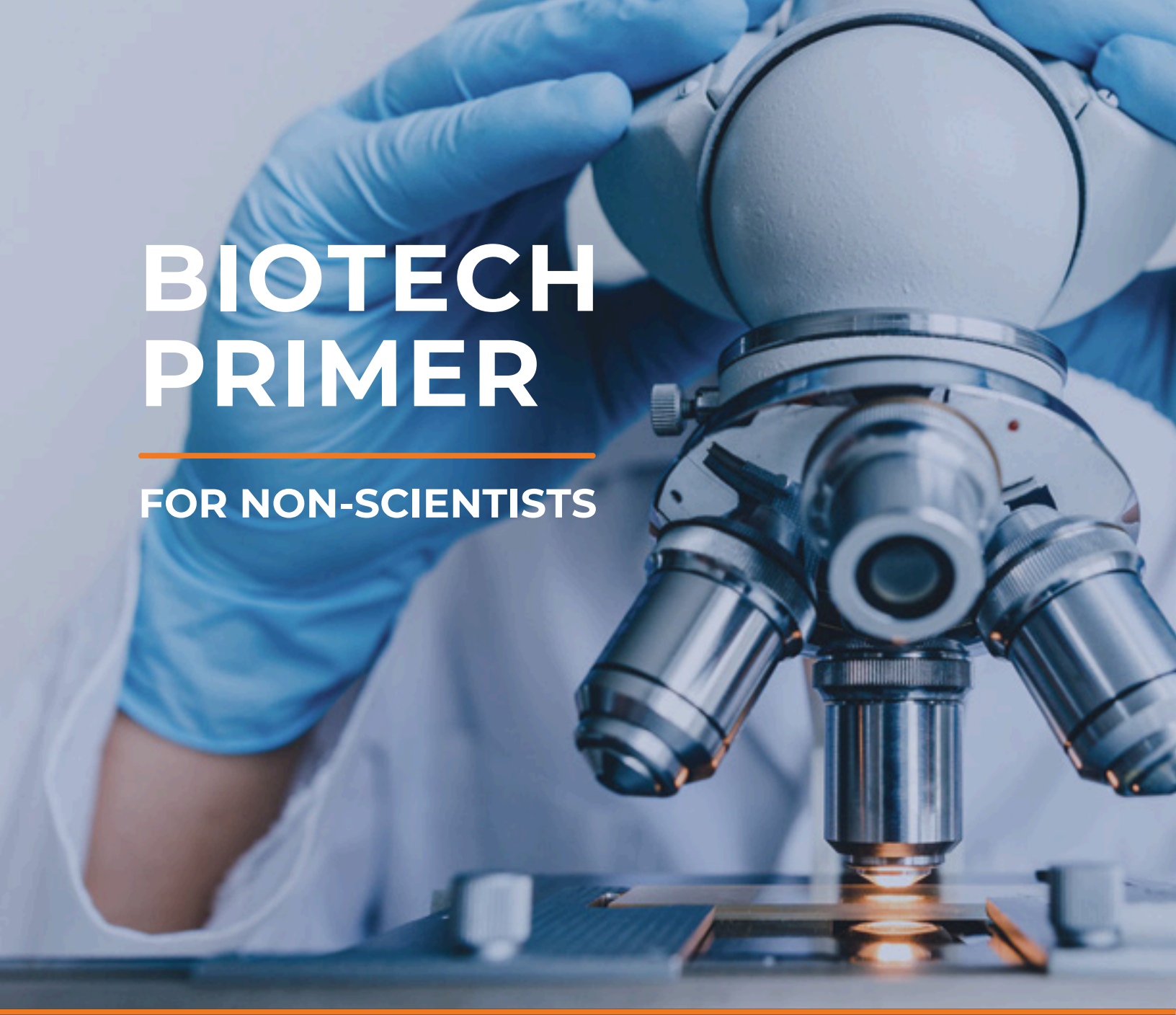

BIOTECH PRIMER

FOR NON-SCIENTISTS

COURSE CATALOG

Unlock the world of biotechnology with Biotech Primer's comprehensive course catalog. From foundational science to pharmaceutical drug development, business dynamics, medical device innovation, and global regulatory standards, our expert-led courses are designed to equip non-scientists with the knowledge and skills needed to thrive in the biotech industry.

biotechPrimer
Life Science Training From Industry Experts

Bio OFFICIAL
Education Alliance Partner

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Baltimore, Maryland
www.BiotechPrimer.com

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Biotechnology for Non-Scientists

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MICROCOURSES

For more information contact
Training@BiotechPrimer.com
Class registration @BiotechPrimer.com

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BIOTECH PRIMER
OUR ADVANTAGE

Our Content

Choose From Our 4 Life Science Pillars

Our content is structured around five core categories, which we refer to as “Life Science Pillars.”

- Biotech for Non-Scientists
- Drug Development
- Drug Manufacturing
- Medical Devices

Choose From Our On-Demand or Live Curricula

Content within each life science pillar can be delivered live, on-demand, or through a blended learning approach, offering maximum flexibility.

Choose the Course Level Suitable for You

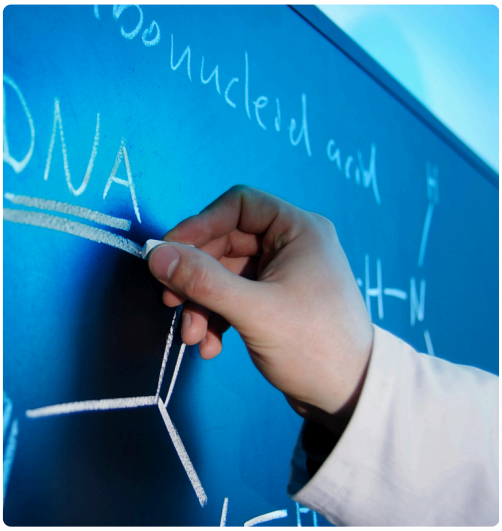
Not sure where to begin? Use our level system to identify where to start. Some courses have suggested prerequisites to ensure you have the necessary background knowledge to be successful.

Level 1 Beginner	Level 2 Intermediate	Level 3 Advanced
For those new to the science or the industry	For those with general scientific understanding	For those with advanced scientific knowledge

Our Instructors

Biotech Primer instructors bring a wealth of industry experience to the table, ensuring that you receive nothing but the most relevant and practical life science knowledge. Drawing on their diverse backgrounds, these seasoned professionals are well-versed in the real-world challenges you may encounter.

Our dedicated industry instructors have worked with companies of all sizes, from multinational corporations to innovative start-ups. They have witnessed and actively shaped the ever-evolving landscape of biotechnology and medical devices.



Over 150,000 individuals trained since 2001

Why We're Different

Competitive Pricing
We offer subscriptions and course packages for convenience and savings.

IT Support Team
Submit a ticket to our tech team at any time of the day! You are our top priority. Same day response time.

Learn in 10 Languages
Our microcourses offer subtitles and transcripts in 10 languages, including English, Japanese, Chinese, Korean, Spanish, French, French Canadian, Russian, Hindi, and Arabic.

LinkedIn Certificate Integration
Click our unique link and download your verified certificate directly to your LinkedIn Certification and License profile.

Our On-Demand Courses

Microcourses

Benefit from access to interactive, animated 60-minute courses.

Features

- CPE credits
- Verified certificates
- Link to display certificate on LinkedIn
- Interactive exercises and assessments
- Executive certifications
- Subtitles in 10 languages
- Viewable transcripts in 10 languages
- Viewable PDF of course slides
- IT support by real humans

Deep Dive Programs

Benefit from access to course bundles that are 5- to 9-hours long.

Features

- CPE credits
- Verified certificates
- Link to display certificate on LinkedIn
- Viewable workbook
- IT support by real humans

Our Live Courses

Live Courses

Bring our predesigned, two-day courses in-house. Training delivered worldwide to your organization, onsite or online.

Features

- Verified certificate
- Link to display certificate on LinkedIn
- Interactive activities: labs, case studies, polls, discussions
- Course workbook

Customized Training

Custom training, built for your team and delivered anywhere. Start with our proven courses and tailor the content, depth, and focus to match your organization's exact learning goals.

Features

- Verified certificate
- Link to display certificate on LinkedIn
- Interactive activities: labs, case studies, polls, discussions
- Course workbook

Contact Training@BiotechPrimer.com to set up a call to discuss your training needs.

Our Unique Approach

Real-Time Interaction
Engage in live sessions with dynamic discussions, hands-on activities, and real-time collaboration with instructors and peers.

Tailored Training
Adapt our training to meet your organization's specific learning objectives, ensuring the content is relevant and impactful.

Expert-Led Sessions
Learn directly from experienced professionals who bring real-world insights and up-to-date information.

BIOTECH PRIMER
EXECUTIVE CERTIFICATIONS

Executive Certifications: Advance your career and set yourself apart with our expert executive certification programs.

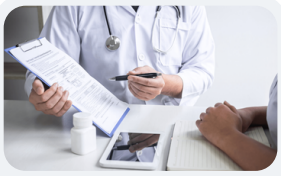
CPE Credits: Earn NASBA-approved Continuing Professional Education (CPE) credits, often needed for licensing and professional requirements.

Biotech Primer Offers Maximum Flexibility

Biotech Primer caters to your learning style and offers maximum flexibility. Our content is delivered on-demand and live, and our courses can be purchased individually, in bundles, or by subscription.

Executive Certifications Opportunities

The following 4 programs provide CPE credits and certification in a specific life science discipline.



Drug Development Executive Certification

Master the pivotal commercial, regulatory, and scientific strategies for a successful drug launch.

Biotechnology Executive Certification

Conquer the core and advanced scientific concepts essential to the biopharmaceutical field and your credibility.

Drug Manufacturing Executive Certification

Achieve proficiency in drug manufacturing, focusing on compliance, quality control, and production processes.

Medical Device Executive Certification

Gain the science, business, and regulatory expertise to develop successful medical devices, including molecular diagnostics.

BIOTECH PRIMER
SUBSCRIPTIONS

Subscription Opportunities

The following two programs provide unlimited access to our on-demand and Executive Certifications. Choose a monthly or yearly subscription.

On Demand Courses Subscription

- Includes the entire Deep Dive and Microcourse libraries
- 100+ hours of content
- CPE credits awarded
- Validated certificates earned
- Link to display your certificate on LinkedIn
- Monthly and yearly subscription pricing
- 3-day free trial available

Executive Certification Subscription

- Earn 4 Executive Certifications
- Includes the entire Deep Dive and Microcourse libraries
- 100+ hours of content
- CPE credits awarded
- Validated Executive Certifications awarded
- Link to display your certification on LinkedIn
- Yearly subscription pricing
- 3-day free trial available

Flexible Options

The following eight live courses are also available as on-demand options.

- BioBasics 101: The Biology of Biotech for the Non-Scientist
- BioBasics 201: Targeted Therapeutics Explained for the Non-Scientist
- Drug Development Immersion
- Biopharmaceutical Commercialization Immersion
- Commercialization Readiness From Preclinical to First Launch
- Drug Pricing, Policy, and Utilization Immersion
- Medical Device Development Immersion
- Revenue Forecasting and Epidemiology Immersion

Enhance Your Curriculum with Our Tailored Programs

Instantly Expand Your Curriculum: Our wide array of white-labeled courses allows your organization to expand its online training curriculum instantaneously.

Flexible Delivery: Your choice of content delivery includes live online, live onsite, on-demand, or a blended learning approach.

Customized Training: Choose from our live course agendas or have us develop a personalized course for your organization.

Attractive Discounts: Maximize the value of your investment; the more microcourses purchased, the lower the price per class.

Corporate Account Advantage for On-Demand Learning

Our on-demand classes offer an excellent way for organizations to conveniently access learning at their convenience. These short, focused microcourses allow your employees to engage with material and apply new knowledge immediately, which is ideal for fast-paced professional environments.

Enterprise

Use our Learning Management System (LMS) to manage your company's account. Assign classes, view an individual's progress, and download reports.

Integration Bridge

Seamlessly connect your organization's LMS to ours. Your employees access all our courses on your LMS. Easy and convenient.

Customized Live Training for Targeted Organizational Growth

Our tailored training programs are delivered globally, either live onsite or online, by our experienced industry experts. Customize our courses to align perfectly with your organization's learning objectives. This flexibility ensures your team receives the most relevant and impactful training precisely when and where needed.

BIOTECH PRIMER
OUR COMPETITVE PRICING

Pricing

The training types listed below are designed for individuals. Purchase directly from our secure website and accelerate your life science career.

On-Demand

Individual Courses		**Monthly**
Microcourse		$190
Course Bundles		**Yearly**
Deep Dive Programs		$895
Single Executive Certifications		**Yearly**
Drug Development Executive Certification		$2850
Biotechnology Executive Certification		$2850
Drug Manufacturing Executive Certification		$2850
Medical Device Executive Certification		$2850
Subscriptions	**Monthly**	**Yearly**
Executive Certification Subscription	N/A	$359/month
On-Demand Subscription	$229/month	$199/month

Volume Discount

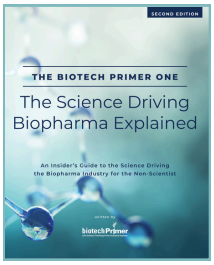
Our competitive microcourse pricing for groups maximizes the value of your investment. Corporate accounts are granted one year of unlimited access to all purchased microcourses.

Total Number of Microcourses	Discount Percentage per Microcourse	Price per Microcourse per Person
1-9	none	$190
10-20	20%	$152
21-100	30%	$133
101-1000+	40%	$114

BIOTECH PRIMER
OUR PUBLICATIONS

Our Books Available on Amazon

The Biotech Primer One: The Science Driving Biopharma Explained This 120-page illustrated book offers a clear overview of biopharma's fundamental science and processes, helping readers grasp the core principles of the life science industry.



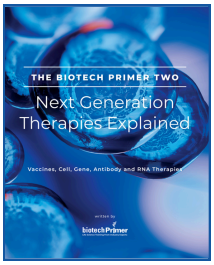
★★★★★

"This book brought me up to speed very quickly, and I keep it on a shelf at my desk as a reference still today."

★★★★★

"I was looking for a book to help me catch up with the technical aspect of the Life Science industry. I would say that this book has been an enjoyable read as it was very well illustrated."

The Biotech Primer Two: Next Generation Therapies Explained is designed for non-scientists to learn how novel medicines treat diseases. This 170-page book covers key therapies like cell and gene treatments, RNA drugs, and vaccines, in an accessible, easy-to-read format.



★★★★★

"I had some science background in undergrad, and this book has been invaluable in getting me up to speed in my field and understanding the broader industry."

★★★★★

"This book has helped me immensely as I transitioned into the biotech pharma industry."

Our Blog: The Primer

The Primer: Science Made Simple is Biotech Primer's weekly blog on all things life science. The blog's mission is to explain a science topic in four minutes, helping the layperson become more scientifically literate. Register today at BiotechPrimer.com and get The Primer sent right to your inbox each Tuesday.

★★★★★

"Quick, informative, and perfect for busy professionals."

★★★★★

"Valuable blend of science and business insights. The Primer blog is one of my go-tos for industry news."

BIOTECH PRIMER

Executive Certifications

biotechPrimer
Life Science Training From Industry Experts

Biotechnology Executive Certification

Courses: 12
CPE Credits: 14.5
Access: 1 Year

OVERVIEW

The Biotechnology Executive Certification focuses on the basic and advanced scientific concepts relevant to the biopharmaceutical industry. These executive certifications are designed to highlight a commendable level of proficiency and commitment to ongoing professional development.

To achieve the Biotechnology Executive Certification, participants must complete the series of courses listed below and pass the final exam with a minimum score of 75% within a 12-month period. By completing this program, individuals earn a total of 14.5 NASBA-sponsored CPE credits.

COURSES

- The Biology of Biotech
- Genetic Engineering Primer
- Immunology Primer 101
- Immunology Primer 201
- Antibody Primer
- Biosimilars Primer
- Gene Therapy Primer
- Cell Therapy Primer
- Biopharma Business Acumen Primer
- Clinical Development 101: General Principles
- Biomanufacturing Primer
- Pharmaceutical Manufacturing Primer
- Comprehensive Final Exam

Drug Development Executive Certification

Courses: 12
CPE Credits: 13.5
Access: 1 Year

OVERVIEW

The Drug Development Executive Certification examines the commercial, regulatory, and scientific considerations crucial for a successful drug approval and launch. The Drug Development Executive Certification demonstrates a high level of proficiency and a commitment to ongoing professional development.

To achieve the Drug Development Executive Certification, participants must complete the series of courses listed below and pass the final exam with a minimum score of 75% within a 12-month period. By completing this program, individuals earn a total of 13.5 NASBA-sponsored CPE credits.

COURSES

- Biopharma Business Acumen Primer
- Small Molecule Drug Discovery Primer 101
- Small Molecule Drug Discovery Primer 201
- Drug Discovery of Biologics Primer 101
- Drug Discovery of Biologics Primer 201
- Preclinical Development Primer 101
- Preclinical Development Primer 201
- Drug Approval Primer
- Clinical Development 101: General Principles
- Clinical Development 201: Phase I
- Clinical Development 301: Phase II/III
- Clinical Development 401: Phase IV
- Comprehensive Final Exam

Drug Manufacturing Executive Certification

Courses: 11
CPE Credits: 13.5
Access: 1 Year

OVERVIEW

The Drug Manufacturing Executive Certification offers comprehensive training for individuals seeking to learn about the production of drugs. This certification covers the essential aspects of small and large molecule drug manufacturing. Gain valuable insights and advanced knowledge in compliance, quality control, and production processes necessary in a highly regulated environment.

To achieve the Drug Manufacturing Executive Certification, participants must complete the series of courses listed below and pass the final exam with a minimum score of 75% within a 12-month period. By completing this program, individuals earn a total of 13.5 NASBA-sponsored CPE credits.

COURSES

- The Biology of Biotech
- Genetic Engineering Primer
- Biomanufacturing Primer
- Pharmaceutical Manufacturing Primer
- Gene Therapy Manufacturing Primer 101
- Gene Therapy Manufacturing Primer 201
- cGMP Primer
- CMC Primer
- Biosimilars Primer
- Lab Worker Biosafety Primer
- OSHA Bloodborne Pathogen Standard Primer
- Comprehensive Final Exam

Medical Device Executive Certification

Courses: 9
CPE Credits: 12.0
Access: 1 Year

OVERVIEW

The Medical Device Executive Certification provides valuable insights into the development process, compliance standards, and quality control protocols for medical device development. This certification equips participants with the foundational knowledge necessary to excel in a medical device company.

To achieve the Medical Device Executive Certification, participants must complete the series of courses listed below and pass the final exam with a minimum score of 75% within a 12-month period. By completing this program, individuals earn a total of 12.0 NASBA-sponsored CPE credits.

COURSES

- The Biology of Biotech
- Diagnostic Development Primer
- Diagnostics' Role in Medicine Today
- DNA-Based Diagnostics Primer
- Protein-Based Diagnostics Primer
- Diagnostic Measurements Primer
- Medical Device Commercialization Primer
- Medical Device Development Primer
- Medical Device Approval Primer
- Comprehensive Final Exam

BIOTECH PRIMER

BIOTECHNOLOGY FOR NON-SCIENTISTS

biotechPrimer
Life Science Training From Industry Experts

BioBasics 101

The Biology of Biotech for the Non-Scientist

Live | Level Beginner
Two Day Agenda
Customization is available for in-house training

OVERVIEW

BioBasics 101: The Biology of Biotech for the Non-Scientist offers a fascinating exploration of the fundamental science that underpins the life sciences. It examines the pivotal roles of the FDA, NIH, academia, and pharmaceutical companies and how they collaborate to drive scientific breakthroughs. It thoroughly explains the biological foundation of cells, DNA, RNA, and proteins, uncovering their applications in biopharmaceuticals. Building on this foundational knowledge, BioBasics 101 outlines the genetic basis of diseases, highlighting the devastation caused by mutations and the impact of genomics and proteomics on personalized medicine. This program culminates in genetic engineering and biomanufacturing, where all the essential biology principles learned are applied. Get ready to revolutionize your understanding of the life science industry with this interactive training—contact us today to learn how to bring BioBasics 101 in-house!

Five Takeaways:

1. Describes the fundamental roles of DNA, RNA, and proteins in human biology to better understand how biotech products are developed.
2. Summarizes the core functions and the relationship between the FDA, NIH, academia, and industry in the biotech innovation ecosystem.
3. Differentiates between small molecule and large molecule drugs to support more informed strategic and investment decisions.
4. Identifies the genetic basis of diseases and the impact of genomics and proteomics on personalized medicine.
5. Explains the types of immunotherapies and summarizes how each mitigates disease.

AGENDA

DAY ONE

Introductions 15 minutes

Industry Overview: Setting the Stage 75 minutes

Biopharma U.S. Clusters
Drugs defined
Small molecule drug characteristics and examples
Large molecule drugs (biologics) characteristics and examples
Drug size and targets
Drug modalities
The regulatory agencies and industry
Drug development process
New molecular entities, generics, and biosimilars
Knowledge flow from federal labs to academia to industry
Research support companies
Funding sources

Break 15 minutes

Biology: The Basis of Biopharma 75 minutes

Molecules critical to life
Cell structure
Industry application: checkpoint inhibitors
Cell function: growth and multiplication
Cell function: protein production
Categories of proteins
Cell function: communication
A closer look: Kinase enzymes and cancer
Industry application: agonist and antagonist drugs

Lunch 60 minutes

DNA: Biopharma's Blueprint 60 minutes

History of DNA discovery
DNA organization: chromosomes and genes
Chromosomal translocation
DNA structure
Industry application: chromosome abnormalities
Lab: DNA isolation and extraction from strawberries
DNA replication
Industry application: PCR

Break 15 minutes

Proteins: Biopharma's Workhorse 60 minutes

RNA structure
DNA vs RNA structure comparison
Proteins defined
How DNA codes for proteins
RNA processing: gene regulation step
Codons: decoding protein synthesis
Activity: amino acid sequence
Protein structure
Chaperone therapeutics
Post-translational modifications (PTM)
Gene expression
Epigenetics
Industry application: epigenetic medicine
The proteome and AI
First AI-generated medicines

Wrap-Up 15 minutes

DAY TWO

Day One Review 15 minutes

Genetic Basis of Disease 75 minutes
Chromosomes and genetic variation
Alleles: dominant and recessive genes
Phenotype and genotype
Mutations
Genetic variation
Activity: taste test
Genetic basis of disease
Monogenic and polygenic diseases
Rare diseases and mutations
Industry application: precision medicine
Understanding mutations: HER2+ breast cancer
Precision medicine: dosage, safety, efficacy

Break 15 minutes

Genomics: Understanding the Genetic Basis of Disease 60 minutes
Genome and genomics defined
Intergenic DNA
Industry application: pharmacogenomics
Genomic technologies: microarrays and gene sequencing
Microarray applications: drug discovery and genotyping
Sequencing applications: drug discovery and diagnostics
Industry application: big data and rare disease
Personalized medicine: integrating the 'omics'

Lunch 60 minutes

Genetic Engineering: Manipulating DNA to Create Cures 60 minutes
Plasmids
Restriction enzymes
Recombinant DNA
Plasmid components and their functions
Making a recombinant plasmid
Recombinant proteins in healthcare
Making recombinant proteins

Break 15 minutes

Biomanufacturing: Producing Cures 60 minutes
Biomanufacturing defined
Bacterial vs mammalian cell lines
Establishing a production cell line
Types of cell banks
Cell bank production
Cell bank qualification
Upstream production
Downstream production
Fill/finish process
Quality aspects overview

Course Wrap-Up and Evaluation 15 minutes

BioBasics 201

Targeted Therapeutics Explained for the Non-Scientist

Live | Level Intermediate
Two Day Agenda
Customization is available for in-house training

OVERVIEW

BioBasics 201: Targeted Therapeutics Explained for the Non-Scientist explores the fascinating world of immunology and the breakthrough therapeutics it inspires. It begins with the intricate workings of the human immune system, meticulously describing the cells and actions used by the body to stop disease. This program then digs deep into the medications that support the immune system when cancer or infection overwhelms it. Vaccines, therapeutic antibodies, gene and cell therapies, RNA medicines, and genome editing are explored in significant detail. BioBasics 201 highlights the pivotal roles, mechanisms of action, and next-generation innovation of each revolutionary treatment. Contact us today to learn how to bring BioBasics 201 in-house to your team!

Five Takeaways:

1. Identifies the key immune system mechanisms that protect against cancer and infectious diseases.
2. Describes how immunology research has been translated into commercial immunotherapy products and pipeline strategies.
3. Lists vaccine platforms and explain how each activates immunological memory to support public health and commercial deployment.
4. Categorizes therapeutic antibody mechanisms, including monoclonals, ADCs, bispecifics, and checkpoint inhibitors, to assess clinical and market differentiation.
5. Compares DNA- and RNA-based therapies to assess their distinct scientific and commercial benefits.

AGENDA

Immunology: Introduction to the Human Immune System 45 minutes

Tissues of the immune system
Non-specific and specific immunity
Key immune cell roles
Immune signaling: cytokines
Industry application: cytokine storm

Immunology: How Our Body Fights Disease 90 minutes

Non-specific immune response
Industry application: inflammation
Specific immune response
Activation of the immune system
B-cells
Antibodies: structure and function
Industry application: monoclonal antibodies
Complement response
T-cells
Regulation of the immune system
PD-1 and CTLA-4
Industry application: tumor suppression of T-cells

Targeted Biologics: Vaccines 80 minutes

Immunological memory
How vaccines work
Vaccine platforms
DNA and RNA vaccines
Industry application: universal flu vaccine

Focus On: Oncology 25 minutes

Cancer
Growth factor signaling
Industry application: Gleevec
Immunosuppressive tumor microenvironment
Cancer immunotherapy

Targeted Biologics: Antibody Therapies 30 minutes

Therapeutic antibodies
Polycloncal vs monoclonal antibodies
Therapeutic antibody mechanisms of action
Antibody-drug conjugates
Biospecific antibodies
Industry application: PD-1 and PD-L1
Industry application: CTLA-4
Next generation checkpoint inhibitors

Targeted Biologics: Cell Therapies 65 minutes

How immune cells are used for cell therapy
CAR structure and function
Selected CAR therapies
CAR variations: CAR-NK, CAR-MA
Industry application: targeting solid tumors
Autologous vs allogeneic cell therapies
How are CARs made?
CAR-T safety: controlling activation
Industry application: CARs treatment for autoimmunity

Targeted Biologics: RNA Therapies 50 minutes

RNAs role in the cell
RNA's role in disease
Therapeutic areas
Types of RNA-based therapies
Antisense
siRNA Therapies
Industry application: Kynamro
Exon inclusion and exon skipping
Industry application: Spinraza

Targeted Biologics: Gene Therapies
60 minutes
Gene therapy in vivo and ex vivo
DNA delivery via viral vectors
Viral vector platforms
Gene therapy composition
AAV and lentivirus characteristics
Industry application: Luxturna
Industry application: Zolgensma
AAV neutralizing antibodies
Gene therapy and biomarkers
Durability of effect
RMAT designation
Risks and challenges

Targeted Biologics: Genome Editing
30 minutes
Gene therapy vs genome editing
Zinc finger nucleases (ZFN)
- ZFN therapeutic areas
- How ZFN work
- ZFN in the clinic
- ZFN safety

CRISPR
- CRISPR therapeutic areas
- How CRISPR works
- CRISPR safety
- CRISPR in the clinic
- Industry application: PD-1 knockouts
- Activity: CRISPR babies
- CRISPR as RNA editor
- CRISPR diagnostics
- Industry application: SHERLOCK and DECETR

Immunotherapies: An Overview
20 minutes
Immunotherapy defined
Types of immunotherapies
- Therapeutic antibodies
- Oncolytic virus therapy
- Vaccines
- Cell therapy (CAR-T)

Course Wrap Up and Evaluation 15 minutes

Immunotherapy Immersion:

A Non-Scientist Guide to Immune-Based Medicine

Live | Level Intermediate

Two Day Agenda

Customization is available for in-house training

OVERVIEW

Immunotherapy Immersion: A Non-Scientist Guide to Immune-Based Medicine, explicitly designed for non-scientists, explores the fascinating world of immunology and the breakthrough therapeutics it inspires. The program begins with the intricate workings of the human immune system, meticulously describing the cells and actions used by the body to stop disease. It then digs deep into the medications that aid the immune system when cancer or autoimmune disease overwhelms it. Oncolytic virus therapy, monoclonal and bispecific antibody medications, antibody conjugate drugs, gene therapy, CRISPR, and CAR-T, among other immunotherapy approaches, are introduced in significant detail. This training highlights the pivotal roles, mechanisms of action, and next-generation innovation of each revolutionary treatment. Call us today to learn how to bring Immunotherapy Immersion in-house to your team!

Five Takeaways:

1. Identifies the key immune system mechanisms that protect against cancer and infectious diseases.
2. Describes how immunology research has been translated into commercial immunotherapy products and pipeline strategies.
3. Lists vaccine platforms and explain how each activates immunological memory to support public health and commercial deployment.
4. Categorizes therapeutic antibody mechanisms, including monoclonals, ADCs, bispecifics, and checkpoint inhibitors, to assess clinical and market differentiation.
5. Compares DNA- and RNA-based therapies to assess their distinct scientific and commercial benefits.

AGENDA

DAY ONE

Introductions 15 minutes

Immunotherapy: Biology Basics 30 minutes
DNA and proteins
Gene expression
Mutations

Immunology: How Our Body Fights Disease 75 minutes
Roles of immune system tissues and key cells
Non-specific and specific immunity
Immune signaling cytokines
Industry application: cytokine storm
Industry application: inflammation
Activation of the immune system
B-cells and T-cells
Antibodies: structure and function
Industry application: monoclonal antibodies
Complement response
Regulation of the immune system: PD-1 and CTLA-4

Break 15 minutes

Immunotherapy Indications: Cancer and Autoimmune Disease 45 minutes
Cancer fundamentals
How cancer causes disease
Mutations, oncogenes, and tumor suppressor genes
Immunosuppressive tumor microenvironment
Selected immunotherapy approaches to cancer
Industry application: BCG and bladder cancer
Autoimmune fundamentals
How autoimmune disease causes disease
Selected immunotherapy approaches to autoimmune disease

Lunch 60 minutes

Cytokines and Inhibitors 35 minutes
Cytokine fundamentals
How cytokine immunotherapy works
Cytokine clinical applications
TNF-α inhibitors and IL inhibitor fundamentals
How inhibitors work
Inhibitor clinical applications for autoimmune diseases

Oncolytic Virus Therapy 40 minutes
Oncolytic virus therapy fundamentals
Design and engineering of oncolytic viruses
How oncolytic virus therapy works
Clinical applications of oncolytic virus therapies
Strengths and weaknesses of this approach
Future direction of oncolytic virus therapy

Break 15 minutes

Monoclonal and Bispecific Antibodies 45 minutes
Monoclonal antibody (mAbs) fundamentals
How mAbs work
mAbs clinical applications and selected approved products
Strengths and weaknesses mAbs
Bispecific antibodies (BsAbs) fundamentals
How BsAbs work
BsAbs clinical applications and selected approved products
Strengths and weaknesses of BsAbs
Next-generation BsAbs

Wrap-Up 15 minutes

DAY TWO

Day One Review 15 minutes

Antibody-Drug Conjugates 40 minutes
Antibody-drug conjugates (ADC) fundamentals
How ADCs work
ADC clinical applications and selected approved products
Strengths and weaknesses of ADCs
Next-generation ADCs

Checkpoint Inhibitors 40 minutes
Checkpoint inhibitor fundamentals
How checkpoint inhibitors work
Checkpoint Inhibitors' clinical applications
Industry applications: PD-1, PD-L1, CTLA-4
Strengths and weaknesses of checkpoint inhibitors
Next-generation checkpoint inhibitors

Gene Therapy 70 minutes
Gene therapy fundamentals
In vivo and ex vivo approaches
How gene therapy works
Viral vector platforms and their characteristics
Focus on AAV and lentivirus
AAV tropism key features
AAV vector constructs
Gene therapy clinical applications
Industry applications: Luxturna and Zolgensma
Challenges: durability and neutralizing antibodies
Strengths and weaknesses of gene therapy
The future of gene therapy

Lunch 60 minutes

CRISPR, BASE, and PRIME Editing 70 minutes
Gene editing fundamentals
Approaches: CRISPR, PRIME, and BASE editing
CRISPR/Cas9 fundamentals
How CRISPR/Cas9 works
CRISPR clinical applications
Industry application: PD-1 knockouts
Activity: CRISPR babies
Next-generation CRISPR, PRIME, and BASE editing fundamentals
How PRIME and BASE editing works
Strengths and weaknesses of CRISPR, PRIME, and BASE editing

Break 15 minutes

CAR-T 50 minutes
Chimeric antigen receptor fundamentals
Autologous vs allogeneic cell therapies
CAR structure and function
Selected CAR therapy approaches
How CAR-T, CAR-NK, CAR-MA, CAR-Til work
Industry application: targeting solid tumors
Industry application: CAR treatment for autoimmunity
Strengths and weaknesses of CARs treating autoimmunity
Next-generation CARs

Course Wrap-Up and Evaluation 15 minutes

Regenerative Medicine Immersion:

A Non-scientist Guide to Stem, Gene, and Cell Therapies

Live | Level Intermediate

Two Day Agenda

Customization is available for in-house training

OVERVIEW

Regenerative Medicine Immersion: A Non-scientist Guide to Stem, Gene, and Cell Therapies explores a field focused on developing therapies to replace injured, diseased, or defective cells, tissues, or organs with the goal of restoring their function. This program begins with a quick review of basic molecular biology concepts to set the stage. The follow-on sections analyze the various regenerative approaches, including stem cells, tissue engineering, gene therapy, gene editing, and cell therapy. This introductory examination includes discussions of each drug's role, programming processes, applications, benefits, and limitations. The last section examines the business aspects of regenerative medicine, explaining the challenges and key considerations for gene and cell therapy companies. Call us to learn how to bring Regenerative Medicine Immersion in-house to your team!

Five Takeaways:

1. States the characteristics and describes the differences between types of stem cells, including induced pluripotent stem cells.
2. Summarizes the risks and medical challenges associated with gene therapy.
3. Describes the structure and function of the CAR receptor and provides an overview of CAR-T, CAR-NK, CAR-MA, and CAR-Til's mechanisms of action.
4. Compares the various gene editing techniques, such as Zinc-Finger Nucleases (ZFN), CRISPR, BASE editing, and PRIME editing.
5. Lists the steps of tissue engineering.

AGENDA

DAY ONE

Introductions 15 minutes

Regenerative Medicine Basic Biology
60 minutes
Cells
Chromosome structure and function
DNA structure and function
Gene expression
Protein structure and function
Mutations
Genetic disorders
Rare disease

Break 15 minutes

Introduction to Regenerative Medicines
30 minutes
Regenerative medicine defined
Regenerative medicine timeline
First regenerative medicines: skin grafts and bone marrow transplants

Stem Cells 60 minutes
Role of stem cells
Stem cell types and their functions
Embryonic stem cell fundamentals
Induced pluripotent stem cell (iPSC) fundamentals

Lunch 60 minutes

Stem Cells 60 minutes
Steps to program, modify, and process iPSC
Stem cell characterization and certificate of analysis
Strengths and weaknesses of stem cell therapies
Autologous and allogeneic cells defined
Advantages/disadvantages of autologous and allogenic cells
Stem cell clinical applications
Next-generation stem cells

Break 15 minutes

Tissue Engineering and Biomaterials
60 minutes
Tissue engineering defined
The process of engineering tissue
Scaffolds used
Cells used
Signaling molecules used
Growing tissues and organs

Wrap-Up 15 minutes

DAY TWO

Day One Review 15 minutes

Gene Therapy 75 minutes
Gene therapy fundamentals
In vivo and ex vivo approaches
How gene therapy works
Viral vector platforms and their characteristics
Focus on AAV and lentivirus
AAV tropism key features
AAV vector constructs
Gene therapy clinical applications
Industry applications: Luxturna and Zolgensma
Challenges: durability and neutralizing antibodies
Strengths and weaknesses of gene therapy
The future of gene therapy

Break 15 minutes

Gene Editing 75 minutes
Gene editing fundamentals
Approaches: ZNF, CRISPR, PRIME, and BASE editing
Zinc Finger Nuclease (ZFN) fundamentals
How ZFN work
CRISPR/Cas9 fundamentals
How CRISPR/Cas9 works
CRISPR clinical applications
Industry application: PD-1 knockouts
Activity: CRISPR babies
Next-generation CRISPR
PRIME and BASE editing fundamentals
How PRIME and BASE editing works
Strengths and weaknesses of ZNF, CRISPR, PRIME, and BASE editing

Lunch 60 minutes

Cell Therapy 90 minutes
Cell therapy clinical landscape
Viral vectors used in cell therapy
In vivo and ex vivo cell therapy
Chimeric antigen receptor fundamentals
Autologous vs allogeneic cell therapies
CAR structure and function
Selected CAR therapy approaches
How CAR-T, CAR-NK, CAR-MA, CAR-Til work
CAR-T clinical application
Industry application: targeting sickle cell disease
Industry application: targeting solid tumors
Industry application: targeting autoimmunity
Strengths and weaknesses of CARs treating autoimmunity
Next-generation CARs

Break 15 minutes

The Business of Regenerative Medicine 30 minutes
Medical risks and challenges for gene therapy
Key considerations for gene therapy companies
Ideal gene therapy project traits
The future of genetic medicine

Course Wrap-Up and Evaluation 15 minutes

Deep Dive BioBasics 101

The Biology of Biotech for the Non-Scientist

Recorded Live | Level Beginner
8 Hours | 8 Courses
CPE Credits: 11

OVERVIEW

Deep Dive BioBasics 101 features the same content, interactive exercises, and materials as the live version.

BioBasics 101: The Biology of Biotech for the Non-Scientist offers a fascinating exploration of the fundamental science that underpins the life sciences. It examines the pivotal roles of the FDA, NIH, academia, and pharmaceutical companies and how they collaborate to drive scientific breakthroughs. It thoroughly explains the biological foundation of cells, DNA, RNA, and proteins, uncovering their applications in biopharmaceuticals. Building on this foundational knowledge, BioBasics 101 outlines the genetic basis of diseases, highlighting the devastation caused by mutations and the impact of genomics and proteomics on personalized medicine. This course bundle culminates in genetic engineering and biomanufacturing, where all the essential biology principles learned are applied. Get ready to revolutionize your understanding of the life science industry in this interactive eight-course program—register today**!**

Five Takeaways:

1. Describes the fundamental roles of DNA, RNA, and proteins in human biology to better understand how biotech products are developed.
2. Summarizes the core functions and the relationship between the FDA, NIH, academia, and industry in the biotech innovation ecosystem.
3. Differentiates between small molecule and large molecule drugs to support more informed strategic and investment decisions.
4. Identifies the genetic basis of diseases and the impact of genomics and proteomics on personalized medicine.
5. Lists types of immunotherapies and summarize how each mitigates disease.

AGENDA

COURSE ONE

Industry Overview 45 minutes

Healthcare industry sectors
Industry hubs and associations
FDA and industry
NIH and industry
Academia and industry
Research support companies
Funding

COURSE TWO

Biology: Basis of Biopharma 60 minutes

Process of biotechnology
Molecules critical to life
Cell structure
Industry application: receptors and drug targets
Industry application: mitochondria disease
Cell functions: signaling, protein production
Focus on cell signaling
Industry application: cell signaling and cancer

COURSE THREE

DNA: Biopharma's Blueprint 45 minutes

History of DNA discovery
DNA structure
DNA organization: chromosomes and genes
Industry application: chromosome abnormalities
DNA function: coding for proteins
Industry application: pharmacogenomics
DNA replication
Industry application: PCR

COURSE FOUR

Proteins: Biopharma's Workhorse 40 minutes

How DNA codes for proteins
Chaperone therapeutics
Industry application: pharmacological chaperone
Post-translational modifications (PTM)
Industry application: PTM and biologics
Industry application: drug discovery
Gene expression
Epigenetics
Industry application: epigenetic medicines

COURSE FIVE

Genetic Engineering 55 minutes

Plasmids
Restriction enzymes
Recombinant DNA and plasmids
Recombinant proteins
Making recombinant proteins
Pharm animals and plants
Recombinant proteins in healthcare

COURSE SIX

Genetic Basis of Disease 75 minutes

Alleles
Phenotype and genotype
Dominant and recessive genes
Industry application: disease and genes
Mutations: source of genetic variation
Causes of mutations
Genetic basis of disease
Industry application: genome-wide studies
Monogenic and polygenic diseases
Industry application: sickle cell anemia
Industry application: cancer
Precision medicine
Companion diagnostics
Industry application: HER2+ and Herceptin

COURSE SEVEN

Genomics: Understanding the Genetic Basis of Disease 45 minutes

Genomics defined
Non-coding DNA: the regulome
Identifying mutations that cause disease
Common genetic diseases
Rare genetic disease
Industry application: identifying mutations
DNA microarrays (gene chips)
Microarrays uses
Third generation gene sequencing
Industry application: big data and rare disease
Personalized medicine: integrating the 'omics
Industry application: comparative genomics

COURSE EIGHT

Drugs Mitigate Disease: An Overview 90 minutes

Categories and characteristics of drugs
Small molecule drugs
- Antibiotics
- Peptide drugs

Large molecule drugs (biologics)
- Vaccines
- Therapeutic antibodies
- Immunotherapies
- Gene therapies
- Cell therapies
- Stem therapies

Evaluation 20 minutes

Deep Dive BioBasics 201

Targeted Therapeutics Explained for the Non-Scientist

Recorded Live | Level Intermediate
9 Hours | 10 Courses
CPE Credits: 11

OVERVIEW

Deep Dive BioBasics 201 features the same content, interactive exercises, and materials as the live version.

BioBasics 201: Targeted Therapeutics Explained for the Non-Scientist explores the fascinating world of immunology and the breakthrough therapeutics it inspires. It begins with the intricate workings of the human immune system, meticulously describing the cells and actions used by the body to stop disease. This course bundle then digs deep into the medications that aid the immune system when cancer or infection overwhelms it. Vaccines, therapeutic antibodies, gene and cell therapies, RNA medicines, and genome editing are explored in significant detail. BioBasics 201 highlights the pivotal roles, mechanisms of action, and next-generation innovation of each revolutionary treatment. Get ready to increase your understanding of the life science industry in this interactive ten-course program—register today!

Five Takeaways:

1. Identifies the key immune system mechanisms that protect against cancer and infectious diseases.
2. Describes how immunology research has been translated into commercial immunotherapy products and pipeline strategies.
3. Lists vaccine platforms and explain how each activates immunological memory to support public health and commercial deployment.
4. Categorizes therapeutic antibody mechanisms, including monoclonals, ADCs, bispecifics, and checkpoint inhibitors, to assess clinical and market differentiation.
5. Compares DNA- and RNA-based therapies to assess their distinct scientific and commercial benefits.

AGENDA

COURSE ONE

Immunology: Introduction to the Human Immune System 45 minutes

Tissues of the immune system
- Non-specific and specific immunity
- Key immune cell roles
- Immune signaling: cytokines
- Industry application: cytokine storm

COURSE TWO

Immunology: How Our Body Fights Disease 90 minutes

Non-specific immune response
Industry application: inflammation
Specific immune response
Activation of the immune system
B-cells
Antibodies: structure and function
Industry application: monoclonal antibodies
Complement response
T-cells
Regulation of the immune system
- PD-1 and CTLA-4

Industry application: tumor suppression of T-cells

COURSE THREE

Targeted Biologics: Vaccines 80 minutes

Immunological memory
How vaccines work
Vaccine platforms
DNA and RNA vaccines
Industry application: universal flu vaccine

COURSE FOUR

Focus On: Oncology 25 minutes

Cancer
Growth factor signaling
Industry application: Gleevec
Immunosuppressive tumor microenvironment
Cancer immunotherapy

COURSE FIVE

Targeted Biologics: Antibody Therapies 30 minutes

Therapeutic antibodies
Polyclonal vs monoclonal antibodies
Therapeutic antibody mechanisms of action
Antibody-drug conjugates
Biospecific antibodies
Industry application: PD-1 and PD-L1
Industry application: CTLA-4
Next-generation checkpoint inhibitors

COURSE SIX

Targeted Biologics: Cell Therapies 65 minutes

How immune cells are used for cell therapy
CAR structure and function
Selected CAR therapies
CAR variations: CAR-NK, CAR-MA
Industry application: targeting solid tumors
Autologous vs allogeneic cell therapies
How are CARs made?
CAR-T safety: controlling activation
Industry application: CARs treatment for autoimmunity

COURSE SEVEN

Targeted Biologics: RNA Therapies 50 minutes

RNAs role in the cell
RNA's role in disease
Therapeutic areas
Types of RNA-based therapies
Antisense
siRNA Therapies
Industry application: Kynamro
Exon inclusion and exon skipping
Industry application: Spinraza

COURSE EIGHT

Targeted Biologics: Gene Therapies

60 minutes

Gene therapy in vivo and ex vivo
DNA delivery via viral vectors
Viral vector platforms
Gene therapy composition
AAV and lentivirus characteristics
Industry application: Luxturna
Industry application: Zolgensma
AAV neutralizing antibodies
Gene therapy and biomarkers
Durability of effect
RMAT designation
Risks and challenges

COURSE NINE

Targeted Biologics: Genome Editing

30 minutes

Gene therapy vs genome editing
Zinc finger nucleases (ZFN)
- ZFN therapeutic areas
- How ZFN work
- ZFN in the clinic
- ZFN safety

CRISPR
- CRISPR therapeutic areas
- How CRISPR works
- CRISPR safety
- CRISPR in the clinic
- Industry application: PD-1 knockouts
- Activity: CRISPR babies
- CRISPR as RNA editor
- CRISPR diagnostics
- Industry application: SHERLOCK and DECETR

COURSE TEN

Immunotherapies: An Overview

20 minutes

Immunotherapy defined
Types of immunotherapies
- Therapeutic antibodies
- Oncolytic virus therapy
- Vaccines
- Cell therapy (CAR-T)

Course Evaluation 20 minutes

The Biology of Biotech

On-Demand Microcourse | Level One | 85 Minutes

Suggested Prerequisite: None

CPE Credits: 2.0

OVERVIEW

The Biology of Biotech is the perfect place to start your journey into understanding the world of biotechnology. This foundational class offers invaluable insights into the science behind groundbreaking medical advancements. It provides a comprehensive understanding of DNA, proteins, and cells, explaining how they are manipulated to create innovative therapies and diagnostic tools. It also highlights the connection between genetic mutations and diseases, offering valuable insights into disease diagnosis and treatment. The Biology of Biotech equips learners with the necessary knowledge to navigate the complex field of biotechnology. Don't miss the chance to elevate your healthcare knowledge by registering for this class today!

Five Takeaways:

1. Define DNA, RNA, and proteins to establish a foundation for understanding the biopharmaceutical industry.
2. Identify how genes are expressed to appreciate their role in targeted drug development.
3. Differentiate eukaryotic and prokaryotic cells to understand production strategies for biologics.
4. Summarize the central dogma of molecular biology to initiate a framework for understanding biopharma innovations.
5. Classify major biomolecules to better evaluate technologies across the biotech pipeline.

AGENDA

The Cell: The Biotech Advantage

Biotechnology defined
Types of cells
Organelle structures and functions
Industry application: antagonist vs agonist

DNA and Proteins: The Biotech Workhorses

DNA structure and functions
Industry application: PCR
Genomes and genomics
Gene expression
Protein synthesis
  mRNA, tRNA, codons, anticodons
Post-translational modifications
  Glycosylation and phosphorylation
Protein structures and functions

Genetic Variation: Understanding Disease

Normal, abnormal chromosomes
Alleles and traits
Mutations: types and causes
  Single nucleotide polymorphisms (SNPs)
Genetic basis of disease
Monogenic and polygenic disease
Industry application: identifying mutations
Companion diagnostics
Precision medicine
  Dosage, interactions, metabolism, safety

Genetic Engineering Primer

On-Demand Microcourse | Level Two | 50 Minutes
Suggested Prerequisite: The Biology of Biotech
CPE Credits: 1.0

OVERVIEW

Genetic Engineering Primer explores the foundational science of genetic modification, which was the impetus for the creation of the biotechnology industry in the 1980s. This class provides a solid foundation in restriction enzyme and plasmid use, molecular tools that offer endless possibilities for research, drug discovery, drug development, and biomanufacturing. Genetic Engineering Primer methodically traces the steps taken to create recombinant protein therapies that continue to revolutionize modern medicine. Don't miss this opportunity to equip yourself with the knowledge to set you apart in the conversation—enroll in Genetic Engineering Primer today!

Five Takeaways:

1. Describe how DNA is modified to support drug discovery and manufacturing
2. List the steps for creating recombinant DNA and recombinant protein.
3. Demonstrate how restriction enzymes and plasmids are used in genetic engineering.
4. Evaluate the advantages and disadvantages of bacterial and mammalian production cell lines for biomanufacturing.
5. Categorize the recombinant protein therapies used for treating patients.

AGENDA

DNA and Proteins: The Tools of Genetic Engineering
DNA structure and function
Cell signaling
Protein synthesis
  Transcription and translation
Post-translational modifications
Protein examples and functions

Recombinant DNA: The Blueprint of Genetic Engineering
Recombinant DNA function
Recombinant DNA structure
Recombinant DNA synthesis
Restriction enzymes and plasmids uses explained

Recombinant Proteins: The Product of Genetic Engineering
Recombinant protein defined
Recombinant protein synthesis in bacterial cells
Recombinant protein synthesis in mammalian cells
Characteristics of bacterial and mammalian cell production
Monoclonal antibody production
Uses of recombinant proteins in healthcare
  Therapeutic antibodies and fusion proteins
Recombinant protein synthesis in animals and plants

Antibody Primer

On-Demand Microcourse | Level Three | 70 Minutes
Suggested Prerequisite: The Biology of Biotech, Immunology Primer 101, Immunology Primer 201
CPE Credits: 1.5

OVERVIEW

Antibody Primer offers an immersive exploration of antibodies, explaining their crucial role in research and the clinic. This class begins with an insight into the unique architecture of antibodies and details how their structure directs function. With special attention to the mechanisms of action for monoclonal antibodies, antibody-drug conjugates, bispecific antibodies, and checkpoint inhibitors, this primer highlights the capabilities of these unique molecules to fight disease. This class ends with a survey of standard antibody-based diagnostics, including ELISA, bead immunoassays, and lateral flow immunochromatographic assays, showcasing their purpose and workflows. Enroll today and become fluent in the science of antibodies!

Five Takeaways:

1. Summarize how antibody structure influences antibody functions to support analysis of therapeutic antibody platforms.
2. Select antibody characteristics that enhance drug targeting to evaluate potential market advantages.
3. Differentiate antibody types by mechanisms of action to guide licensing or investment decisions.
4. Recognize antibody-drug conjugates and their benefits in oncology and other indications.
5. Outline the production process for monoclonal antibodies to understand manufacturing timelines and risks.

AGENDA

Antibodies Overview
Antibody structure
Antibody types and functions: IgM, IgD, IgG, IfA, IgE
Antibody mechanism of actions to fight disease
Antigen, immunogen, and epitope defined
Generation of antibody diversity in the lab
Antibody production in both mice and phage display

Antibodies as Therapeutics
Monoclonal antibodies structure and various mechanism of actions
Antibody-drug conjugates structure and mechanism of action

Antibodies as Therapeutics
Bispecific antibodies structure and mechanism of action
Checkpoint inhibitors structure and mechanism of action

Antibodies as Diagnostics
Antibody use in ELISA
ELISA uses and how to read results
Antibody use in bead immunoassay
Bead immunoassay uses and how to read results
Antibody use in lateral flow immunochromatographic assay
Lateral flow immunochromatographic assay uses and how to read results

Immunology Primer 101

On-Demand Microcourse | Level Two | 40 Minutes
Suggested Prerequisite: The Biology of Biotech
CPE Credits: 1.0

OVERVIEW

Immunology Primer 101 reveals the intricate workings of the human immune system, highlighting the difference between non-specific and specific immunity. It uncovers the mysteries of how our bodies combat cancer and infections, exploring the roles of immune cells and tissues acting in our defense. This class showcases the remarkable link between our natural defenses and headline-grabbing therapeutic antibodies developed by the biopharmaceutical industry. These therapies have revolutionized disease treatment for a host of diseases. Immunology Primer 101 is the perfect starting point for those new to understanding immunotherapies. Don't miss the chance to join us!

Five Takeaways:

1. Define innate and adaptive immunity to better understand how the human body fights disease.
2. List key immune cells and their functions to better communicate with scientific teams.
3. Differentiate between epitopes, antigens, antibodies, and receptors to interpret immunology data.
4. Organize the steps of an immune response to clarify therapeutic intervention points.
5. Recognize how immune dysregulation contributes to disease and drug development opportunities.

AGENDA

Immune System Overview
Immunology defined
Immune system tissues
Immune tissue functions
Origin of immune cells

Disease
Disease categories
Types of infectious agents
Characteristics of pathogens

Components of the Immune System
Non-specific and specific immune systems
Phases of the immune response
Types of white blood cells
Hematopoietic stems cells and lineage
Roles of white blood cells

Immunology Primer 201

On-Demand Microcourse | Level Three | 55 Minutes
Suggested Prerequisite: Immunology Primer 101
CPE Credits: 1.0

OVERVIEW

Immunology Primer 201 builds on the foundational knowledge from Immunology Primer 101 and is a complete immersion into the specific immune system. This advanced class aims to spotlight the complexity of how disease occurs and how the human body responds. From disease recognition to disease elimination, this primer comprehensively accounts for the remarkable processes that keep humans healthy. This class ends with specific attention to the immune system's memory B-cells and memory T-cells that fight reinfection, which has direct implications for vaccine technology. Join Immunology Primer 201 to learn the science that inspired immunotherapies and vaccines. Enroll today!

Five Takeaways:

1. Summarize advanced immune signaling pathways to support the evaluation of immunotherapies.
2. Describe how T-cells and B-cells are activated in various disease states to assess therapy targets.
3. Indicate the role of immune checkpoints in cancer to understand the rationale behind checkpoint inhibitor drugs.
4. Compare the immune responses elicited by vaccines versus those induced by natural infection to inform vaccine mechanisms of action.
5. Classify monoclonal antibodies by mechanism to evaluate product pipelines and partnerships.

AGENDA

Non-Specific Immunity
Primary and secondary defense response
Roles of host defense proteins, neutrophils, eosinophils, macrophages, cytokines
PRR, PAMP, DAMP interactions and functions
Cytokine activation of immune cells

Specific Immunity
Specific immune response
Components of the specific immunity
Roles of immunogens, antigens, epitopes
B-cell structures and functions
Plasma cells, memory B-cells, antibodies
T-cell structures and functions
Cytotoxic T-cells, helper T-cells, memory T-cells
Role of cytotoxins

Immune System Activation
Pathogen exposure
Macrophage engagement
Macrophage activation by PAMP
Macrophage present immunogen
Helper T-cell recognize presented immunogen to release cytokines
B-cell activation
Plasma B-cells and antibody release
Memory B-cell production

Gene Therapy Primer

On-Demand Microcourse | Level Two | 90 Minutes
Suggested Prerequisite: The Biology of Biotech
CPE Credits: 2.0

OVERVIEW

Gene Therapy Primer presents the scientific principles and regulatory intricacies of manipulating DNA to cure rare diseases. This class uncovers the mechanics of viral vectors and the thought process behind selecting the perfect vector for each unique application. It provides valuable insight into critical factors determining which diseases are suitable for gene therapy intervention and why. Get an in-depth understanding of the FDA approval process and the rigorous standards used to evaluate the safety and effectiveness of gene therapies. Enroll now in Gene Therapy Primer and become well-versed in this medical revolution!

Five Takeaways:

1. Define gene therapy and its purpose to evaluate therapeutic potential and investment value.
2. List viral and non-viral vectors used for gene delivery to assess development options.
3. Differentiate between vivo and ex vivo gene therapies to understand platform implications.
4. Summarize key safety and regulatory challenges to anticipate development timelines and risks.
5. Classify gene therapies by mechanism to support competitive landscape assessments.

AGENDA

Introduction to Gene Therapy
Genetic basis of human cells
Gene expression
Genetic basis of disease
Causes of monogenic and polygenic diseases
Process of delivering DNA via gene therapy
in vivo vs ex vivo gene therapy
CAR-T therapy
Gene therapy administration
Cell and gene therapy clinical pipeline
Zolgensma and SMA
Medical risks and challenges

Viral Vector Delivery Options
Major viral vector platforms
Vectors of choice
AAVs for different cell types
Targeting non-dividing and dividing cells
AAV neutralizing antibodies

Viral Vector Delivery Options
AAV vector construct
AAV9 for SMA
Manufacturing expression platforms

The Gene Therapy Industry
Gene therapy landscape
Key considerations for a gene therapy company
Ideal gene therapy project traits
Key IP considerations
Gene therapy clinical development pathway
Clinical trial modifications for gene therapy drugs
Determining efficacy: protein quantification
Long-term follow-up: durability
Safety issues: adverse events
Monitoring adverse events
Regenerative medicine advanced therapy designation

Cell Therapy Primer

On-Demand Microcourse | Level Two | 45 Minutes

Suggested Prerequisite: The Biology of Biotech, Gene Therapy Primer

CPE Credits: 1.0

OVERVIEW

Cell Therapy Primer offers a comprehensive introduction to cell therapy development, manufacturing, and commercialization. This class delves into the scientific benefits and challenges of autologous and allogeneic cell therapies. Cell Therapy Primer focuses especially on Chimeric Antigen Receptors (CARs), their proven approach to treating blood cancer, and their potential applications in solid tumors and beyond. The course also introduces stem cell therapies and applications in regenerative medicine. Enroll now to gain an understanding of the groundbreaking potential of cell therapy!

Five Takeaways:

1. Define cell therapy and how it differs from traditional biologics to frame strategic conversations.
2. Recognize the role of stem cells and immune cells in therapy design to assess pipeline relevance.
3. Compare autologous and allogeneic approaches to understand the trade-offs between manufacturing and scalability.
4. Describe the clinical and commercial challenges of cell therapies to evaluate business feasibility.
5. Organize the regulatory approval process for cell therapies to support go-to-market planning.

AGENDA

Introduction to Cell Therapy

First cell therapies
Cell types used for cell therapy
Source of cell types
Autologous and allogenic cell lines
Advantages and disadvantages

Chimeric Antigen Receptor (CAR)

Types of lymphocytes and their functions
MHC molecules and their role in immune response
Types of antigens found on cancer cells
Tactics used by cancer to evade the immune system
The rationale behind designing CAR

Commercial Landscape of CAR-T Cells

Design of CAR-T cells
Production of CAR-T cells
Side effects of CAR-T cell therapy
Advantages and disadvantages of CAR-T cell therapy
Approved CAR-T cell therapy products

Next-Generation Therapies

Attempts to improve existing CAR-T cell therapies
Other cell lines for cell therapy
Stem cell therapy

Biosimilars Primer

On-Demand Microcourse | Level Two | 65 Minutes
Suggested Prerequisite: The Biology of Biotech
CPE Credits: 1.0

OVERVIEW

Biosimilars Primer demystifies the science, manufacturing, and regulatory pathways behind biosimilar drug approval. Explore how protein structure, biologic drug types, and production conditions impact biosimilarity. Learn how companies address safety, immunogenicity, and regulatory requirements through real-world FDA and EMA case studies. Enroll today

Five Takeaways:

1. Define what constitutes a biosimilar to understand regulatory pathways and approval hurdles.
2. Identify the analytical methods used to demonstrate biosimilarity for investor and partner confidence.
3. Compare biosimilars with generics to clarify the differences in their development and commercialization.
4. Describe global biosimilar regulatory frameworks to inform go-to-market strategy.
5. Indicate the economic and strategic value of biosimilars in expanding patient access and market share.

AGENDA

Proteins
Protein types and their functions
  Enzymes, antibodies, receptors
Protein synthesis: transcription and translation
Protein structure and how it determines function
Post-translational modifications
  Purpose of glycosylation and phosphorylation

Biologics
Biologics in healthcare
Characteristics of biologics
Small molecule drugs vs biologics

Biosmilars
The product is the process
Generic vs biosimilar
FDA and EMA biosimilar regulatory process

Manufacturing
Establishing production cell lines
Cell bank types and purposes
Upstream process: seeding and scale-up
Downstream processing: harvesting and purification

Manufacturing *continued*
Biosimilar formulation
Stability studies

Safety and Regulation
Protein complexity
Immunogenicity
Clinical impact of neutralizing and non-neutralizing antibodies
Data exclusivity
Gaining approval for biosimilars
  Preclinical and clinical trials

Biosimilar Case Studies
Case Study 1: Changes In Amino Acid Sequence Affect Properties Of Biologics
Case Study 2: Impurity Profile May Results In Differences In Immunogenicity
Case Study 3: Careful Analysis Of Proposed Biosimilar Product May Detect Significant Differences Before Clinical Trials
Case Study 4: Packaging Changes May Have Serious Safety Consequences

DNA-Based Diagnostics Primer

On-Demand Microcourse | Level Two | 44 Minutes
Suggested Prerequisite: The Biology of Biotech, Diagnostic Measurements Primer
CPE Credits: 1.0

OVERVIEW

DNA-Based Diagnostics Primer is the ultimate guide to the molecular science driving standard diagnostic tools used in research and clinical settings. This primer breaks down the critical technology that drives these diagnostic advancements, including Polymerase Chain Reaction (PCR), microarrays, Next-Generation Sequencing (NGS), and microRNA diagnostics. Each diagnostic tool is thoroughly explained, highlighting its purpose, when it is used, and how it harnesses the power of DNA to detect and analyze specific genetic sequences. This class provides a comprehensive understanding of the scientific principles that underpin DNA-based diagnostics. Gain entry into the fast-paced field of DNA-molecular diagnostics by registering for this course today!

Five Takeaways:

1. Define DNA-based diagnostics and explain their applications in disease detection.
2. List key platforms like PCR, microarrays, and next-generation sequencing, and their impact on diagnostic innovation.
3. Describe how genomic mutations are identified and interpreted to guide clinical care.
4. Summarize the regulatory landscape for DNA-based diagnostics to inform the go-to-market strategy.
5. Classify key applications of DNA-based diagnostics for their clinical and commercial relevance.

AGENDA

Polymerase Chain Reaction (PCR) Technology
Review: DNA structure and sequence
Uses of PCR diagnostics
The science of PCR
Uses of diagnostic DNA probes
DNA sequence detection
DNA probe sensitivity
Methodology for DNA sequence detection
PCR diagnostic
Quantitative real-time PCR (qPCR) diagnostic

Microarray Technology
Review: single nucleotide polymorphism (SNP)
Uses of SNP chip diagnostics
The science of SNP chips
Hybridization assay
SNP chip detection
Reading SNP chip output
SNP chip example: Detecting Alzheimer's disease

Generation Sequencing (NGS) Technology
Uses of NGS diagnostics
The science of NGS
NGS platforms
Reversible dye terminator
Ion semiconductor
Ion torrent
Whole genome sequencing diagnostics

microRNA Technology
Uses of microRNA diagnostics
The science of microRNA
Advantages of microRNA diagnostics
Non-invasive testing methods
Variation detection benefits

Protein-Based Diagnostics Primer

On-Demand Microcourse | Level Two | 40 Minutes
Suggested Prerequisite: The Biology of Biotech, Diagnostics' Role in Medicine Today, Diagnostic Measurements Primer
CPE Credits: 1.0

OVERVIEW

Protein-Based Diagnostics Primer provides a clear overview of key tools used to detect diseases, including ELISA, bead immunoassays, lateral flow assays, and chromatography. Learn how these technologies measure, separate, and analyze proteins in both research and clinical settings. Enroll today to boost your understanding of protein-based diagnostics!

Five Takeaways:

1. Define protein-based diagnostics and their role in biomarker detection and disease monitoring.
2. Identify standard diagnostic methods, such as ELISA, Western blot, and mass spectrometry, to understand their clinical and commercial relevance.
3. Describe the analytical challenges in detecting low-abundance biomarkers accurately.
4. Recognize how protein diagnostics support companion diagnostics and personalized medicine.
5. Outline regulatory and validation steps specific to protein-based assay development.

AGENDA

Defining Protein-Based Diagnostics
Science of biomarkers
Protein-based diagnostic examples

Antibody Technology
Antibody structure and function
Antibody characteristics
Antibodies as quantitative detection reagents
Antibodies detect epitopes
Advantages of antibody detection reagents

Enzyme-Linked Immunosorbent Assay (ELISA) Technology
ELISA uses
Quantitative protein detection
Science of ELISA diagnostics
Reading ELISA multi-well plate results
Multiplexed ELISA
Types of multi-well plates and volumes
Rapid multiplexed analyzers

Bead Immunoassay Technology
Bead immunoassay uses
Science of bead immunoassays
Reading bead immunoassay diagnostics
Cell sorter

Lateral Flow Assay (LFA) Technology
LFA uses
Science of LFA
Reading LFA diagnostics
LFA diagnostic examples

Chromatography Technology
Protein chromatography uses
Types of chromatography
Ion exchange chromatography
Affinity exchange chromatography
Size exclusion chromatography
Reading chromatography diagnostics
Chromatography diagnostic examples

Biopharma Business Acumen Primer

On-Demand Microcourse | Level One | 45 Minutes

Suggested Prerequisite: None

CPE Credits: 1.0

OVERVIEW

Biopharma Business Acumen Primer provides a comprehensive understanding of the business considerations needed to develop and bring a life-saving cure to the marketplace. It begins with an exploration of the financing vehicles and sources required to develop a cure. The class then examines the intricacies of intellectual property management, followed by a focus on lifecycle management strategies for medicines so sponsors can wring out the maximum value of each asset. Biopharma Business Acumen ends by breaking down the complex world of U.S. drug pricing. This course provides the knowledge necessary to navigate the challenges and opportunities in the healthcare field. Enroll today and contribute to the vital mission of bringing cures to those in need!

Five Takeaways:

1. Define core business drivers in biopharma to better understand how scientific decisions impact profitability.
2. Indicate when and which financing sources are likely to occur during drug discovery and development to meet financial needs.
3. List key patent concepts and describe their significance in maximizing intellectual property protection.
4. Describe the various strategies biopharma companies use to extend a drug's life cycle and describe their impact on market longevity.
5. Describe strategic approaches used to price a drug product effectively.

AGENDA

Financing a Cure

Basic financing vehicles
Financing sources
What investments are made when during the development process

IP Management of a Cure

Key patent concepts
Types of patents
Exclusivity law in the U.S.

Lifecycle Management of a Cure

Lifecycle management defined
FDA regulations regarding lifecycle management
Drug revenue post launch
Types of lifecycle management

Financing a Life Science Company Primer

On-Demand Microcourse | Level One | 80 Minutes

Suggested Prerequisite: None

CPE Credits: 2.0

OVERVIEW

Life Science Company Finances Primer explores the economic and funding strategies behind drug development. It examines how biotech startups and academic research serve as innovation hubs for large pharmaceutical companies. Topics include R&D outsourcing, orphan drug incentives, licensing agreements, and the venture capital process. The course also explains financing mechanisms such as NIH grants, equity investments, and IPOs. Participants gain insight into how scientific innovation and financial partnerships drive product development in the life sciences industry. Register today and up your biotech finance acumen!

Five Takeaways:

1. Define the primary funding stages in biotech to understand startup and growth capital needs.
2. List common funding sources to evaluate financial pathways.
3. Describe term sheets, valuations, and equity dilution to inform fundraising negotiations.
4. Compare investor expectations at various stages of development to tailor pitches effectively.
5. Recognize how capital structure impacts long-term strategy and decision-making.

AGENDA

Key Investors Along Development Timeline

Non-profit research institutions

Biotech start-ups

Large biopharma

Finding Technologies

Academic institutions

  Academic licensing

Discovery

In-licensing

Acquisition

Funding Sources

Grants and contracts

Common equity

Convertible debt

Preferred stock

Start-ups/biopharma partnerships

Venture capital

Public markets

Applying for a Life Science Job

On-Demand Microcourse | Level One | 40 Minutes

Suggested Prerequisite: None

OVERVIEW

Applying for a Life Science Job demonstrates the power of a well-crafted resume and cover letter and why both are crucial for landing your dream life science job. This class outlines the step-by-step process of writing a compelling resume and cover letter that stands out from the crowd. It details how to tailor both documents to each opportunity and showcase your unique skills and experiences. The culmination is two exciting, hands-on activities: writing your resume and cover letter! Get ready to excel in your job search—enroll today and unlock your career potential!

Five Takeaways:

1. Define key resume components that effectively highlight both scientific and business acumen.
2. List strategies to tailor resumes and cover letters for life science roles.
3. Recognize how to align experience with job descriptions in the life sciences.
4. Describe methods for identifying and pursuing roles in life science companies.
5. Outline best practices for showcasing transferable skills to break into the industry.

AGENDA

The Ultimate Resume Builder
What is a resume?
Why is a resume important?
Ten-step process to write a resume
Customize your resume
Activity: write your resume

The Art of the Cover Letter
What is a cover letter?
Why is a cover letter important?
Nine-step process to write a cover letter
Customize your cover letter
Activity: write your cover letter

Interviewing for a Life Science Job

On-Demand Microcourse | Level One | 40 Minutes

Suggested Prerequisite: None

OVERVIEW

Interviewing for a Life Science Job showcases proven strategies to prepare for successful interviews with engaging activities to reinforce learning. This class uncovers the significance of self-analysis and explores useful tools, including the renowned Myers-Briggs Personality Test. It teaches how to create an impactful digital profile on LinkedIn and to find job opportunities using suggested job boards. Additionally, this course delves deep into interview preparation—from researching the company to mastering the art of nonverbal communication, which plays a pivotal role in creating positive impressions. The course ends with common interview questions and responses to ensure a polished, professional performance. Be ready to crush your interview and register today!

Five Takeaways:

1. Define the types of interviews used in the life science industry to prepare with confidence.
2. Identify common questions and themes asked by employers to improve response quality.
3. Summarize using the STAR method to structure clear, compelling answers to questions.
4. Describe how to communicate technical and soft skills during interviews.
5. Recognize positives and negatives when evaluating life science job opportunities.

AGENDA

Preparing for the Interview

Analyze your personality
Personality tests
Myers-Briggs Personality Test
Activity: personality test
Creating a digital profile
Activity: create your LinkedIn profile
Finding job openings
Job boards
Activity: searching job boards
Key documents

Facing an Interview

Interview preparation
Research the company
The job description
Dress appropriately
Necessary documents to bring
Body language
The follow-up
Common interview questions and answers
Prepare answers for interview questions

BIOTECH PRIMER

DRUG DEVELOPMENT FOR NON-SCIENTISTS

biotechPrimer
Life Science Training From Industry Experts

Drug Development Immersion

Live | Level Beginner
Two Day Agenda
Customization is available for in-house training

OVERVIEW

Drug Development Immersion explores the commercial, regulatory, and scientific factors that pave the way for a successful drug launch. It begins by comparing the characteristics of small and large molecule drugs, agonist and antagonist drugs, and their desirable qualities. A high-level overview of the nuanced go/no-go decision-making process, where management carefully assesses each drug candidate, is provided. This program unveils the intricacies of regulatory compliance, expedited programs, and special designations. It details the dynamic process of drug development, including trial design options, endpoint choices, and experimental/control group concepts. Drug Development Immersion culminates with real-world evidence initiatives, drug launch best practices, pharmacovigilance expectations, and lifecycle management strategies. Contact us today to learn how to bring this course in-house to your team!

Five Takeaways:

1. Become proficient in the terminology and acronyms used in preclinical and clinical development.
2. States the roles of regulatory agencies worldwide and lists the tools they use to ensure approved drugs are safe and efficacious.
3. Cites the testing criteria in preclinical development that ensure a candidate drug is safe and supports first-in-human clinical trials.
4. Explores the rationale, study design, and special considerations for both traditional and non-traditional clinical trial phases.
5. Discusses the launch process and post-approval drug safety monitoring to ensure continued safety and efficacy for patients.

AGENDA

DAY ONE

Introductions 15 minutes

Setting the Stage 75 minutes
Small and large molecule drug characteristics
Desirable drug characteristics
Agonist and antagonist drugs
Route of administration based on drug type
Traditional drug development pathway
Gene and cell therapy development pathway
Drug development metrics
Chances of success, timelines, and costs

Break 15 minutes

The Business of Drug Development 75 minutes
Integrated drug development process
Stage gates: go/no go decisions
Target product profile
Draft label
Activity: understanding the draft label
U.S. patents and market exclusivity

Lunch 45 minutes

The Regulatory Process 75 minutes
Regulatory agencies and compliance worldwide
PDUFA, GDUFA, BsUFA
Generics and biosimilars approval pathways
FDA/sponsor meeting timeline
FDA expedited programs
Voucher system
FDA and EMA orphan drug designation
EMA user fees and review times
EMA expedited reviews and designations
FDA and EMA approval process
Regulatory compliance

Break 15 minutes

Preclinical Development 60 minutes
Preclinical development pre-IND/CTA
Preclinical data objectives
Safety testing terms
Nonclinical studies
Toxicology, pharmacology, pharmacokinetics
IND/CTA filings
Authorization to proceed to clinical trials

Wrap-Up 15 minutes

DAY TWO

The Players: Who Is Involved? 45 minutes
Subjects, sponsors, investigators
Ethics committees/investigational review board
Informed consent
Contract research organizations
Patient advocacy groups
Data monitoring committees (DMC)
How DMC impacts clinical trials

General Principles: Ethics and Risk 45 minutes
Risk assessment and management
Bias and data integrity
Controlling bias: blinding and randomization

Break 15 minutes

Conduct of Clinical Trials 60 minutes
Clinical research purpose
Introduction to study design elements
Endpoints
Inclusion/exclusion criteria
Placebos and control groups
Adverse events and safety reports
Clinical trial documentation
Data management and trial master files

Clinical Development Phase I 45 minutes
Purpose of Phase I
Design and conduct of Phase I
Selection of dose: MAD and SAD
Phase IA and IB
Bioequivalence trials
Combined Phase I/II

Lunch 45 minutes

Clinical Development Phase II 45 minutes
Purpose of Phase II
Phase IIA and IIB
Randomized control trials
Statistical considerations
Null hypothesis, P value, type 1 and 2 errors
Activity: introduction to clinical statistics

Clinical Development Phase III 45 minutes
Purpose of Phase III
Phase IIIB
Trial designs: parallel, crossover, adaptive
Database cleaning, lock and unblinding
Regulatory application submittal

Clinical Development Phase IV 30 minutes
Real-world evidence initiatives
Launch and lifecycle management
Drug safety and pharmacovigilance

Wrap-Up and Evaluation 15 minutes

Biopharmaceutical Commercialization Immersion

Live | Level Beginner
Two Day Agenda
Customization is available for in-house training

OVERVIEW

Biopharmaceutical Commercialization Immersion explores the strategic aspects of bringing a drug product to market and maximizing its commercial potential. It showcases the different phases of the product life cycle and the real-world decisions that have a profound impact on a drug's success. From early planning to pre-launch activities, this program uncovers the secrets to evaluating opportunities and creating a brand that resonates with a target disease audience. It navigates the world of health economics, teaches cost-effectiveness analysis, and maximizes a workflow for patient access to the drug product. Call us today to learn how we can bring an immersive learning experience to your team!

Five Takeaways:

1. Identifies key commercialization success factors and their value as a core, differentiating competency.
2. Showcases a commercialization "toolbox" that can be immediately and practically applied.
3. Explores a comprehensive understanding of the product launch process.
4. Recognizes key issues, opportunities, and challenges of an effective commercialization strategy and tactics.
5. Discusses tools needed to build compelling value-demonstration stories that help optimize reimbursement and market access.

AGENDA

DAY ONE

Introductions 20 minutes

Introduction to Commercialization
70 minutes
Strategic commercialization: what it is and isn't
Product life cycle phases: timing and activities
Decisions affecting commercial potential
Optimizing commercial value

Break 15 minutes

Early Planning 75 minutes
Early product planning activities
Evaluating an opportunity
Developing a target product profile (TPP)
Market sizing: assessing commercial potential
Activity: how the TPP informs the drug label which informs promotional claims

Lunch 45 minutes

Pre-Launch Planning 90 minutes
Pre-launch activities
Creating the brand SWOT
Insight-driven market research
Leveraging data to inform strategic decisions
Mapping the patient journey
Differentiated brand positioning
Building a value proposition to engage customers

Break 15 minutes

Pre-Launch Planning *(continued)* 45 minutes
Case Study: Cialis vs Viagra
Business strategies: 5 key questions to ask
Creating a strategic brand plan
Activity: uncovering the strategic plan

Wrap-Up 15 minutes

DAY TWO

Creating the Value Proposition 90 minutes
Leveraging health economics to create value
Pay for performance models
Optimizing value of hecon assessment
Real-world initiatives
Pharmacoeconomics
Cost-effectiveness analysis
Health technology assessments
Ensuring patients have access to your product

Break 15 minutes

Launch Planning 45 minutes
Launch planning activities
Market access
Value-based payment models
Disease education, premarket development
Scientific pillars and key messages
FDA guidelines covering promotions and advertising

In-Line Planning 45 minutes
In-line planning activities
Key performance indicators (KPI)
Critical success factors
Post launch threats

Lunch 45 minutes

Building and Sustaining Competitive Advantage 60 minutes
Commercial drivers, levers, and key success factors
Lifecycle management challenges
Risk management strategies
Multichannel marketing
Key elements of customer engagement model
Marketing mix resource allocation
Developing key brand performance measures

Break 15 minutes

Loss of Exclusivity (LOE) Commercialization Planning 45 minutes
LOE planning activities
LOE timing considerations
Market dynamics and regulatory challenges
LOE strategies

Wrap-Up and Evaluation 30 minutes

Commercialization Readiness from Preclinical to First Launch

Live | Level Beginner

Half-Day Agenda

Customization is available for in-house training

OVERVIEW

Commercialization Readiness from Preclinical to First Launch will equip early-stage biotechnology leaders and their teams with the commercialization knowledge they need to strategically position their organizations for financing success and meeting critical Commercial and Medical Affairs milestones. Beginning with Phase I, this interactive program will cover the phase-specific commercialization activities and preparation emerging companies need to make for a successful first launch, including market analysis with competitive landscape assessment, the commercialization roadmap development including launch critical success factors, FTEs and dollar spend required for launch, market access pricing and reimbursement, value proposition development, and go-to-market preparation and regulatory considerations. Contact us today and bring this training in-house so you and your team can learn strategies for a successful launch!

Five Takeaways:

1. Articulates the reasons behind the failure of most commercial launches to help improve strategies and increase the chances of success.
2. Examines the impact of the IRA on development portfolios to provide insights into resource optimization, allocation, and portfolio performance enhancement.
3. Provides a well-defined commercialization roadmap to guide a successful product launch and ensure a smooth transition from development to market.
4. Explains market access, pricing, and reimbursement strategies for effectively positioning a product in the market, ensuring its affordability and availability to patients.
5. Explores the creation of a competent sales force and a strong distribution network for successfully launching and promoting a product in the market.

AGENDA

Why Most Commercial Launches Fail 30 minutes

Commercial Imperatives That Impact Value: Preclinical – Phase I 60 minutes

Target product profiles and differentiation
"Defensible" revenue forecasting
Impacts of the IRA on development portfolios
Portfolio prioritization
ISAN naming
Early commercialization visioning

Break 15 minutes

Commercial and Medical Affairs Imperatives: Phase II–Phase III (pre-data) 60 minutes

Commercialization roadmap: the commercial vision and costs (to inform corporate strategy)
MD, payer, and HEOR market research: key inputs for pivotal trial design
KOL development
Scientific narrative
MSL
Key hires
Commercialization alternatives

Lunch 60 minutes

Commercial and Medical Affairs Imperatives: Positive Data Readout to Launch 50 minutes

Updated commercial assessment (revenue forecast)
Product strategy and marketing
Market access, pricing, and reimbursement (MAPR)
Health economics and outcomes research
Sales force
Distribution
Commercial ops and analytics
Training

Medical Affairs Imperatives 55 minutes

Scientific narrative, KOLs, and publication planning
Medical education
Medical affairs (Phase IV's & ISTs, pharmacovigilance)
Launch critical success factors
Brand name
Branding
Value proposition
Information technology
Hiring plan

Life Cycle Management 30 minutes

Course Wrap-Up and Evaluation 15 minutes

Deep Dive Drug Development Immersion

Recorded Live | Level Beginner
9 Hours | 11 Courses
CPE Credits: 11.5

OVERVIEW

Deep Dive Drug Development Immersion features the same content, interactive exercises, and materials as the live version.

Drug Development Immersion explores the commercial, regulatory, and scientific factors that pave the way for a successful drug launch. It begins by comparing the characteristics of small and large molecule drugs, agonist and antagonist drugs, and their desirable qualities. A high-level overview of the nuanced go/no-go decision-making process, where management carefully assesses each drug candidate, is provided. This course bundle unveils the intricacies of regulatory compliance, expedited programs, and special designations. It details the dynamic process of drug development, including trial design options, endpoint choices, and experimental/control group concepts. Drug Development Immersion culminates with real-world evidence initiatives, drug launch best practices, pharmacovigilance expectations, and lifecycle management strategies. Register today and up your drug development acumen!

Five Takeaways:

1. Provides the terminology and acronyms used in preclinical and clinical development.
2. States the roles of regulatory agencies worldwide and lists the tools they use to ensure approved drugs are safe and efficacious.
3. Cites the testing criteria in preclinical development that ensure a candidate drug is safe and supports first-in-human clinical trials.
4. Explores the rationale, study design, and special considerations for both traditional and nontraditional clinical trial phases.
5. Discusses the launch process and post-approval drug safety monitoring to ensure continued safety and efficacy for patients.

AGENDA

COURSE ONE

Setting the Stage 95 minutes

Small and large molecule drug characteristics
Desirable drug characteristics
Agonist and antagonist drugs
Route of administration based on drug type
Traditional drug development pathway
Gene and cell therapy development pathway
Drug development metrics
Chances of success, timelines, and costs

COURSE TWO

The Business of Drug Development 25 minutes

Integrated drug development process
Stage gates: go/no go decisions
Target product profile
Draft label
Activity: draft label
U.S. patents and market exclusivity

COURSE THREE

The Players: Who Is Involved 40 minutes

Subjects, sponsors, investigators
Ethics committees/investigational review board
Informed consent
Contract research organizations
Patient advocacy groups
Data monitoring committees (DMC)
How DMC impacts clinical trials

COURSE FOUR

General Principles: Ethics and Risk 25 minutes

Risk assessment and management
Bias and data integrity
Controlling bias: blinding and randomization

COURSE FIVE

The Regulatory Process 80 minutes

Regulatory agencies and compliance worldwide
PDUFA, GDUFA, BsUFA
Generics and biosimilars approval pathways
FDA/sponsor meeting timeline
FDA expedited programs
Voucher system
FDA and EMA orphan drug designation
EMA user fees and review times
EMA expedited reviews and designations
FDA and EMA approval process
Regulatory compliance

COURSE SIX

Preclinical Development 80 minutes

Preclinical development pre-IND/CTA
Preclinical data objectives
Safety testing terms
Nonclinical studies
Toxicology, pharmacology, pharmacokinetics
IND/CTA filings
Authorization to proceed to clinical trials

COURSE SEVEN

Conduct of Clinical Trials 75 minutes

Clinical research purpose
Introduction to study design elements
Endpoints
Inclusion/exclusion criteria
Placebos and control groups
Adverse events and safety reports
Clinical trial documentation
Data management and trial master files

COURSE EIGHT

Clinical Development Phase I 30 minutes

Purpose of Phase I
Design and conduct of Phase I
Selection of dose: MAD and SAD
Phase IA and IB
Bioequivalence trials
Combined Phase I/II

COURSE NINE

Clinical Development Phase II 25 minutes

Purpose of Phase II
Phase IIA and IIB
Randomized control trials
Statistical considerations
  Null hypothesis, P value, type 1 and 2 errors
Activity: introduction to clinical statistics

COURSE TEN

Clinical Development Phase III 50 minutes

Purpose of Phase III
Phase IIIB
Trial designs: parallel, crossover, adaptive
Database cleaning, lock, and unblinding
Regulatory application submittal

COURSE ELEVEN

Clinical Development Phase IV 15 minutes

Real-world evidence initiatives
Launch and lifecycle management
Drug safety and pharmacovigilance

Evaluation 20 minutes

Deep Dive Biopharmaceutical Commercialization Immersion

Recorded Live | Level Beginner
8 Hours | 8 Courses
CPE Credits: 10

OVERVIEW

Biopharmaceutical Commercialization Immersion course features the same content, interactive exercises, and course materials as the live version.

Biopharmaceutical Commercialization Immersion explores the strategic aspects of bringing a drug product to market and maximizing its commercial potential. It showcases the different phases of the product life cycle and the real-world decisions that have a profound impact on a drug's success. From early planning to pre-launch activities, this course bundle uncovers the secrets to evaluating opportunities and creating a brand that resonates with a target disease audience. It navigates the world of health economics, teaches cost-effectiveness analysis, and maximizes a workflow for patient access to the drug product. Register today and learn how to commercialize a drug product successfully!

Five Takeaways:

1. Identifies key commercialization success factors and their value as a core, differentiating competency.
2. Provides a commercialization "toolbox" that can be immediately and practically applied.
3. Explains a comprehensive understanding of the product launch process.
4. Showcases key issues, opportunities, and challenges of an effective commercialization strategy and tactics.
5. Explores tools needed to build compelling and effective value-demonstration stories that help optimize reimbursement and market access.

AGENDA

COURSE ONE

Introduction to Commercialization 67 minutes

Strategic commercialization: what it is and isn't
Product lifecycle phases: timing and activities
Decisions affecting commercial potential
Optimizing commercial value

COURSE TWO

Early Planning 72 minutes

Early product planning activities
Evaluating an opportunity
Developing a target product profile (TPP)
Market sizing: assessing commercial potential
Activity: how the TPP informs the drug label which informs promotional claims

COURSE THREE

Pre-Launch Planning 107 minutes

Pre-launch activities
Creating the brand SWOT
Insight-driven market research
Leveraging data to inform strategic decisions
Mapping the patient journey
Differentiated brand positioning
Building a value proposition to engage customers
Case Study: Cialis vs Viagra
Business strategies: 5 key questions to ask
Creating a strategic brand plan
Activity: Uncovering the strategic plan

COURSE FOUR

Creating the Value Proposition 97 minutes

Leveraging health economics to create value
Pay for performance models
Optimizing value of the HECON assessment
Real-world initiatives
Pharmacoeconomics
Cost-effectiveness analysis
Health technology assessments
Ensuring patients have access to your product

COURSE FIVE

Launch Planning 57 minutes

Launch planning activities
Market access
Value-based payment models
Disease education, premarket development
Scientific pillars and key messages
FDA guidelines covering promotions and advertising

COURSE SIX

In-Line Planning 20 minutes

Key performance indicators
Post-launch threats

COURSE SEVEN

Building and Sustaining Competitive Advantage 21 minutes

Lifecycle management challenges
Risk management strategies
Multichannel marketing
Developing key brand performance measures

COURSE EIGHT

Loss of Exclusivity 23 minutes

Commercialization planning
LOE timing considerations
LOE strategies
Market dynamics
Regulatory challenges

Evaluation 20 minutes

Deep Dive Drug Pricing, Policy, and Utilization Immersion

Recorded Live | Level Beginner
5 Hours | 5 Courses
CPE Credits: 6.5

OVERVIEW

Drug Pricing, Policy, and Utilization Immersion course features the same content, interactive exercises, and course materials as the live version.

Drug Pricing, Policy, and Utilization Immersion exposes the complexities of the United States healthcare market by detailing how competing forces, including the U.S. Federal government, the insurance industry, and healthcare providers, influence formulary systems, which in turn determine how patients access, use, and pay for medications. It delves deep into the intertwining pharmacoepidemiology and pharmacoeconomic data from commercial and government databases that shape drug policy and pricing. This interactive course bundle presents basic cost-effectiveness and quality of life calculation exercises to highlight the types of decisions faced by various drug development teams. Created and taught by a distinguished healthcare economist and social scientist, this engaging program is a must for anyone new to healthcare policy and pricing—grab your seat today!

Five Takeaways:

1. Defines foundational pricing concepts to understand how therapies are valued across healthcare systems.
2. Identifies the roles of payers, PBMs, and government agencies in shaping drug access and affordability.
3. Describes U.S. pricing policies to assess their impact on commercialization strategy.
4. Summarizes how real-world utilization and health economics data inform reimbursement decisions.
5. Outlines policy trends and reforms to anticipate risks and opportunities in global pricing environments.

AGENDA

COURSE ONE

Setting the Stage 30 minutes
Clinical development overview
FDA adverse events reporting system

COURSE TWO

Drug Placement Into Formularies 60 minutes
Types of formulary systems
Considerations and issues for placement
Value proposition and drug price
Medicare, Medicaid, private insurers
Single payer markets
Pharmacy benefits manager role
Manufacturer rebates
Tiering systems, prior authorization, step therapy
Patient adherence considerations

COURSE THREE

Pharmacoepidemiology and Drug Use Safety 60 minutes
Pharmacoepidemiology
Individual and population drug safety
Prospective drug utilization evaluation
Retrospective drug utilization review
Drug use research using commercial databases
Drug use research using federal databases
Evidence-based medicine
Development of drug use guidelines

COURSE FOUR

Pharmacoeconomics 60 minutes
Health economics
Cost-of-illness analysis
Cost-minimization analysis
Cost-benefit analysis
Cost-effectiveness analysis
Cost-utility analysis
Quality of life evaluation
Quality-adjusted life years

COURSE FIVE

Drug Pricing and Marketing 60 minutes
Pricing strategies
Brand and generic/biosimilar drugs
Drug product lifecycle
Pricing surveys, pricing companies
Economic complements and substitutes
Specific buyers' contracts (VA, 340b program)
Price discrimination abilities
Marketing strategies
Patient assistance programs
Role of direct-to-consumer advertising

Evaluation 20 minutes

Small Molecule Drug Discovery Primer 101

On-Demand Microcourse | Level One | 55 Minutes
Suggested Prerequisite: None
CPE Credits: 1.0

OVERVIEW

Small Molecule Drug Discovery Primer 101 teaches the essential steps to finding and bringing new compounds to market. From identifying potential drug targets to optimizing lead compounds, this class illustrates how scientists refine small molecule drugs before they undergo preclinical and clinical trials. Learn how proven techniques, such as computational modeling, in vitro testing, and animal studies, are essential in identifying promising medicinal options. Don't miss this opportunity to become conversant in the fast-paced world of pharmaceutical research!

Five Takeaways:

1. Define small molecule drugs and how they interact with biological targets to inform product assessments.
2. Classify small molecule drug types to understand product differentiation in the market.
3. Describe the basic steps of the small molecule drug discovery process to establish a foundation for understanding the biopharmaceutical industry.
4. List characteristics of druggable targets to align with early-stage investment priorities.
5. Recognize the role of high-throughput screening in identifying drug candidates to support the R&D strategy.

AGENDA

Introduction to Drug Discovery
Types of drugs
Drug target and drug candidate defined
Small molecule drug characteristics
Drug efficacy vs effectiveness
Drug discovery cost and success rates
Drug discovery workflow
Drug development stages

Drug Targets
Drug target identification
In silico, in vitro, in vivo testing
Genetic evaluation
Choosing a target

Drug Targets continued
Target validation
RNAi testing
Reproducibility

Drug Candidates
Drug candidate identification
High-throughput screening
Computer-aided drug design
Lead candidate selection
Drug candidate's desirable characteristics
Lead candidate optimization
Drug discovery to preclinical development

Small Molecule Drug Discovery Primer 201

On-Demand Microcourse | Level Two | 55 Minutes

Suggested Prerequisite: Small Molecule Drug Discovery Primer 101

CPE Credits: 1.0

OVERVIEW

Small Molecule Drug Discovery Primer 201 builds upon the foundational knowledge from Small Molecule Drug Discovery Primer 101. This class takes a deep dive into early screening techniques, including discovery platforms, high-throughput screening, and novel target identification. It breaks down the strategies used for lead optimization, along with drug design methodology and approaches. Uncover the crucial criteria for transitioning from discovery to development, including how to rigorously evaluate data from in silico, in vitro, and in vivo assets. Join Small Molecule Drug Discovery Primer 201 and continue to increase your pharmaceutical research knowledge!

Five Takeaways:

1. Identify structure-activity relationships (SAR) to understand the rationale behind candidate selection.
2. Compare in vitro and in vivo models used during discovery to assess data quality and risk.
3. Summarize key metrics for potency, selectivity, and ADME to support investment decisions.
4. Outline the iterative process of medicinal chemistry to appreciate development timelines.
5. Differentiate hit identification from lead optimization to engage in more strategic pipeline discussions.

AGENDA

Overview
Steps in drug discovery
Screening considerations
Bringing a new therapeutic to market

Early Screening
Drug discovery platforms
Target identification processes
High-throughput screening

Target Validation
Target validation processes
Target selection

Lead Optimization Criteria
Screening strategies and pathways
Lead optimization
Drug design methods and approaches

Discovery to Development Transition Criteria
In silico, in vitro, and in vivo data criteria
Safety and efficacy

Drug Discovery of Biologics Primer 101

On-Demand Microcourse | Level One | 45 Minutes
Suggested Prerequisite: None
CPE Credits: 1.0

OVERVIEW

Drug Discovery of Biologics Primer 101 is a must-have class for those new to medicines derived from living organisms. It delves deep into the five-step drug discovery process, spanning target identification and verification to candidate identification, validation, and optimization. This class reveals the utility of in silico, in vitro, and in vivo disease models in elucidating functional pharmacology activity. Drug Discovery of Biologics Primer 101 ends by demonstrating how the data analysis is used to make crucial candidate drug 'go' or 'no-go' decisions. Seize this opportunity to learn the fundamentals of biologics drug discovery. Reserve your spot now!

Five Takeaways:

1. Compare the characteristics of small molecule drugs and biologics to establish a foundation to understand the biopharma industry.
2. Define biologics and how they interact with drug targets to inform product assessments.
3. Describe the basic steps of the biologics drug discovery process to establish a foundation for understanding the biopharmaceutical industry.
4. State the average time and cost to discover a biologic to support accurate budgeting and resource planning.
5. List the methodologies used in drug target identification and validation to anticipate preclinical resource needs.

AGENDA

Overview
Drug discovery, development, and commercialization process
Activities, costs, and timing

Early Selection, Target ID, and IgG Subtypes
Small and large molecule drug comparison
Antibody production, selection, and humanization
Target identification processes
Antibody screening considerations

Affinity Maturation and Pharmaceutical Liabilities
Structure based affinity maturation
CMC liabilities in antibodies

Antibody Diversity and Alternative Formats
Antibody therapeutic classes
Immune checkpoint inhibitors
Antibody classes in R&D

Discovery to Development and Transition Criteria
Targeted decision making data analysis
Transition criteria for biologic development candidates

Drug Discovery of Biologics Primer 201

On-Demand Microcourse | Level Two | 45 Minutes
Suggested Prerequisite: Drug Discovery of Biologics Primer 101
CPE Credits: 1.0

OVERVIEW

Drug Discovery of Biologics Primer 201 provides a deeper look into therapeutic antibody discovery, focusing on screening, affinity maturation, and CMC considerations. Explore four key antibody classes, including checkpoint inhibitors, and learn how early data drives candidate selection and transition to preclinical development. Enroll today to advance your expertise in biologic drug discovery!

Five Takeaways:

1. Summarize the discovery workflow to establish a foundation for understanding the biotech industry.
2. Indicate the assays and data needed to enable go/no-go investment decisions when choosing a drug candidate.
3. Differentiate between the master and working cell banks to anticipate resource needs.
4. Recognize biologics-specific CMC considerations that impact the development timeline and cost.
5. List the transition criteria to assess if a drug candidate falls within the predicted parameters for development success.

AGENDA

Drug Discovery Workflow
Drug target identification
Drug target validation
Drug candidate identification
Lead candidate selection
Lead candidate optimization
Preclinical development overview
Clinical development overview

Affinity Maturation and CMC Liabilities
Structure-based affinity maturation
Targeted diversification methods
Chain shuffling
Formulation
CMC liabilities
Aggregation, Solubility, Immunogenicity

Early Drug Candidate Selection
Drug size and complexity
Drug target interaction
Discovery process criteria

Early Drug Candidate Selection *continued*
In silico, in vitro, and in vivo models
Human immunoglobulin functions and structures
Fc and Fab regions

Antibody Diversity
Therapeutic antibody classes
Canonical blocking antibodies, ADCs, Reactivators of the immune response, Antibody-like molecules
Cell banking: Master and working cell banks

Discovery to Development Criteria
In vitro quantitative activity profile
In vitro ADME studies
Pharmacokinetic studies
In vivo efficacy studies
Pharmacokinetic biomarkers
Pilot safety/toxicity studies
Comparative genetics
Clinical dose estimation
Candidate transition criteria

Preclinical Development Primer 101

On-Demand Microcourse | Level One | 55 Minutes
Suggested Prerequisite: Small Molecule Drug Discovery Primer 101, Drug Discovery of Biologics 101
CPE Credits: 1.5

OVERVIEW

Preclinical Development Primer 101 introduces the key steps and standards of early-stage drug development before clinical trials begin. Learn how pharmacology, PK/PD, and toxicology shape a strong drug candidate, and explore the IND application process. Join now to build your foundation in preclinical development!

Five Takeaways:

1. Define preclinical development and its purpose in reducing the risk of clinical entry.
2. Itemize the types of safety and efficacy studies required before IND submission.
3. Describe pharmacokinetics and pharmacodynamics (PK/PD) studies to assess biological behavior.
4. Recognize the importance of GLP compliance to ensure regulatory acceptance.
5. Summarize key milestones and decision points in preclinical development to inform investment planning.

AGENDA

The Big Picture
Development timing and costs
In silico, in vitro, in vivo studies
Safety and efficacy endpoints
Preclinical short term studies
Animal models

Pharmacology
Pharmacology defined
Pharmacology: Antagonists and agonist drugs
Pharmacology measurements
Binding, potency, and efficacy assays
Dose-response curves
Receptor occupancy assay

Pharmacokinetics and Pharmacodynamics
Pharmacokinetics explained
Measuring pharmacokinetics
Pharmacokinetics: absorption and metabolism
Measuring pharmacodynamics
Regulatory requirements
GXP compliance
Bioanalytical assay: small/large molecule drugs
Validation timeline

Toxicology
Preclinical design schedule
Dose level selection
Routes of exposure and formulation
Species selection and three R's
Survey of main toxicology studies
Therapeutic margin and adverse events
Toxicology study data and its interpretation

Preclinical IND/CTA
Common technical document
IND and CTA filings
Types of INDs
FDA animal rule
Interpretation

Preclinical Development Primer 201

On-Demand Microcourse | Level Two | 55 Minutes
Suggested Prerequisite: Preclinical Development Primer 101
CPE Credits: 1.0

OVERVIEW

Preclinical Development Primer 201 builds on the basics with real-world examples of the data and tests needed for a successful IND submission. Explore key efficacy and safety studies—like pharmacology, ADME, hERG, DART, and more—and learn how to assess results for therapeutic margin and dosing. Enroll now to deepen your understanding of preclinical testing strategies!

Five Takeaways:

1. Describe the major preclinical and clinical development phases.
2. Correlate dose level and ROA in animals to humans to ensure translational relevance.
3. Compare IND-enabling study design across therapeutic areas for program optimization.
4. Outline preclinical data requirements for global regulatory submissions.
5. Calculate how sample study size impacts therapeutic margins and adverse reactions for regulatory strategy.

AGENDA

Overview
Drug development metrics
Preclinical development overview
Investigational New Drug (IND)
Clinical Trial Application (CTA)
Pre-IND: pharmacology, PK, toxicology

Pharmacology
Binding assay: Law of Mass Action
Potency assay: Dose-response curves
Efficacy assay: Full, partial, inverse agonist, and antagonist drugs
Antagonist and agonist drug MOA
Product design: ROA, acute vs chronic, dose, container

Pharmacokinetics
ADME
GXP compliance: GLP, GMP, GCP
Bioanalytical assay: API concentration
Bioanalytical assay workflow and timeline
Validation and qualification criteria
PK and PD measurements

Toxicology
Animal model/species selection
Concordance of animal and human toxicities
Differences between animals and humans: Subjects, doses, diagnostic procedures
Preclinical testing: Mutagenicity, hERG, acute/chronic toxicity, safety pharmacology, PK, PD, ADME, DART, carcinogenicity testing
Therapeutic margin
Adverse effects
Example: 1 month rat study analysis

Nonclinical IND/CTA
Filing IND/CTA
Common technical document
Module 2 summaries
Module 4 reports
FDA's animal rule

Drug Approval Primer

On-Demand Microcourse | Level One | 60 Minutes
Suggested Prerequisite: None
CPE Credits: 1.0

OVERVIEW

Drug Approval Primer offers a comprehensive overview of how small molecule drugs and biologics receive the regulatory green light for human use. With greater emphasis on the FDA, this class aims to demystify the game-changing Prescription Drug User Fee Act (PDUFA) and provide step-by-step guidance on the drug development application process. From the preclinical Investigational New Drug Application (IND) to the post-clinical New Drug Application (NDA) and Biologic License Applications (BLA), this primer covers each stage. It showcases the FDA meeting and response timeline, the tools used to enforce its laws, and strategies to expedite approvals for life-saving medicines. Acquire the regulatory knowledge needed to successfully navigate the drug approval process with the Drug Approval Primer microcourse. Grab your spot today to gain insights into the process of bringing new drugs to market!

Five Takeaways:

1. Compare regulatory approval pathways in the U.S. and EU to inform global development strategies.
2. List major FDA submission types, including IND, NDA, BLA, and their business implications.
3. Summarize the roles of the FDA and EMA in drug evaluation to align expectations across markets.
4. Differentiate between accelerated, breakthrough, and fast-track designations for strategic positioning.
5. Recognize how regulatory milestones impact valuation and funding decisions.

AGENDA

Introduction to the Regulatory Process
FDA and EMA organization and mission
Global harmonization drug testing requirements

IND/CTA Filing
IND and CTA applications
Types and timing of IND filing

User Fee Programs
PDUFA in conjunction with drug manufacturers, the FDA, and patients
FDA and EMA interactions with industry

Orphan Drugs and Expedited Pathways
Criteria for speeding up drug reviews
FDA and EMA orphan drug pathways

Market Approval
NDA and BLA approval pathways
MMA approval pathways
Generics approval pathway
Biosimilar approval pathway

Clinical Development 101: General Principles

On-Demand Microcourse | Level One | 55 Minutes
Suggested Prerequisite: Preclinical Development Primer 101, Preclinical Development Primer 201, Drug Approval Primer
CPE Credits: 1.0

OVERVIEW

Clinical Development 101: General Principles sets the stage for the entire Biotech Primer clinical development series by covering the essential terms, milestones, and considerations needed to understand the clinical development process. This Primer dives into the core principles of current Good Clinical Practices and how to manage risk for study volunteers. Clinical Development 101 focuses on the most relevant study designs, inclusion/exclusion criteria for selecting participants, and ethical considerations that must be met. The class ends by establishing master data management and reporting standards required for regulatory filings. Register now for Clinical Development 101: General Principles and establish a baseline understanding of clinical trials.

Five Takeaways:

- Define the four phases of clinical trials to frame the drug development lifecycle.
- Outline key protocol elements to support understanding of clinical trial design.
- Identify the roles of sponsors, CROs, and investigators to navigate partnerships effectively.
- Summarize Good Clinical Practice (GCP) guidelines to ensure quality and compliance.
- Categorize clinical trial endpoints to evaluate study outcomes and ROI.

AGENDA

Clinical Development Introduction
Drug development milestones
Clinical research and clinical studies
Streamlining development in evidence-based medicine, translational medicine, and patient centric trials

Clinical Trials: Basic Principles
Core principals of good clinical practices (GCP)
Risk management in clinical trials
Clinical trial designs

Conducting Clinical Trials
Inclusion and exclusion criteria
Institutional review boards
Clinical trial data management
Clinical trial data reporting

Clinical Development 201: Phase I

On-Demand Microcourse | Level Two | 50 Minutes
Suggested Prerequisite: Clinical Development 101
CPE Credits: 1.0

OVERVIEW

Clinical Development 201: Phase I provides insights into Phase 0 and Phase I clinical trials, including their purpose and regulatory requirements. This microcourse showcases the indispensable role of gathering preliminary pharmacokinetics and pharmacodynamics data to determine the appropriate dosage of experimental treatments. Strategies of Single Ascending Dose (SAD), Multiple Ascending Doses (MAD), and Maximum Tolerated Dose (MTD) protocols are explained in thorough detail. Clinical Development 201 outlines how researchers vigilantly monitor participants, meticulously collect vital safety data, and expertly evaluate the effectiveness of new treatments using well-defined endpoints. Don't miss this opportunity to enhance your clinical trials expertise. Enroll now to secure your seat!

Five Takeaways:

1. Describe the purpose of Phase I trials in assessing safety, tolerability, and dosing.
2. List common Phase I study designs, including SAD and MAD, to inform regulatory requirements.
3. Differentiate healthy volunteer studies from patient trials to support protocol review.
4. Recognize key success metrics in Phase I to anticipate progression risks.
5. Outline regulatory interactions required during Phase I to streamline timelines.

AGENDA

Clinical Trial Prerequisites
Preclinical to Phase I clinical trials
Clinical trial sequencing
IRB, IB, IND, and CTA requirements

Phase 0/I Study Designs and Objectives
Phase 0 clinical trials
Phase I clinical trials
Bioequivalence studies

Phase I Conducting the Clinical Study
Maximum tolerated dose (MTD), single ascending dose (SAD), multiple ascending dose (MAD), pharmacokinetics, and pharmacodynamics data
Endpoints assessed in Phase I clinical trials
Clinical trial safety reports

Clinical Development 301: Phase II/III

On-Demand Microcourse | Level Three | 55 Minutes

Suggested Prerequisite: Clinical Development 101, Clinical Development 201

CPE Credits: 1.5

OVERVIEW

Clinical Development 301: Phase II/III focuses on the purpose and critical differences between well-controlled Phase II and III studies. This microcourse expertly explains the art of trial design and how each protocol measures efficacy via primary and secondary endpoints. Section two focuses on pharmacovigilance and the pivotal role of independent Data Safety Monitoring Boards who exhaustively review data to make critical recommendations about trial continuation, modification, or termination. Clinical Development 301 reveals the regulatory considerations of special designations that can accelerate the drug candidates' development. The class ends with an explanation of the New Drug Application (NDA) and Biologics License Application (BLA) that must be filed with and approved by the FDA to receive drug marketing approval. Join us to continue building your expertise in clinical development!

Five Takeaways:

1. Summarize the objectives of Phase II and III trials in establishing efficacy and confirming safety.
2. Compare Phase II proof-of-concept with Phase III confirmatory studies to guide expectations.
3. Define primary and secondary endpoints used in pivotal trials to assess go/no-go investment decisions.
4. Indicate enrollment and retention challenges that can delay development.
5. Describe how statistical plans and sample sizes impact regulatory acceptance and commercialization.

AGENDA

Phase II/III Introduction

Transition from Phase I to Phases II and III
Elements of a well controlled clinical trial
Primary, secondary, and surrogate endpoints

Phase II/III Objective and Design

Phase II and Phase III clinical trial characteristics and endpoints
Pivotal study, adaptive trial, basket trial, and umbrella trial
Data safety monitoring board function

Phase II/III Special Designations

FDA orphan drug designations, EMA orphan drug status, and EU prime designation
Clinical development for rare disease therapy

Clinical Development 401: Phase IV

On-Demand Microcourse | Level Three | 50 Minutes
Suggested Prerequisite: Drug Approval Primer, Clinical Development 101, Clinical Development 201, Clinical Development 301
CPE Credits: 1.0

OVERVIEW

Clinical Development 401: Phase IV uncovers what happens after a new drug gains approval and enters the marketplace. This class, the 4th and final in the comprehensive Biotech Primer Clinical Development series, exposes the crucial role of regulatory agencies in protecting public health by monitoring all drugs' pharmacovigilance in real-world conditions. The FDA's safety information and adverse events reporting program called MedWatch is highlighted. Don't miss out on this opportunity to be informed on post-approval drug considerations. Complete your understanding of the clinical trial process by signing up for Clinical Development 401: Phase IV today!

Five Takeaways:

1. Define the purpose of Phase IV trials in monitoring long-term safety and real-world effectiveness.
2. List data types collected in post-marketing studies to assess product value.
3. Identify pharmacovigilance obligations that impact regulatory compliance and brand trust.
4. Summarize how Phase IV studies support competitive advantage.
5. Recognize strategic uses of Phase IV for market expansion and lifecycle management.

AGENDA

Post Approval Clinical Trials
Key clinical milestones in drug development
Phase IV clinical trials
Limitations of Phase I-III clinical trials

Pharmacovigilance and Post-Marketing Safety Follow-Up
Drug safety: pharmacovigilance
Safety detection and analysis
Regulatory actions: post-approval risk mitigation

Real-World Evidence
Real-world evidence initiatives
Real-world data supporting regulatory decision making

Biopharma Business Acumen Primer

On-Demand Microcourse | Level One | 45 Minutes

Suggested Prerequisite: None

CPE Credits: 1.0

OVERVIEW

Biopharma Business Acumen Primer provides a comprehensive understanding of the business considerations needed to develop and bring a life-saving cure to the marketplace. It begins with an exploration of the financing vehicles and sources required to develop a cure. The class then examines the intricacies of intellectual property management, followed by a focus on lifecycle management strategies for medicines so sponsors can wring out the maximum value of each asset. Biopharma Business Acumen ends by breaking down the complex world of U.S. drug pricing. This course provides the knowledge necessary to navigate the challenges and opportunities in the healthcare field. Enroll today and contribute to the vital mission of bringing cures to those in need!

Five Takeaways:

1. Define core business drivers in biopharma to better understand how scientific decisions impact profitability.
2. Indicate when and which financing sources are likely to occur during drug discovery and development to meet financial needs.
3. List key patent concepts and describe their significance in maximizing intellectual property protection.
4. Describe the various strategies biopharma companies use to extend a drug's life cycle and describe their impact on market longevity.
5. Describe strategic approaches used to price a drug product effectively.

AGENDA

Financing a Cure

Basic financing vehicles

Financing sources

What investments are made when during the development process

IP Management of a Cure

Key patent concepts

Types of patents

Exclusivity law in the U.S.

Lifecycle Management of a Cure

Lifecycle management defined

FDA regulations regarding lifecycle management

Drug revenue post launch

Types of lifecycle management

Financing a Life Science Company Primer

On-Demand Microcourse | Level One | 80 Minutes

Suggested Prerequisite: None

CPE Credits: 2.0

OVERVIEW

Life Science Company Finances Primer explores the economic and funding strategies behind drug development. It examines how biotech startups and academic research serve as innovation hubs for large pharmaceutical companies. Topics include R&D outsourcing, orphan drug incentives, licensing agreements, and the venture capital process. The course also explains financing mechanisms such as NIH grants, equity investments, and IPOs. Participants gain insight into how scientific innovation and financial partnerships drive product development in the life sciences industry. Register today and up your biotech finance acumen!

Five Takeaways:

1. Define the primary funding stages in biotech to understand startup and growth capital needs.
2. List common funding sources to evaluate financial pathways.
3. Describe term sheets, valuations, and equity dilution to inform fundraising negotiations.
4. Compare investor expectations at various stages of development to tailor pitches effectively.
5. Recognize how capital structure impacts long-term strategy and decision-making.

AGENDA

Key Investors Along Development Timeline

Non-profit research institutions
Biotech start-ups
Large biopharma

Finding Technologies

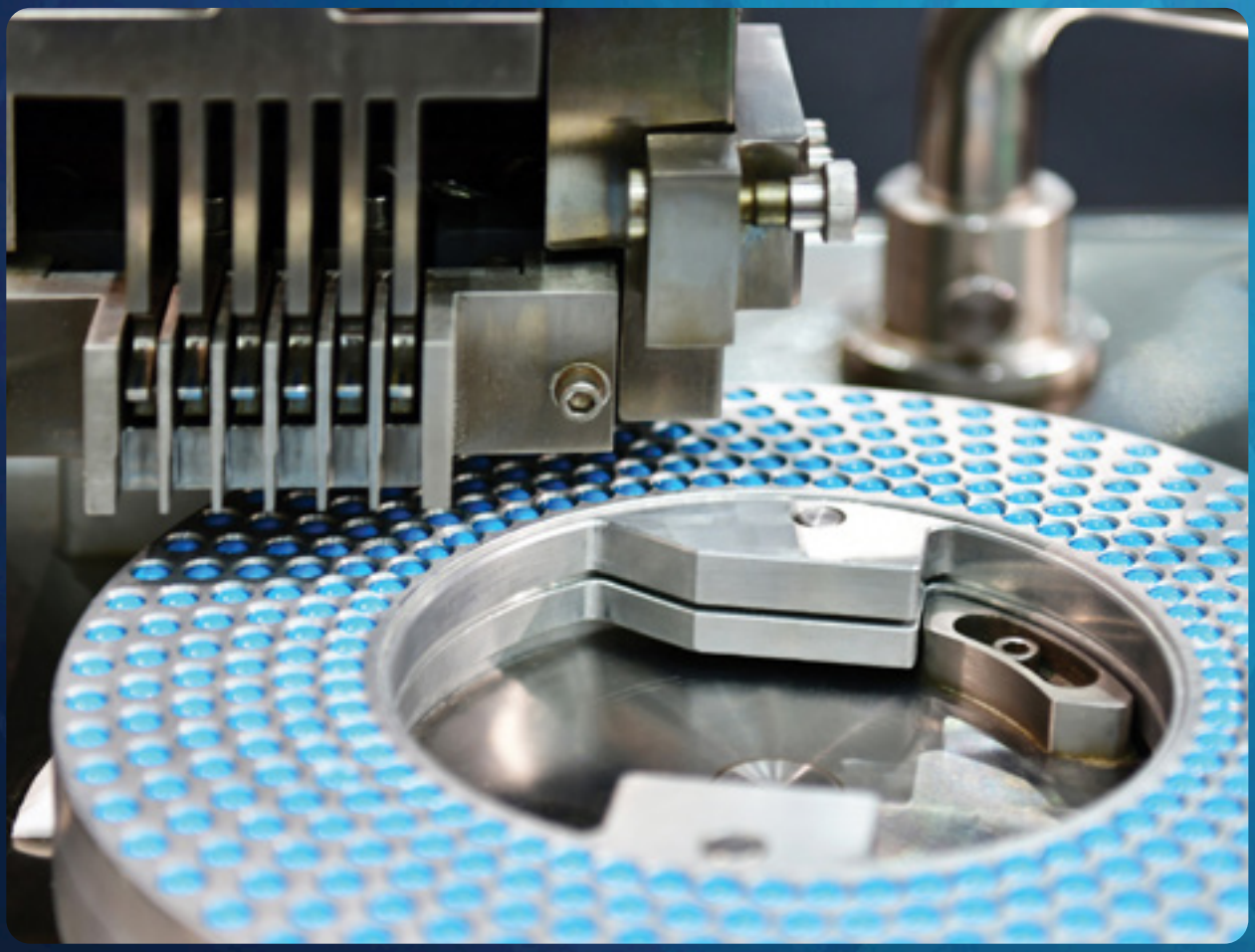
Academic institutions
  Academic licensing
Discovery
In-licensing
Acquisition

Funding Sources

Grants and contracts
Common equity
Convertible debt
Preferred stock
Start-ups/biopharma partnerships
Venture capital
Public markets

BIOTECH PRIMER

DRUG MANUFACTURING FOR NON-SCIENTISTS



biotechPrimer
Life Science Training From Industry Experts

Biomanufacturing Immersion

Live Course | Level Intermediate
One Day
Course customization is available for in-house training

OVERVIEW

Gain a comprehensive understanding of biomanufacturing, from essential inputs and production processes to regulatory requirements and emerging trends. This course equips business professionals with the knowledge to navigate the biomanufacturing landscape effectively.

Takeaways:

1. Learn the core biomanufacturing processes – from genetic engineering and cell banking to upstream and downstream production.
2. Gain insight into regulatory and quality requirements – focusing on FDA regulations, cGMP practices, and QA/QC protocols.
3. Explore emerging trends and business considerations – including advanced manufacturing techniques, cost drivers, and partnerships with CMOs/CDMOs.

AGENDA

Biomanufacturing Inputs 60 minutes
Genetic Engineering
Cell Lines
Cell Banks
Supply Chain Considerations

Biomanufacturing Production 60 minutes
Upstream Production
Downstream Production
Fill and Finish
Equipment Used
Cost Drivers

AGENDA

Production Differences 80 minutes
Monoclonal Antibody Production
Vaccine Production
Cell Therapy Production
Gene Therapy Production

Regulatory and Quality Aspects 60 minutes
Global Regulatory Landscape
Focus on FDA
Current Good Manufacturing Practices (cGMP)
Chemistry Manufacturing and Controls (CMC)
Batch Records and Lot Testing
Quality Control and Quality Assurance (QC/QA)

Emerging Trends in Biomanufacturing
30 minutes
Continuous Manufacturing
Advanced Manufacturing and AI

The Business of Biomanufacturing
50 minutes
Cost Drivers
Infrastructure Requirements
Workforce
CMOs and CDMOs Partnerships
Investment Trends

CMC Primer

On-Demand Microcourse | Level One | 45 Minutes
Suggested Prerequisite: None
CPE Credits: 1.0

OVERVIEW

CMC Primer breaks down the critical role of Chemistry, Manufacturing, and Controls in drug development and patient safety. Learn how CMC fits into each development stage, from discovery to post-launch, and explore real-world case studies and regulatory requirements. Enroll today to gain insight into this essential drug development discipline!

Five Takeaways:

1. Discuss the purpose of CMC to understand regulatory submission requirements.
2. Summarize how CMC manufacturing and analytical data support product quality and safety.
3. Outline how CMC decisions impact timelines, scalability, and commercial success.
4. List key CMC elements required for IND and BLA filings to anticipate documentation needs.
5. Identify the CMC data in the Common Technical Document to inform regulatory strategy.

AGENDA

CMC: Drug Development Considerations
CMC components and their importance
CMC implementation in the Common Technical Document
CMC in discovery and preclinical development
CMC in clinical development and post-launch

CMC: In Action
Purpose of the chemistry component
CMC chemistry assessments
Studies in API identification, formulation, compatibility, stability, impurity, polymorphism, solubility, morphology
Case study: Zantac
Purpose of the manufacturing component
CMC manufacturing assessments
Validation, batch records, facility design, quality control, environmental monitoring, scale-up, process validation
Case study: Children's Dimetapp
Purpose of the controls component

CMC: In Action *(continued)*
CMC controls assessments
Specification, batch analysis, change control, analytical procedures, analytical method validation, stability control
Case study: Riomet

CMC: Regulatory Considerations
Importance of CMC in regulatory submissions
Product quality and safety, regulation compliance, transparency, accountability, and risk management
CMC data considerations
CMC in post-marketing surveillance
Batch consistency, stability monitoring, change control, regulatory compliance, and adverse events monitoring
Five CMC measures post-approval
Common CMC challenges
Process variability and regulatory changes
Case study: Vioxx

cGMP Primer

On-Demand Microcourse | Level Two | 50 Minutes

Suggested Prerequisite: The Biology of Biotech, Genetic Engineering Primer

CPE Credits: 1.0

OVERVIEW

cGMP Primer introduces the fundamentals of current Good Manufacturing Practices, including global regulations and the six core pillars: QMS, facilities, training, materials, documentation, and validation. Learn how inspections, Establishment Inspection Report (EIR), and 483s shape compliance and test your knowledge with real-world case studies. Enroll today to build your cGMP foundation!

Five Takeaways:

1. Define current Good Manufacturing Practices (cGMP) to understand compliance obligations.
2. Describe the core principles of cGMP, including documentation, validation, and quality oversight.
3. List FDA inspection triggers and common findings to prepare for audit readiness.
4. Recognize how cGMP and Quality Management Systems (QMS) support patient safety.
5. Analyze the FDA's observations on cGMP non-compliance and suggest corrective actions using case studies.

AGENDA

Understanding cGMP

Importance of cGMP
Global cGMP laws and publications
cGMPs for biologics, medical devices, and blood
cGMP implementation challenges
Global harmonization of cGMP benefits and challenges

cGMP Pillars 1-3

Pillar 1: Quality Management System (QMS)
- Document management
- Quality risk management
- Production and in-process controls
- Complaints and recalls
- Audits and inspections
- Continuous improvement

Pillar 2: Premises and Equipment
- Facility design, SOPs, HVAC systems

Pillar 3: Personnel Training
- Roles and responsibilities, qualifications, PPE

cGMP Pillars 4-6

Pillar 4: Material Management
- Procurement
- Receipt and inspection
- Storage and handling
- Inventory management
- Material traceability
- Disposal and disposition

Pillar 5: Documentation and Records
- Required cGMP documents
- Data integrity and ALCOA+

Pillar 6: Validation and Qualification
- Critical aspects of validation
- Validation framework and V-model
- Validation through production stages

cGMP Non-Compliance

FDA inspections and outcomes
FDA inspection classifications by product
FDA inspection report
Top reasons for 483s
Case Study 1: RemedyRepack Inc.
Case Study 2: NeilMed Pharmaceuticals Inc

Genetic Engineering Primer

On-Demand Microcourse | Level Two | 50 Minutes

Suggested Prerequisite: The Biology of Biotech

CPE Credits: 1.0

OVERVIEW

Genetic Engineering Primer explores the foundational science of genetic modification, which was the impetus for the creation of the biotechnology industry in the 1980s. This class provides a solid foundation in restriction enzyme and plasmid use, molecular tools that offer endless possibilities for research, drug discovery, drug development, and biomanufacturing. Genetic Engineering Primer methodically traces the steps taken to create recombinant protein therapies that continue to revolutionize modern medicine. Don't miss this opportunity to equip yourself with the knowledge to set you apart in the conversation—enroll in Genetic Engineering Primer today!

Five Takeaways:

1. Describe how DNA is modified to support drug discovery and manufacturing
2. List the steps for creating recombinant DNA and recombinant protein.
3. Demonstrate how restriction enzymes and plasmids are used in genetic engineering.
4. Evaluate the advantages and disadvantages of bacterial and mammalian production cell lines for biomanufacturing.
5. Categorize the recombinant protein therapies used for treating patients.

AGENDA

DNA and Proteins: The Tools of Genetic Engineering

DNA structure and function
Cell signaling
Protein synthesis
  Transcription and translation
Post-translational modifications
Protein examples and functions

Recombinant DNA: The Blueprint of Genetic Engineering

Recombinant DNA function
Recombinant DNA structure
Recombinant DNA synthesis
Restriction enzymes and plasmids uses explained

Recombinant Proteins: The Product of Genetic Engineering

Recombinant protein defined
Recombinant protein synthesis in bacterial cells
Recombinant protein synthesis in mammalian cells
Characteristics of bacterial and mammalian cell production
Monoclonal antibody production
Uses of recombinant proteins in healthcare
  Therapeutic antibodies and fusion proteins
Recombinant protein synthesis in animals and plants

Pharmaceutical Manufacturing Primer

On-Demand Microcourse | Level Two | 45 Minutes
Suggested Prerequisite: none
CPE Credits: 1.0

OVERVIEW

Pharmaceutical Manufacturing Primer provides a comprehensive look at small molecule drug production, from API synthesis and purification to formulation, dosage forms, and packaging. Acquire knowledge of key manufacturing methods, regulatory requirements, and essential supply chain concepts, including cold chain logistics and anti-counterfeiting measures. Enroll today to master the fundamentals of pharmaceutical manufacturing!

Five Takeaways:

1. Summarize the pharmaceutical manufacturing processes to understand how small molecule drugs are produced.
2. Define formulation and list the four most common small molecule formulations to support competitive advantage.
3. Describe quality control and quality assurance considerations to ensure regulatory compliance.
4. Identify key anti-counterfeiting strategies in pharmaceutical distribution to maximize ROI.
5. Analyze the complexities of the pharmaceutical supply chain, including track and trace and cold chain management, for strategic planning.

AGENDA

Chemical Synthesis
Advantages of small molecule drugs
Small molecule drug ingredients
  Active pharmaceutical ingredient (API) - Excipients
Small molecule drug characteristics
Types of chemical synthesis
  Organic: linear and convergent
  Steroselective: R and S enantiomers

Purification
Process and goals of purifying API
  Crystallization
  Distillation
  Chromatography: ion exchange, reverse phase, size exclusion
API production regulations
Supplier validation purpose and requirements

Formulation
Formulation defined
Key formulation goals
Characteristics of dosage forms
Tablets, capsules, suspensions, emulsions

Packaging
Fill and finish purpose and methods
Packaging purpose, process, and regulations
Tamper resistance components
Counterfeit protection methods
Anti-counterfeit technologies
Supply chain
  Cold chain management
Shipping validation

Biomanufacturing Primer

On-Demand Microcourse | Level Two | 50 Minutes

Suggested Prerequisite: The Biology of Biotech, Genetic Engineering Primer

CPE Credits: 1.0

OVERVIEW

Biomanufacturing Primer offers a clear introduction to the science behind biologic drug production. Explore key topics like cell lines, cell banks, upstream and downstream processing, and how bacterial vs. mammalian systems impact manufacturing. Discover cutting-edge advancements, including continuous processing and single-use technologies. Register today to build your foundation in biomanufacturing!

Five Takeaways:

1. Define biomanufacturing and cell banking to learn how biologics are produced.
2. Describe the differences in production for bacterial and mammalian cell lines.
3. Summarize upstream, downstream, and harvesting processes to evaluate capacity, quality, and cost drivers.
4. Recognize key regulatory and quality elements that influence manufacturing timelines and compliance.
5. Identify how single-use systems are used in to support facility assessments.

AGENDA

Cell Lines

Bacterial and mammalian cell line development
Bacterial and mammalian cell line differences
Monoclonal antibody production
Types of commercial eukaryotic cell lines

Cell Banks

Identification of best clone
Purpose of cell banks
Master cell bank production
Working cell bank production

Upstream Bioprocessing

Cell growth optimization
Growth media considerations
Bioreactor considerations
Scale-up process

Downstream Bioprocessing

Harvesting process
  Secreted proteins outside the cell and proteins retained in the cell
Purification process: chromatography
Formulation process
Packaging process
Testing protocols: SQIPP

Advancements in Biomanufacturing

Critical to quality attributes
Continuous upstream and downstream bioprocessing
  Advantages and disadvantages
  Single use technologies
Benefits and risks

Gene Therapy Manufacturing Primer 101

On-Demand Microcourse | Level Two | 50 Minutes
Suggested Prerequisite: The Biology of Biotech, Genetic Engineering Primer, Biomanufacturing Primer, Gene Therapy Primer
CPE Credits: 1.0

OVERVIEW

Gene Therapy Manufacturing Primer 101 introduces the fundamentals of AAV production, comparing key platforms and exploring the AAV cassette, upstream and downstream processing, and bioreactor types such as hyperstacks and iCellis. The course wraps with an overview of CMC requirements, including identity, potency, purity, and sterility testing. Enroll today to build your foundation in gene therapy manufacturing!

Five Takeaways:

1. Outline the components and steps of gene therapy manufacturing to assess process complexity.
2. Determine how serotypes influence viral tropism and impact targeting efficiency.
3. Classify types of vectors and their manufacturing challenges for strategic evaluation.
4. List the guidance essential to follow during AAV gene therapy manufacturing for regulatory approval.
5. Recognize unique quality and safety requirements for gene therapy production.

AGENDA

AAV Properties
AAV structures and functions
AAV serotypes
Tissue tropism of popular AAV serotypes
AAV characteristics

AAV Production Platforms
4 AAV production platform comparisons
Key features of AAV vector DNA
The AAV cassette
Cell bank production
Master cell bank and working cell bank
AAV double-stranded and single-stranded DNA

AAV Upstream Bioprocessing
Stages of AAV manufacturing
Suspension and adherent cell lines
Upstream bioprocessing steps
Small and large batch production
Bioreactors: hyperstacks, icellis

AAV Downstream Bioprocessing
Cell harvesting
Downstream bioprocessing
Purification platforms: chromatography, filters, centrifugation
Fill and finish
Packaging
AAV viral vector manufacturing workflow

AAV CMC
Role of CMC
ICH Q5A, ICH Q5B, ICH Q5D, ICH Q5E
Identity testing
Potency testing
Quality testing
Purity testing
Sterility testing
CMC regulatory and development considerations
AAV manufacturing challenges

Gene Therapy Manufacturing Primer 201

On-Demand Microcourse | Level Three | 65 Minutes

Suggested Prerequisite: Gene Therapy Manufacturing Primer 101

CPE Credits: 1.5

OVERVIEW

Gene Therapy Manufacturing Primer 201 is a deep dive into cGMP AAV production, focusing on advanced manufacturing platforms like TT, rBV/Sf9, HSV/BHK, and PCL. Explore CMC strategies, raw materials, purification methods, and analytical testing for safety and quality. Gain a detailed understanding of the regulatory landscape influencing AAV gene therapy. Enroll now to expand your expertise in advanced gene therapy manufacturing.

Five Takeaways:

1. Summarize process development considerations specific to gene therapy platforms.
2. Identify scalability and yield challenges that impact commercial viability.
3. Compare production methods for AAV, lentivirus, and other vectors to guide platform decisions.
4. Describe analytical testing strategies for potency, purity, and identity in gene therapy products.
5. Indicate regulatory expectations for CMC data to ensure gene therapy product approval.

AGENDA

AAV Overview

AAV characteristics
AAV manufacturing characteristics
AAV cDNA delivery

AAV Vectors

AAV protein capsid
Role of viral proteins: VP1, VP2, VP3
AAV serotypes and tissues
Capsid tropism
AAV cDNA genome sequence
AAV dsDNA and ssDNA
Advantages and disadvantages of dsDNA
AAV vector genome design
Lytic and latent AAV lifecycle stages

AAV Manufacturing and Controls

Recombinant AAV gene therapy vectors
Manufacturing challenges
Upstream bioprocessing
AAV vector production platforms
Transient transformation (TT)
Bacolovirus expression (rBV/Sf9
Herpes simplex expression (HSV/BHK)
Producer cell lines (PCL)
Production platform differences
Bioreactor volume differences among platforms
iCellis bioreactor
Downstream bioprocessing
TT CMC and cGMP strategies
TT critical raw materials: fetal bovin serum, polyethylenine, benzonase
rBV/sF9 CMC and cGMP strategies
HSV/BHK CMC and cGMP strategies
PLC CMC and cGMP strategies
Downstream purification strategies
AAV vector product characterization
AAV vector analytics
Safety, identity, potency, quality, purity testing
Viral vector manufacturing facility design
AAV vector regulatory considerations

Biosimilars Primer

On-Demand Microcourse | Level Two | 65 Minutes
Suggested Prerequisite: The Biology of Biotech
CPE Credits: 1.0

OVERVIEW

Biosimilars Primer demystifies the science, manufacturing, and regulatory pathways behind biosimilar drug approval. Explore how protein structure, biologic drug types, and production conditions impact biosimilarity. Learn how companies address safety, immunogenicity, and regulatory requirements through real-world FDA and EMA case studies. Enroll today

Five Takeaways:

1. Define what constitutes a biosimilar to understand regulatory pathways and approval hurdles.
2. Identify the analytical methods used to demonstrate biosimilarity for investor and partner confidence.
3. Compare biosimilars with generics to clarify the differences in their development and commercialization.
4. Describe global biosimilar regulatory frameworks to inform go-to-market strategy.
5. Indicate the economic and strategic value of biosimilars in expanding patient access and market share.

AGENDA

Proteins
Protein types and their functions
  Enzymes, antibodies, receptors
Protein synthesis: transcription and translation
Protein structure and how it determines function
Post-translational modifications
  Purpose of glycosylation and phosphorylation

Biologics
Biologics in healthcare
Characteristics of biologics
Small molecule drugs vs biologics

Biosmilars
The product is the process
Generic vs biosimilar
FDA and EMA biosimilar regulatory process

Manufacturing
Establishing production cell lines
Cell bank types and purposes
Upstream process: seeding and scale-up
Downstream processing: harvesting and purification

Manufacturing *continued*
Biosimilar formulation
Stability studies

Safety and Regulation
Protein complexity
Immunogenicity
Clinical impact of neutralizing and non-neutralizing antibodies
Data exclusivity
Gaining approval for biosimilars
  Preclinical and clinical trials

Biosimilar Case Studies
Case Study 1: Changes In Amino Acid Sequence Affect Properties Of Biologics
Case Study 2: Impurity Profile May Results In Differences In Immunogenicity
Case Study 3: Careful Analysis Of Proposed Biosimilar Product May Detect Significant Differences Before Clinical Trials
Case Study 4: Packaging Changes May Have Serious Safety Consequences

Laboratory Worker Biosafety Primer

On-Demand Microcourse | Level One | 60 Minutes
Suggested Prerequisite: OSHA Bloodborne Pathogen Standard Primer
CPE Credits: 1.5

OVERVIEW

Laboratory Worker Biosafety Primer covers essential biosafety practices to protect workers, the environment, and the public. Learn how to assess infectious agent risk using the WHO framework and apply the hierarchy of controls—from lab design to PPE. Ideal for any science workspace. Register today and stay safe on the job!

Five Takeaways:

1. Define biosafety levels (BSL 1–4) and what they mean for lab worker responsibilities.
2. Identify proper PPE, equipment, and procedures for working safely with biohazards.
3. List exposure prevention strategies to support a culture of lab safety.
4. Describe emergency response procedures for accidental exposure to infectious agents.
5. Recognize how day-to-day practices contribute to lab compliance and personal protection.

AGENDA

Infectious Agent Identification
Biosafety guidelines and manuals
Infectious biological agents and select agents
Four biosafety risk levels
Disease-causing organisms or toxins

Risk Assessment of Infectious Agents
Risk factor considerations
Tools for assessing risk
Infectious biological agent risk group classifications
Facility risk assessment levels
Human risk assessment
WHO process and framework

Engineering Controls
Five levels of hierarchy of controls
  Elimination, substitution, engineering control, administrative control, personal protective equipment (PPE)
Laboratory design

Administrative Controls
Occupational health program
Emergency response
Laboratory biosecurity
Training
Job rotations
Sanitary requirements
Risk control measures
Primary biosafety regulations
  U.S. requirements
  International requirements
Regulatory agency reference lists

Personal Protective Equipment (PPE)
Selecting proper PPE
Hazards in risk assessment
Commonly used PPE
Specialized PPE
Low risk vs high risk

Implementing a Biosafety Program Primer

On-Demand Microcourse | Level One | 40 Minutes
Suggested Prerequisite: Laboratory Worker Biosafety Primer, OSHA Bloodborne Pathogen Standard Primer
CPE Credits: 1.0

OVERVIEW

Implementing a Biosafety Program Primer provides a practical overview of building and managing effective biosafety and biosecurity programs. Learn how to classify biological agents, assign roles to key personnel, and apply workplace controls. The course also covers breach reporting and investigation protocols. Enroll today to strengthen your organization's biosafety framework!

Five Takeaways:

1. Define biosafety and its importance in protecting employees and research integrity.
2. Outline the essential elements of a biosafety program to support lab management strategy.
3. Describe risk assessment practices for handling biohazardous materials.
4. Recognize compliance requirements from OSHA, CDC, and NIH to prevent legal liability.
5. Organize lab safety roles and responsibilities to ensure effective biosafety implementation.

AGENDA

Principles
Biosafety program goals explained
Biosecurity program goals explained
Biological agents and select agents defined
Biosafety and biosecurity institutional requirements
Biosafety guidelines for workers
Biosafety manual importance and content
Assessing risk
Biosafety levels

Personnel
Institutional Biosafety Committee (IBC)
IBC roles and responsibilities
Biosafety officer duties
Chief scientific officer and principal investigator duties
Biohazard worker responsibilities
Head of facility duties
Animal care and handling director duties

Practices
Guidance's
Inventory system considerations
Training programs based on job function
Change management implementation
Communication practices: reporting and signage

Controls
Risk assessment considerations
Mitigations that minimize risk
Work practice controls
Decontamination and disposal controls
Facility design controls
Equipment controls
Biosecurity controls: physical and IT
Transport controls
Emergency plan controls

OSHA Bloodborne Pathogen Standard Primer

On-Demand Microcourse | Level One | 45 Minutes
Suggested Prerequisite: Laboratory Worker Biosafety Primer
CPE Credits: 1.0

OVERVIEW

OSHA Bloodborne Pathogen Standard Primer teaches how to prevent the spread of infectious diseases through safe handling of biohazardous materials. Learn the key requirements for PPE, disinfection, spill response, and compliance documents, such as exposure control plans. Enroll today to ensure OSHA compliance and protect yourself and your team!

Five Takeaways:

1. Define OSHA's Bloodborne Pathogen Standard to understand legal safety requirements in labs.
2. List potential sources of occupational exposure to mitigate risk in biotech environments.
3. Recognize the components of an Exposure Control Plan for regulatory compliance.
4. Summarize the proper use of personal protective equipment (PPE) to safeguard employee health.
5. Indicate training and documentation practices to ensure workplace accountability and safety.

AGENDA

Biosafety Basics
Chain of infection
Biohazardous material
Human body fluids
Infectious clinical specimens
Infected animals, surfaces, or equipment
Sharps

OSHA Bloodborne Pathogen Standard
Coverage and requirements
Occupation risk
Other potentially infectious materials
HIV, HBV, and HCV
Universal precautions
Biosafety levels
Universal safe work practices
Personal protective equipment (PPE)

OSHA Work Practices
Hand hygene
Splash and sprays
Aerosols

OSHA Work Practices
Biohazard labels
Biological safety cabinets (BSC)
Waste streams
Labeling and shipping
Disinfectants

OSHA Emergency Response Procedures
Spills SOP
Emergency response procedure
Incident follow-up SOP
Necessary documents
- OSHA Bloodborne Pathogen Standard
- Biosafety manual
- Exposure control plan
- Waste management plan
- Biological safety cabinet SOP
- Emergency plan
- Annual training plan and records
- Employee medical records
- Vaccination records
- Sharps injury reports

BIOTECH PRIMER

MEDICAL DEVICE FOR NON-SCIENTISTS

biotechPrimer
Life Science Training From Industry Experts

Medical Device Development Immersion

Live Course | Level Beginner
Two Day Agenda
Customization is available for in-house training

OVERVIEW

Medical Device Development Immersion showcases the fascinating aspect of medical device development. Beginning with an overview of the dynamic medical device industry, this program quickly navigates the changing regulatory environment and pathways devices undertake for FDA or EMA marketing approval. Throughout this training, an interactive activity involves building a medical device prototype to reinforce the five development phases: market opportunity, evaluation, design, verification, and manufacturing. The strategies that drive successful medical device businesses, including reimbursement considerations that ensure these game-changing inventions reach patients, complete the program. Learn from an industry expert with 30 years of experience in both large and start-up medical device companies. Call today to learn how to bring this course in-house to your team!

Five Takeaways:

1. Showcases the complete medical device development lifecycle to inform strategic planning and mitigate risks.
2. Identifies the five core phases—market opportunity, evaluation, design, verification, and manufacturing—to align development milestones.
3. Describes the regulatory and quality standards that shape device design and approval strategies.
4. Outlines critical cross-functional activities required to advance a device from concept to commercialization.
5. Summarizes how reimbursement and clinical utility drive product adoption and market success.

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
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 and Evaluation 15 minutes

Deep Dive Medical Device Development Immersion

Recorded Live | Level Beginner
10 Hours | 10 Courses
CPE Credits: 11.5

OVERVIEW

Medical Device Development Immersion features the same content, interactive exercises, and course materials that are given in the live version.

Medical Device Development Immersion showcases the fascinating aspects of medical device development. Beginning with an overview of the dynamic medical device industry, this course bundle quickly navigates the changing regulatory environment and pathways devices undertake for FDA or EMA marketing approval. Throughout this program, an interactive activity of building a medical device prototype reinforces the five development phases—market opportunity, evaluation, design, verification, and manufacturing. The strategies that drive successful medical device businesses, including reimbursement considerations that ensure these game-changing inventions reach patients, complete the training. Learn from an industry expert with 30 years of experience in both large and start-up medical device companies—register today!

Five Takeaways:

1. Defines the complete medical device development lifecycle to inform strategic planning and mitigate risks.
2. Identifies the five core phases—market opportunity, evaluation, design, verification, and manufacturing—to align development milestones.
3. Describes the regulatory and quality standards that shape device design and approval strategies.
4. Outlines critical cross-functional activities required to advance a device from concept to commercialization.
5. Summarizes how reimbursement and clinical utility drive product adoption and market success.

AGENDA

COURSE 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

COURSE 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

AGENDA

COURSE 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

COURSE 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

COURSE 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

COURSE SIX

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

COURSE 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

COURSE EIGHT

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

COURSE 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
MDUFA III
Submission approval timelines

COURSE TEN

Commercialization 15 minutes
Reimbursement strategy
CMS vs FDA
Issues affecting private payers

Evaluation 20 minutes

Diagnostics' Role In Medicine Today

On-Demand Microcourse | Level One | 41 Minutes

Suggested Prerequisite: None

CPE Credits: 1.0

OVERVIEW

Diagnostics' Role In Medicine Today introduces the ever-expanding molecular diagnostics industry. This class defines the groundbreaking field of qualitative and quantitative biomarker measurements. These crucial measurements help identify diseases, select treatments, and monitor chosen therapies. Get ready to explore a wide range of foundational diagnostics used in both research and clinical settings, such as immunochemistry, microbiology, and infectious disease diagnostics. The course ends by focusing on companion diagnostics. The showstopper is a culminating case study on HER2 cancer/Herceptin that highlights real-world evidence of how companion diagnostics help patients receive appropriate therapy. Learn foundational concepts applied in the research and clinic settings and become diagnostic proficient—enroll today!

Five Takeaways:

1. Cite how molecular diagnostics uses novel biomarkers to create new investment and business growth opportunities.
2. Describe the critical role of diagnostics in guiding treatment decisions and improving patient outcomes.
3. Summarize the business case for diagnostic use in precision medicine.
4. Identify types of diagnostic tests and their applications across preventive care, disease management, and personalized medicine.
5. Recognize how diagnostics influence reimbursement and market access for companion drug products.

AGENDA

Defining Diagnostics

Qualitative measurements
Quantitative measurements
Single and multiple measurements
Biomarker measurements
Diagnostic screening and diagnosis
Diagnostic drug selection
Diagnostic treatment monitoring
Diagnostic management

Types of Diagnostics

General chemistry
Immunochemistry
Hematology
Cytology
Microbiology
Infectious disease
Anatomic imaging
Molecular

Companion Diagnostics

Genetic variation concepts
Genetic basis of disease
Monogenetic disease
Polygenetic disease
Diagnostics and selecting a treatment
Focus on HER2 cancer and Herceptin diagnostic
Customizing therapy: treatment selection
Customizing therapy: dosage selection

Diagnostic Development Primer

On-Demand Microcourse | Level One | 41 Minutes
Suggested Prerequisite: Diagnostics Role in Medicine Today
CPE Credits: 1.0

OVERVIEW

Diagnostic Development Primer is a comprehensive guide to navigating the complex approval process for In Vitro Diagnostics (IVD) and Laboratory-Developed Tests (LDTs). Learn how U.S. agencies regulate diagnostics, explore Class I–III pathways, and understand Quality System Regulations (QSR) requirements for design and manufacturing. The course concludes with a clear breakdown of reimbursement, from inpatient DRG codes to outpatient CPT codes. Enroll today to master diagnostic development!

Five Takeaways:

1. Compare the FDA and CMS diagnostic regulatory oversight to align with clinical and regulatory planning.
2. Outline the U.S. regulatory process for IVD and LDTs to compare development considerations.
3. Recognize the regulatory differences between Class I, II, and III diagnostics to navigate compliance.
4. Define the Quality System Regulations (QSR) to support product approval.
5. Describe the challenges of securing diagnostic reimbursement in the U.S. to anticipate financial impact and inform market strategy.

AGENDA

Development and Regulation
Clinical test requirements
Approval pathways
FDA oversight
CMC oversight
In vitro diagnostics (IVD) requirements
Laboratory developed tests (LDT) requirements
Closer look: multivariate index assay (IVDMIA)
CLIA labs
FDA IVD guidance and CMC LDT guidance

FDA Classification and Approval Pathways
FDA approval pathways
Class I regulations
Class II regulations
Class III regulations
Determining diagnostic risks
General and special controls
Premarket notification (PMN)
Premarket approval (PMA)
510(k)
De novo 510(k)
Quality system regulations (QSR)
QSR informs design and manufacturing
FDA submission requirements
European Union submission requirements

Reimbursement
Strategies for reimbursement
Medicare, Medicaid, hospital
Inpatient: DRG codes
Outpatient: CPT codes
Private payer
Technology evaluation considerations
Methods of economic evaluations
Cost-minimization
Cost-effectiveness
Cost-utility
Cost-benefit

Diagnostic Measurements Primer

On-Demand Microcourse | Level Three | 47 Minutes

Suggested Prerequisite: Diagnostic Development Primer, DNA-Based Diagnostics Primer, Protein-Based Diagnostics Primer

CPE Credits: 1.0

OVERVIEW

Diagnostic Measurements Primer teaches how specificity, sensitivity, false positives/false negatives, and true positives/true negatives shape diagnostic accuracy and regulatory approval. Learn to construct and interpret standard curves, explore data variability and bimodal distribution, and analyze real-world case studies in breast and prostate cancer diagnostics. Register today to build your skills in evaluating diagnostic performance!

Five Takeaways:

1. Define direct vs. indirect diagnostic measurements to evaluate test design and clinical utility.
2. List measurement parameters required for regulatory submissions, including sensitivity, specificity, and predictive value, that influence FDA approval.
3. Summarize how a diagnostic measures accuracy and reliability to drive investor confidence in diagnostic technologies.
4. Describe methods for ensuring reproducibility and minimizing error during diagnostic development.
5. Recognize how robust measurement informs regulatory acceptance and payer coverage.

AGENDA

Introduction to Measurements
Requirements for regulatory approval
Types of diagnostic measurements
Direct and indirect measurements
Determining unknown analyte concentrations
Standard curve estimations
Constructing and reading a standard curve
Science of colorimetric assays

Variability of Measurements
Variability defined
Distribution of values
Graphic display of distributions
Bimodal distribution
Variability factors

Examples of Test Distributions
Blood pressure and cholesterol
Bimodel distribution
Ideal distribution

Testing Accuracy
Measurement considerations
Accuracy defined
False positive and false negative defined
Specificity and sensitivity defined
Reading specificity and sensitivity distributions
Reading true positive and true negative distributions
Reading false negatives and false positive distributions
Reading positive and negative predictive value distributions
Reading low prevalence distributions
Case Study: mammograph for breast cancer
Case Study: PSA diagnostic for prostate cancer

Antibody Primer

On-Demand Microcourse | Level Three | 70 Minutes

Suggested Prerequisite: The Biology of Biotech, Immunology Primer 101, Immunology Primer 201

CPE Credits: 1.5

OVERVIEW

Antibody Primer offers an immersive exploration of antibodies, explaining their crucial role in research and the clinic. This class begins with an insight into the unique architecture of antibodies and details how their structure directs function. With special attention to the mechanisms of action for monoclonal antibodies, antibody-drug conjugates, bispecific antibodies, and checkpoint inhibitors, this primer highlights the capabilities of these unique molecules to fight disease. This class ends with a survey of standard antibody-based diagnostics, including ELISA, bead immunoassays, and lateral flow immunochromatographic assays, showcasing their purpose and workflows. Enroll today and become fluent in the science of antibodies!

Five Takeaways:

1. Summarize how antibody structure influences antibody functions to support analysis of therapeutic antibody platforms.
2. Select antibody characteristics that enhance drug targeting to evaluate potential market advantages.
3. Differentiate antibody types by mechanisms of action to guide licensing or investment decisions.
4. Recognize antibody-drug conjugates and their benefits in oncology and other indications.
5. Outline the production process for monoclonal antibodies to understand manufacturing timelines and risks.

AGENDA

Antibodies Overview

Antibody structure

Antibody types and functions: IgM, IgD, IgG, IfA, IgE

Antibody mechanism of actions to fight disease

Antigen, immunogen, and epitope defined

Generation of antibody diversity in the lab

Antibody production in both mice and phage display

Antibodies as Therapeutics

Monoclonal antibodies structure and various mechanism of actions

Antibody-drug conjugates structure and mechanism of action

Antibodies as Therapeutics

Bispecific antibodies structure and mechanism of action

Checkpoint inhibitors structure and mechanism of action

Antibodies as Diagnostics

Antibody use in ELISA

ELISA uses and how to read results

Antibody use in bead immunoassay

Bead immunoassay uses and how to read results

Antibody use in lateral flow immunochromatographic assay

Lateral flow immunochromatographic assay uses and how to read results

DNA-Based Diagnostics Primer

On-Demand Microcourse | Level Two | 44 Minutes
Suggested Prerequisite: The Biology of Biotech, Diagnostic Measurements Primer
CPE Credits: 1.0

OVERVIEW

DNA-Based Diagnostics Primer is the ultimate guide to the molecular science driving standard diagnostic tools used in research and clinical settings. This primer breaks down the critical technology that drives these diagnostic advancements, including Polymerase Chain Reaction (PCR), microarrays, Next-Generation Sequencing (NGS), and microRNA diagnostics. Each diagnostic tool is thoroughly explained, highlighting its purpose, when it is used, and how it harnesses the power of DNA to detect and analyze specific genetic sequences. This class provides a comprehensive understanding of the scientific principles that underpin DNA-based diagnostics. Gain entry into the fast-paced field of DNA-molecular diagnostics by registering for this course today!

Five Takeaways:

1. Define DNA-based diagnostics and explain their applications in disease detection.
2. List key platforms like PCR, microarrays, and next-generation sequencing, and their impact on diagnostic innovation.
3. Describe how genomic mutations are identified and interpreted to guide clinical care.
4. Summarize the regulatory landscape for DNA-based diagnostics to inform the go-to-market strategy.
5. Classify key applications of DNA-based diagnostics for their clinical and commercial relevance.

AGENDA

Polymerase Chain Reaction (PCR) Technology
Review: DNA structure and sequence
Uses of PCR diagnostics
The science of PCR
Uses of diagnostic DNA probes
DNA sequence detection
DNA probe sensitivity
Methodology for DNA sequence detection
PCR diagnostic
Quantitative real-time PCR (qPCR) diagnostic

Microarray Technology
Review: single nucleotide polymorphism (SNP)
Uses of SNP chip diagnostics
The science of SNP chips
Hybridization assay
SNP chip detection
Reading SNP chip output
SNP chip example: Detecting Alzheimer's disease

Generation Sequencing (NGS) Technology
Uses of NGS diagnostics
The science of NGS
NGS platforms
Reversible dye terminator
Ion semiconductor
Ion torrent
Whole genome sequencing diagnostics

microRNA Technology
Uses of microRNA diagnostics
The science of microRNA
Advantages of microRNA diagnostics
Non-invasive testing methods
Variation detection benefits

Protein-Based Diagnostics Primer

On-Demand Microcourse | Level Two | 40 Minutes
Suggested Prerequisite: The Biology of Biotech, Diagnostics' Role in Medicine Today, Diagnostic Measurements Primer
CPE Credits: 1.0

OVERVIEW

Protein-Based Diagnostics Primer provides a clear overview of key tools used to detect diseases, including ELISA, bead immunoassays, lateral flow assays, and chromatography. Learn how these technologies measure, separate, and analyze proteins in both research and clinical settings. Enroll today to boost your understanding of protein-based diagnostics!

Five Takeaways:

1. Define protein-based diagnostics and their role in biomarker detection and disease monitoring.
2. Identify standard diagnostic methods, such as ELISA, Western blot, and mass spectrometry, to understand their clinical and commercial relevance.
3. Describe the analytical challenges in detecting low-abundance biomarkers accurately.
4. Recognize how protein diagnostics support companion diagnostics and personalized medicine.
5. Outline regulatory and validation steps specific to protein-based assay development.

AGENDA

Defining Protein-Based Diagnostics
Science of biomarkers
Protein-based diagnostic examples

Antibody Technology
Antibody structure and function
Antibody characteristics
Antibodies as quantitative detection reagents
Antibodies detect epitopes
Advantages of antibody detection reagents

Enzyme-Linked Immunosorbent Assay (ELISA) Technology
ELISA uses
Quantitative protein detection
Science of ELISA diagnostics
Reading ELISA multi-well plate results
Multiplexed ELISA
Types of multi-well plates and volumes
Rapid multiplexed analyzers

Bead Immunoassay Technology
Bead immunoassay uses
Science of bead immunoassays
Reading bead immunoassay diagnostics
Cell sorter

Lateral Flow Assay (LFA) Technology
LFA uses
Science of LFA
Reading LFA diagnostics
LFA diagnostic examples

Chromatography Technology
Protein chromatography uses
Types of chromatography
Ion exchange chromatography
Affinity exchange chromatography
Size exclusion chromatography
Reading chromatography diagnostics
Chromatography diagnostic examples

Medical Device Development Primer

On-Demand Microcourse | Level Two | 57 Minutes

Suggested Prerequisite: Medical Device Approval Primer

CPE Credits: 1.5

OVERVIEW

Medical Device Development Primer walks you through the five key stages of device development—from market evaluation and concept testing to design, manufacturing, and scale-up. Learn how FDA guidance, risk assessment, and reimbursement shape go/no-go decisions. Enroll today to navigate the full development journey with confidence!

Five Takeaways:

1. Define the phases of medical device development to frame timelines and milestones.
2. Summarize key design controls, including risk analysis, usability, and engineering inputs.
3. Identify the five-phase framework for translating ideas into approved devices.
4. Describe the impact of market need and competitive landscape on device strategy.
5. Recognize how regulatory classification shapes the product development pathway.

AGENDA

Market Opportunity Evaluation
Consumer requirements
Reimbursement
Risk analysis and management plan
Product development plan
Phase I review and finalization

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

Engineering Design
Product requirement specifications
Product indications
Usability engineering and human factors
Graphical user interface and instructions for use
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

Medical Device Approval Primer

On-Demand Microcourse | Level Two | 57 Minutes

Suggested Prerequisite: Medical Device Development Primer

CPE Credits: 1.5

OVERVIEW

Medical Device Approval Primer takes a close look at the complex world of regulatory approval pathways. With a focus on the FDA and EMA agencies, it identifies the regulatory compliance requirements and different medical device classifications, from Class I to III, that are critical to ensuring patient safety. This primer provides insight into the FDA and EMA organizational structure and approval pathways, such as 510(k), De Novo 510(k), PMN, and PMA. Learn about the importance of Quality System Regulations (QSR) requirements, Good Laboratory Practices (GLP), and Good Clinical Practices (GCP) used worldwide in medical device development. Become fluent in assessing risk and choosing the appropriate medical device approval pathway—grab your seat today!

Five Takeaways:

- Define FDA and EU regulatory pathways for medical devices to inform regulatory strategy.
- List key submission elements, including safety, effectiveness, and quality documentation.
- Outline the risk differences between device Class I, II, and III for strategic planning purposes.
- Describe how clinical data supports approval and reimbursement decisions.
- Recognize how approval strategies affect commercialization and investor confidence.

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 - III risk and controls
FDA approval pathways
510(k) and De novo 510(k)
Premarket notification (PMN)
Premarket approval (PMA)
Regulatory compliance requirements
Good Laboratory Practices (GLP)
Good Clinical Practices (GCP)
Good manufacturing practices (cGMP)

Medical Device Regulation *continued*

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

Medical Device Commercialization Primer

On-Demand Microcourse | Level Three | 55 Minutes
Suggested Prerequisite: Medical Device Development Primer, Medical Device Approval Primer
CPE Credits: 1.0

OVERVIEW

Medical Device Commercialization Primer navigates the intricacies of the approval pathways, the excitement of a launch, and the rigors of post-market surveillance. This class reveals best practices for business preparations, sales, marketing, and reimbursement—ensuring corporate-wide readiness and effective healthcare promotion. It wraps up by highlighting the sponsor's responsibility for monitoring device performance to ensure ongoing patient safety and FDA compliance. Join us for the fast-paced Medical Device Commercialization Primer and equip yourself with the tools and knowledge to create a successful commercialization plan for your medical device. Register now!

Five Takeaways:

1. Define the commercialization process for devices from regulatory approval to market launch.
2. Identify key stakeholders, including clinicians, payers, and purchasing groups, and their role in bringing a medical device to market.
3. Describe sales and distribution models used in the medical device sector to support revenue growth.
4. Summarize the pricing and reimbursement considerations that impact the adoption of medical devices.
5. Outline marketing and product positioning strategies for competitive advantage.

AGENDA

Approval
Purpose of clinical trials
Mandatory clinical trials
Investigational device exemption (IDE)
Types of IDEs • Components of the IDE
Clinical trials in the U.S. and outside the U.S.
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