Advanced Regulatory Strategy for Diagnostics 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 In Vitro Diagnostics (IVD) industry is undergoing a profound and rapid transformation, driven by innovations in Digital Health, Artificial Intelligence (AI), and Companion Diagnostics (CDx). In this complex, high-stakes environment, an Advanced Regulatory Strategy is not merely a compliance task but a critical business imperative for achieving Global Market Access and sustainable growth. The landmark implementation of the European Union's In Vitro Diagnostic Regulation and the evolving policy landscape at the US FDA particularly concerning Laboratory Developed Tests and Software as a Medical Device mandates a deep, strategic shift for diagnostics manufacturers. Advanced Regulatory Strategy for Diagnostics Training Course provides the next-level expertise needed to transition from reactive compliance to a proactive, globally-aligned regulatory function that minimizes risk, optimizes product lifecycles, and accelerates the delivery of next-generation diagnostic solutions to patients worldwide.

This intensive program moves beyond basic regulatory filing to focus on Strategic Regulatory Intelligence, Risk-Based Classification, and leveraging Real-World Evidence (RWE) to support regulatory submissions. Participants will master the intricacies of creating robust Technical Documentation under the IVDR framework, including advanced Performance Evaluation Plans (PEP) and managing complex changes for AI/ML-enabled IVDs using Predetermined Change Control Plans (PCCPs). We integrate practical case studies on successful approvals and post-market challenges, ensuring attendees can immediately apply learned strategies to their current product portfolio. By focusing on cross-functional alignment from R&D and Clinical Affairs to Quality Systems and Reimbursement this course is designed to empower regulatory leaders to strategically navigate the convergence of technology, policy, and global harmonization efforts to secure a competitive advantage in the rapidly advancing diagnostics market.

Programme Curriculum

Advanced Regulatory Strategy for Diagnostics Training Course

Introduction

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Course Duration

10 days

Course Objectives

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

1. Formulate a Global Regulatory Strategy for new and evolving IVD products, including Companion Diagnostics (CDx).
2. Master IVDR Risk Classification and implement a gap analysis for legacy devices transitioning from the IVD Directive (IVDD).
3. Develop and execute robust Performance Evaluation Plans (PEP) and Performance Evaluation Reports (PER) using Real-World Data (RWD).
4. Navigate the complex regulatory pathway for Software as a Medical Device (SaMD) and AI-Driven Diagnostics.
5. Design and apply Predetermined Change Control Plans (PCCPs) for machine learning models to ensure Algorithmic Transparency and continuous compliance.
6. Strategically leverage Scientific Advice and pre-submission meetings with global Competent Authorities and Notified Bodies.
7. Integrate Regulatory Intelligence into the entire IVD Product Lifecycle Management process to mitigate future risks.
8. Establish and maintain compliance with EUDAMED requirements, including Unique Device Identification (UDI) and data submission.

9. Develop a proactive Post-Market Surveillance (PMS) and Post-Market Performance Follow-up (PMPF) system to minimize vigilance risks.
10. Align regulatory timelines with Reimbursement Strategy and Health Technology Assessment (HTA) to ensure market adoption.
11. Interpret and apply emerging standards for cybersecurity, data privacy (HIPAA, GDPR), and Interoperability in digital diagnostics.
12. Design Co-Development Strategies for Companion Diagnostics (CDx) to align drug and diagnostic regulatory submissions.
13. Lead internal and external Regulatory Audits and manage complex non-conformities and CAPA processes.

Target Audience

1. Regulatory Affairs Managers/Directors
2. Quality Assurance (QA) Professionals
3. Clinical Affairs Managers.
4. R&D and Product Development Engineers
5. Senior Management/Executives
6. Consultants and Lawyers.
7. Person Responsible for Regulatory Compliance (PRRC).
8. Reimbursement and Market Access Specialists.

Course Modules

1. Global Strategy Frameworks and Trends

- Contrasting US FDA, EU IVDR, and other major frameworks
- Strategic implications of the FDA's LDT Proposed Rule and its impact on lab operations.
- Integrating Regulatory Intelligence for pro-active strategy development and risk assessment.
- Analysis of global regulatory trends for Decentralized Diagnostics and Point-of-Care Testing
- Case Study: The strategic shift from IVDD to IVDR for a multi-product portfolio and managing the Notified Body bottleneck.

2. IVDR In-Depth: Classification and Conformity

- Detailed application of the new Annex VIII IVDR classification rules
- Selecting the optimal conformity assessment procedure
- Requirements for the Person Responsible for Regulatory Compliance (PRRC) and their liabilities.
- Developing the EU Declaration of Conformity and the role of the Authorized Representative.
- Case Study: Reclassifying a legacy Class B genetic test to Class C under IVDR and the subsequent Technical Documentation overhaul.

3. Technical Documentation & Design Dossier Mastery

- Structuring the Technical Documentation (TD) compliant with IVDR Annexes II and III.
- Requirements for the Summary of Safety and Performance (SSCP) for high-risk devices.
- Managing the transition from paper-based files to integrated Digital Quality Systems.
- The essential contents of the Device Description and Specification and Labeling files.
- Case Study: Successful TD submission for a Class D companion diagnostic and addressing Notified Body questions on manufacturing consistency.

4. Advanced Performance Evaluation

- Designing the Performance Evaluation Plan to meet evolving clinical evidence requirements.
- The critical distinction between Scientific Validity, Analytical Performance, and Clinical Performance.
- Leveraging Real-World Evidence and literature-based data for the Performance Evaluation Report
- Statistical and methodological considerations for different IVD types
- Case Study: Using a bridging study and published literature to demonstrate clinical performance for an IVDR Class B novel biomarker assay.

5. Regulatory Pathways for Software as a Medical Device (SaMD)

- Understanding the IMDRF framework and its application to SaMD classification
- US FDA guidance on Medical Device Software and the Pre-Cert pilot program learnings.
- Developing software lifecycle documentation, including requirements, testing, and V&V
- Cybersecurity requirements and ensuring data integrity and patient safety.
- Case Study: Strategy for a mobile-based diagnostic image analysis app transitioning from a general wellness device to a Class II SaMD.

6. AI and Machine Learning (AI/ML) Diagnostics

- Regulatory strategy for locked and Adaptive AI/ML algorithms.
- The critical importance of the Predetermined Change Control Plan for iterative algorithm updates.
- Data governance, bias mitigation, and algorithm transparency in submissions.
- Validation requirements for AI/ML generalizability, clinical utility, and model drift monitoring.
- Case Study: Obtaining FDA clearance for a machine learning model using a PCCP for anticipated annual updates based on new patient data.

7. Companion Diagnostics (CDx) Co-Development Strategy

- The dual regulatory path.
- Mastering the Co-Development Agreement between the pharmaceutical and diagnostic partner.
- Designing and executing a single, unified clinical trial to support both drug and CDx applications.
- Navigating the regulatory requirements for Next-Generation Sequencing (NGS)-based CDx platforms.
- Case Study: Review of a failed co-development effort due to unaligned timelines and a successful global launch example

8. Quality Management System (QMS) & Audits

- Deep dive into ISO 13485:2016 and its alignment with IVDR/FDA QSR requirements.
- Preparing for and successfully managing Notified Body and Competent Authority Inspections and Audits.
- Advanced techniques for managing Corrective and Preventive Action and non-conformities.
- Supplier qualification, control, and ensuring regulatory compliance across the supply chain.
- Case Study: Addressing critical non-conformity findings related to process validation during a surprise Notified Body audit.

9. Post-Market Surveillance (PMS) and Vigilance

- Designing the PMS Plan and Post-Market Performance Follow-up (PMPF) Plan.
- The process and data requirements for mandatory Vigilance Reporting
- Advanced techniques for data collection and signal detection in active and passive PMS systems.
- Strategies for managing and executing a large-scale Field Safety Corrective Action (FSCA) or product recall.

- Case Study: The decision-making process for determining if a minor software bug constitutes a reportable adverse event under IVDR.

10. EUDAMED and Unique Device Identification (UDI)

- Detailed instruction on data submission to the EUDAMED database for economic operators.
- Implementing Unique Device Identification (UDI) requirements at the product and packaging levels.
- Ensuring data accuracy and managing changes to UDI/EUDAMED records throughout the product lifecycle.
- The strategic value of EUDAMED data for post-market intelligence and competitive analysis.
- Case Study: Successfully registering a high-volume Class B IVD and its associated labeling and UDI data across all six EUDAMED modules.

11. Global Harmonization and Rest-of-World (ROW) Strategies

- Strategy for simultaneous or sequential global market submissions
- Leveraging Medical Device Single Audit Program for multi-jurisdictional QMS compliance.
- Addressing regional variations in labeling, language, and clinical data acceptance.
- Regulatory paths for specific markets, including China NMPA and Brazil ANVISA.
- Case Study: Developing a global launch plan for a high-risk IVD, utilizing MDSAP to accelerate approval in Canada, Australia, and Brazil.

12. Strategic Risk Management (ISO 14971:2019)

- Integrating ISO 14971:2019 throughout the entire product lifecycle from concept to retirement.
- Advanced techniques for risk analysis, evaluation, and control for novel technologies.
- Documenting the Risk Management File and linking it to the Technical Documentation.
- The role of risk management in classifying devices and determining performance study scope.
- Case Study: Assessing and mitigating the cybersecurity risk for a networked IVD instrument used in a hospital setting.

13. Regulatory and Reimbursement Convergence

- Understanding the intersection of Regulatory Approval and Health Technology Assessment (HTA).
- Designing clinical trials to generate both regulatory evidence and economic evidence for payers.
- The role of CPT codes, coverage, and payment rates in the US market.
- Early engagement strategies with payers and reimbursement authorities.
- Case Study: Developing a regulatory-reimbursement dossier for a novel liquid biopsy test to secure both FDA approval and favorable national coverage.

14. Regulatory Affairs for Combination Products and Advanced Therapies

- Regulatory classification and submission requirements for Combination Products
- The role of the Office of Combination Products (OCP) at the FDA and designation of the primary mode of action.
- Regulatory considerations for IVDs related to Advanced Therapy Medicinal Products (ATMPs).
- Ensuring cross-functional collaboration between drug and device regulatory teams.
- Case Study: Navigating the pre-market review process for a closed-loop system combining a diagnostic sensor and a drug delivery component.

15. Crisis Management and Ethical Compliance

- Developing a Regulatory Crisis Communications Plan for major issues
- Managing regulatory inquiries, warning letters, and responding to FDA 483s.
- Ethical Considerations in AI-driven diagnostics, data privacy, and patient consent.
- The critical role of Compliance Culture and training in preventing systemic regulatory failures.
- Case Study: Responding to a major data breach and the subsequent regulatory reporting obligations under GDPR and HIPAA.

Training Methodology

The course is delivered using a Blended Learning Approach designed for senior professionals, focusing on practical application and strategic decision-making:

- Expert-Led Lectures.
- Interactive Workshops.
- In-Depth Case Studies & Simulations.
- Regulatory Mock Panel.
- Cross-Functional Role-Play.
- Resource Toolkit.

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
28 Sep 2026	09 Oct 2026	Online	$2,000
28 Sep 2026	09 Oct 2026	Physical	$3,000
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0

Ready to enroll or request a customized program? Book online or contact us:

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