Advanced Formulation for Oral Delivery of 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 rapid evolution of biopharmaceutical pipelines and the growing market for protein and peptide therapeutics have created a critical unmet need for non-invasive drug delivery. Parenteral administration, while effective, suffers from significant drawbacks, including high healthcare costs, poor patient compliance, and complexity in self-administration. The industry's focus is now intensely directed towards achieving the holy grail: oral delivery of biologics. This challenge is formidable, demanding innovative advanced formulation strategies to overcome the harsh physiological barriers of the gastrointestinal (GI) tract, namely acidic degradation, enzymatic proteolysis, and poor mucosal permeation of large, hydrophilic molecules. Advanced Formulation for Oral Delivery of Biologics Training Course provides a deep dive into the state-of-the-art technologies and scientific principles that are successfully transitioning these molecules from injection to oral pill, driving the next wave of patient-centric drug development.

This specialized program moves beyond theoretical discussion, offering a comprehensive, practical toolkit for designing and optimizing next-generation oral biologic formulations. Participants will explore cutting-edge delivery platforms, including nanoparticle-based systems, microneedle-in-a-pill technology, and advanced absorption enhancers like SNAC. We integrate core principles of Quality-by-Design (QbD), advanced analytical characterization, and the latest regulatory science to ensure a robust and scalable development pathway. By analyzing pivotal real-world case studies, such as the oral GLP-1 receptor agonist, attendees will gain the strategic and technical expertise required to accelerate their own pipeline. Completion of this course equips formulation scientists and bioprocess engineers with the mastery to effectively address the biopharmaceutical challenges of oral biotherapeutics, significantly enhancing bioavailability and unlocking the full therapeutic potential of these life-saving drugs.

Programme Curriculum

Advanced Formulation for Oral Delivery of Biologics Training Course

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Course Objectives

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

1. Strategize to overcome the physiological barriers of the Gastrointestinal (GI) Tract for macromolecular drugs.
2. Evaluate and select appropriate absorption enhancers for various biologics.
3. Design novel nanoparticle-based delivery systems for enhanced oral uptake.
4. Apply Quality-by-Design (QbD) principles to establish a robust and reproducible oral biologic formulation process.
5. Master the selection and functional use of excipients to protect biologics from enzymatic degradation and acidic pH.
6. Analyze the pharmacokinetic (PK) and pharmacodynamic (PD) profiles unique to oral biotherapeutics.
7. Develop robust stability-indicating assays and advanced analytical methods for product characterization.
8. Formulate Oral Solid Dosage (OSD) forms specifically optimized for sensitive large molecules.
9. Explore the clinical translation and commercial manufacturing scale-up challenges of oral biologics.
10. Assess the potential of microneedle-in-a-pill and other device-assisted delivery technologies.
11. Navigate the regulatory science and CMC requirements for novel oral biologic products.
12. Implement strategies for targeted delivery to specific segments of the intestine
13. Utilize relevant in vitro-in vivo correlation (IVIVC) models for predictive formulation development.

Target Audience

1. Formulation Scientists and Researchers
2. Bioprocess/Development Engineers
3. R&D Directors and Managers overseeing biologic development
4. Analytical and Quality Control (QC) Scientists
5. Regulatory Affairs Professionals
6. Biopharmaceutical Consultants
7. Pharmacists and Toxicologists focused on drug absorption
8. Academia specializing in drug delivery

Course Modules

Module 1: Biologics and the GI Barrier: The Oral Challenge

- Unique physicochemical properties of peptides and proteins
- Detailed review of GI tract barriers.
- Low bioavailability and high inter-subject variability challenges.
- Case Study: Analyzing the market drivers for non-invasive delivery of monoclonal antibodies.
- The current landscape of approved and clinical-stage oral biologics.

Module 2: Advanced Excipient Selection for Protection & Stability

- Excipients for stabilization.
- Designing pH-responsive enteric coatings for targeted intestinal release.
- Utilizing protease inhibitors to co-formulate and mitigate enzymatic breakdown.
- Role of surfactants and lipids in enhancing solubility and membrane interaction.
- Case Study: Formulating with SNAC to enhance absorption of large molecules.

Module 3: Nanoparticle-Based Delivery Systems

- Design and formulation of polymeric nanoparticles for encapsulation and protection.
- Developing stable liposomes and micelles for improved mucosal transport.
- Mucoadhesive systems to increase residence time at the absorption site.
- Physicochemical characterization: particle size, zeta potential, and drug loading.
- Case Study: Development of chitosan-coated nanoparticles for oral insulin delivery.

Module 4: Absorption Enhancers and Permeation Technologies

- Mechanisms of permeation enhancers.
- Chemical modification strategies to improve intrinsic permeability
- The role of carrier-mediated transport and exploitation of natural uptake pathways.
- Cell-Penetrating Peptides (CPPs) and receptor-mediated endocytosis.
- Case Study: Utilizing transient permeability enhancers (TPE) in an oral octreotide formulation.

Module 5: Oral Solid Dosage (OSD) Forms for Biologics

- Formulation strategies for oral capsules and compressed mini-tablets.
- Controlled and sustained release matrix systems.
- lyophilization, spray drying, and hot-melt extrusion for dry powder encapsulation.
- Challenges of tablet compression and shear stress sensitivity for biologics.
- Case Study: Developing a high-dose, delayed-release oral protein tablet for localized GI action.

Module 6: Device-Assisted Oral Delivery Platforms

- Introduction to the concept of microneedle-in-a-pill
- Mechanistic action and design considerations for device-assisted delivery.
- Engineering capsules for localized delivery and injection within the GI tract.
- Safety, pain-free delivery, and tissue response considerations.
- Case Study: The latest clinical progress of the RaniPill or similar platform technologies.

Module 7: Quality-by-Design (QbD) in Oral Biologics

- Defining the Quality Target Product Profile (QTPP) for oral biologics.
- Identification of Critical Quality Attributes (CQAs).
- Risk assessment and linking CQAs to Critical Process Parameters (CPPs).
- Design of Experiments (DoE) for formulation and process optimization.
- Case Study: Applying QbD to optimize the enteric coating process for an oral peptide drug.

Module 8: Advanced Analytical Characterization

- Techniques for assessing protein integrity and higher-order structure (HOS) in the formulation.
- Use of Mass Spectrometry (MS) and Chromatography for stability profiling.
- Analyzing particle properties.
- Developing reliable dissolution testing methods that mimic GI conditions.
- Case Study: Developing a stability-indicating assay to monitor degradation products in a novel oral formulation.

Module 9: In Vitro and Ex Vivo Model Selection

- Selecting appropriate Caco-2 and other cell-based in vitro permeation models.
- Using Franz Diffusion Cells and Ussing Chambers for ex vivo studies.
- Simulating the GI environment.
- Predicting first-pass metabolism and drug-drug interactions.
- Case Study: Comparing dissolution and permeation data across in vitro models to predict human absorption.

Module 10: Preclinical and Clinical PK/PD Studies

- Designing in vivo animal studies for initial proof-of-concept and efficacy.
- Interpreting Pharmacokinetic (PK) profiles.
- Understanding and mitigating high intra- and inter-subject variability.
- Establishing a meaningful In Vitro-In Vivo Correlation (IVIVC).
- Case Study: Analyzing the PK data of oral Semaglutide (Rybelsus) to understand its absorption.

Module 11: Scale-Up and Manufacturing Challenges

- Addressing unit operation challenges specific to large molecule Oral Solid Dosage manufacturing.
- Process validation and technology transfer considerations for novel formulations.
- Maintaining aseptic processing and product stability during scale-up.
- Implementation of Process Analytical Technology (PAT) for real-time monitoring.
- Case Study: Troubleshooting a manufacturing deviation during the spray-drying of an encapsulated biologic.

Module 12: Regulatory Strategy and CMC Documentation

- Understanding current FDA and EMA guidance for novel drug delivery systems.
- CMC requirements for excipients, process controls, and final product release.
- Strategies for justifying new and non-compendial excipients.
- Preparing the Investigational New Drug (IND) and New Drug Application (NDA) filing sections.
- Case Study: Reviewing the regulatory pathway and key submission details for an approved oral peptide.

Module 13: Formulation for Localized GI Biologics

- Designing formulations for action within the GI tract.
- Strategies for targeting the colon via pH and time-dependent release.
- Formulation considerations for biologics intended to modulate the gut microbiome.
- Challenges in measuring localized drug concentration and therapeutic effect.
- Case Study: Developing an oral antibody fragment for the treatment of inflammatory bowel disease (IBD).

Module 14: Future Trends: AI and Computational Formulation

- Use of Artificial Intelligence (AI) and Machine Learning (ML) for predictive formulation.
- In silico modeling to predict stability and absorption of novel molecules.
- High-throughput screening and automation in excipient selection.
- The role of computational fluid dynamics (CFD) in device design.
- Case Study: Demonstrating an AI model to prioritize lead formulations based on predicted human bioavailability.

Module 15: Formulation Stability and Shelf Life Extension

- Strategies to mitigate chemical and physical degradation.
- Designing appropriate primary packaging and container-closure systems.
- ICH stability testing guidelines (ICH Q1A) for oral biologic products.
- Developing long-term storage conditions and temperature excursion strategies.
- Case Study: Investigating a root cause of aggregation in an oral formulation and redesigning the excipient system.

Training Methodology

This course employs a dynamic, blended learning approach to ensure maximum knowledge retention and practical application:

- Interactive Lectures.
- Case Study Analysis
- Hands-on Workshops/Simulations.
- Group Problem-Solving
- Expert Q&A 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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