Regulatory Strategy for Companion 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

In today?ÇÖs rapidly evolving healthcare landscape, Regulatory Strategy for Companion Diagnostics (CDx) plays a pivotal role in ensuring that diagnostic tests used in conjunction with targeted therapies meet the stringent requirements set by regulatory bodies. As precision medicine continues to reshape the future of healthcare, the importance of regulatory compliance, market access, and risk management for companion diagnostics has never been more critical. Regulatory Strategy for Companion Diagnostics Training Course is designed to equip professionals with the knowledge and strategic acumen needed to navigate this complex landscape, from initial **biomarker discovery** and co-development to market access and post-market surveillance. Participants will learn about global regulatory frameworks, industry best practices, and strategies for successful product development and commercialization.

This course delves deep into the regulatory requirements for CDx products, focusing on the FDA, EMA, and other global regulatory agencies. With an emphasis on clinical trials, regulatory submissions, market authorization, and post-market surveillance, professionals will gain actionable insights to streamline the regulatory approval process for companion diagnostics. The curriculum combines theoretical knowledge with real-world case studies, preparing participants to effectively design and implement regulatory strategies for companion diagnostics. By the end of the program, attendees will be equipped with the tools needed to reduce regulatory risk, speed up product launches, and ensure the successful integration of diagnostics with therapeutic products.

Programme Curriculum

Regulatory Strategy for Companion Diagnostics Training Course

Introduction

The convergence of diagnostics and therapeutics is rapidly transforming modern healthcare, ushering in the era of **precision medicine** and **personalized treatment**. At the heart of this revolution are **companion diagnostics (CDx)**, in vitro diagnostic devices that provide critical information essential for the safe and effective use of a corresponding therapeutic product. The development and commercialization of these integrated drug-device products present a unique set of **regulatory challenges**, requiring a sophisticated understanding of global and regional frameworks like the FDA's Premarket Approval (PMA) pathway and the EU's In Vitro Diagnostic Regulation (IVDR). Regulatory Strategy for Companion Diagnostics Training Course is designed to equip professionals with the knowledge and strategic acumen needed to navigate this complex landscape, from initial **biomarker discovery** and co-development to market access and post-market surveillance.

Navigating the **regulatory pathway** for companion diagnostics is a strategic imperative for biopharmaceutical and diagnostic companies. It requires a deep understanding of evolving requirements, including clinical trial design, analytical and clinical validation, and the critical need for **co-development planning** to align drug and diagnostic timelines. This training will provide a comprehensive, practical guide to developing a robust **regulatory strategy** that minimizes risk, streamlines the approval process, and ensures that life-saving personalized therapies reach patients efficiently. Through expert-led sessions and hands-on case studies, participants will learn how to build effective cross-functional teams, manage complex submissions, and anticipate the future trends shaping the CDx market.

Course Duration

10 days

Course Objectives

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

- Define companion diagnostics and explain their pivotal role in personalized medicine.
- Analyze the global regulatory landscape for CDx, including FDA, EMA, and other key international frameworks.
- Formulate an integrated regulatory strategy for the co-development of a drug and its associated CDx.
- Identify and address critical challenges in clinical trial design for CDx.
- Master the requirements for analytical and clinical validation of CDx assays.
- Develop a robust plan for regulatory submissions, including technical documentation and dossiers.
- Navigate the intricacies of the scientific consultation process with regulatory bodies.
- Implement strategies for post-market surveillance and lifecycle management of CDx.
- Evaluate the business models and collaborative partnerships between biopharma and diagnostic companies.
- Assess the impact of emerging technologies like Next-Generation Sequencing (NGS) and liquid biopsy on CDx regulation.
- Understand the unique considerations for CDx in immuno-oncology and other therapeutic areas.
- Mitigate risks associated with off-label use of diagnostics.
- Strategize for market access and reimbursement in a value-based healthcare system.

Target Audience

This course is designed for a diverse group of professionals involved in the development and commercialization of healthcare products, including:

- Regulatory Affairs Professionals: Seeking to specialize in the complexities of CDx.
- Clinical Research Scientists.
- R&D and Product Development Managers.
- Quality Assurance and Compliance Specialists.
- Market Access and Reimbursement Professionals.
- Biopharma Executives: Leading teams in the precision medicine space.
- Diagnostic Company Leaders: Driving strategic partnerships and product pipelines.
- Biomarker Scientists: Translating discoveries into regulatory-ready products.

Course Outline

Module 1: Introduction to Precision Medicine and Companion Diagnostics

- Defining Precision Medicine.
- Role of Companion Diagnostics.
- Types of companion diagnostics
- Global market growth and key drivers.
- Ethical and Legal Considerations.
- **Case studies:** Importance of regulatory compliance

Module 2: Regulatory Frameworks and Pathways

- FDA Regulatory Pathways: PMA vs. 510(k), and the De Novo classification.
- Understanding the new regulatory landscape for CDx.
- International Harmonization: ICH and other global initiatives.
- Early Regulatory Engagement: Pre-submission and scientific consultation.
- Global Regulatory Strategy: Navigating different country-specific requirements.
- **Case studies:** Navigating country-specific regulatory environments

Module 3: Co-Development and Clinical Trial Design

- Integrated Development Plan.
- Biomarker Identification and Validation.
- Master protocols, umbrella, and basket trials.
- Powering studies for co-development.
- Managing the CTA (Clinical Trial Assay) vs. CDx pathway.
- **Case studies:** Key challenges in clinical trial design

Module 4: Analytical and Clinical Validation

- Analytical Validation: Precision, accuracy, and reproducibility.
- Establishing clinical utility and performance.
- Linking clinical trial assays to the final CDx product.
- Ensuring specimen integrity and quality.
- Regulatory considerations for CDx software.
- **Case Studies**: Preparing a regulatory submission for CDx

Module 5: Regulatory Submissions and Documentation

- Pre-Market Approval (PMA) Submission.
- Technical Documentation (EU.
- Labeling and Instructions for Use

- FDA eSTAR and eCopy submissions
- Responding to Regulatory Inquiries: Managing deficiencies and supplements
- **Case studies**: Key challenges in gaining market access

Module 6: Post-Market Surveillance and Lifecycle Management

- Post-Market Surveillance (PMS.
- Adverse Event Reporting.
- Managing changes to an approved CDx.
- Periodic Safety Update Reports.
- CDx Lifecycle: From initial approval to next-generation assays.
- **Case Studies:** Risk management in post-market surveillance and approval.

Module 7: Quality Management Systems (QMS) for CDx

- Overview of QMS in the CDx industry
- Key quality control standards
- Document control and traceability
- Implementing QMS in CDx development
- **Case studies:** Validation and verification processes

Module 8: Business and Commercial Strategy

- Diagnostic company and biopharma collaboration.
- Market Access and Reimbursement.
- Value-based and competitive pricing.
- Market entry and launch strategies.
- **Case Studies**: Evaluating potential CDx opportunities.

Module 9: Regulatory Strategy Planning

- Crafting a regulatory strategy for CDx
- Stakeholder collaboration in strategy development
- Key milestones in the regulatory lifecycle
- Managing timelines and budgets
- **Case Study:** Non-Small Cell Lung Cancer (NSCLC) and EGFR mutations.

Module 10: Personalized Medicine and CDx

- Relationship between personalized medicine and companion diagnostics
- Regulatory requirements for personalized treatments
- Designing regulatory strategies for personalized therapies
- Integration of diagnostic and therapeutic strategies
- **Case studies:** Research in personalized medicine and CDx

Module 11: Market Authorization and Reimbursement Pathways

- Understanding market authorization processes
- Reimbursement strategies for CDx
- Regulatory approval timelines
- Post-launch monitoring and reporting
- **Case Study:** Obtaining market authorization and secure public reimbursement

Module 12: Clinical Data Management for Regulatory Approvals

- Best practices in clinical data management
- Data standards and regulatory compliance
- Statistical analysis for CDx validation
- Interpreting clinical data for regulatory approval
- **Case studies** on clinical data success

Module 13: Ethical and Legal Considerations in Companion Diagnostics

- Ethical considerations in CDx development
- Legal aspects of patient consent and privacy
- Regulatory requirements for data protection
- Navigating ethical dilemmas in CDx approval
- **Case studies** in ethics and legal challenges

Module 14: Final Project: Developing a CDx Regulatory Strategy

- Project Kick-off: Defining a new CDx product.
- Strategy Document: Drafting a comprehensive regulatory plan.
- Stakeholder Analysis: Mapping key internal and external players.
- Risk Assessment: Identifying potential regulatory hurdles.
- **Final Presentation**: Presenting the strategy to a panel.

Module 15: Emerging Technologies and Trends

- Next-Generation Sequencing (NGS.
- Liquid Biopsy: The rise of non-invasive diagnostics.
- Regulatory frameworks for AI-driven CDx.
- Navigating PD-L1, TMB, and MSI.
- Expanding CDx into infectious diseases and CNS disorders.
- **Case studies** in regulatory success in emerging markets

Training Methodology

Our training methodology combines theoretical knowledge with practical application to ensure a comprehensive and engaging learning experience.

- Expert-Led Lectures.
- Interactive Workshops.
- In-Depth Case Studies.
- Role-Playing and Simulations.
- Peer-to-Peer Learning.
- Guest Speakers.
- Q&A Sessions: Direct interaction with instructors to address specific challenges.
- Practical Project

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

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

Register Online Now