Regulatory Strategy for Combination Products 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

Regulatory Strategy for Combination Products Training Course is designed to provide professionals with a comprehensive understanding of the complex regulatory framework surrounding combination products. With the increasing integration of drug, device, and biologic technologies, navigating the regulatory requirements set by agencies like the FDA and EMA has become crucial for compliance and successful product approval. This course equips participants with the necessary tools to design and implement effective regulatory strategies for these hybrid products, ensuring that they meet safety, efficacy, and quality standards while optimizing market entry and lifecycle management.

As the combination products sector continues to grow, understanding how to address regulatory challenges and streamline approval processes is essential for companies looking to maintain a competitive edge. This training focuses on the key aspects of combination product regulations, including classification, design controls, premarket approval, post-market surveillance, and risk management. Through a combination of theoretical knowledge and practical case studies, participants will gain the expertise to manage regulatory affairs efficiently, mitigate risks, and drive compliance across the product lifecycle.

Programme Curriculum

Regulatory Strategy for Combination Products Training Course

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Course Objectives

1. Understand the regulatory landscape for combination products across global markets.
2. Identify the classification systems for combination products and their regulatory requirements.
3. Analyze FDA and EMA guidelines for combination product approval and lifecycle management.
4. Navigate the complexities of premarket approval pathways, including NDA, PMA, and BLA.
5. Learn about risk management practices and strategies in the development of combination products.
6. Develop strategies for maintaining compliance with post-market surveillance regulations.
7. Master the submission requirements for combination products, including IND, IDE, and NDA submissions.
8. Examine labeling and advertising requirements for combination products under global regulations.
9. Understand the challenges of integrating drug and device components in combination products.
10. Leverage digital health technologies and software as part of regulatory submissions.
11. Explore key strategies for dealing with regulatory inspections and audits.
12. Gain insights into the regulatory impact of combination products on clinical trials and patient outcomes.
13. Build practical regulatory strategies for the commercialization of combination products.

Target Audience

1. Regulatory Affairs Professionals
2. Product Development Teams
3. Compliance Managers in Pharmaceutical and Medical Device Companies
4. Clinical Research Professionals
5. Quality Control and Assurance Managers
6. Legal Advisors in the Life Sciences Industry
7. Senior Executives in Pharmaceutical Companies
8. Entrepreneurs and Innovators in Healthcare Technology

Course Modules

Module 1: Introduction to Combination Products

- Definition of combination products
- Types of combination products
- Case study: Regulatory bodies and their role (FDA, EMA)

- Importance of understanding regulations
- Overview of global regulatory differences

Module 2: Regulatory Classification of Combination Products

- FDA classification criteria
- Classification under the EU Medical Devices Directive
- Hybrid products and their regulatory impact
- Combination product categories
- Case study: Regulatory classification challenges

Module 3: Premarket Approval Strategies

- Premarket approval (PMA) vs NDA vs BLA
- Regulatory submission requirements
- Importance of early regulatory strategy planning
- Key elements of a successful premarket approval application
- Case study: Accelerated approval process

Module 4: Risk Management in Combination Products

- Identifying risks in combination product development
- Implementing risk management frameworks
- Risk assessment tools
- Post-market risk management
- Case study: Effective risk mitigation in product development

Module 5: Post-Market Surveillance and Compliance

- FDA?ÇÖs post-market surveillance requirements
- Managing adverse event reporting
- Monitoring product safety post-launch
- Managing recalls and corrective actions
- Case study: Real-world post-market surveillance challenges

Module 6: Labeling and Advertising Regulations

- Labeling requirements for combination products
- Global advertising and marketing compliance
- FDA vs EMA labeling guidelines
- Misbranding and enforcement actions
- Case study: Labeling issues in combination products

Module 7: Clinical Trials for Combination Products

- Designing clinical trials for hybrid products
- Regulatory approval for combination product trials
- Compliance with GxP regulations
- Handling adverse event reporting during trials
- Case study: Clinical trial delays in combination products

Module 8: Quality Management Systems (QMS)

- ISO 13485 and GMP requirements for combination products
- Implementing QMS in product development
- Audits and inspections
- Continuous improvement processes
- Case study: QMS failures and product recalls

Module 9: Navigating Regulatory Inspections

- Understanding FDA inspections for combination products
- Preparing for international inspections
- Common inspection findings and how to address them
- Inspection readiness best practices
- Case study: Handling an FDA audit

Module 10: Digital Health Technologies and Regulations

- Regulatory considerations for software and mobile applications
- FDA guidelines for digital health products
- Incorporating digital health technologies in combination products
- Risk and privacy considerations
- Case study: FDA?ÇÖs stance on digital health technology

Module 11: Global Regulatory Considerations

- Understanding regional regulatory differences
- Navigating the approval process in emerging markets
- Regulatory harmonization initiatives
- Case study: Regulatory challenges in Asia-Pacific
- Market entry strategies for international markets

Module 12: Advanced Regulatory Strategies

- Strategies for fast-track approvals
- Dealing with regulatory uncertainties
- Planning for post-approval changes
- Impact of evolving regulatory frameworks
- Case study: Managing complex regulatory scenarios

Module 13: Strategic Market Access for Combination Products

- Understanding reimbursement and pricing
- Market access considerations across global markets
- Regulatory impact on market entry strategy
- Partnerships and collaborations in the market
- Case study: Access strategy for combination products in Europe

Module 14: Product Lifecycle Management

- Managing combination product lifecycle
- Regulatory considerations through the product lifecycle
- Planning for post-market modifications and updates
- Developing global lifecycle management strategies

- Case study: Lifecycle management of a successful combination product

Module 15: Preparing for the Future: Regulatory Innovations

- The future of combination products regulations
- Emerging regulatory trends
- Impact of artificial intelligence on regulatory strategy
- The role of real-world evidence in regulatory approvals
- Case study: Predicting future regulatory challenges

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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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