freedom-to-operate.
7. Identify key molecular modification and formulation techniques for creating a successful Biobetter Candidate.
8. Appraise the Pharmacokinetic (PK) and Pharmacodynamic (PD) equivalence requirements for biosimilars.
9. Mitigate the risks associated with Immunogenicity in both biosimilar and biobetter development.
10. Construct effective Market Access & Pricing Strategies to drive payer and prescriber acceptance.
11. Implement successful Lifecycle Management strategies for originator products in a competitive environment.
12. Integrate AI and Machine Learning into R&D to accelerate cell line development and process optimization.
13. Anticipate future trends in Next-Generation Biologics and accelerated approval pathways.

Target Audience

1. Regulatory Affairs Professionals
2. R&D Scientists & Researchers
3. Clinical Development & Medical Affairs Managers
4. CMC & Quality Assurance (QA/QC) Specialists
5. Business Development & Commercial Strategy Executives
6. Intellectual Property (IP) & Legal Counsel
7. Project & Portfolio Managers
8. Pharmacists & Formulary Decision-Makers

Course Modules

Module 1: The Global Biologics and Biosimilars Landscape

- Biologics, Biosimilars, Biobetters (Biosuperiors).
- Market Dynamics
- Regulatory Foundation
- The need for a cohesive follow-on biologic portfolio strategy.
- Perspective of Payers, Prescribers, and Patients.
- Case Study: Tracing the evolution of the EU biosimilars market post-infliximab approval.

Module 2: Analytical Similarity: The Foundation of a Biosimilar

- Regulatory requirement for a robust demonstration of "highly similar".
- Physicochemical properties, molecular structure, biological activity, and purity.
- LC-MS, NMR, CE, and functional cell-based assays.
- Defining the limits of natural variability vs. meaningful difference.
- How changes in the cell line or process affect the final product's similarity.
- Case Study: Analytical data package for a successful Filgrastim biosimilar submission.

Module 3: Biopharmaceutical CMC & Quality by Design (QbD)

- Defining the Quality Target Product Profile (QTPP) and Critical Quality Attributes (CQAs).
- Ensuring the manufacturing process consistently delivers a product of required quality.
- Implementing in-process controls, specifications, and process analytical technology (PAT).
- Achieving stability and high concentration in a new formulation.
- Navigating the complexities of scale-up and technology transfer for biologics.
- Case Study: Implementing a QbD approach for an IgG1 monoclonal antibody biosimilar.

Module 4: Non-Clinical & Preclinical Development

- The need for reduced, targeted, or waived non-clinical safety studies.
- Comparative Pharmacokinetics/Pharmacodynamics.
- Justifying the use of relevant species for testing.
- Early strategies for predicting and mitigating immune response risk.
- Ensuring comparability across different batches of reference product.
- Case Study: Justification for waiving a chronic toxicity study in a biosimilar development plan.

Module 5: Clinical Development Strategy for Biosimilars

- The Comparative Clinical Trial.

- Choosing clinical endpoints and statistical non-inferiority margins.
- Ensuring the proposed route and schedule are clinically relevant.
- Integrating analytical, non-clinical, and clinical data to support similarity.
- Establishing a risk-management plan for long-term safety monitoring.
- Case Study: Design and execution of a phase III trial for an anti-TNF-?? biosimilar

Module 6: Extrapolation and Indication Expansion

- Using similarity data to gain approval for all indications of the reference product.
- Justifying extrapolation based on mechanism of action (MOA) and receptor binding.
- Differences in requirements between the FDA and the EMA on extrapolation.
- Addressing challenges in heterogeneous diseases
- Presenting a compelling case to regulators for safe and effective use.
- Case Study: Successful extrapolation for an oncology biosimilar to non-oncology indications.

Module 7: Interchangeability and Switching Studies

- The FDA's Interchangeable Designation.
- Designing multiple-switch trials to assess safety and efficacy upon transition.
- State-level substitution laws and the practical application of interchangeability.
- Strategies for building trust and adoption post-approval.
- How other jurisdictions handle automatic substitution.
- Case Study: Examining the clinical data package for the first interchangeable biosimilar in the US.

Module 8: Intellectual Property (IP) and Legal Strategy

- Navigating the statutory framework for US biosimilar litigation.
- Comprehensive analysis of the originator's patent portfolio.
- Balancing early market entry against potential infringement lawsuits.
- Developing a new, defensible patent portfolio for the improved product.
- Understanding the 12-year US and 10-year EU data exclusivity periods.
- Case Study: Analysis of a major patent settlement between an originator and a biosimilar developer.

Module 9: Biobetters: Engineering Superiority and New IP

- Shifting the goal from similarity to superiority
- Molecular Modification Techniques.
- Pharmacokinetic Enhancement
- Moving from IV to subcutaneous (SC) administration for patient ease.
- Why biobetters require a full BLA and de novo clinical development.
- Case Study: Strategic analysis of a PEGylated G-CSF as a biobetter defense strategy.

Module 10: Manufacturing and Supply Chain Excellence

- Biomanufacturing Economics.
- Strategic decisions on facility design and capacity.
- Establishing a global, robust, and qualified vendor network.
- Ensuring consistency across multiple manufacturing sites.
- Managing regulatory submissions for changes in the manufacturing process.
- Case Study: Overcoming supply chain disruptions in a multi-region biosimilar launch.

Module 11: Market Access, Pricing, and Commercialization

- Establishing a compelling cost-effectiveness argument for payers.
- Negotiating placement and ensuring broad reimbursement coverage.
- Educating clinicians, administrators, and patient advocacy groups.
- Navigating complex government and hospital purchasing systems.
- Forecasting and Inventory Management.
- Case Study: Evaluating the launch success of an anti-VEGF biosimilar based on pricing and market uptake.

Module 12: Risk Management and Post-Marketing Surveillance

- Establishing rigorous systems for reporting adverse events.
- Differentiating between known and new safety signals for biosimilars.
- Nomenclature and Traceability
- Handling Immunogenicity Signals.
- Harmonizing safety reporting across major jurisdictions.
- Case Study: Analysis of post-marketing data on immunogenicity for an approved biosimilar.

Module 13: Future Trends: Next-Generation Biologics & AI

- The rise of Bispecific Antibodies and Antibody-Drug Conjugates
- Platform Technology
- Artificial Intelligence (AI) in R&D.
- Regulatory Convergence
- Accelerated Approval Pathways.
- Case Study: The role of AI in optimizing cell culture media for high-yield biomanufacturing.

Module 14: Organizational Strategy and Portfolio Management

- Portfolio Selection.
- Strategic alliances for manufacturing capacity or market penetration.
- Assessing internal capabilities against the competitive landscape.
- Establishing clear milestones for project advancement or termination.
- Optimizing budgets across analytical, clinical, and commercial arms.
- Case Study: Benchmarking the biosimilar entry strategy of a leading global pharmaceutical company.

Module 15: Regulatory Submission and Lifecycle Management

- The Common Technical Document (CTD)
- Briefing Document Preparation:
- Responding to Deficiencies
- Lifecycle Management
- Global Harmonization Efforts.
- Case Study: Review of a successful EMA Scientific Advice meeting on a complex biosimilar.

Training Methodology

The course employs a highly interactive, case-study-driven, and practical methodology:

- Interactive Lectures
- Deep Dive Case Studies
- Scenario-Based Workshops.
- 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
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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