Advanced Inhalation Product Testing and Quality 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 successful development and quality control of Orally Inhaled and Nasal Drug Products (OINDPs) is a highly specialized and rapidly evolving field critical for treating respiratory diseases like asthma and COPD. This advanced training program is engineered to address the growing global demand for expertise in In Vitro Bioequivalence (IVBE), Analytical Method Validation, and regulatory compliance. Advanced Inhalation Product Testing and Quality Training Course provides a deep dive into the Critical Quality Attributes (CQAs) of inhalation products, focusing on the sophisticated analytical methodologies required to ensure patient safety and therapeutic efficacy. Participants will master the intricacies of performance testing, including Aerodynamic Particle Size Distribution (APSD) and Delivered Dose Uniformity (DDU), which are foundational to demonstrating product quality and interchangeability across different markets.

The curriculum places a strong emphasis on practical application and compliance with major global pharmacopeial standards and regulatory guidance. Through a blend of theoretical knowledge, hands-on lab techniques, and real-world Case Studies, attendees will learn to navigate the complex Regulatory Landscape for generic and novel inhaled products. We explore advanced topics such as Extractables and Leachables (E&L), Quality by Design (QbD) principles in product development, and the implementation of Data Integrity protocols. By equipping professionals with Advanced Analytical Techniques and a comprehensive understanding of Product Lifecycle Management, this course is the essential next step for individuals looking to become leaders in the Respiratory Drug Delivery and Pharmaceutical Quality sectors.

Programme Curriculum

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10 days

Course Objectives

1. Master the principles and execution of Delivered Dose Uniformity (DDU) testing for all OINDP types per current pharmacopeia guidelines.
2. Perform and interpret Aerodynamic Particle Size Distribution (APSD) analysis using the Next Generation Impactor (NGI) and other advanced tools.
3. Develop and validate Advanced Analytical Methods for inhalation products, ensuring ICH Q2(R1) compliance and robustness.
4. Apply Quality by Design principles to optimize formulation and manufacturing processes for reproducible product performance.
5. Design and execute comprehensive Extractable and Leachable (E&L) studies for container closure and device components.
6. Formulate a robust Regulatory Strategy for global submissions focusing on In Vitro Bioequivalence (IVBE).
7. Troubleshoot common analytical and performance testing failures specific to respiratory drug products.
8. Understand the quality and testing challenges associated with emerging fields like Inhaled Biologics and gene therapy.
9. Implement Data Integrity and GMP compliance standards throughout the inhalation testing laboratory.
10. Interpret and apply complex Pharmacopeia Requirements from USP?ƒ¿601?ƒ?, Ph. Eur. 2.9.18, and relevant FDA/EMA guidance documents.
11. Characterize and control the Critical Quality Attributes (CQAs) of drug substance and excipients
12. Evaluate and verify the performance of different Inhaler Device Types
13. Lead Product Lifecycle Management activities, including post-approval changes and stability protocol management.

Target Audience

1. Analytical Scientists and Chemists in Quality Control (QC) or R&D.
2. Quality Assurance (QA) and Compliance Managers.
3. Regulatory Affairs Professionals specializing in CMC for respiratory products.
4. Formulation Scientists and Product Development Engineers.
5. Technical Directors and Lab Supervisors overseeing OINDP testing.
6. Professionals from Contract Research Organizations (CROs) and Contract Manufacturing Organizations (CMOs).
7. Pharmaceutical Engineers involved in device design and process validation.
8. Auditors and Inspectors from Regulatory Bodies.

Course Outline

Module 1: Foundational Principles of Respiratory Drug Delivery

- OINDPs Classification.
- Anatomy and physiology of the lung as a drug target.
- DDU, APSD, Fine Particle Fraction (FPF).
- Introduction to Pharmacopeia Requirements and global standards.
- Case Study: Correlating CQA failure with potential patient health risk.

Module 2: Delivered Dose Uniformity (DDU) Testing Mastery

- Principles of DDU and Dose Content Uniformity (DCU) testing.
- Dosage Unit Sampling Apparatus (DUSA) for pMDI and DPI.
- Method development and validation for DDU across different devices.
- Statistical analysis and interpretation of DDU data.
- Case Study: OOS Investigation of a low-dose pMDI batch DDU failure.

Module 3: Aerodynamic Particle Size Distribution (APSD)

- Theory of Cascade Impaction and the importance of APSD.
- In-depth operation of the Next Generation Impactor (NGI) and accessories.
- Data processing, Mass Balance, and calculation of key metrics (MMAD, GSD).
- Influence of test parameters: flow rate, pre-separator, and mouthpieces.
- Case Study: Optimizing NGI setup to reduce variability in a complex DPI product.

Module 4: Advanced OINDP Analytical Methods

- Method development and Method Validation for the active pharmaceutical ingredient
- Particle Characterization techniques.
- Analysis of propellants and residual solvents in pMDIs.
- Impactor cleaning, coating, and control of re-entrainment effects.
- Case Study: Validating a rapid laser diffraction method as a process control tool.

Module 5: Regulatory Compliance and Strategy

- Overview of global Regulatory Landscape for OINDPs.
- The role of In Vitro Bioequivalence (IVBE) in generic drug development.
- Chemistry, Manufacturing, and Controls requirements for inhalation products.
- Post-approval changes and supplements in the Product Lifecycle Management.

- Case Study: Navigating an FDA deficiency letter requiring additional IVBE data.

Module 6: Extractables and Leachables (E&L) Assessment

- Fundamentals of E&L studies for device and container closure systems.
- Analytical techniques for identifying and quantifying E&L
- Designing and executing robust E&L protocols.
- Material selection and control to mitigate E&L risks.
- Case Study: Conducting an E&L Assessment for a new polymer used in a nasal spray component.

Module 7: Quality by Design (QbD) in Inhalation Development

- Defining the Quality Target Product Profile (QTPP) and CQAs.
- FMEA, Fishbone Diagram to identify Critical Process Parameters (CPPs).
- Design of Experiments (DoE) for formulation and process optimization.
- Establishing a Control Strategy for inhalation products.
- Case Study: Implementing QbD to improve powder blending and content uniformity for a new DPI.

Module 8: Stability Testing and Product Shelf-Life

- Designing ICH-Compliant Stability Protocols
- Testing requirements for physical and chemical stability
- Data trending, statistical analysis, and shelf-life determination.
- Stability challenges unique to pMDIs
- Case Study: Investigating an OOT result in an accelerated stability study and implementing CAPA.

Module 9: Inhaler Device Performance and Qualification

- Device characterization tests
- The role of Human Factors engineering in device design and patient use.
- Device-drug interaction and its impact on performance.
- Acceptance testing for device components and incoming materials.
- Case Study: Analyzing a patient usability study to identify a critical design flaw affecting drug delivery.

Module 10: Data Integrity and Lab Compliance

- Principles of ALCOA+ and regulatory expectations for Data Integrity.
- Validating computerized systems
- Audit trails, electronic signatures, and data governance.
- Ensuring GMP compliance in the OINDP quality control lab.
- Case Study: Remediating a laboratory's data management system to achieve Part 11 compliance.

Module 11: Advanced Topics in Inhalation

- Development and testing of Inhaled Biologics.
- Novel and emerging Respiratory Drug Delivery systems
- Computational Fluid Dynamics (CFD) and in-silico modeling applications.
- Challenges in developing fixed-dose combination inhalation products.
- Case Study: Exploring the analytical hurdles for an inhaled monoclonal antibody formulation.

Module 12: Troubleshooting OINDP Testing Failures

- Systematic approach to OOS Investigation and root cause analysis.

- Impact of sample preparation and operator technique on variability.
- Controlling environmental factors in the lab.
- Revalidation strategies following equipment or method changes.
- Case Study: Root cause investigation of high variability in APSD testing across different analysts.

Module 13: Comparative Product Assessment and Equivalence

- Principles of In Vitro Equivalence (IVE) and its regulatory acceptance.
- Comparison of generic and reference products
- Statistical tests for comparing performance profiles.
- The importance of realistic patient use profiles in comparative testing.
- Case Study: Designing an IVE study protocol to support a generic DPI submission.

Module 14: Nebulizer and Nasal Spray Testing

- Testing methodologies for nebulized solutions and suspensions.
- Droplet size analysis and its impact on lung deposition.
- Performance testing for nasal sprays
- Regulatory requirements specific to nasal drug products.
- Case Study: Optimizing the spray pattern of a nasal drug to meet regulatory specifications.

Module 15: Laboratory Management and Continuous Improvement

- Best practices for method transfer and inter-laboratory studies.
- Technician training, competency assessment, and human error reduction.
- Instrumentation calibration, maintenance, and qualification (IQ/OQ/PQ).
- Risk-based auditing of OINDP quality control processes.
- Case Study: Implementing a Lean Six Sigma project to streamline DDU/APSD workflow.

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.com 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
07 Sep 2026	18 Sep 2026	Online	$4,000
14 Sep 2026	25 Sep 2026	Online	$4,000
21 Sep 2026	02 Oct 2026	Online	$4,000
28 Sep 2026	09 Oct 2026	Online	$4,000
05 Oct 2026	16 Oct 2026	Online	$4,000
12 Oct 2026	23 Oct 2026	Online	$4,000
19 Oct 2026	30 Oct 2026	Online	$4,000
26 Oct 2026	06 Nov 2026	Online	$4,000

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