Advanced Dissolution Testing and IVIVC 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 Dissolution Testing and IVIVC Training Course dives deep into the critical intersection of Dissolution Science and In Vitro-In Vivo Correlation, empowering pharmaceutical professionals to accurately predict and ensure the clinical performance of drug products. Dissolution testing is no longer merely a Quality Control (QC) measure but a sophisticated, biorelevant tool essential for modern drug product development, Quality by Design, and regulatory submission strategies. Mastering advanced dissolution methodologies, including the use of biorelevant media and specialized apparatus, is vital for characterizing complex dosage forms like modified-release and novel drug delivery systems. The ability to develop a truly discriminatory dissolution method directly translates into robust batch-to-batch consistency and serves as a crucial foundation for establishing a reliable IVIVC.

A successful IVIVC acts as a powerful, scientifically sound, in-vitro surrogate for costly and time-consuming bioequivalence (BE) studies and bioavailability (BA) assessments. The focus of this program is on practical application, covering the mathematical models, statistical validation, and the essential regulatory frameworks that govern the development, evaluation, and application of IVIVC. By linking the in-vitro drug release profile with the in-vivo plasma concentration, participants will gain the expertise to make science-based decisions on formulation optimization, justifying post-approval changes, and accelerating the overall time-to-market for life-saving medicines. This expertise is a key differentiator in today's highly competitive and compliance-driven global pharmaceutical landscape.

Programme Curriculum

Advanced Dissolution Testing and IVIVC Training Course

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Course Duration

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Course Objectives

1. Master Biorelevant Dissolution method development and selection for challenging APIs and complex dosage forms.
2. Develop and validate Discriminatory Dissolution Methods for Immediate-Release and Modified-Release products.
3. Design and implement Physiologically Based Biopharmaceutics Modeling to support dissolution testing.
4. Establish and validate Level A IVIVC using state-of-the-art Deconvolution and Convolution techniques.
5. Apply IVIVC as a Surrogate for Bioequivalence studies and justify subsequent Biowaivers.
6. Navigate Global Regulatory Guidance for IVIVC submission and acceptance.
7. Effectively Troubleshoot Out-of-Specification and Out-of-Trend dissolution results.
8. Implement Quality by Design principles for dissolution method lifecycle management.
9. Select and qualify Advanced Dissolution Apparatus
10. Use Statistical Methods for robust comparison of dissolution profiles and setting specifications.
11. Predict the in-vivo impact of Scale-Up and Post-Approval Changes using a validated IVIVC.
12. Characterize the performance of Novel Drug Delivery Systems and specialty dosage forms.
13. Integrate Process Analytical Technology and Real-Time Release Testing (RTRT) into dissolution processes.

Target Audience

1. Analytical Development Scientists & Managers
2. Formulation and Drug Product Development Scientists
3. Quality Control and Quality Assurance Professionals
4. Regulatory Affairs Specialists and Consultants
5. Pharmacokinetic/Biopharmaceutics Scientists

6. Chemistry, Manufacturing, and Controls Experts
7. Research & Development Directors and Project Managers
8. Scientists involved with Generic Drug Development

Course Modules

Module 1: Foundations of Dissolution Science and Biopharmaceutics

- Noyes-Whitney and Nernst-Brunner Theory.
- Understanding the Biopharmaceutics Classification System and its IVIVC implications.
- Physiological factors impacting oral absorption.
- Sink and non-sink conditions; selection of appropriate dissolution volume.
- Case Study: Application of BCS to justify Biowaiver for a newly developed IR product.

Module 2: Advanced Dissolution Apparatus and Techniques

- In-depth review of USP Apparatus 1-7 and non-compendial methods.
- Apparatus selection strategy for specialized dosage forms
- Mechanical Qualification and Performance Verification Test
- Instrumentation setup, automation, and minimizing operational variability.
- Case Study: Designing a dissolution test for a Transdermal Patch using USP Apparatus 5

Module 3: Biorelevant Dissolution Media Development

- Formulation and application of Simulated Gastric Fluid and Simulated Intestinal Fluid
- Biorelevant media for fed/fasted state testing
- Use of surfactants and enzymes to mimic in-vivo conditions and enhance predictability.
- Method development for poorly soluble and poorly permeable drugs.
- Case Study: Developing a biorelevant method to predict the Food Effect on a BCS Class II drug.

Module 4: Dissolution Method Development for Modified Release Products

- Rationale for developing Multi-Point Dissolution Profiles.
- Selecting conditions for Extended-Release, Delayed-Release, and Pulsatile systems.
- Setting acceptance criteria for MR products.
- The concept of Discriminating Power and ensuring method robustness.
- Case Study: Optimizing dissolution conditions to detect a critical process change in an ER tablet coating thickness.

Module 5: Principles and Regulatory Framework of IVIVC

- Definition, purpose, and different levels of IVIVC
- Regulatory expectations and guidance for IVIVC in submissions.
- When and why IVIVC is required or recommended
- Experimental design for IVIVC studies.
- Case Study: Review of an FDA guidance document detailing the data required for a Level A IVIVC submission.

Module 6: In-Vivo Data Acquisition and Deconvolution

- Fundamentals of Pharmacokinetics
- Methods for estimating the In-Vivo Input Function

- Deconvolution Techniques for obtaining in-vivo absorption.
- Selecting appropriate Reference Formulation for IVIVC studies.
- Case Study: Performing Wagner-Nelson deconvolution on clinical plasma concentration data to determine the in-vivo absorption profile.

Module 7: Level A IVIVC Modeling: Correlation Establishment

- The concept of Point-to-Point Correlation.
- Selecting appropriate Dissolution and Absorption Models
- Linear vs. Non-Linear Correlation approaches and mathematical equations.
- Regression analysis and statistical evaluation for the correlation.
- Case Study: Building a Level A IVIVC model using WinNonlin or equivalent software on two MR batches.

Module 8: IVIVC Validation and Predictive Performance

- Internal Validation
- External Validation
- Acceptance criteria for internal and external predictability error.
- Handling of outlier data and improving the correlation.
- Case Study: Calculating the Percent Prediction Error for Cmax and AUC for an external validation batch.

Module 9: Application of IVIVC as a Bioequivalence Surrogate

- Using validated IVIVC to set and justify Biopharmaceutic Specifications.
- Simulation of BE studies based on dissolution profile limits.
- Statistical BE Assessment and calculating the probability of passing.
- Using IVIVC to support Biowaivers for post-approval changes
- Case Study: Simulating the in-vivo Cmax and AUC for a batch with a dissolution profile at the edge of the specification range.

Module 10: Scale-Up and Post-Approval Changes

- Review of SUPAC-IR and SUPAC-MR guidelines.
- Determining the impact of Formulation and Process Changes on dissolution and IVIVC.
- Using IVIVC to justify the lack of need for a new Clinical Bioequivalence Study.
- Bridging strategies and regulatory reporting categories for changes.
- Case Study: Utilizing a Level A IVIVC to support a major equipment change without a clinical study.

Module 11: Dissolution for Novel Drug Delivery Systems

- Challenges in testing Nanoparticles, Liposomes, and Amorphous Solid Dispersions
- Specialized dissolution methods.
- Setting release specifications for complex and multi-particulate systems.
- IVIVC approaches for Targeted and Stimuli-Responsive Drug Delivery.
- Case Study: Designing a two-stage dissolution test for an Amorphous Solid Dispersion formulation to capture supersaturation and precipitation.

Module 12: Dissolution Method Validation and Life Cycle Management

- Phase-appropriate validation
- Validation parameters.
- ICH Q2 and ICH Q12 applications.

- Handling and investigating Out-of-Specification and Out-of-Trend results.
- Case Study: Performing a Method Robustness Study to determine the Critical Method Parameters of a dissolution test.

Module 13: Statistical Comparison of Dissolution Profiles

- Model-Dependent vs. Model-Independent approaches.
- Application and limitations of the f2?Çï Similarity Factor and f1?Çï Difference Factor.
- Using ANOVA and other statistical tools for dissolution data comparison.
- Developing statistically sound acceptance criteria for batch comparison.
- Case Study: Calculating the f2?Çï value to demonstrate Bio-Irrelevance of an in-vitro change for a regulatory submission.

Module 14: Quality by Design in Dissolution Testing

- Defining the Analytical Target Profile and Method Operating Range
- Risk assessment and identifying Critical Method Parameters
- Using Design of Experiments to establish the Method Design Space.
- Continuous method performance verification and monitoring.
- Case Study: Applying a DoE to optimize pH and stirring speed for a discriminating dissolution method.

Module 15: Integrating PAT and Future Trends

- Use of Process Analytical Technology for real-time monitoring.
- Concept of Real-Time Release Testing as a surrogate for dissolution.
- The role of Physiologically Based Biopharmaceutics Modeling in refining IVIVC.
- Miniaturization, Microfluidics, and in-silico modeling.
- Case Study: Discussion on a successful FDA submission utilizing Fiber-Optic UV Probes for continuous, automated dissolution profile generation.

Training Methodology

The training will adopt a highly **interactive and practical** approach, blending theoretical concepts with hands-on application:

- Expert-Led Lectures.
- Hands-on Workshops
- Case Studies and Group Exercises.
- Regulatory Mock Audits.
- Q&A and Peer-to-Peer Discussion.

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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