Advanced Bioassay Development and Validation 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 rapidly evolving landscape of biologics, cell and gene therapies, and novel therapeutic modalities demands rigorous, robust, and reliable bioassays. These assays are the critical tools for assessing product potency, stability, pharmacokinetics (PK), and immunogenicity throughout the drug development lifecycle, from early discovery through commercialization. Advanced Bioassay Development and Validation Training Course delves into the state-of-the-art methodologies and regulatory compliance required to design, optimize, and fully validate sophisticated biological assays. Participants will master techniques for working with complex biological matrices, ensuring data integrity, and navigating the latest ICH, FDA, and EMA guidance on method validation, positioning them as leaders in biopharmaceutical quality control (QC) and assay lifecycle management.

The modern bioassay specialist must move beyond traditional approaches, embracing high-throughput screening (HTS), multiplexing technologies, and advanced statistical analysis. This program focuses on developing fit-for-purpose assays including cell-based assays, ligand-binding assays (LBAs), and qPCR/ddPCR methods that meet stringent Good Manufacturing Practice (GMP) requirements. By emphasizing risk-based approaches and hands-on application of Quality by Design (QbD) principles, the course provides the strategic knowledge necessary to accelerate drug development timelines, minimize costly re-work, and ensure the quality assurance (QA) and regulatory submission success of novel biological products.

Programme Curriculum

Advanced Bioassay Development and Validation Training Course

Introduction

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Course Objectives

1. Master Assay Lifecycle Management from concept through commercialization and post-marketing surveillance.
2. Apply Quality by Design (QbD) principles to bioassay development for built-in quality.
3. Design robust Cell-Based Potency Assays for biologics.
4. Execute comprehensive Method Validation studies adhering to ICH Q2(R1) and current FDA/EMA guidance.
5. Calculate and interpret Relative Potency and Non-Parallelism using advanced statistical software
6. Develop sensitive and specific Immunogenicity Assays (ADA, NAb) for gene and cell therapies.
7. Optimize Ligand-Binding Assays (LBAs), including ELISA and MSD platforms, for PK/PD analysis.
8. Implement best practices for Critical Reagent Management to ensure assay long-term stability and performance.
9. Troubleshoot common issues in Complex Matrix Effects and Sample Pre-treatment protocols.
10. Ensure Data Integrity and compliance with 21 CFR Part 11 standards in a GMP/GLP environment.
11. Differentiate between Qualification and Validation for assays used in different regulatory phases.
12. Explore emerging technologies like ddPCR and Microfluidics for process-related impurity testing.
13. Create compliant Standard Operating Procedures (SOPs) and complete Validation Reports for regulatory submission files.

Target Audience

1. Bioanalytical Scientists and R&D Researchers
2. Quality Control (QC) Analysts and Managers
3. Assay Development Specialists in Pharma/Biotech
4. Regulatory Affairs Professionals focused on CMC/Quality
5. Quality Assurance (QA) Auditors and Specialists
6. Toxicology and Pharmacokinetics (PK) Scientists

7. Senior Technicians seeking career advancement
8. Contract Research Organization (CRO) Scientists

Course Modules

Module 1: Bioassay Strategy and Lifecycle Management

- Defining the Target Product Profile (TPP) and its impact on assay choice.
- Integrating Assay Design with CMC Strategy.
- The 3-Stage Assay Lifecycle.
- Implementing Risk-Based Approaches in early development.
- Case Study: Choosing a Tiered Potency Assay Strategy for a Novel Antibody.

Module 2: Quality by Design (QbD) in Assay Development

- Defining the Method Measurement Procedure (MMP) and Analytical Target Profile (ATP).
- Identifying Critical Method Parameters (CMPs) and Critical Reagent Attributes (CRAs).
- Using Design of Experiments (DoE) for rapid optimization and defining the Design Space.
- Establishing System Suitability Criteria based on assay performance.
- Case Study: Using DoE to Optimize Cell Concentration and Incubation Time in a Cytotoxicity Assay.

Module 3: Advanced Cell-Based Potency Assays (CBPAs)

- Designing Target-Specific Functional Assays
- Selecting and qualifying Stable Cell Lines and appropriate endpoints
- Techniques for minimizing Assay Drift and ensuring Cell Culture Consistency.
- Troubleshooting high Inter-Plate and Inter-Day Variability.
- Case Study: Developing a Complex Signaling Pathway Activation Assay for a Bispecific Antibody.

Module 4: Ligand-Binding Assays (LBAs) for Titer and PK

- Platform Selection: Comparing ELISA, MSD, AlphaLISA, and Western Blot.
- Optimization of Coating, Blocking, and Detection Reagents for sensitivity.
- Managing Hook Effect and ensuring accurate measurement at high concentration.
- Strategies for measuring drug concentration in Complex Biological Matrices
- Case Study: Optimizing a High-Throughput MSD Assay for Non-Clinical PK Sample Analysis.

Module 5: Immunogenicity Assay Development and Tiered Testing

- The Tiered Approach to Anti-Drug Antibody (ADA) Testing: Screening, Confirmation, and Neutralization.
- Strategies for overcoming Drug Tolerance and Target Interference.
- Developing Neutralizing Antibody (NAb) Assays
- Risk assessment for Cell and Gene Therapy Immunogenicity.
- Case Study: Validation of an ADA Assay for a Product with High Circulating Drug Levels.

Module 6: Statistical Analysis for Bioassays

- Understanding and calculating the Standard Curve
- Advanced Parallelism Testing and the concept of Relative Potency.
- Setting acceptance criteria for Accuracy, Precision, Linearity, and Range.
- Statistical justification for Dilutional Linearity and Minimum Required Dilution (MRD).
- Case Study: Interpreting Non-Parallelism in a Multi-Product Potency Assay and its Regulatory Impact.

Module 7: Method Validation Planning and Execution (ICH Q2(R1) Focus)

- Creating a robust Validation Plan (VP) that aligns with regulatory expectations.
- Defining and testing all Validation Parameters: Specificity, LOD/LOQ, Range, etc.
- Executing the Transfer of a Validated Method to a QC environment.
- Addressing deviations and Out-of-Trend (OOT) results during validation.
- Case Study: Designing a Full Validation Study for a GMP-Phase Potency Assay.

Module 8: Qualification vs. Validation: Phase-Appropriate Approaches

- Defining the data required for Pre-Clinical and Early Clinical (Phase 1) assay qualification.
- The transition point from Qualification to Full Validation
- The concept of Partial Validation for method modifications or new matrices.
- Risk-based approach for Phase-Appropriate Validation.
- Case Study: Comparing the Qualification Report for a Discovery Assay vs. the Validation Report for a Commercial Assay.

Module 9: Critical Reagent Management

- Strategies for sourcing, Characterization, and Qualification of critical reagents
- Establishing Reagent Stability and setting appropriate Expiry Dates.
- Creating a robust Reagent Lot-to-Lot Bridging Study protocol.
- The impact of Reagent Criticality on assay performance.
- Case Study: Troubleshooting an Assay Failure Caused by a New Lot of Detection Antibody.

Module 10: Regulatory and Compliance Standards (GMP/GLP)

- Review of current ICH, FDA, and EMA Guidance for Bioassay Validation.
- Understanding Data Integrity principles and ALCOA+ criteria.
- Compliance with 21 CFR Part 11 for electronic records and signatures.
- Preparing for a Regulatory Inspection and Auditing Bioanalytical Labs.
- Case Study: Responding to an FDA 483 Observation related to Assay Documentation.

Module 11: Troubleshooting and Method Maintenance

- Developing a systematic approach to Troubleshooting assay failures.
- Conducting Method Performance Monitoring and Trending Analysis.
- Implementing Change Control for validated methods.
- Strategies for handling Out-of-Specification (OOS) and Out-of-Trend (OOT) results.
- Case Study: Identifying and Correcting the Root Cause of a Persistent High CV% in a QC Assay.

Module 12: Assays for Gene and Cell Therapy Products

- Developing Plaque Assays and Infectivity Assays for viral vectors
- qPCR/ddPCR for Vector Titer, Genome Copy Number, and Residual DNA/Host Cell DNA.
- Assays for Viability, Purity, and Potency of Cell Therapy products.
- Regulatory considerations for In Vivo Potency Assays.
- Case Study: Designing a Potency Assay for a CAR-T Cell Product based on Target Cell Killing.

Module 13: Emerging Bioassay Technologies

- Introduction to Microfluidics and Automated Liquid Handling for HTS.

- The use of Mass Spectrometry (MS) in advanced bioanalysis.
- Label-Free Technologies for binding kinetics.
- Multiplexing assays for simultaneous measurement of multiple analytes.
- Case Study: Evaluating the Feasibility of Transitioning a Manual ELISA to a Fully Automated, Multiplexed Platform.

Module 14: Documentation and Reporting

- Structure and content of the Standard Operating Procedure (SOP).
- Writing a comprehensive Validation Report that satisfies regulatory needs.
- Best practices for Laboratory Notebooks and raw data archiving.
- Presenting and defending Bioassay Data during regulatory submissions.
- Case Study: Review and Critique of a Non-Compliant Validation Report Draft.

Module 15: Process-Related Impurity and Residual Assays

- Host Cell Protein (HCP) and Leachable/Extractable testing.
- Assays for Residual DNA/RNA and Process Residuals
- Setting appropriate Acceptance Criteria for impurity assays based on toxicity data.
- Validation requirements for Limit Tests vs. Quantitative Assays.
- Case Study: Validation of an ELISA for Host Cell Protein based on a High-Risk Biologic Product.

Training Methodology

This course utilizes a **blended learning approach** combining **theory with practical application**. Methodology includes:

- Interactive Lectures and Group Discussions led by industry experts.
- Case Studies and Real-World Problem-Solving sessions.
- Hands-on Statistical Workshops using industry-standard software.
- Template Review for SOPs, Validation Plans, and Reports.
- Q&A Forums focusing on specific regulatory challenges.

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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