Advanced Phage Therapy and 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

The escalating global crisis of Antimicrobial Resistance (AMR) has underscored the urgent need for novel, targeted therapeutic solutions, with Bacteriophage Therapy emerging as a highly promising alternative to conventional antibiotics. This intensive course moves beyond foundational phage biology to explore the cutting edge of personalized medicine and advanced biologics development. Participants will master the complex interplay of phage-host dynamics, the art of phage cocktail formulation for biofilm eradication, and the critical regulatory pathways governing clinical integration. The curriculum emphasizes the strategic combination of lytic phages with existing antimicrobials known as phage-antibiotic synergy to combat Multi-Drug Resistant (MDR) and Extensively Drug-Resistant (XDR) bacterial infections, offering a tangible path toward the next generation of infectious disease management.

Advanced Phage Therapy and Biologics Training Course is specifically engineered to bridge the translational gap between laboratory science and clinical deployment, focusing on Good Manufacturing Practice (GMP) for phage production, rigorous phage characterization, and sophisticated bioinformatics for genome annotation and safety assessment. By exploring advanced concepts like phage engineering, synthetic biology, and targeted delivery systems, the course positions graduate at the forefront of the "Post-Antibiotic Era." It provides the essential, actionable knowledge required to design, manage, and execute successful clinical trials and to build robust, ethical, and compliant phage therapy programs within academic, governmental, and commercial organizations.

Programme Curriculum

Advanced Phage Therapy and Biologics Training Course

Introduction

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Course Duration

10 days

Course Objectives

Upon completion, participants will be able to:

1. Analyze the latest clinical trial data for phage therapy against ESKAPE pathogens.
2. Design protocols for isolating and characterizing novel lytic phages for clinical use.
3. Evaluate the principles of phage-antibiotic synergy and their application in biofilm disruption.
4. Master bioinformatic tools for phage genome annotation, safety assessment, and virulence factor identification.
5. Navigate the FDA/EMA regulatory landscape for Investigational New Drug (IND) and compassionate use applications.
6. Formulate optimized phage cocktails for personalized medicine approaches.
7. Implement Quality Control (QC) and Good Manufacturing Practice (GMP) standards in phage production facilities.
8. Assess the challenges and opportunities of phage delivery systems, including nanoparticle encapsulation.
9. Differentiate between lytic and temperate phages and their implications for therapy.
10. Develop strategies to mitigate and manage phage resistance in bacterial populations.
11. Examine the role of phage display and synthetic biology in developing engineered biologics.
12. Conduct a robust risk-benefit analysis for initiating phage therapy protocols in a clinical setting.
13. Discuss the phage-microbiome interactions and their impact on long-term patient health

Target Audience

1. Infectious Disease Physicians.
2. Clinical Microbiologists/Scientists.

3. Pharmaceutical/Biotech R&D Scientists.
4. Regulatory Affairs Professionals.
5. Hospital Pharmacists.
6. Public Health Officials.
7. Immunologists.
8. Bioengineers/Synthetic Biologists.

Course Modules

Module 1: The New Era of Antimicrobial Resistance (AMR)

- Global burden and economic impact of MDR and XDR infections.
- Overview of ESKAPE pathogens and their resistance mechanisms.
- Market failure and the urgency for novel biologics and therapeutic alternatives.
- Phages as a naturally evolved, self-replicating solution to the antibiotic crisis.
- Introduction to the principles of personalized medicine in infectious diseases.
- Case Study: Analysis of a CRISPR?êÆedited Salmonella phage for biocontrol in livestock, demonstrating non-human applications and advanced engineering.

Module 2: Foundational Phage Biology and Lytic Cycles

- Structural components and classification of Bacteriophages.
- Detailed review of the lytic cycle and its clinical requirements.
- Mechanisms of host recognition, DNA injection, and progeny release.
- Distinguishing lytic from lysogenic phages and safety screening.
- Molecular basis of phage-host dynamics and multiplicity of infection (MOI).
- Case Study: Analyzing the failure of a phage therapy due to the accidental use of a temperate phage and subsequent lysogenic conversion.

Module 3: Phage Isolation and Characterization Protocols

- Techniques for isolating phages from environmental and clinical sources
- High-throughput methods for determining host range and plaque morphology.
- Phage titration and preparing high-titer lysates
- Advanced physicochemical characterization
- Identifying and eliminating undesirable phage characteristics
- Case Study: A successful program for isolating phages against a hospital-acquired carbapenem-resistant Klebsiella pneumoniae (**CRKP)** strain.

Module 4: Advanced Phage Bioinformatics and Genomics

- Tools and workflows for phage genome annotation.
- Predictive analysis for virulence factors, lysogeny, and antibiotic resistance genes.
- Phage safety screening protocols using in silico methods.
- Comparative genomics to identify core genes and evolutionary relationships.
- Data management and sharing best practices
- Case Study: Using genomic sequencing to definitively prove the novelty and safety of a phage candidate before moving to preclinical trials.

Module 5: Phage-Antibiotic Synergy (PAS) and Combination Therapies

- Molecular mechanisms of phage-antibiotic synergy and antagonism.

- In vitro and in vivo methods for synergy testing
- Designing Phage Cocktail formulations to broaden host range and reduce resistance.
- Strategies for resensitizing MDR bacteria to conventional antibiotics.
- The clinical rationale for Hybrid Phage/Antibiotic Therapy.
- Case Study: Treatment of a chronic bone infection with a phage-ceftazidime combination, demonstrating resensitization of a Pseudomonas aeruginosa strain.

Module 6: Targeting and Eradicating Biofilms

- The biology and clinical significance of bacterial biofilms.
- Mechanisms by which phages penetrate and disrupt biofilm matrix.
- Formulation strategies for enhanced biofilm clearance.
- In vitro and ex vivo models for testing phage activity against mature biofilms.
- Clinical applications for chronic infections.
- Case Study: Successful clearance of a Cystic Fibrosis-related P. aeruginosa lung infection using a nebulized phage cocktail with confirmed **depolymerase** activity.

Module 7: Phage Engineering and Synthetic Biology

- Introduction to genetic modification of phages
- Designing engineered phages for enhanced lytic activity and reduced immunogenicity.
- Developing phages as targeted delivery systems for antimicrobials or gene editing tools.
- Ethical and biosafety considerations for deploying genetically modified organisms
- Phage display technology for identifying novel therapeutic peptides and antibodies.
- Case Study: Developing a eukaryotic gene therapy vector based on a modified phage backbone for targeted delivery to human cells.

Module 8: Quality Control (QC) and GMP Manufacturing

- Principles of Good Manufacturing Practice (GMP) for therapeutic biologics.
- Establishing a Phage Bank and ensuring master and working stocks purity.
- Endotoxin testing, sterility, and in vitro activity verification.
- Scale-up and bioreactor manufacturing protocols for clinical-grade phages.
- Regulatory requirements for product consistency and batch-to-batch variation.
- Case Study: Troubleshooting and resolving a GMP violation related to high endotoxin levels in a clinical batch of phage lysate.

Module 9: Preclinical Development and Safety Pharmacology

- Designing relevant animal models for systemic and localized phage therapy.
- Pharmacokinetics (PK) and Pharmacodynamics (PD) studies of phages
- Assessing acute and chronic phage toxicity in mammalian models.
- Monitoring anti-phage antibody response and adverse effects.
- Interpreting preclinical data to define safe dosing strategies.
- Case Study: PK/PD profiling of an intravenous phage product, showing rapid renal clearance and the need for frequent dosing adjustments.

Module 10: Regulatory Pathways for Phage Therapy (US/EU)

- Detailed breakdown of the FDA's Investigational New Drug (IND) application process.
- Understanding and utilizing Emergency/Expanded Access protocols.

- EMA/European Medicines Agency regulations and national frameworks
- Key differences between a Biologic and a drug in the regulatory context.
- Drafting the Chemistry, Manufacturing, and Controls (CMC) section for a regulatory submission.
- Case Study: Reviewing a successful eIND application for a critically ill patient, including the ethical and logistical challenges.

Module 11: Clinical Trial Design and Management

- Designing Phase 1, 2, and 3 trials for novel antimicrobial agents.
- Defining robust primary and secondary endpoints
- Challenges in conducting trials for personalized medicine and rare infections.
- Biostatistics for small clinical populations and adaptive trial design.
- Monitoring and reporting adverse events and managing endotoxin release
- Case Study: Analysis of the Phagoburn trial results, focusing on the trial design's impact on observed efficacy outcomes.

Module 12: Phage Delivery and Formulation Systems

- Routes of administration: Intravenous, topical, inhalation, and oral delivery.
- Nanoparticle encapsulation and other advanced systems for targeted release.
- Maintaining phage viability under different storage and delivery conditions.
- Developing phage hydrogels and medical device coatings for localized therapy.
- Practical aspects of preparing the phage product at the point of care.
- Case Study: Development of an inhalable phage powder for treating drug-resistant Mycobacterium abscessus lung infections.

Module 13: Phage-Microbiome and Immunology

- The impact of phages on the commensal human microbiome.
- Antibody formation and immune complex clearance.
- Bacteriophage-mediated horizontal gene transfer (HGT) and safety concerns.
- The concept of the "phageome" and its role in human health.
- Differentiating between innate immune response and adverse reactions.
- Case Study: Investigating the gut phageome shifts following intravenous phage therapy for a systemic infection.

Module 14: Clinical Applications in Critical Care and Surgery

- Phage therapy for Prosthetic Joint Infections (PJI) and chronic osteomyelitis.
- Treating complicated Urinary Tract Infections (UTIs) and pyelonephritis.
- Applications in severe sepsis and endocarditis with MDR etiology.
- Phages in wound care, burns, and chronic ulcer management.
- Best practices for interdisciplinary collaboration
- Case Study: A life-saving phage-antibiotic combination used to treat a patient with Acinetobacter baumannii prosthetic valve endocarditis.

Module 15: Ethical, Legal, and Commercial Landscape

- Ethical frameworks for compassionate use and experimental therapies.
- Intellectual Property (IP) strategies.
- Global policies on antimicrobial stewardship and phage integration.

- Building a Phage Biopharma startup model.
- Scaling up production and achieving global regulatory harmonization.
- Case Study: Legal analysis of a country's shift from exclusive antibiotic-only policy to an officially sanctioned phage center model.

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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