Digital Health and Regulatory Considerations 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 Digital Health sector is undergoing a rapid, technology-driven evolution, marked by the explosive growth of Artificial Intelligence (AI), Software as a Medical Device (SaMD), and Decentralized Clinical Trials (DCTs). This wave of HealthTech innovation promises unprecedented gains in efficiency, personalized care, and global patient access. However, this progress is tightly coupled with navigating an increasingly complex global Regulatory Landscape, including the European MDR, US FDA frameworks, and stringent rules on Data Privacy and Cybersecurity. Successful deployment of these solutions requires a proactive, compliance-first approach to mitigate risks like algorithmic bias and ensure data interoperability via standards like Fast Healthcare Interoperability Resources

Digital Health and Regulatory Considerations Training Course is specifically designed to bridge the critical gap between technological advancement and regulatory necessity. Participants will gain practical, actionable expertise in establishing robust Quality Management Systems (QMS), mastering the nuances of SaMD classification, and developing a strategic Regulatory Pathway for their products. By focusing on real-world case studies and emphasizing risk management, the program empowers professionals to confidently bring safe and effective digital health solutions to market, ensuring both patient safety and sustained business growth in this dynamic, high-stakes environment.

Programme Curriculum

Digital Health and Regulatory Considerations Training Course

Introduction

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Course Objectives

1. Accurately determine the risk class and regulatory pathway for Software as a Medical Device (SaMD) products under international frameworks.
2. Apply and ensure compliance with key global standards, including FDA (510(k), De Novo) and EU Medical Device Regulation (MDR).
3. Design, document, and maintain a functional Quality Management System (QMS) specifically tailored for digital health and HealthTech companies.
4. Address the unique regulatory and ethical challenges associated with Generative AI and Machine Learning algorithms in clinical decision support.
5. Understand and implement FHIR APIs and compliance requirements like the Cures Act and TEFCA to facilitate seamless health data exchange.
6. Develop comprehensive strategies for Cybersecurity risk assessment and mitigation across the digital health product lifecycle.
7. Ensure strict adherence to global Data Privacy regulations, including HIPAA and GDPR, for all patient data.
8. Manage the regulatory and operational aspects of conducting Decentralized Clinical Trials using remote monitoring tools.
9. Formulate a cohesive Regulatory Strategy that optimizes market access speed while ensuring long-term sustainable compliance.
10. Create high-quality, audit-ready Technical Documentation and Clinical Evaluation Plans (CEP/CER) for regulatory submissions.
11. Connect regulatory approval to Value-Based Care models and market access strategies.
12. Implement systems for robust Post-Market Surveillance (PMS), vigilance, and continuous algorithm monitoring.
13. Identify and develop solutions to minimize algorithmic bias to ensure equity and fairness in AI-driven health outcomes.

Target Audience

1. Regulatory Affairs Professionals
2. HealthTech/Startup Founders
3. Software Engineers & Developers.
4. Quality Assurance (QA) Managers.
5. Clinical/Medical Affairs Leaders.
6. Product Managers & Strategists.
7. Data Scientists & AI/ML Engineers.
8. Healthcare Executives & Legal Counsel.

Course Modules

Module 1: Introduction to Digital Health & the Regulatory Ecosystem

- Defining Digital Health, mHealth, and Telehealth.
- The concept of Software as a Medical Device and General Wellness Apps.
- Overview of the global Regulatory Landscape
- Case Study: The regulatory journey of a wellness tracking app suddenly claiming diagnostic capabilities.
- The pivotal role of data interoperability and FHIR standards.

Module 2: SaMD Classification and Risk

- Understanding the IMDRF Risk Framework for SaMD.
- FDA's risk-based classification system
- EU MDR risk classification rules
- Case Study: Classifying a diagnostic AI tool for retinopathy versus a simple appointment reminder app
- Defining the Intended Purpose as the foundation of regulatory strategy.

Module 3: Quality Management Systems (QMS) for Digital Health

- Core requirements of ISO 13485 and FDA Quality System Regulation (QSR).
- Implementing Agile/DevOps methodologies under a controlled QMS.
- Managing Software Validation and Design Control documentation.
- Case Study: A QMS audit failure due to inadequate version control and risk management during a software update.
- Structuring the Device Master Record (DMR) and Technical File/Design History File

Module 4: The Regulatory Pathway: FDA Submissions

- Detailed procedures for 510(k) premarket notification.
- The De Novo pathway for novel low-to-moderate risk devices.
- Preparing the Premarket Application (PMA) for high-risk SaMD.
- Case Study: A SaMD company successfully utilizing the Pre-Submission process to get early FDA feedback.
- Understanding the Digital Health PDURS framework.

Module 5: The Regulatory Pathway: EU MDR Compliance

- Key principles and structure of the Medical Device Regulation (MDR).
- Role of the Notified Body and obtaining the CE Mark.
- Technical Documentation and Person Responsible for Regulatory Compliance
- Case Study: A US company facing delays in EU market access due to inadequate conformity assessment procedures under MDR.

- Post-Brexit considerations and the UKCA Mark.

Module 6: Data Privacy Regulations (HIPAA & GDPR)

- Core tenets of the US HIPAA Security and Privacy Rules and HITECH Act.
- Understanding the EU General Data Protection Regulation and lawful bases for processing health data.
- Implementing a Privacy by Design and Security by Design approach.
- Case Study: Analyzing a major fine for a health app that failed to secure Protected Health Information and gain explicit consent.
- Requirements for a Data Protection Impact Assessment.

Module 7: Cybersecurity for Medical Devices

- FDA Cybersecurity Guidance and IEC 62304
- Developing a robust Cybersecurity Risk Management plan.
- Managing vulnerabilities and the importance of a Software Bill of Materials
- Case Study: Responding to a critical zero-day vulnerability discovered in a remote monitoring device post-launch.
- Strategies for securing data at rest and in transit

Module 8: Artificial Intelligence (AI/ML) in Healthcare Regulation

- Defining Generative AI and Large Language Models in clinical workflows.
- Regulatory frameworks for "Locked" and "Continuously Learning" algorithms.
- Addressing Algorithmic Bias and fairness in model development and training data.
- Case Study: A regulatory body requiring a halt in deployment of an AI diagnostic tool due to demonstrable bias across different patient demographics.
- Documentation of Performance Monitoring and transparency in decision-making.

Module 9: Clinical Evaluation and Evidence Generation

- Purpose and creation of the Clinical Evaluation Plan (CEP).
- Conducting the Clinical Evaluation Report (CER) and state-of-the-art review.
- Utilizing Real-World Evidence (RWE) from wearables and apps for regulatory submissions.
- Case Study: Using a retrospective analysis of de-identified patient data to successfully support a SaMD claim without a traditional clinical trial.
- Requirements for clinical Post-Market Clinical Follow-up (PMCF).

Module 10: Decentralized Clinical Trials (DCTs) and Remote Monitoring

- Regulatory flexibility and challenges introduced by DCTs.
- Using Remote Patient Monitoring (RPM) devices and wearables in clinical studies.
- The role of eConsent and digital platforms for patient recruitment and engagement.
- Case Study: An international clinical trial streamlined by replacing in-person visits with certified digital health tools and telehealth check-ins.
- Data integrity and chain of custody for remotely collected data.

Module 11: Interoperability and Health Data Exchange

- Deep dive into the FHIR standard and its use cases.
- Regulatory drivers for interoperability
- Technical and policy considerations for connecting with Electronic Health Records

- Case Study: A new diagnostic platform achieving rapid hospital adoption by integrating seamlessly with Epic/Cerner systems via SMART on FHIR.
- Building a strategy for achieving Trusted Exchange Framework compliance.

Module 12: Risk Management

- Implementing the ISO 14971 process for medical device risk management.
- Techniques for risk analysis, evaluation, and control.
- Integrating risk management throughout the product lifecycle.
- Case Study: A company's documentation successfully demonstrating that all identified software failures have been mitigated to an acceptable level of risk.
- Linking risk management activities back to the QMS and design controls.

Module 13: Post-Market Surveillance and Vigilance

- Establishing a Post-Market Surveillance (PMS) Plan.
- Global requirements for Vigilance and Incident Reporting
- Managing changes and updates to a certified device
- Case Study: A company navigating a multi-jurisdictional recall due to a critical software bug found post-market.
- Continuous monitoring and feedback loop for quality improvement.

Module 14: Health Economics and Regulatory Strategy

- Connecting Regulatory Approval to Reimbursement and market access.
- Understanding payer perspectives and demonstrating Value-Based Care outcomes.
- Developing regulatory claims that support a strong commercial narrative.
- Case Study: A digital therapeutic securing premium reimbursement by demonstrating superior cost-effectiveness evidence to regulatory and payer bodies.
- Strategic balancing of regulatory compliance and product innovation speed.

Module 15: Audits, Inspections, and Global Market Entry

- Preparation for FDA Inspections and Notified Body Audits.
- Strategies for navigating common audit findings
- Overview of regulatory requirements in emerging markets
- Case Study: A company successfully passing an unannounced audit by having immediate access to all required Technical Documentation via their electronic QMS.
- Best practices for training and fostering a continuous Culture of Compliance.

Training Methodology

The course employs a Blended Learning approach optimized for professional regulatory education, emphasizing practical application and retention over passive instruction.

- Interactive Workshops.
- Real-World Case Studies & Simulations.
- Microlearning Modules.
- Practical Tools & Templates.
- Gamification & Quizzes.

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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