Advanced Drug Formulation and Delivery Systems 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

Advanced Drug Formulation and Delivery Systems Training Course provides pharmaceutical scientists, R&D professionals, and formulation experts with cutting-edge knowledge in Advanced Drug Formulation and Next-Generation Delivery Systems. The current landscape of drug development is rapidly evolving, driven by complex APIs, increasing regulatory scrutiny, and the demand for enhanced patient compliance. This course dives deep into overcoming solubility and bioavailability challenges using principles like Quality by Design, exploring novel technologies such as nanomedicine, biopharmaceutical formulation, and personalized drug delivery strategies. Participants will gain the specialized expertise necessary to design and optimize novel dosage forms, ensuring successful transition from preclinical candidates to commercially viable, high-performance medicines in the competitive global market.

The curriculum is structured around the practical application of theoretical concepts, focusing on targeted drug delivery, sustained-release technologies, and the formulation of large-molecule biopharmaceuticals. We place a special emphasis on leveraging digital tools and Process Analytical Technology to achieve data-driven formulation development and accelerate time-to-market. By mastering these advanced methodologies, including the intricacies of mRNA/gene therapy delivery and implantable devices, professionals will be equipped to tackle the most demanding formulation challenges, drastically improve therapeutic efficacy, and uphold the highest standards of product quality and regulatory compliance in modern pharmaceutical manufacturing.

Programme Curriculum

Advanced Drug Formulation and Delivery Systems Training Course

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Course Objectives

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

1. Master Quality by Design principles for robust, risk-managed formulation development.
2. Design effective Nanomedicine systems for enhanced solubility and targeting.
3. Evaluate and implement strategies for optimizing Biopharmaceutical Formulation stability and delivery.
4. Utilize advanced techniques for improving the Bioavailability of poorly water-soluble APIs
5. Develop targeted strategies for Oral Peptide Delivery overcoming enzymatic and permeability barriers.
6. Apply principles of Personalized Drug Delivery and 3D printing in dose form customization.
7. Design and characterize various Sustained and Controlled-Release technologies
8. Integrate Process Analytical Technology for real-time formulation monitoring and control.
9. Navigate the unique formulation challenges of mRNA and Gene Therapy Delivery systems.
10. Implement best practices in Solid-State Characterization to manage polymorphism and cocrystals.
11. Troubleshoot common issues in the scale-up of Continuous Manufacturing for solid and liquid dose forms.
12. Analyze the pharmacokinetics and pharmacodynamics interplay in Targeted Drug Delivery Systems.
13. Ensure Regulatory Compliance in line with global standards for novel dosage forms.

Target Audience

1. Formulation Scientists/R&D Researchers.
2. Process Development Engineers
3. Quality Assurance/Control Specialists.
4. Analytical Chemists.
5. Biopharmaceutical Professionals.
6. Project Managers.
7. Regulatory Affairs Personnel.
8. Academia/Post-Doctoral Fellows.

Course Modules

Module 1: Foundations of Quality by Design (QbD)

- Establishing the Quality Target Product Profile and Critical Quality Attributes
- Risk assessment tools in formulation design.
- Defining and controlling Critical Material Attributes and Critical Process Parameters
- Developing Design Space and Control Strategy documentation.
- Case Study: Implementing QbD for the formulation of an orally disintegrating tablet

Module 2: Enhancing Solubility and Bioavailability

- Understanding the Biopharmaceutics Classification System and formulation challenges.
- Techniques for size reduction: micronization, nano-milling, and spray drying.
- Lipid-based Drug Delivery Systems and self-emulsifying drug delivery systems
- Formulation of Amorphous Solid Dispersions for Class II drugs.
- Case Study: Designing an ASD formulation to improve the dissolution rate of Itraconazole.

Module 3: Solid-State Characterization and Stability

- Identifying and controlling polymorphism, solvates, and hydrates.
- Use of PXRD, DSC, and TGA for solid-state analysis.
- Formulation of cocrystals and salts to modulate physical properties.
- Strategies for accelerated and long-term stability testing
- Case Study: Mitigating phase transition issues in an active pharmaceutical ingredient during scale-up.

Module 4: Nanomedicine and Nanoparticle Delivery Systems

- Fundamentals of liposomes, solid lipid nanoparticles, and polymeric nanoparticles.
- Methods of fabrication: precipitation, emulsification, and microfluidics.
- Surface modification and stealth technology for extended circulation.
- Toxicity and regulatory considerations for nanomedicines.
- Case Study: Reviewing the formulation and manufacturing of a successful Doxorubicin liposomal product.

Module 5: Biopharmaceutical Formulation

- Stability challenges: aggregation, denaturation, and particle formation in proteins.
- Selection of buffers, surfactants, and stabilizers for monoclonal antibodies
- Formulation of high-concentration biologics for subcutaneous injection.
- Developing lyophilized and liquid stable formulations.
- Case Study: Troubleshooting instability issues in a therapeutic protein formulation.

Module 6: Advanced Parenteral and Implantable Systems

- Design of long-acting injectable suspensions and solutions.
- Biodegradable polymer-based implants for sustained release.
- Ocular and intrathecal delivery formulation challenges.
- Sterilization techniques and aseptic processing considerations.
- Case Study: Developing a 3-month sustained-release hormonal implant.

Module 7: Oral Controlled and Sustained Release

- Kinetics and mechanisms of drug release

- Matrix systems and reservoir systems
- Gastroretentive, colon-targeted, and pulsatile release technologies.
- In-vitro dissolution and in-vivo correlation (IVIVC) establishment.
- Case Study: Designing a once-daily extended-release formulation for a hypertension drug.

Module 8: Targeted Drug Delivery

- Passive targeting vs. active targeting
- Designing stimuli-responsive drug delivery systems.
- Brain-specific drug delivery strategies
- Immunoconjugates and Antibody-Drug Conjugates formulation principles.
- Case Study: Analysis of a clinical-stage tumor-targeted nanoparticle system.

Module 9: Transdermal and Topical Delivery Systems

- Skin structure, barrier function, and penetration enhancement techniques.
- Design of patches, gels, and microneedle arrays.
- Iontophoresis and sonophoresis for enhanced drug permeation.
- Formulation of dermatological products with enhanced stability.
- Case Study: Comparing flux profiles of different transdermal patch designs for nicotine replacement.

Module 10: Personalized and 3D Printing in Dosage Forms

- Fundamentals of 3D printing technologies in pharmaceuticals.
- Customized dosing and polymedication dosage forms.
- Rapid prototyping of clinical trial materials.
- Regulatory approval pathway for 3D-printed medicines
- Case Study: Designing a pediatric dose form using 3D printing to adjust API load precisely.

Module 11: Process Analytical Technology (PAT) Implementation

- Principles and benefits of implementing PAT in formulation and manufacturing.
- Key analytical tools: NIR, Raman Spectroscopy, and FBRM
- Real-time release testing and process monitoring.
- Data management and multivariate analysis in PAT systems.
- Case Study: Using NIR to monitor blend uniformity in a continuous tablet compression line.

Module 12: Continuous Manufacturing for Solid Dosage Forms

- Comparison of batch vs. continuous processing in pharmaceutical manufacturing.
- Equipment and flow sheet design for continuous granulation, drying, and blending.
- Process control and automation in a fully continuous line.
- Regulatory implications and filing requirements for continuous processes.
- Case Study: Planning the transition from batch to continuous manufacturing for a blockbuster drug.

Module 13: Formulation of Nucleic Acid Products

- The unique fragility and degradation pathways of mRNA and DNA.
- Lipid Nanoparticles as the primary delivery vehicle for nucleic acids.
- Sterile filtration, fill-finish, and ultra-cold chain storage requirements.
- Viral vectors formulation and stability.
- Case Study: Examining the LNP formulation used in a successful COVID-19 mRNA vaccine.

Module 14: Pharmaceutical Packaging and Device Integration

- Primary, secondary, and tertiary packaging considerations for stability and protection.
- Designing and testing drug-device combination products.
- Extractables and leachables studies and material selection.
- Human factors engineering and patient-centric device design.
- Case Study: Analyzing failure modes in a pre-filled syringe system and mitigation strategies.

Module 15: Regulatory Strategy and Documentation

- Chemistry, Manufacturing, and Controls section requirements for novel dosage forms.
- Preparing regulatory dossiers focusing on formulation justification.
- Post-approval changes and variation management
- Handling QbD-related documentation and lifecycle management.
- Case Study: Evaluating the required documentation for a new 505 application utilizing a novel sustained-release technology.

Training Methodology

This course utilizes a **Blended Learning Approach** designed for maximum knowledge retention and practical skill development:

1. Expert-Led Lectures.
2. Hands-on Workshops.
3. Real-World Case Studies.
4. Group Problem-Solving
5. Simulations.

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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