Advanced Diagnostics and Biomarker 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 dawn of Precision Medicine has made Advanced Diagnostics and Biomarker Validation the most critical and high-demand skills in the modern biomedical and pharmaceutical landscape. This intensive, one-page training course introduction is meticulously designed for life science professionals who need to master the cutting-edge methodologies that bridge Biomarker Discovery with Clinical Implementation. The global drive toward personalized healthcare, fueled by Multi-Omics technologies and AI-driven Diagnostics, necessitates a robust understanding of how to reliably identify, analytically validate, and clinically qualify novel Prognostic and Predictive Biomarkers. By focusing on the entire Translational Pipeline, from target identification to Regulatory Strategy and Commercialization, this course provides the essential, hands-on knowledge required to accelerate innovative diagnostic products to market, ensuring their Analytical Reliability and Clinical Utility in various disease areas.

Advanced Diagnostics and Biomarker Validation Training Course goes beyond foundational theory, offering an actionable framework for tackling the real-world complexities of Diagnostic Assay Development. Participants will gain proficiency in navigating the technical challenges of diverse platforms, including Liquid Biopsy for Non-Invasive Diagnostics, Next-Generation Sequencing, and Digital Pathology. A central theme is the development of Context of Use driven validation plans, which are crucial for achieving Regulatory Approval for Companion Diagnostics (CDx). Ultimately, this course empowers scientists, researchers, and regulatory affairs specialists to become leaders in the field, capable of designing and executing robust validation studies that underpin the shift to Personalized Therapeutics and significantly improve Patient Outcomes through accurate, early-stage, and mechanism-based diagnostics.

Programme Curriculum

Advanced Diagnostics and Biomarker Validation Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Master the Biomarker Discovery Pipeline and Target Validation using Multi-Omics data
2. Design Analytical Validation strategies for diverse diagnostic platforms
3. Implement robust protocols for establishing assay Accuracy, Precision, Linearity, and Limit of Detection/Quantitation
4. Navigate the critical steps of Clinical Validation and determining Clinical Utility and Cost-Effectiveness for novel tests.
5. Apply Bioinformatics and Machine Learning for complex Biomarker Data Analysis and risk stratification.
6. Understand the development and regulatory pathways for Companion Diagnostics and In Vitro Diagnostics
7. Evaluate the utility and technical challenges of Liquid Biopsy for Non-Invasive Diagnostics.
8. Manage Pre-Analytical Variables to ensure Assay Reliability.
9. Develop strategies for integrating Digital Pathology and Computational Pathology into biomarker assessment workflows.
10. Analyze the role of Prognostic and Predictive Biomarkers in Oncology and Precision Therapeutics.
11. Interpret and comply with global Regulatory Guidelines for diagnostic device approval.
12. Formulate a business case and Commercialization Strategy for a new advanced diagnostic test.
13. Utilize Statistical Methods appropriate for Biomarker-Based Risk Stratification and cut-off determination.

Target Audience

1. R&D Scientists and Research Associates in pharmaceutical, biotechnology, and diagnostic companies.
2. Biomarker Scientists and Translational Medicine Specialists.
3. Laboratory Directors and Clinical Pathologists labs.
4. Regulatory Affairs and Quality Assurance professionals.
5. Bioinformaticians and Data Scientists.
6. Clinical Trial Managers and Clinical Operations Staff.
7. Product Managers and Commercialization Strategists for diagnostic devices.
8. Academic Researchers and Post-Doctoral Fellows.

Course Modules

Module 1: Foundational Concepts in Precision Medicine

- The shift from traditional diagnostics to Personalized Healthcare.
- Classification and Context of Use of biomarkers
- The essential stages of the Biomarker Translational Pipeline.
- Introduction to Assay Qualification and the importance of Analytical Reliability.
- Overview of Multi-Omics technologies in discovery.
- Case Study: The discovery and classification of HER2 as a predictive biomarker for breast cancer treatment.

Module 2: Biomarker Discovery & Target Identification

- Strategies for generating and prioritizing candidates from High-Throughput Screening.
- Utilization of Genomic, Transcriptomic, and Epigenetic markers.
- Leveraging Proteomics and Mass Spectrometry for circulating proteins.
- Applying Bioinformatics and AI/ML algorithms for signature identification.
- Filtering candidates based on Biological Plausibility and Commercial Feasibility.
- Case Study: Using whole exome sequencing (WES) and ML to identify a novel multi-gene signature for sepsis prognosis.

Module 3: Pre-Analytical Variables and Sample Quality

- Impact of Sample Type on assay performance.
- Best practices for Sample Collection, Processing, and Storage
- Standardization of protocols to minimize Pre-Analytical Variability.
- Techniques for assessing sample Integrity
- Handling of challenging samples for Liquid Biopsy applications.
- Case Study: Analyzing the effect of delayed blood processing time on cfDNA fragment yield and resulting variant allele frequency (VAF).

Module 4: Analytical Validation Design

- Defining the Performance Characteristics required for the Context of Use
- Designing studies for Accuracy, Precision, and Linearity.
- Methods for establishing Limit of Detection (LOD) and Limit of Quantitation
- Assessing Specificity and Robustness
- Statistical methods for calculating performance metrics and acceptance criteria.
- Case Study: Designing an Analytical Validation plan for a new NGS panel for Somatic Mutations in solid tumors.

Module 5: NGS-Based Assay Validation

- Specific validation considerations for Targeted Sequencing and Whole Exome Sequencing
- Establishing Bioinformatics Pipeline validity
- Quality metrics and acceptance criteria for Read Depth and Coverage Uniformity.
- Validation of low-frequency variant detection and Limit of Blank
- Addressing Inter-Laboratory Reproducibility for multi-site trials.
- Case Study: Validation of a commercial NGS panel for identifying HRR mutations for PARP Inhibitor therapy.

Module 6: Liquid Biopsy Validation

- The science and validation challenges of Circulating Tumor DNA and cfDNA.
- Validation for Exosomal markers and Circulating Tumor Cells
- Establishing Assay Sensitivity for minimal residual disease monitoring.
- Comparison of different analytical platforms for VAF detection.
- Regulatory expectations for Non-Invasive Diagnostics in screening and monitoring.
- Case Study: Validation of a ctDNA assay for post-surgical recurrence monitoring in colorectal cancer

Module 7: Immunohistochemistry and In Situ Hybridization

- Validation of IHC assays: Reagent lot-to-lot variability and scoring reproducibility.
- Establishing internal and external Quality Control procedures for IHC.
- Validation and interpretation of In Situ Hybridization assays.
- The role of Digital Pathology and Computational Pathology in automated scoring.
- Validation of multiplex IHC for assessing the Tumor Microenvironment.
- Case Study: Achieving concordance in PD-L1 IHC scoring across different clinical sites for immunotherapy selection.

Module 8: Statistical Methods for Validation

- Appropriate use of Receiver Operating Characteristic (ROC) curves and Area Under the Curve
- Methods for setting the optimal Clinical Cut-Off
- Calculating and interpreting Sensitivity, Specificity, Positive Predictive Value, and Negative Predictive Value
- Statistical design for Method Comparison and Bridging Studies.
- Handling Censored Data and survival analysis in Prognostic biomarker studies.
- Case Study: Determining the optimal clinical cut-off for a serum protein biomarker to diagnose early-stage liver cancer, maximizing PPV.

Module 9: Clinical Validation and Study Design

- Defining the target population and appropriate Clinical Endpoint.
- Designing prospective vs. retrospective studies for Prognostic vs. Predictive biomarkers.
- Criteria for establishing Clinical Utility and medical necessity.
- Developing a Statistical Analysis Plan for clinical trials involving biomarkers.
- Strategies for managing Biomarker Assays in multi-national clinical trials.
- Case Study: Designing a Phase III trial to clinically validate a novel Predictive Biomarker for response to an existing targeted therapy.

Module 10: Companion Diagnostics (CDx) Development

- The concept of Co-Development of a drug and its CDx.
- Regulatory requirements and pathways for Premarket Approval of a CDx.
- Addressing the Technical Feasibility and Clinical Timelines in the co-development plan.
- Challenges in Harmonizing the Assay Performance with the drug's clinical benefit.
- Post-market surveillance and labeling requirements for CDx.
- Case Study: The Co-Development journey of a BRAF inhibitor drug and its associated diagnostic test.

Module 11: Regulatory Strategy (FDA & EMA)

- Overview of global Regulatory Pathways in the US and EU
- Structuring and preparing the Premarket Submission package
- The importance of Quality Management Systems and ISO 13485.
- Understanding the role of Risk Classification in regulatory strategy.
- Guidance on Ethical and Informed Consent issues in biomarker testing.
- Case Study: Navigating the regulatory landscape for a novel Point-of-Care (POC) diagnostic device in a high-risk infectious disease setting.

Module 12: Bioinformatics & AI-Driven Diagnostics

- Principles of Data Management and integration of Multi-Omics data.
- Validation of Machine Learning models for Diagnostic Risk Prediction.
- Techniques for reducing Overfitting and ensuring model Generalizability.
- The role of Computational Pathology in image analysis and feature extraction.
- Regulatory scrutiny and guidelines for AI-Based Diagnostics
- Case Study: Training and validating a Deep Learning model to automatically diagnose diabetic retinopathy from retinal images.

Module 13: Pharmacogenomics and Personalized Therapeutics

- Role of Germline and Somatic Biomarkers in guiding drug therapy.
- Validation of Pharmacodynamic and Safety Biomarkers.
- Using biomarkers for Patient Stratification in clinical trials.
- Dose Optimization and therapeutic monitoring using biomarker readouts.
- Challenges and opportunities in implementing PGx testing in routine care.
- Case Study: Utilizing CYP450 genotyping as a Pharmacogenomic Biomarker to guide anti-depressant dosing.

Module 14: Quality Management Systems and Lab Accreditation

- Implementing a Quality Management System in a diagnostic laboratory.
- Understanding and preparing for Accreditation
- Procedures for Document Control and Audit Readiness.
- Designing and managing an External Quality Assessment program.
- Strategies for continuous Process Improvement and Quality Assurance.
- Case Study: A diagnostic lab achieving and maintaining ISO 15189 accreditation for a complex molecular test.

Module 15: Commercialization and Health Economics

- Developing a Target Product Profile for a diagnostic test.
- Strategies for securing Reimbursement and demonstrating Economic Value

- Market Access challenges and the payer perspective on Advanced Diagnostics.
- Intellectual property considerations and Licensing for proprietary biomarkers.
- Analyzing the Cost-Effectiveness of a Biomarker-Guided Therapy.
- Case Study: Building a Health Economic Model to justify the Cost-Effectiveness of a new CDx for a high-cost drug.

Training Methodology

The course employs an immersive, **Blended Learning** approach, ensuring both deep theoretical understanding and practical application.

- Interactive Lectures
- Case Studies & Workshops.
- Group Project/Simulation.
- Expert Panel Q&A.
- Software Demonstrations.

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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