Advanced Microbiome Therapeutics Development 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 human microbiome represents a revolutionary frontier in modern medicine, transitioning rapidly from academic discovery to clinical translation and drug development. Advanced Microbiome Therapeutics Development Training Course is an intensive, executive-level training designed for professionals seeking to master the entire translational pipeline of microbiome-based therapies, from target identification and preclinical development through to Live Biotherapeutic Product manufacturing and global regulatory compliance. With the market projected for exponential growth driven by breakthroughs in personalized medicine and the gut-brain axis, expertise in next-generation probiotics, synthetic biology, and multi-omics data analysis is critical for maintaining a competitive edge in this dynamic biotech landscape.

This program delves into the scientific foundations of host-microbe interactions and the mechanisms of action (MoA) of therapeutic candidates, providing hands-on experience with advanced bioinformatic tools and emphasizing Quality by Design (QbD) principles for robust Good Manufacturing Practices (cGMP). Participants will gain the strategic insights needed to navigate complex FDA and EMA regulatory pathways, ensuring a deep, actionable understanding of intellectual property (IP) and commercialization strategies. Mastering these skills is essential for leaders poised to drive the development of novel, effective MBT for diseases ranging from Inflammatory Bowel Disease (IBD) and oncology to neurodegenerative disorders.

Programme Curriculum

Advanced Microbiome Therapeutics Development Training Course

Introduction

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Course Duration

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Course Objectives

1. Master the principles of Microbiome Engineering and Synthetic Consortia design.
2. Evaluate advanced Omics Data Analysis for Biomarker Discovery.
3. Design robust Preclinical Models and in Vivo Validation studies for Live Biotherapeutic Products
4. Navigate global Regulatory Strategy for MBT development
5. Implement Good Manufacturing Practices and Quality by Design in LBP production.
6. Apply principles of the Gut-Brain Axis for Neurotherapeutics development.
7. Identify promising Targeted Metabolite and Postbiotic therapeutic candidates.
8. Structure effective Clinical Trial Design for diverse microbiome indications.
9. Leverage Artificial Intelligence (AI) and Machine Learning (ML) for accelerated R&D.
10. Assess the efficacy and safety of Fecal Microbiota Transplantation (FMT) alternatives and derivatives.
11. Develop strong Intellectual Property (IP) and Patenting Strategies in the microbiome space.
12. Analyze the competitive Market Landscape and Commercialization strategies for novel MBT.
13. Integrate Host-Microbe Interaction data to refine Mechanism of Action (MoA) hypotheses.

Target Audience

1. R&D Scientists and Project Managers in Biotechnology and Pharmaceutical companies.
2. Clinical Development Directors and Managers focused on novel therapeutics.
3. Regulatory Affairs Specialists and Quality Assurance Personnel in LBP/Biologics.
4. Bioinformaticians and Data Scientists working with NGS data.
5. Venture Capital Analysts and Business Development Executives evaluating MBT investments.
6. Academic Researchers and Postdoctoral Fellows transitioning to industry or translational science.
7. Manufacturing Engineers and CMC Leads.
8. Intellectual Property Attorneys specializing in life sciences and biologics.

Course Modules

Module 1: Foundational Microbiome Science & MoA

- Ecosystem Dynamics
- Host-Microbe Crosstalk.
- Dysbiosis and Disease.
- Mechanism of Action (MoA).
- Case Study: Analyzing a successful CDI therapeutic?ÇÖs MoA

Module 2: Advanced Microbiome Omics Technologies

- Metagenomics & Shotgun Sequencing.
- Metatranscriptomics & Metabolomics.
- Data Quality Control.
- Biomarker Discovery.
- Case Study: Using Metabolomics to track Short-Chain Fatty Acid (SCFA) production in a clinical trial.

Module 3: Bioinformatics & AI/ML in R&D

- Bioinformatics Pipeline
- AI for Target ID.
- Visualizing and interpreting complex microbial ecological networks.
- Predictive Modeling.
- Case Study: Applying ML to predict patient response to an Immune Checkpoint Inhibitor based on pre-treatment Gut Microbiome.

Module 4: Live Biotherapeutic Product (LBP) Development

- Strain Selection & Characterization
- Vector Construction.
- Delivery Formulations
- Strain Colonization.
- Case Study: Analyzing the challenges and solutions in developing an oral capsule FMT product.

Module 5: Synthetic Biology & Microbiome Engineering

- Rational Design of Consortia.
- Genetic Circuits.
- CRISPR-Based Editing
- Implementing biological containment and kill-switch mechanisms.
- Case Study: Review of a company using Engineered Probiotics to deliver a therapeutic peptide locally in the gut.

Module 6: Preclinical in Vitro and in Vivo Models

- In Vitro Assays.
- Gnotobiotic Models
- Establishing preclinical endpoints for therapeutic potential and toxicology.
- Understanding the pharmacokinetics and pharmacodynamics of a living drug.
- Case Study: Validating the efficacy of a LBP candidate in a preclinical IBD animal model.

Module 7: cGMP and CMC for LBP

- Implementing QbD principles from strain isolation to final product.
- Optimization of fermentation, growth, and biomass generation.

- Purification, stabilization, and lyophilization techniques for viability.
- Testing for purity, potency, identity, and stability (shelf-life).
- Case Study: Addressing cGMP challenges in scaling up production of a Defined Bacterial Consortium.

Module 8: Regulatory Strategy (FDA & EMA)

- Investigational New Drug (IND) Submission.
- Navigating the regulatory status of FMT vs. defined LBP vs. Postbiotics.
- Strategies for successful interaction with FDA and EMA during development.
- Global Harmonization.
- Case Study: Reviewing the FDA approval pathway for the first FMT-derived therapeutic.

Module 9: Clinical Trial Design for MBT

- Establishing maximum tolerated dose and initial MoA in humans.
- Designing statistical power and choosing clinically meaningful primary endpoints.
- Using Biomarkers for targeted enrolment.
- Informed consent and risks unique to living therapeutics.
- Case Study: Examining the design of a pivotal Phase III trial for a LBP in Oncology.

Module 10: Targeting the Gut?ÇôBrain Axis (GBA)

- The role of the microbiome in mood, cognition, and Neuroinflammation.
- Development of LBP for CNS disorders
- Targeting SCFA, neurotransmitters, and hormones influenced by gut bacteria.
- Utilizing behavioral and neurological assays in animal models.
- Case Study: Analyzing the clinical results of a Psychobiotic trial for Major Depressive $\mathbfDisorder}$ (MDD).

Module 11: Next-Gen Probiotics and Postbiotics

- Advantages of multi-strain LBP over single-strain probiotics.
- Metabolites, cell-free filtrates, and bacterial components as therapeutics.
- Utilizing bacteriophages for targeted subtractive microbiome manipulation.
- Navigating the regulatory line between supplements and prescribed therapeutics.
- Case Study: Evaluating the commercial and clinical potential of a Postbiotic for Atopic Dermatitis.

Module 12: IP and Competitive Strategy

- Writing claims for microbial strains, consortia, methods of use, and production processes.
- Analyzing the competitive IP landscape and mitigating risk.
- Protecting unique manufacturing and formulation know-how.
- Structuring strategic partnerships between biotech and pharma.
- Case Study: IP dispute analysis over a key LBP composition patent.

Module 13: Commercialization and Market Access

- Sizing the opportunity in IBD, Oncology, and Metabolic therapeutic areas.
- Preparing health economics and outcomes research (HEOR) data.
- Determining the price point for a novel MBT in a crowded market.
- Understanding the M&A landscape for microbiome companies.
- Case Study: Developing a global launch plan for a new LBP targeting a chronic disease.

Module 14: Safety and Toxicology

- Potential for Antibiotic Resistance Gene transfer and immune activation.
- Specific AE concerns for living drugs and FMT.
- Standard and specialized assays for LBP safety assessment.
- Strategies for manufacturing and clinical trials to ensure patient safety.
- Case Study: Analyzing a major safety alert related to a contamination event in FMT materials.

Module 15: Emerging Trends and Future Outlook

- Therapeutics targeting the skin, lung, and vaginal microbiomes.
- Microbiome-Drug Interactions.
- The role of Companion Diagnostics in patient selection.
- Anticipating changes in FDA and EMA guidance for Engineered LBP.
- Case Study: Exploring the promise and challenges of using LBP to enhance **Cancer Immunotherapy**.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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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