biotechPrimer
Industry Knowledge Delivered

BioTech Primer Company Portfolio 2016

Stacey Franklin
CEO, BioTech Primer Inc.
T. 410.491.2946
Franklin@BiotechPrimer.com

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Curriculum Examples

biotechPrimer
Industry Knowledge Delivered

BioTech Primer Inc. delivers current, industry relevant training so professionals understand the science, business, and regulatory processes essential to the Biotechnology, Pharmaceutical, Molecular Diagnostics and Medical Device healthcare sectors. With continuously updated materials and industry experts behind the podium, we provide the most engaging instruction anywhere.

- Understand the science & technology driving the healthcare industry
- Integrate your science & business operations
- Bring in-depth knowledge to your sales force
- Help your team converse more effectively with industry clients, colleagues, scientists
- Enable your entire staff to recognize opportunities
- Ready your company for your latest product launch
- Prime outside consultants & vendors to work with your firm

Content Expertise

Biotechnology for Non-Scientists
Drug Development Focused on Biologics
Molecular Diagnostics for Non-Scientists
Medical Device Development
Biosafety & Biorisk for Researchers

Delivery Options

Onsite: In-house, customized training for companies worldwide
Online: On-demand learning for individuals; customized for organizations
Open Enrollment: Pre-scheduled courses for individuals held in convenient locations
Publications: The Biotech Primer book, WEEKLY e-newsletter, & Life Science Innovations Explained e-Book, a compendium of biotech knowledge.

Our Instructors offer extensive industry experience. By drawing on their backgrounds, these seasoned professionals are steeped in the real world situations you face. They have developed drugs, diagnostics and medical devices for companies ranging from multinational corporations to start-ups.

Our Courses are on-point, thorough and taught by one dedicated industry educator, not by 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 & dynamic discussions
- Industry war stories to help you avoid lessons hard learned by others

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Biotechnology for the Non-Scientist

Below find a listing of our unrivaled biotech courses for the non-scientist. Any of these courses can be customized to help everyone on your team get on the same page and better understand the science, business decisions and regulatory hurdles specific to your company products.

Onsite Courses: In-house, customized training tailored for organizations worldwide

BioImmersion™ is a three-day, in-depth course highlighting the basic science applications required for understanding today's fast-paced marketplace. The course begins with a review of biology fundamentals, laying the groundwork for a better understanding of the technology upon which the biotech industry is built. Emphasizing healthcare applications, students will describe the key differences between small molecule and biologic drugs; discuss the impact of biosimilars on the biologics space; review recent advances in personalized medicine; and examine the processes of both small and large molecule discovery and development. The final portion of the course applies the science and technology concepts covered earlier to specific disease areas of particular relevance to the biopharmaceutical industry: infectious disease, diabetes, obesity, and oncology. Gain a comprehensive understanding of how the technologies, that drive the industry, come together to deliver new products.

BioBasics™ is a two-day, intensive course starting with a review of scientific concepts required for understanding biotechnology applications. Building on this knowledge, the course uses healthcare-specific examples to explore biologic drugs, biosimilars, personalized medicine, stem cell and regenerative medicine, culminating in drug discovery and development. Develop a working knowledge of the fundamental industry terms and applications, enabling more effective communication with colleagues and stakeholders.

BioBriefing™ is a one-day, fast-paced course giving a high-level overview of the key science concepts required for understanding basic biotechnology applications. Using industry-specific examples, participants will discuss biologic drugs, personalized medicine, and drug discovery and development. Gain an understanding of the fundamental terms and concepts needed to navigate the rapidly changing biotechnology industry.

Drug Development Immersion is a two-day, intensive course concentrating on the regulatory, commercial and scientific considerations required to successfully bring a drug to market. Discussion points will feature both small molecule and biologic products. Numerous war stories and personal accounts are used to illustrate the decision-making process companies use, giving participants a working knowledge of strategic development.

BioFacilities Primer is a one-day course furthering your understanding of the unique real estate and facility requirements of the dynamic and highly regulated biotech and pharmaceutical industries. Advance your knowledge of key performance and specific uses driving the cost of developing and operating these technical facilities.

Medical Devices & Molecular Diagnostics

Below find a listing of our most popular medical device and molecular diagnostic courses for anyone who needs to better understanding of the development process. Any of these courses can be customized to help everyone on your team get on the same page and better understand the development and regulatory hurdles specific to your company products.

Onsite Courses: In-house, customized training tailored for organizations worldwide

MedDevice Development Immersion is a two-day course examining all aspects of medical device development. Starting with an overview of the different types of devices and the different industry sectors, the course then delves into the changing regulatory environment. This includes a discussion of the different regulatory pathways and a comparison of FDA vs. EU approval processes. The five phases of medical device development – evaluation, design, verification, and manufacturing – are described in detail. Develop an understanding of the entire process required to bring a new medical device to market.

Diagnostics Development Primer is a one-day course exploring how diagnostics are developed, approved and reimbursed. Participants will learn how the strength of a diagnostic test is measured, and how that information is used by companies and regulatory agencies to evaluate new diagnostics. Different categories of diagnostic devices and their different approval pathways will be discussed. Concepts specific to the diagnostic sector, including sensitivity, specificity, false positives, false negatives and ROC curves will be emphasized. The course culminates in an overview of the medical device approval process, including a discussion of possible pathways to approval and reimbursement strategies, enabling more effective diagnostic development.

The Science of Molecular Diagnostics is a one-day course exploring the growing role of molecular diagnostics within healthcare. Participants will learn about a range of diagnostic tests, focusing on molecular diagnostics. The basic science that these diagnostics rely on will be described, including PCR, next-generation DNA sequencing, microRNA, DNA, proteins and antibodies. The class will also include a discussion of related ideas such as biomarkers, pharmacogenomics, and companion diagnostics. Learn to more effectively manage current and emerging diagnostic technologies.

Biosafety & Biorisk

Below find our most popular biosafety course created for those who manage or work in a laboratory setting. This course can be customized to help everyone in your laboratory get up to speed quickly on standard and common safety practices.

Onsite Course: In-house, customized training tailored for organizations worldwide

Biosafety Primer is a two-day course providing an overview of biotechnology concepts relevant to biorisk and biosafety issues encountered within research settings. Biorisk management is a set of practices and principles that are rapidly becoming critical for biotechnology, vaccine and biological production, and R&D industries. In essence, biorisk management provides a foundation for the safe management of potentially hazardous biological and infectious agents and toxins. The use of many of these agents are regulated, and compliance is mandatory. But even outside of regulatory parameters, industry best-practice dictates these industries have robust biorisk management programs in place. Learn how to identify and remedy potential laboratory safety issues.

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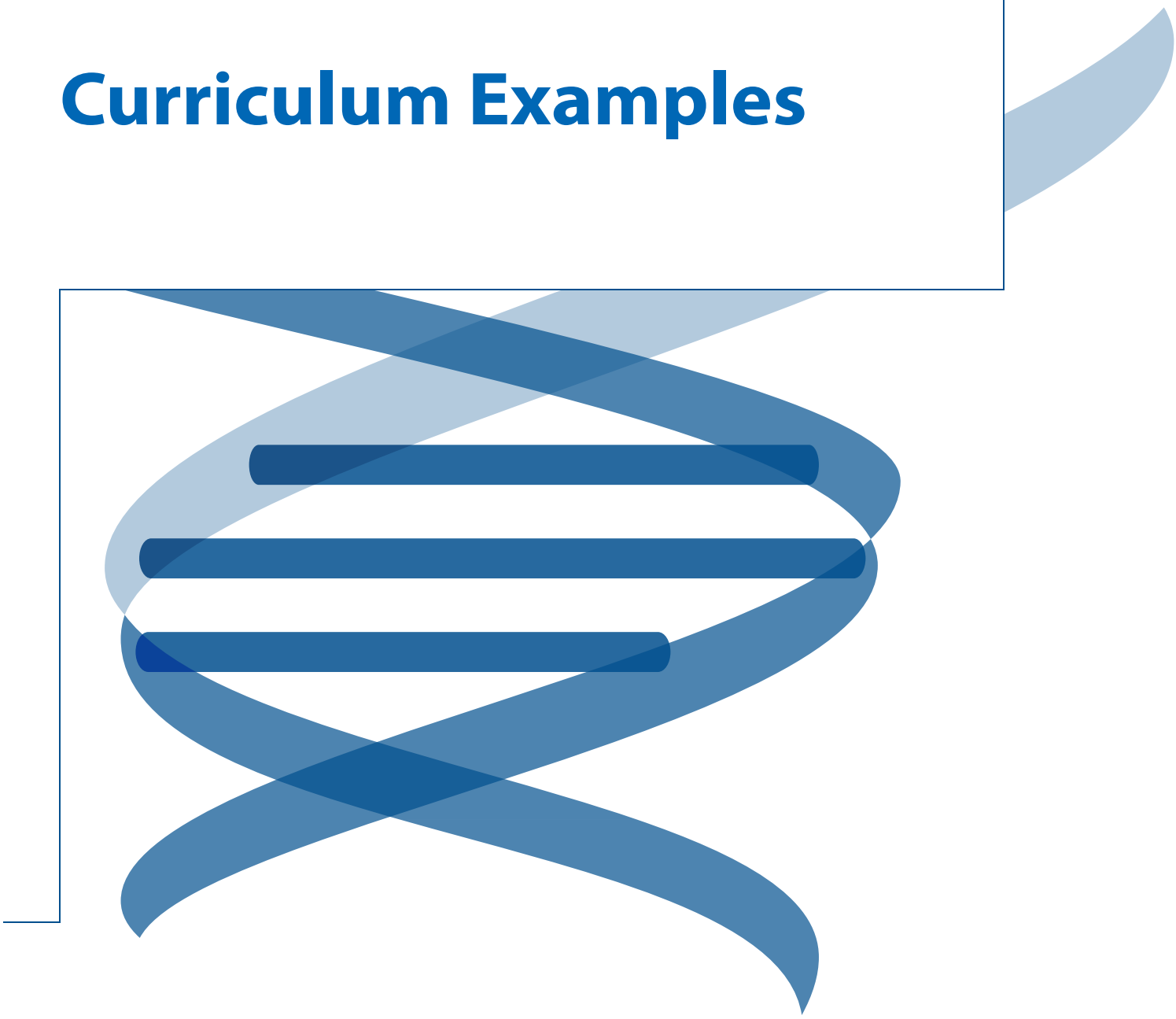
Curriculum Examples



BioImmersion™

BioImmersion is a three-day, in-depth course that provides the foundation required for understanding today's fast-paced biotech marketplace. Beginning with an overview of the basic science needed to understand new drug discovery and development, the course emphasizes healthcare applications. Participants discover the key differences between small molecule and large molecule biologic drugs; discuss the impact of biosimilars on the biologics space; review recent advances in personalized medicine; and gain an understanding of the science behind buzz words like "RNA therapeutics", CART", "immune checkpoint inhibitors" and "DARPINS" The final portion of the course applies the science and technology concepts covered earlier to specific disease areas of particular relevance to the biopharmaceutical industry. Participants complete the course with a comprehensive understanding of how the technologies driving the industry come together to deliver new products.

Day One

Industry Overview *9:00-10:15*
Biotechnology Defined
Industry Sectors: Healthcare, Agriculture, Industry & Environment
Research Support
Companies & Contract
Research Organizations
The Intersection of Academia & Industry

Break *10:15-10:30*

Biology Basics & Cell Signaling *10:30-11:30*
Biotechnology Goals
Cell Structure & Function
Proteins: Critical to Cellular Function
Cellular Communication: Cell Signaling Pathways
Lab: DNA Isolation & Extraction

DNA: Biotech's Blueprint *11:30-12:30*
The History of DNA Discovery
DNA Structure & Function
DNA Replication
Chromosomes & Genes
How DNA Codes for Proteins
Protein Structure & Function
The Proteome

Lunch *12:30-1:30*

Genetic Variation *1:30-2:45*
Alleles
Mutations: The Source of Genetic Variation
Genetic Basis of Disease
Genome-Wide Association Studies
Stratified Medicine & Companion Diagnostics
Pharmacogenomics
Activity: Genetic Taste Test

Break *2:45-3:00*

Making Biologics *3:00-4:15*
Biologics vs. Small Molecule Drugs
Recombinant DNA
Polymerase Chain Reaction (PCR)
Production Platforms: Bacterial & Mammalian Cells
Production Platforms: Animals & Plants
Fusion Protein Therapeutics
Biosimilars: Definition & Approval Pathway
Patents & Data Exclusivity

Q&A/Review *4:15-4:30*

Day Two

Biomanufacturing *9:00-10:00*
Cell Line Development & Cell Banking
Scale-Up
Harvest & Purification
Formulation, Fill & Finish
Lab: Column Chromatography

Immune System & Intro to Antibodies *10:00-11:15*
Cells of the Immune System
Non-specific Immune Response: Inflammation
Specific Immune Response: T-cells & B-cells
Antibodies: Structure & Function
Immunological Memory
How Vaccines Work
Making the Annual Flu Vaccines
Advances in Vaccine Technology: DNA Vaccines & Cancer Vaccines

Break *11:15-11:30*

BioImmersion™ *Continued*

Day Two

Antibodies as Therapeutics *11:30-12:30*
Polyclonal vs. Monoclonal Antibodies
Making Therapeutic Antibodies: Hybridomas, Phage Display, Genetically Engineered Mice
Humanized vs. Fully Human Antibodies
Antibody Constructs: Fab, Bispecific & Trispecific Antibodies
Monoclonal Antibodies as Therapeutics: Mechanisms of Action
Monoclonal Antibodies in Infectious Disease: RSV & Ebola
Antibody-Drug Conjugates In Development: Immunotherapy for Alzheimer's

Lunch *12:30-1:30*

Genomics *1:30-2:45*
Genomics Defined
Non-Coding DNA: The Regulome
DNA Microarrays (Gene Chips)
Next Generation Sequencing
Applications of Next Generation Sequencing
From Big Data to Rare Disease
Third Generation Sequencing
Personalized Medicine: Integrating the 'Omics
Comparative Genomics
Activity: Microarray to Determine Drug Metabolism

Break *2:45-3:00*

Controlling Gene Expression *3:00-4:15*
RNA Therapeutics: Antisense, siRNA, and microRNA
Changing Gene Expression: Exon-Skipping Therapy
Gene Therapy
Genome Editing

Q&A/Review *4:15-4:30*

Day Three

Stem Cells & Regenerative Medicine *9:00-10:00*
Properties of Stem Cells
Promises & Challenges
Induced Pluripotent Stem Cells
Stem Cells in the Clinic
Organ and Tissue Replacement

Oncology *10:00-11:15*
How Mutations Cause Cancer
Cancer Therapies
Traditional vs. Biotech Treatment Strategies
Druggable Targets
Signaling Network Complexity
Cancer Genomics
Immune System Checkpoint Therapies
Chimeric Antigen Receptor Therapies (CART)
Future Therapies

Break *11:15-11:30*

Drug Discovery *11:30-12:30*
Rational Drug Discovery
Target Identification & Validation
Therapeutic Options
Assay Development & High Throughput Screening
In Vitro Safety & Efficacy Testing
Biomarkers

Lunch *12:30-1:30*

Drug Development *1:30-2:30*
Regulatory Agencies
Preclinical & Clinical Trials
Pharmacovigilance
Desirable FDA Designations
Orphan Drugs

Break *2:30-2:45*

Newly Approved & In Development *2:45-4:00*
DARPINS
Viruses & Antivirals
New Vaccines: Universal Flu Vac, HIV Vac, Viral Cancer Vac
Microbiome & Related Therapies
Bispecific Antibodies
Circulating Tumor Cells: Detection & Capture

Wrap Up *4:00-4:30*

BioBasics™

BioBasics is a two-day, intensive course starting with a review of scientific concepts required for understanding the biopharma industry. Building on this knowledge, the course delves into the cause of disease, the drug discovery process used to identify therapeutics, and the biomanufacturing standards followed to produce therapeutics. Day two begins with an explanation of how the body fights disease and how various medicines work (on the molecular level) to aid the body back to health.

Day One

Biology: The Basis of Biotech *9:00-10:15*
Biotechnology Goals
Cell Structure & Function
Proteins: Critical to Cellular Function
Cellular Communication: Cell Signaling Pathways
Lab: DNA Isolation & Extraction

Break *10:15-10:30*

DNA: Biotech's Blueprint *10:30-11:30*
DNA Structure & Function
Chromosomes & Genes
How DNA Codes for Proteins
Protein Structure & Function
The Proteome

Genetic Variation *11:30-12:30*
Alleles
Mutations: The Source of Genetic Variation
Epigenetics
Genetic Basis of Disease
Stratified Medicine
Companion Diagnostics
Activity: Genetic Variation Taste Test

Lunch *12:30-1:30*

Making Biologics *1:30-2:45*
Biologics vs. Small Molecule Dugs
Recombinant DNA
Polymerase Chain Reaction (PCR)
Production Platforms: Bacterial & Mammalian Cells
Production Platforms: Animals & Plants
Fusion Protein Therapeutics
Biosimilars: Definition & Approval Pathway
Patents & Data Exclusivity

Break *2:45-3:00*

Biomanufactuing *3:00-4:15*
Cell Line Development & Cell Banking
Scale-Up, Harvest & Purification
Formulation, Fill & Finish
Activity: Column Chromatography

Q&A/Review *4:15-4:30*

Day Two

Immune System & Antibodies 9:00-*10:15*
Non-Specific & Specific Immune Response
Antibodies: Structure & Function
Immunological Memory
How Vaccines Work
Advances in Vaccine Technology

Break *10:15-10:30*

Antibodies as Therapeutics *10:30-11:30*
Polyclonal vs. Monoclonal Antibodies
Making Therapeutic Antibodies: Phage Display
Antibody Constructs: Fab, Bispecific & Trispecific
Monoclonal Antibodies as Therapeutics
Monoclonal Antibodies in Infectious Disease
In Development: Immunotherapy for Alzheimer's

Genomics *11:30-12:30*
Non-Coding DNA: The Regulome
DNA Microarrays (gene chips)
Next Generation & Third Generation Sequencing
Activity: Microarray to Determine Drug Metabolism

Lunch *12:30-1:30 (provided)*

Controlling Gene Expression *1:30-2:30*
RNA Therapeutics: Antisense, siRNA, microRNA
Changing Gene Expression: Exon-Skipping Therapy
Gene Therapy & Genome Editing

Break *2:30-2:45*

Stem Cells & Regenerative Medicine *2:45-3:30*
Properties, Promises & Challenges of Stem Cells
Induced Pluripotent Stem Cells
Stem Cells in the Clinic

Newly Approved & In Development *3:30-4:15*
Immune System Checkpoint Therapies
Chimeric Antigen Receptor Therapies (CART)
Viral Cancer Vaccine
Microbiome & Related Therapies

Q&A/Review *4:15-4:30*

BioBriefing™

BioBriefing is a one-day, fast-paced course giving a high-level overview of the key science concepts required for understanding basic biotechnology applications. Using industry-specific examples, participants will discuss biologic drugs, personalized medicine, and drug discovery and development. Gain an understanding of the fundamental terms and concepts needed to navigate the rapidly changing biotechnology industry.

Industry Overview *9:00-9:30*
Biotechnology Defined
Healthcare Sectors: Biotech, Pharma, Diagnostics, MedDevice

The Basis of Biotech *9:30-10:15*
Biotechnology Goals
Cell Structure & Function
Lab: DNA Isolation & Extraction

Break *10:15-10:30*

Biotech's Blueprint *10:30-11:15*
DNA Structure & Function
Chromosomes & Genes
How DNA Codes for Protein
Protein Structure & Function

The Future of Medicine *11:15-12:00*
Mutations
Genetic Variation & Disease
Stratified Medicine
Companion Diagnostics
Activity: Genetic Variation Taste Test

Lunch *12:00-1:00*

Making Biologics *1:00-1:45*
Plasmids
Recombinant DNA
Genetically Engineered Cells
Recombinant Proteins
Biologics

Therapeutic Antibodies *1:45-2:45*
Antibodies Structure & Function
Monoclonal, Bispecific & Trispecific Antibodies
How monoclonal Antibodies Cure Disease
Therapeutic Applications

Break *2:45-3:00*

Drug Discovery & Development *3:00-4:15*
Rational Drug Discovery
Target Identification & Validation
Therapeutic Options
Drug Development Time Line
Regulatory Agencies
Preclinical & Clinical Trials

Q&A/Review *4:15-4:30*

Learn Onsite

Drug Development Immersion

Drug Development Immersion is an intensive two-day course concentrating on the regulatory, commercial and scientific considerations required to successfully bring a drug to market. Discussion points will feature both small molecule and biologic products. Numerous personal accounts and war stories are used to illustrate the decision-making process companies use, giving participants a working knowledge of strategic development.

Day One

Introductions *9:00-9:15*

Drug Development Overview *9:15-10:00*
Success Metrics & Chances of Success
Time Line & Costs
FDA Approvals

Drugs Defined *10:00-10:45*
Drug Defined
Types of Drugs
Product & Data Exclusivity
Approval Process for Generics: FDA & EMA
Approval Process for Biosimilars: FDA & EMA

Break *10:45-11:00*

Where Do Drugs Come From? *11:00-12:00*
Target Identification
Potential Targets: Pharmacology
Target Validation
Assay Development
Screening
Animal Models
Lead Optimization
Case Study: Multiple Sclerosis
Drug Development Organizations

Lunch *12:00-1:00*

Global Integrated Development *1:00-1:30*
The Integrated Development Process
Project Teams
Stage Gates

General Strategic Development Considerations *1:30-2:15*
Draft Label
Therapeutic Target Profile

Break *2:15-2:30*

The FDA & EMA Regulatory Process *2:30-4:15*
History of Regulation
FDA Mission & Organization
EMA Mission & Organization
International Conference on Harmonization (ICH)
PDUFA
REMS
FDA Formal Meetings With Sponsors
EMA Formal Meetings With Sponsors
Briefing Pack
Special Protocol Assessment (SPA)
Regulatory Interactions & Tools
Generics & Biosimilars
Orphan Drugs
Regulatory Compliance
Regulatory Compliance: Case Study

Q&A/Review *4:15-4:30*

Day Two

Product Design & Manufacturing *9:00-10:15*
Chemical Manufacturing Controls
Product Design
Routes of Administration
Making Proteins in Cells
Biomanufacturing Overview
Cell Line & Cell Bank Development
Upstream & Downstream Bulk Processing
Formulation, Fill & Finish
Stability & Analytical Testing of Protein Products
Small Molecule Manufacturing Overview
Small Molecule Formulation
Label, Package & Distribution

Break *10:15-10:30*

Preclinical Development: The IND & CTA *10:30-12:00*
Preclinical Development Pre-IND/CTA
Mutagenicity & Carcinogenicity Testing
Toxicology
Reproductive & Developmental Toxicology
Safety Pharmacology
Absorption, Distribution, Metabolism, Excretion
Preclinical Trials & Overview

Drug Development Immersion *Continued*

Lunch *12:00-1:00*

Clinical Development *1:00-3:00*
Ethical Considerations
Clinical Protocols
Investigator Sites
Study Design Considerations
Study Design Choices
Endpoint Choices
Statistical Considerations
ANOVA & ACOVA
Phase I
Phase IIA & IIB
Phase IIIA & IIIB
Adaptive Design
NDA & MAA Approval Process Overviews

Product Launch *3:00-4:15*
Launch Overview & Teams
Core Product Strategy
Manufacturing & Supply Chain
Payer Strategy
Value Proposition
Value Based Pricing
Sales Force Readiness
Healthcare Professional Strategy
Patient Strategy
Compliance
Medical Affairs Readiness
Pharmacovigilance
Phase IV
Life Cycle Management

Q&A/Review *4:15-4:30*

MedDevice Development Immersion

MedDevice Development Immersion is a two-day course examining all aspects of medical device development. Starting with an overview of the different types of devices and the different industry sectors, the course then delves into the changing regulatory environment. This includes a discussion of the different regulatory pathways and a comparison of FDA vs. EU approval processes. The five phases of medical device development – market opportunity, evaluation, design, verification, and manufacturing – are described in detail. Develop an understanding of the entire process required to bring a new medical device to market.

Day One

Medical Device Overview *9:00-10:30*
Medical Device Defined
Medical Device Diversity
Industry Sectors & Top Companies
History Of Device Regulation
FDA Approval Pathways: 501(K) & PMA

Break *10:30-10:45*

Medical Device Regulations *10:45-12:00*
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 & Combination Devices

Lunch *12:00-1:00*

Medical Device Regulations *continued 1:00-2:00*
Regulatory Challenges
- Diagnostics
- Predicates & New Technologies
- Clinical Trails
- Medical Device Reporting

Medical Device Development *2:00-4:15*
Phase I: Market Opportunity
- Market Analysis
- Risk Management Plan

Phase II: Concept Evaluation
- Formulation Steps & Feasibility

Phase III: Engineering Design Process
- Design & Development
- Prototyping

Q&A/Review *4:15-4:30*

Day Two

Review *9:00-9:30*

Medical Device Development *9:30-11:00*
Phase IV: Verification
Phase V: Manufacturing Transfer
- Documentation
- Equipment IQ/OQ/PQ
- Biocompatibility
- Sterilization
- Shipping & Storage

Break *11:00-11:15*

Medical Device Approval *11:15-1:00*
Clinical Trials
Need For A "Gold Standard"
Regulatory Submissions
Business Preparations
Product Launch Preparations
Coding & Reimbursement

Lunch *1:00-2:00*

Commercialization *2:00-3:15*
Manufacturing Scale-Up
Product Launch
Post-Launch Assessment

Break *3:00-3:15*

Current Issues *3:15-4:15*
The Increasing Role Of The FDA
Why Are The Newest Devices In Europe?

Q&A/Review *4:15-4:30*

Learn Onsite

Diagnostics Development Primer

Diagnostics Development Primer is a one-day course that explores how diagnostics are developed, approved and reimbursed. The course introduces concepts such as sensitivity, specificity, false positives , false negatives, and ROC curves, which are used to determine how well the diagnostic performs. Once the strength of a diagnostic is determined the participants learn how the diagnostic is evaluated by the FDA and the various pathways to approval a company can pursue. The course ends with a look at how diagnostics are reimbursed once in the marketplace.

Diagnostics' Role in Medicine Today *9:00-10:00*
What is a Diagnostic?
Uses of Diagnostic Tests
Types of Diagnostic Tests

Break *10:00-10:15*

Statistical Features of Diagnostics *10:15-11:00*
Diagnostic Need for Gold Standard
Measures
Standard Curve
Measurement & Distribution

Statistical Measures of Tests *11:00-12:00*
False Positive & False Negative
Sensitivity & Specificity
True Positive
Activity: Sensitivity & Specificity

Lunch *12:00-1:00*

Measuring the Strength of a Test *1:00-1:45*
RADAR Sensitivity & Specificity
Receiver Operator Curves (ROC Curves)
Key Points - ROC Curves Reclassification Analysis

Risk of Diagnostics Tests *1:45-2: 30*
Low Prevalence
Mammography
Invasive Procedures

Break *2:30-2:45*

Diagnostic Development & Approval *2:45-3:30*
Testing Against the Gold Standard
Development of Clinical Tests
Pathways to Approval
- Class I
- Class II
- Class III

How Diagnostic Tests Are Reimbursed *3:30-4:15*
Center for Medicare & Medicaid Services (CMS)
Reimbursement In-Hospital & Out-Patient
Methods of Economic Evaluation

Q&A/Review *4:15-4:30*

Learn Onsite

The Science of Molecular Diagnostics

The Science of Diagnostics is a one-day course exploring the growing role of molecular diagnostics within healthcare. Participants will learn about a range of diagnostic tests, focusing on molecular diagnostics. The basic science that these diagnostics rely on will be described, including PCR, next-generation DNA sequencing, microRNA, DNA, proteins and antibodies. The class will also include a discussion of related ideas such as biomarkers, pharmacogenomics, and companion diagnostics. Learn to more effectively manage current and emerging diagnostic technologies.

Role of Diagnostics in Medicine Today *9:00-9:30*
Diagnosis of Disease - Do you have it?
Following a Disease - What's your prognosis?
Following a Treatment - Are you cured?
Carrier - Will you pass it on to your child?

Types of Diagnostics *9:30-10:00*
Blood Test - Biomarkers
Lab: Blood Typing
Physiologic Tests - Blood Pressure, EKG
Anatomic Tests - X-ray, CAT Scan, MRI, Nuclear Markers
Histologic Tests - Biopsy, Pap Smear
Genetic Tests

Break *10:00-10:15*

The Science Behind Diagnostics Part 1: DNA & Genetic Variation *10:15-11:15*
DNA Structure & Function
Lab: DNA Isolation & Extraction
Mutations
Genetic Variation
Activity: Genetic Variation of Taste
Personalized Medicine/Personalized Diagnostics

The Science Behind Diagnostics Part 2: Proteins & Antibodies *11:15-12:00*
DNA to Proteins
Protein Structure & Function
Genetic Disease
Antibodies Defined
Antibody Production

Lunch *12:00-1:00*

DNA & RNA Based Diagnostics *1:00-2:15*
PCR
PCR-Based Viral Detection
qRT-PCR
DNA Chips/SNP Chips
Activity: Microarray for Determining Drug Metabolism
Sequencing The Human Genome: Next Generation Sequencing
microRNA (miRNA) Diagnostics

Break *2:15-2:30*

Antibody & Protein Based Diagnostics *2:30-3:30*
Sandwich Immunoassay
Bead Immunoassay
Multiplexed ELISA
Protein Separation Based on Column Chromatography
Lab: Sickle Cell Anemia Protein Separation Diagnostic

Current Issues *3:30-4:15*
Companion Diagnostics
Lab: Bcr-Abl Variant Detection Lab
IVDMIA
Consumer Genomics

Q&A/Review *4:15-4:30*

BioRisk

BioRisk is a two-day course providing an overview of biotechnology concepts relevant to biorisk and biosafety issues encountered within research settings. Biorisk management is a set of practices and principles that are rapidly becoming critical for biotechnology, vaccine and biological production, and R&D industries. In essence, biorisk management provides a foundation for the safe management of potentially hazardous biological and infectious agents and toxins. The use of many of these agents are regulated, and compliance is mandatory. But even outside of regulatory parameters, industry best-practice dictates these industries have robust biorisk management programs in place. Learn how to identify and remedy potential laboratory safety issues.

Day One

Industry Overview *9:00-10:30*
Definition of Biotech
Industry Sector: Healthcare
Biotech's Driver: Research
Definitions of Biosafety/Biohazard/Biosecurity
Research Facilities: Biosafety Levels
Laboratory Equipment: BSC

Break *10:30-10:45*

The Players *10:45-12:00*
Research Support Companies
Contract Research Organizations (CRO)
Academic Laboratories
Private & Public Companies
Regulatory Sectors: FDA, NIH, CDC, EPA, USDA, OSHA
International Regulatory Agencies

Lunch *12:00-1:00*

Biology Basics *1:00-2:00*
Biotechnology Goals
Mammalian, Virus, Prion & Bacteria
Routes of Exposure & Particle Size
Personal Protective Expression

Break *2:00-2:15*

DNA *2:15-4:15*
DNA Structure & Function
DNA to Proteins
Protein Structure & Function
Genetic Mutations
Genetic Variation
Genetic Disease
Personalized Medicine

Q&A/Review *4:15-4:30*

Day Two

Genetic Engineering *9:00-10:00*
Plasmids
Recombinant DNA
Risk Assessment Requirements
Genetically Engineered Cells
Disease Models

Break *10:00-10:15*

Immune System *10:15-12:00*
Common Pathogens
Exposure to Foreign Agents
Risk Group Classifications
Risk Factors that Influence Exposure
Preventing Exposure
Non-Specific Immune Response
Specific Immune Response
Vaccines

Lunch *12:00-1:00*

Stem Cells *1:00-2:00*
Properties of Stem Cells
Types of Stem Cells
Cloning & Stem Cells
Therapeutic Potential

Break *2:00-2:15*

Drug Development *2:15-4:00*
Preclinical Trials
Animal Use Issues
Safety Review Boards
Clinical Trials
Generics & Biosimilars
Getting a Diagnostic to Market

Q&A/Review *4:00-4:30*

Learn Onsite

BioFacilities Primer

BioFacilities Primer is a one-day course furthering your understanding of the unique real estate and facility requirements of the dynamic and highly regulated biotech and pharmaceutical industries. Advance your knowledge of key performance and specific uses driving the cost of developing and operating these technical facilities.

Facility Types *9:00-9:45*
Beyond Alphabet Soup
Tenant & Landlord Perspectives
Purpose-Driven Facilities

Site Selection Fundamentals *9:45-10:15*
Process-Driven Infrastructure Requirements
Workforce Considerations
Quality of Life
Cost of Living Implications
Permitting Environment

Break *10:15-10:30*

Incentives That Matter *10:30-11:00*
Grants
Low Cost Financing
Permit Fee Waivers
Property & Sales Taxes
Industry-Specific Exemptions
Facility Development Process

Fundamentals *11:00-12:00*
Performance Criteria
Regulatory Requirements
Design & Engineering Criteria
Comprehensive Development Budgets
Schedule Considerations

Lunch *12:00-1:00*

Leasing Fundamentals *1:00-1:45*
Tenant Underwriting
Term Lengths Matched to Developmental Stage
Security Deposits
Tenant Improvement Allowances
Permitted Uses
Expansion Rights
Restoration Clauses

Operating and Compliance Issues *1:45-2:30*
Typical Costs
Strategies to Reduce Operating Costs
Federal Compliance
State & Regional Compliance
Documentation & Record-Keeping

Break *2:30-2:45*

Cost Elements *2:45-3:30*
Typical Costs
Strategies to Reduce Operating Costs

Case Study *3:30-4:15*

Q&A/Review *4:15-4:30*