BIOTECH PRIMER

COURSE SNAPSHOT

Medical Device

biotechPrimer
Life Science Training From Industry Experts

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ABOUT US

Biotech Primer Inc. develops and delivers training to help professionals understand the science, business, and regulatory processes essential to the biotechnology, pharmaceutical, molecular diagnostics and medical device industries. Our industry experts continuously create, update and deliver the most engaging instruction anywhere. We have the experience and expertise needed to prepare companies to make strategic business decisions, navigate important regulatory hurdles, and move healthcare products from the bench to the bedside. To accomplish these goals, we offer a diverse range of learning opportunities, ensuring participants retain and put into practice what they learn.

- Integrate your science and business operations
- Bring in-depth knowledge to your sales force
- Help your team converse more effectively with industry clients, colleagues, and scientists
- Enable your entire staff to recognize new opportunities

OUR SUBJECT EXPERTISE

- Biotechnology for Non-Scientists
- Drug Development
- Drug Manufacturing
- Business of Biotech
- Molecular Diagnostics
- Medical Devices

OUR DELIVERY PLATFORMS

Our training is offered using multiple platforms to better fit your learning preferences and scheduling constraints

- **Live Customized Courses** Tailored training delivered to organizations worldwide live online or live onsite. You can modify the master course agendas to meet your specific learning needs.
- **Live Master Courses** Prescheduled courses for individuals or schedule a master course for your organization.
- **Recorded Master Courses** Offers the same content, exercises and workbook as the live master course, with the ability to take the course on-demand, online when your schedule permits.

- **On-Demand, Short Classes** Short interactive classes for individuals or bulk purchased for organizations.
  - Class transcripts and subtitles available in 9 languages including English, Japanese, Chinese, Spanish, French, French Canadian, Hindi, Arabic, and Russian.
  - Certificate available upon successful class completion.
  - Ability to upload certificate to your LinkedIn education profile.
  - Two corporate account options available for on-demand, short classes
    - **Enterprise:** Manage your own company account with our Learning Management System (LMS). Assign classes and view individual's progress. Enterprise is intuitive and easy-to-manage. No extra cost.
    - **LTI Bridge:** Connect your organizations LMS to Biotech Primer's LMS. Participants log into their company's LMS and take our classes. Integration costs apply.

OUR PRICING

- **Live Customized Courses** The cost of tailored training depends on content, length of course, and number of participants. Discounts given to multiple classes purchased within one year.
- **Live Master Courses** Prescheduled two-day courses for individuals range from $1495-$1695 US.
- **Recorded Master Courses** These courses are 3-12 hours in length and cost $895 US. Participants are given three months to complete each course.
- **On-Demand, Short Classes** Each class is $150 US. BIO members receive special pricing of $120 US per class. Participants are given two weeks to complete the class.

Bulk discount pricing:

Number of total classes	Discount per class	Price per class
10-20*	25%	$112
21–100	30%	$105
101–250	40%	$90
251–500	50%	$75
500 and up	70%	$45

**For BIO member companies only*

OUR COURSE LEVELS

- **Level 1: Foundational** For non-scientists new to biopharma and for those who need a refresher on the fundamental science driving the healthcare industry.
- **Level 2: General** For individuals who possess a general understanding of science basics.
- **Level 3: Advanced** For individuals who have a good grasp of the science.

OUR PUBLICATIONS

- **The Biotech Primer One: The Science Driving Biopharma Explained**
  Learn the basic science driving the biopharma industry in this fully illustrated 120-page book.
- **The Biotech Primer Two: Next Generation Therapies Explained**
  Learn how vaccines, therapeutic antibodies, cell therapy, gene therapy, and RNA therapeutics mitigate disease in this easy-to-read 170-page book. Books available for purchase on Amazon.
- **The WEEKLY**
  White papers that explain the science behind the headlines.

OUR INSTRUCTORS

Biotech Primer instructors offer extensive industry experience. By drawing on their various backgrounds, these seasoned professionals are well-informed on the real-world situations you face. They have developed drugs, diagnostics, and medical devices for companies ranging from multinational corporations to start-ups.

Biotech Primer courses are on point, thorough and taught by one dedicated industry educator, not a patchwork of invited academic lecturers.

You can expect:

- Limited class size so all your questions are answered
- Hands-on labs, thought-provoking case studies, and dynamic discussions so you practice what you learn
- Industry war stories to help you avoid lessons hard learned by others

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LIVE MASTER COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

Medical Device Development Primer

OVERVIEW

Medical Device Development Primer is a fast-paced, one-day preparatory course designed for professionals seeking a basic understanding of the Medical Device industry. This course examines aspects of medical device development, including the five development phases—market opportunity, evaluation, design, verification, and manufacturing. The course delves into the changing regulatory environment and focuses on the different pathways that devices travel for agency approval. Take this course to understand the process required to bring a new medical device to market.

Five Takeaways

1. Fluency in essential terminology and acronyms of the medical device industry.
2. Knowledge of the various approval pathways for a medical device to be marketed to patients.
3. An understanding of how to mitigate risk in a medical device.
4. An improved ability to communicate with engineers, colleagues and clients.
5. The ability to construct a medical device by following the traditional five phases of development.

AGENDA

Medical Device Overview 30 minutes
Medical device defined
Medical device diversity

Medical Device Regulations 60 minutes
Quality system regulations (QSRs)
Current good manufacturing practices
Good laboratory practices
Good clinical practices
Risk management plan
Exemptions

Break 15 minutes

Medical Device Regulations *continued*
90 minutes
Rest of world approval pathways
Home brew and combination devices
Software development
Prototyping
Medical device reporting
Phase IV: verification
Phase V: manufacturing transfer
Documentation
Equipment IQ/OQ/PQ
Regulatory challenges
Diagnostics
Predicates
New technologies
Clinical studies

Lunch 45 minutes

Medical Device Development 90 minutes
Phase I: market opportunity evaluation
Market analysis
Risk management plan
Phase II: concept evaluation
Formulation steps
Feasibility
Phase III: engineering design process
Design and development

Break 15 minutes

Medical Device Approval 45 minutes
Clinical trials
Need for a gold standard
Regulatory submissions
Coding and reimbursement

Wrap-Up 15 minutes

LIVE MASTER COURSE | LEVEL ONE

SUGGESTED PREREQUISITE: NONE

Medical Device Development Immersion

OVERVIEW

Medical Device Development Immersion is a two-day interactive course designed for those who need to understand the business and regulatory considerations of medical device development. The course highlights include the regulatory pathways for FDA or EMA marketing approval; the changing regulatory environment; a detailed explanation of the five development phases—market opportunity, evaluation, design, verification, and manufacturing; and commercialization strategies, including those for reimbursement. Learn from an industry expert with 30 years of experience in both multinational and start-up medical device companies.

Five Takeaways

1. An improved ability to communicate with engineers, colleagues and manufacturers.
2. Fluency in medical device terminology and processes.
3. A toolbox to help design a medical device prototype.
4. Knowledge of the various approval pathways for each medical device class.
5. Strategies for risk mitigation in medical device development and approval.

AGENDA

DAY ONE

Medical Device Overview 90 minutes
Medical device defined
Medical device diversity
Industry sectors and top companies
History of device regulation
FDA approval pathways: 501(K), PMA

Break 15 minutes

Medical Device Regulations 75 minutes
Quality system regulations (QSRs)
Current good manufacturing practices
Good laboratory practices
Good clinical practices
Risk management plan
Exemptions
Rest of world approval pathways
Special categories: home brew, combinations

Lunch 15 minutes

Medical Device Regulations *continued* 45 minutes
Regulatory challenges
Diagnostics
Predicates and new technologies
Clinical trials
Medical device reporting

Medical Device Development 105 minutes
Phase I: market opportunity
Market analysis
Risk management plan
Phase II: concept evaluation
- Formulation steps
- Feasibility

Phase III: engineering design process
- Design
- Development
- Prototyping

Wrap-Up 15 minutes

DAY TWO

Medical Device Development 90 minutes
Phase IV: verification
Phase V: manufacturing transfer
- Documentation
- Equipment IQ/OQ/PQ
- Biocompatibility
- Sterilization
- Shipping and storage

Break 15 minutes

Medical Device Approval 105 minutes
Clinical trials
Need for a gold standard
Regulatory submissions
Business preparations
Product launch preparations
Coding and reimbursement

Lunch 45 minutes

Commercialization 75 minutes
Manufacturing scale-up
Product launch
Post-launch assessment

Break 15 minutes

Current Issues 60 minutes
The increasing role of the FDA
Why are the newest devices in Europe?

Wrap-Up 15 minutes

Medical Device Development Immersion

OVERVIEW

This is the recorded Medical Device Development Immersion course with the same content, interactive exercises, and course materials that are given in the live version. You have 3 months to view this course.

Medical Device Development Immersion is an eight-hour course designed for those who need to understand the business and regulatory considerations of medical device development. The course highlights include the regulatory pathways for FDA or EMA marketing approval; the changing regulatory environment; a detailed explanation of the five development phases—market opportunity, evaluation, design, verification, and manufacturing; and commercialization strategies, including those for reimbursement. Learn from an industry expert with 30 years of experience in both multinational and start-up medical device companies.

Five takeaways

1. Fluency in the essential terminology and acronyms used in the medical device sector.
2. Improved communication with engineers, regulators, colleagues, and clients.
3. Ability to construct a medical device by following the traditional five phases of development.
4. Understanding of the medical device approval pathways in both the USA and European Union.
5. Strategies for risk mitigation in medical device development and approval.

AGENDA

WEEK ONE

Medical Device Overview 40 minutes
History of device regulation
FDA mission and organization
Medical device defined
Special categories: software, in vitro diagnostics, radiation emitting products, mobile medical devices, wellness products

WEEK TWO

Regulatory Approval Pathways 60 minutes
FDA classification of regulatory controls Class I, Class II, Class III devices
510(k), Predicates, de nova 510(k)
Exemptions to Class III devices
Device classification challenges
Combination products
EU device approval pathway

WEEK THREE

Medical Device Regulation 50 minutes
Quality systems regulations
Regulatory compliance: GMP, GLP, GCP
Risk management evaluation
Human factors and usability
Risk analysis plan
Post-market surveillance; MedWatch
FDA post-market actions and penalties

WEEK FOUR

Phase I: Market Opportunity Evaluation 20 minutes
Development process overview
Product development Gantt chart
Regulation of medical device design
Market opportunity evaluation key requirements
Activity: Bionic Walker Customer Requirements

WEEK FIVE

Phase II: Concept Evaluation 30 minutes
Concept evaluation key requirements
Risk analysis plan process
Activity: Bionic Walker Concept Evaluation
Risk acceptability matrix
Quantifying risk
Activity: Bionic Walker Risk Assessment

WEEK SIX

Phase III: Engineering Design 30 minutes
Engineering design key requirements
Specifications
Iterative design
Software design
Documentation

WEEK SEVEN

Phase IV: Verification and Validation 70 minutes
Verification and validation key requirements
Product build strategies for testing
Labeling verification process
Human factor testing process
Standards testing process
Manufacturing tooling testing process
FDA process validation guidance
Biocompatibility and ISO 10993
Activity: Bionic Walker Create A Specification and Test Plan

WEEK EIGHT

Phase V: Manufacturing 30 minutes
Manufacturing key considerations
Manufacturing transfer
Manufacturing scale-up

WEEK NINE

Medical Device Approval
80 minutes

Pre-submission discussions with FDA
Clinical trials
Investigational device exemption (IDE)
Expanded pre-approval access
Approval timelines
FDA submission types
MDUFAIII
Submission approval timelines

WEEK TEN

Commercialization 15 minutes

Reimbursement strategy
CMS vs FDA
Issues affecting private payers

Course Evaluation 20 minutes

ON-DEMAND, SHORT CLASS | LEVEL TWO | 57 MINUTES

SUGGESTED PREREQUISITE:

DIAGNOSTICS' ROLE IN MEDICINE TODAY, MEDICAL DEVICE OVERVIEW AND REGULATION

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Medical Device Development

OVERVIEW

Medical Device Development provides a detailed look at the five stages of medical device development, including market opportunity evaluation, concept evaluation, engineering design, verification and validation, and manufacturing transfer. Understand the FDA guidances for process design, qualification, and monitoring. Learn how risk assessment, reimbursement, and the ability to scale-up manufacturing determine if a product development plan moves forward or not.

Five Takeaways:

1. Understand the importance of the five phases of medical device development.
2. Learn how to evaluate the market opportunity for a novel medical device.
3. Determine the manufacturing feasibility based on a medical device's design.
4. Learn the required prototype specifications needed in device design, documentation, and testing.
5. Explain the FDA validation guidance for process design, qualification, and monitoring.

AGENDA

Market Opportunity Evaluation
Consumer requirements
Product description
Reimbursement
Essential device requirements checklist
Risk analysis and management plan
Product development plan
Business review
Phase I review and finalization

Concept Evaluation
System architecture diagram
User interface requirements
Product requirements document (PRD)
Software requirements and design description
Human factors
Proof of concept: breadboards and models
Risk analysis
Phase II review and finalization

Engineering Design
Product requirement specifications
Product intended use
Product indications
Usability engineering and human factors
Graphical user interface (GUI)
Instructions for use (IFU)
Iterative design and prototyping testing process
Software design phases
Detecting and decreasing software defects
Phase III review and finalization

Verification and Validation

Defining verification and validation
FDA process validation guidance
  Stage 1: process design
  Stage 2: process qualification
  Stage 3: process monitoring
Engineering builds and traceable testing
Packaging design and regulation
Labeling and unique device ID (UDI)
Human factors testing
Manufacturing tooling and equipment
Pilot production builds
Product sterilization
Biocompatibility testing
Packaging validation
Shelf-life analysis
Phase IV review and finalization

Manufacturing Transfer

Cross-functional technology transfer team
Information exchange
Small scale verification
FDA inspections
Phase V review and finalization

ON-DEMAND, SHORT CLASS | LEVEL TWO | 57 MINUTES

SUGGESTED PREREQUISITE:

DIAGNOSTICS' ROLE IN MEDICINE TODAY

The Regulatory Process for Medical Device Approval

OVERVIEW

The Regulatory Process for Medical Device Approval explains how medical devices are regulated in the United States. Medical device classification and each classification's differing approval pathways are outlined in detail. FDA guidelines, quality system regulations, and risk management plans are also discussed in great detail. If you are new to the medical device industry, this class will provide an understanding of the breadth of the industry's regulatory requirements.

Five Takeaways:

1. Identify the medical device industry's major device sectors and worldwide regulatory organizations.
2. Classify medical devices based on potential risks.
3. Explain the major medical device approval pathways.
4. Discuss how the Code of Federal Regulations and Good Practices enforces regulatory compliance.
5. Develop a risk management plan for a medical device.

AGENDA

Medical Device Overview

Medical device defined
Class I, II, III medical devices
Companion diagnostics
FDA medical device categories
Top medical device companies

Medical Device Regulation

Medical device regulation history
FDA organizational structure
Medical device classification and risk
Class I risk and controls
Class II risk and controls
Class III risk and controls
FDA approval pathways
510(k)
De novo 510(k)
Premarket notification (PMN)
Premarket approval (PMA)
Predicate device
Regulatory compliance requirements
Good laboratory practices (GLP)
Good clinical practices (GCP)
Good manufacturing practices (cGMP)
Quality system regulations (QSR) requirements
  Material controls
  Production and process controls
  Design controls
  Corrective and preventative actions
  Records and documents change controls
  Facility and equipment controls
QSR examples: hiring and product development
Risk management plan
Managing human factor risks
Risk analysis plan process
Global regulatory agencies
European Union approval process

ON-DEMAND, SHORT CLASS | LEVEL THREE | 55 MINUTES

SUGGESTED PREREQUISITE:

MEDICAL DEVICE OVERVIEW AND REGULATION, MEDICAL DEVICE DEVELOPMENT

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Medical Device Approval and Commercialization

OVERVIEW

Medical Device Approval and Commercialization explains the medical device approval process from initial regulatory submission through commercialization. Learn the diverse best practices accompanying a successful regulatory outcome, including manufacture scale-up, reimbursement strategy, product launch and post-launch assessment. If you are working in the medical device sector, this course gives you a game plan to undertake a successful launch.

Five Takeaways:

1. Choose the appropriate clinical trial level based on the patient's risk assessment.
2. Explain the approval process to initiate human clinical trials to test a new medical device.
3. List the challenges of launching a new medical device in terms of marketing, sales, reimbursement, and manufacturing scale-up.
4. Outline a reimbursement strategy for coverage, coding, and payment of a medical device.
5. Write a post-launch assessment and surveillance protocol.

AGENDA

Approval
Purpose of clinical trials
Mandatory clinical trials
Investigational device exemption (IDE)
Types of IDEs
Components of the IDE
Clinical trials in the US and outside the US
Approval timelines
Impact of gold standard on IDE
Approval pathways for Class I, II, III

Commercialization
Business preparations
Sales and marketing
Manufacturing scale-up
FDA inspection
Reimbursement strategy
Health plans
Private payers
Product launch
Post-market surveillance and reporting
FDA post-market actions and penalties