Advanced Regulatory and Policy for Personalized Medicine 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 global healthcare paradigm is undergoing a profound transformation, moving from a one-size-fits-all approach to highly individualized patient care enabled by Personalized Medicine (PM). This shift is powered by breakthroughs in genomics, multi-omics data integration, AI-driven diagnostics, and Cell and Gene Therapy (CGT). The unprecedented pace of this scientific innovation has created a critical gap in the existing regulatory and policy frameworks. Advanced Regulatory Science is now paramount, requiring professionals to navigate complex global standards for biomarker validation, companion diagnostics (CDx), and Real-World Evidence (RWE). Advanced Regulatory and Policy for Personalized Medicine Training Course addresses, the need for strategic, future-ready expertise in designing adaptive clinical trials, managing genomic data privacy, and ensuring equitable access to precision therapeutics.

The course provides an in-depth, strategic perspective on the evolving regulatory landscape, focusing on key global agencies like the FDA, EMA, and PMDA. It moves beyond traditional regulatory affairs, emphasizing policy development, health technology assessment (HTA), and innovative reimbursement models crucial for market access. By mastering the intersection of policy, ethics, and emerging technology, participants will be equipped to steer their organizations through regulatory ambiguity. The ultimate goal is to accelerate the safe, effective, and ethical translation of precision medicine breakthroughs into clinical practice, ensuring a competitive edge in this rapidly expanding, high-value healthcare sector.

Programme Curriculum

Advanced Regulatory and Policy for Personalized Medicine Training Course

Introduction

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Course Duration

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Course Objectives

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

1. Strategize and implement Global Regulatory Harmonization frameworks for multi-regional clinical trials in PM.
2. Design Adaptive Trial Designs and Master Protocols for precision oncology and rare disease therapeutics.
3. Evaluate the regulatory pathway for co-developing and approving Companion Diagnostics and their corresponding Targeted Therapies.
4. Master the application of Real-World Evidence (RWE) and Real-World Data (RWD) in regulatory submissions and post-market surveillance.
5. Assess the regulatory and ethical challenges of integrating Artificial Intelligence (AI) and Machine Learning (ML) tools in drug discovery and diagnostics.
6. Develop robust Data Governance and Privacy Policy strategies compliant with major regulations for genomic data sharing.
7. Analyze and influence the development of Value-Based Reimbursement and Health Technology Assessment (HTA) models for high-cost precision therapeutics.
8. Formulate regulatory strategies for Advanced Therapeutic Medicinal Products, including Cell and Gene Therapies (CGT).
9. Navigate the specialized regulatory requirements for Liquid Biopsies and other non-invasive biomarker technologies.
10. Advise on Intellectual Property (IP) strategies and exclusivity pathways for PM products and associated data/algorithms.
11. Implement quality standards like Good Clinical Practice (GCP) and eCTD for complex, data-rich PM submissions.
12. Address Health Equity and Inclusion considerations in clinical trial design and regulatory policy to ensure broad patient access.

13. Lead internal policy development to anticipate and comply with evolving regulations in digital health ecosystems and multi-omics technologies.

Target Audience

1. Regulatory Affairs Professionals in Pharmaceutical, Biotech, and Medical Device companies.
2. Clinical Development/Operations Managers.
3. R&D Strategists and Policy Analysts.
4. In Vitro Diagnostics (IVD) and Companion Diagnostics (CDx) Development Teams.
5. Market Access and Reimbursement Specialists.
6. Bioinformaticians and Data Scientists.
7. Legal and Compliance Officers.
8. Government/Agency personnel, Consultants, and Academics.

Course Modules

1. Foundational Policy and the PM Paradigm Shift

- Personalized and Precision Medicine and the P4 Medicine concept.
- The transition from blockbuster drugs to N-of-1 trial designs.
- Global PM initiatives.
- Global Health Policy
- Case Study: Policy response to the early adoption of direct-to-consumer (DTC) genetic testing and agency jurisdiction.

2. The Global Regulatory Landscape for PM

- Deep dive into FDA frameworks for PM products.
- Advanced Therapy Medicinal Products classification and centralized procedure.
- Understanding PMDA and ICH efforts for Global Harmonization.
- Regulatory Harmonization
- Case Study: Comparison of the FDA and EMA approval process for a complex Cell Therapy product.

3. Regulatory Strategy for Companion Diagnostics (CDx)

- The regulatory requirements for co-development of a drug and its associated CDx.
- Utility and validation of analytical and clinical performance for a CDx.
- Medical Device classifications and their unique regulatory pathways.
- CDx Co-Development
- Case Study: The co-approval and labeling challenge of a KRAS-targeted therapeutic and its specific diagnostic assay.

4. Biomarker Validation and Regulatory Acceptance

- Regulatory standards for a fit-for-purpose biomarker use
- Protocol design and statistical considerations for biomarker validation studies.
- The concept of a "Premarket Approval (PMA)" and "510(k)" for diagnostics.
- Biomarker Validation
- Case Study: Validation and regulatory acceptance of a multi-gene panel test for hereditary cancer risk.

5. Advanced Clinical Trial Design for PM

- Implementation of Master Protocols.
- Statistical and logistical challenges of Adaptive Trial Designs in rare diseases/oncology.
- Ethical and regulatory considerations for trial enrollment based on genomic stratification.
- Adaptive Trial Design
- Case Study: Designing a Platform Trial for multiple investigational drugs across a single disease with different molecular subtypes.

6. Real-World Evidence (RWE) and Data Generation

- Regulatory expectations for using RWE to support new indications or label expansions.
- Sources of Real-World Data.
- Methodological and regulatory standards for ensuring RWE data quality and relevance.
- Real-World Evidence Strategy
- Case Study: Successful use of a patient registry to provide long-term safety and efficacy data for a PM drug.

7. AI and Machine Learning (ML) in Regulatory Submissions

- Regulatory policy for Software as a Medical Device and its PM applications.
- Frameworks for approving "Locked" and "Continuously Learning" algorithms.
- Addressing bias and ensuring algorithm transparency in submissions.
- AI/ML Regulatory Framework
- Case Study: Approval of an AI-based diagnostic tool that uses an evolving algorithm for retinopathy detection.

8. Policy for Cell and Gene Therapy (CGT)

- Specific CBER and EMA guidelines for ATMPs and their manufacturing (CMC) requirements.
- Non-clinical testing and long-term follow-up regulations for CGT products.
- Regulatory pathways for gene editing technologies and in vivo therapies.
- Cell and Gene Therapy Regulation
- Case Study: Navigating the regulatory and ethical hurdles for a first-in-human CRISPR-based therapy trial.

9. Genomic Data Governance and Privacy (ELSI)

- Detailed review of GDPR, HIPAA, and other global data privacy mandates.
- Strategies for achieving de-identification and anonymization of genomic data.
- Challenges of patient consent models for biobanking.
- Genomic Data Privacy
- Case Study: Responding to a data breach involving a large-scale whole-genome sequencing study under strict GDPR rules.

10. Reimbursement and Market Access Policy

- Fundamentals of Health Technology Assessment and its influence on market entry.
- Developing a value proposition for a precision therapeutic and standard of care.
- Value-Based Contracts and Outcomes-Based Reimbursement models.
- Value-Based Reimbursement
- Case Study: Market access challenges and subsequent policy negotiation for a multi-million-dollar gene therapy.

11. Regulatory Aspects of Digital Health and Wearables

- Regulation of Wearable Sensors and Digital Biomarkers as medical devices.
- Integrating Digital Health Technologies into clinical trials and post-market care.
- Cybersecurity and validation requirements for connected devices and telehealth platforms.
- Digital Health Regulatory
- Case Study: Regulatory approval for a patient-facing app used to adjust the dosing of an approved PM drug.

12. Strategic Intellectual Property and Exclusivity

- Patenting strategies for biomarkers, diagnostic algorithms, and personalized dosing regimens.
- Understanding Data and Market Exclusivity pathways for Orphan Drugs and new molecular entities.
- Navigating the IP landscape for generic/biosimilar versions of PM products.
- IP Strategy
- Case Study: Patent litigation and policy implications surrounding a foundational gene-sequencing technology.

13. Chemistry, Manufacturing, and Controls for PM

- Regulatory expectations for manufacturing Autologous and Allogeneic CGT products.
- Ensuring supply chain traceability and Good Manufacturing Practice for individualized products.
- Challenges of small-batch manufacturing and decentralized production models.
- CMC for Advanced Therapies
- Case Study: Addressing a CMC deficiency in an NDA for a small molecule drug that requires a highly specialized delivery system.

14. Post-Market Policy and Lifecycle Management

- Planning for and executing Risk Evaluation and Mitigation Strategies for PM products.
- Regulatory handling of label expansions, new CDx approvals, and post-approval changes.
- Role of Pharmacovigilance and adverse event reporting for targeted therapies.
- Post-Market Surveillance
- Case Study: Regulatory requirement for a new Black Box Warning based on long-term post-market data from a PM drug subpopulation.

15. Future Policy Trends and Health Equity

- Anticipating the regulatory impact of Multi-Omics data integration and single-cell sequencing.
- Policy focus on addressing Health Equity and Inclusion in PM research and access.
- The future role of Regulatory Science in shaping a proactive, agile regulatory environment.
- Health Equity in PM
- Case Study: Developing a policy proposal for mandatory inclusion of diverse patient populations in PM clinical trials.

Training Methodology

The course will utilize an Advanced Blended Learning approach, focusing on practical, problem-solving skills:

- **Interactive Virtual Workshops**.
- **Case Study-Driven Learning**
- **Policy Simulation/Role-Play**.

- **Strategic Project Work**
- **Expert Q&A/Mentorship**.

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

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Physical	$12,000

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