

Advanced Ophthalmic Drug 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

The delivery of therapeutic agents to the eye remains one of the most significant challenges in modern pharmaceuticals due to the eye's formidable physiological barriers, particularly the cornea and the blood-retinal barrier (BRB). Conventional topical eye drops suffer from rapid peroneal clearance, resulting in low ocular bioavailability and necessitating frequent dosing. Advanced Ophthalmic Drug Delivery Systems Training Course provides a critical deep dive into the state-of-the-art novel drug delivery systems (NDDS) engineered to overcome these limitations. We will move beyond traditional formulations to explore sustained-release platforms, targeted drug delivery, and non-invasive technologies for both anterior and posterior segment diseases. The focus is on leveraging nanotechnology, advanced biomaterials, and innovative implantable devices to achieve optimal therapeutic efficacy, reduce systemic side effects, and dramatically improve patient compliance in treating chronic and sight-threatening conditions like glaucoma, age-related macular degeneration (AMD), and diabetic retinopathy (DR).

This program is essential for pharmaceutical scientists, R&D professionals, and clinicians who need to master the design, formulation, and regulatory landscape of the next generation of ocular therapeutics. By examining the latest preclinical and clinical case studies on intravitreal implants, drug-eluting contact lenses, and in situ gelling systems, participants will gain the expertise required to drive product innovation and accelerate the development cycle of commercially viable and highly effective ophthalmic products. The training emphasizes QbD (Quality by Design) principles, cutting-edge manufacturing technologies like 3D printing, and strategies for navigating complex global regulatory pathways for novel ocular medical devices and drug-device combinations.

Programme Curriculum

Advanced Ophthalmic Drug Delivery Systems Training Course

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Course Duration

10 days

Course Objectives

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

1. Master the complex ocular anatomy and physiological barriers
2. Analyze the pharmacokinetics and pharmacodynamics of drugs administered via topical, periocular, and intravitreal routes.
3. Formulate and characterize nanotechnology-based carriers for enhanced ocular penetration.
4. Design sustained-release implantable devices for posterior segment drug delivery.
5. Develop smart hydrogels and in situ gelling systems that exploit pH or temperature phase transition for prolonged corneal retention.
6. Evaluate the utility and design of drug-eluting contact lenses and punctual plugs for anterior segment chronic therapy.
7. Apply principles of mucoadhesion and permeation enhancers to boost the bioavailability of topical formulations.
8. Differentiate between, and select appropriate, strategies for anterior vs. posterior segment targeting
9. Explore emerging non-invasive delivery modalities such as microneedle patches and iontophoresis.
10. Assess the preclinical models and in vitro/in vivo evaluation methods for novel ocular delivery systems.
11. Interpret the regulatory landscape for drug-device combination products in ophthalmology.
12. Integrate Quality by Design (QbD) principles into the development and scale-up of advanced ophthalmic products.
13. Discuss the future trends, including gene therapy delivery and cell-based therapies for retinal diseases.

Target Audience

1. Pharmaceutical Scientists (R&D, Formulation, Analytical).
2. Ophthalmic Drug Delivery Specialists and Engineers.
3. Biotech and Pharma R&D Managers and Directors.
4. Regulatory Affairs Professionals focused on drug-device combinations.
5. Clinical Research Associates/Scientists in Ophthalmology.
6. Biomaterials Scientists and Polymer Chemists.
7. Ophthalmologists and Optometrists involved in research and clinical trials.
8. Intellectual Property (IP) Strategists and Patent Attorneys in the life sciences sector.

Course Modules

Module 1: Ocular Anatomy & Drug Barrier Fundamentals

- Detailed review of the anterior and posterior segment structures
- Blood-Retinal Barrier (BRB) and Blood-Aqueous Barrier (BAB).
- Tear dynamics, precorneal clearance, and physiological factors limiting bioavailability.
- Topical, Systemic, Periocular, and Intravitreal.
- Case Study: Challenges in achieving therapeutic concentrations for RPE-targeted drugs due to the BRB.

Module 2: Enhanced Topical Delivery: The Precorneal Challenge

- Formulation strategies.
- Viscosity modifiers and mucoadhesive polymers for extended residence time.
- Permeation enhancers and prodrug approaches to increase transcorneal flux.
- Design of advanced ocular sprays and foaming formulations.
- Case Study: Development of a hyaluronic acid-based mucoadhesive formulation for dry eye syndrome

Module 3: In Situ Gelling & Phase Transition Systems

- Principles of sol-to-gel transition triggered by temperature, pH, or ions.
- Design and characterization of thermo-responsive and pH-responsive hydrogels
- Impact of rheological properties on drug release and patient comfort/vision blur.
- In vitro gelling capacity and in vivo retention studies.
- Case Study: The formulation and clinical potential of a gellan gum-based in situ gel for sustained glaucoma drug delivery.

Module 4: Ocular Nanotechnology Carriers

- Synthesis and characterization of **polymeric nanoparticles**
- Surface modification and ligand-based targeting.
- Drug encapsulation, loading efficiency, and controlled release kinetics.
- Biodistribution and fate of **nanoparticles** in the anterior and posterior segments.
- **Case Study:** Preclinical data on **pranoprofen nanoparticles** demonstrating enhanced anti-inflammatory action in rabbit eyes.

Module 5: Ocular Nanotechnology Carriers

- Formulation and stability of liposomes and niosomes for ocular delivery.
- Structure, drug conjugation, and enhanced solubility properties.
- Vesicular systems for gene and macromolecule delivery to the retina.

- Scale-up and sterile manufacturing considerations for nanocarriers.
- Case Study: Evaluation of dexamethasone-PAMAM dendrimers for improved delivery to the back of the eye for DR/AMD treatment.

Module 6: Drug-Eluting Contact Lenses & Ocular Inserts

- Mechanism of drug loading and release from hydrogel and silicone hydrogel lenses.
- Design of punctal plugs as a depot system for sustained release into the tear film.
- Soaking, molecular imprinting, and polymerization.
- Oxygen permeability, comfort, and duration of release.
- Case Study: The clinical development and patient experience with a sustained-release intracanalicular dexamethasone insert post-cataract surgery

Module 7: Non-Erodible Ocular Implants

- Biomaterials selection and device architecture.
- Zero-order release kinetics and membrane-controlled diffusion systems.
- Surgical implantation techniques and potential complications.
- Drug loading and long-term stability in the harsh ocular environment.
- Case Study: Detailed analysis of the Retisert/Vitrasert non-erodible implants for chronic posterior segment diseases.

Module 8: Biodegradable Ocular Implants & Microparticulate Systems

- Design of biodegradable polymeric matrices for injection.
- Tailoring degradation rate to match desired therapeutic duration.
- Formulation of suspensions for intravitreal injection and stability challenges.
- Impact of injection volume and needle size on patient experience.
- Case Study: The development and clinical success of the Ozurdex implant for macular edema.

Module 9: Advances in Posterior Segment Targeting

- Limitations of topical and systemic routes for retinal and choroidal diseases.
- Suprachoroidal Space delivery and subretinal injection.
- Delivery devices and specialized needles for targeted posterior delivery.
- Novel excipients and vehicles to enhance drug transit across the vitreous.
- Case Study: The promise and technical challenge of SCS injection systems for delivering large molecule biologics to the macula.

Module 10: Non-Invasive Advanced Technologies

- Fundamentals of microneedle patches for transscleral delivery.
- Iontophoresis and sonophoresis for enhanced drug penetration.
- Controlled microdosing systems for topical drugs.
- Safety, pain assessment, and patient acceptability of novel non-invasive methods.
- Case Study: Results from trials of piezo-print microdosing of latanoprost for glaucoma treatment, focusing on precision and blink reflex.

Module 11: Manufacturing, Scale-Up & Quality by Design (QbD)

- Application of QbD principles to define Critical Quality Attributes for NDDS.
- Sterile manufacturing and aseptic processing for implants and injectables.

- Advanced fabrication techniques.
- Process Analytical Technology (PAT) tools for real-time quality control.
- Case Study: Developing a design space for a sustained-release microsphere formulation to ensure batch-to-batch consistency.

Module 12: Preclinical & Clinical Evaluation

- Relevant animal models for ocular PK/PD studies.
- In vitro release testing and correlation with in vivo performance.
- Clinical trial design for sustained-release devices
- Imaging and analytical techniques for monitoring drug depot in the eye
- Case Study: Interpreting Phase 3 clinical data for a novel sustained-release glaucoma implant, analyzing IOP reduction and duration of effect.

Module 13: Regulatory Landscape for Ophthalmic Products

- Classification of ophthalmic products.
- FDA and EMA (MAA) submission pathways for novel systems.
- Specific regulatory requirements for biomaterials and residual solvents.
- Post-market surveillance and reporting for implantable devices.
- Case Study: Navigating the regulatory path for a novel drug-eluting contact lens from an Investigational Device Exemption (IDE) to market approval.

Module 14: Biologics, Gene & Cell-Based Therapy Delivery

- Challenges in delivering large molecules to the posterior segment.
- Use of Adeno-Associated Virus vectors for ocular gene therapy.
- Delivery of cell suspensions and cell-based drug carriers.
- Strategies to overcome the immunogenicity of viral vectors in the eye.
- Case Study: Clinical developments in subretinal gene therapy for inherited retinal degenerations

Module 15: Commercialization, IP & Future Trends

- Market analysis and commercialization strategies for high-value sustained-release therapeutics.
- Intellectual Property strategies
- Bio-inspired and stimuli-responsive delivery systems.
- The role of Artificial Intelligence (AI) in optimizing drug delivery design and personalized medicine.
- Case Study: Examination of a successful patent litigation or licensing agreement related to a sustained-release implant.

Training Methodology

The training employs an Advanced, Interactive Hybrid Approach designed for specialized professional learning:

- Interactive Lectures.
- Case Study Analysis.
- Q&A/Expert Panel Discussions.
- Workshops & Problem-Solving.
- Pre-reading & Post-Course Resources.

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

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