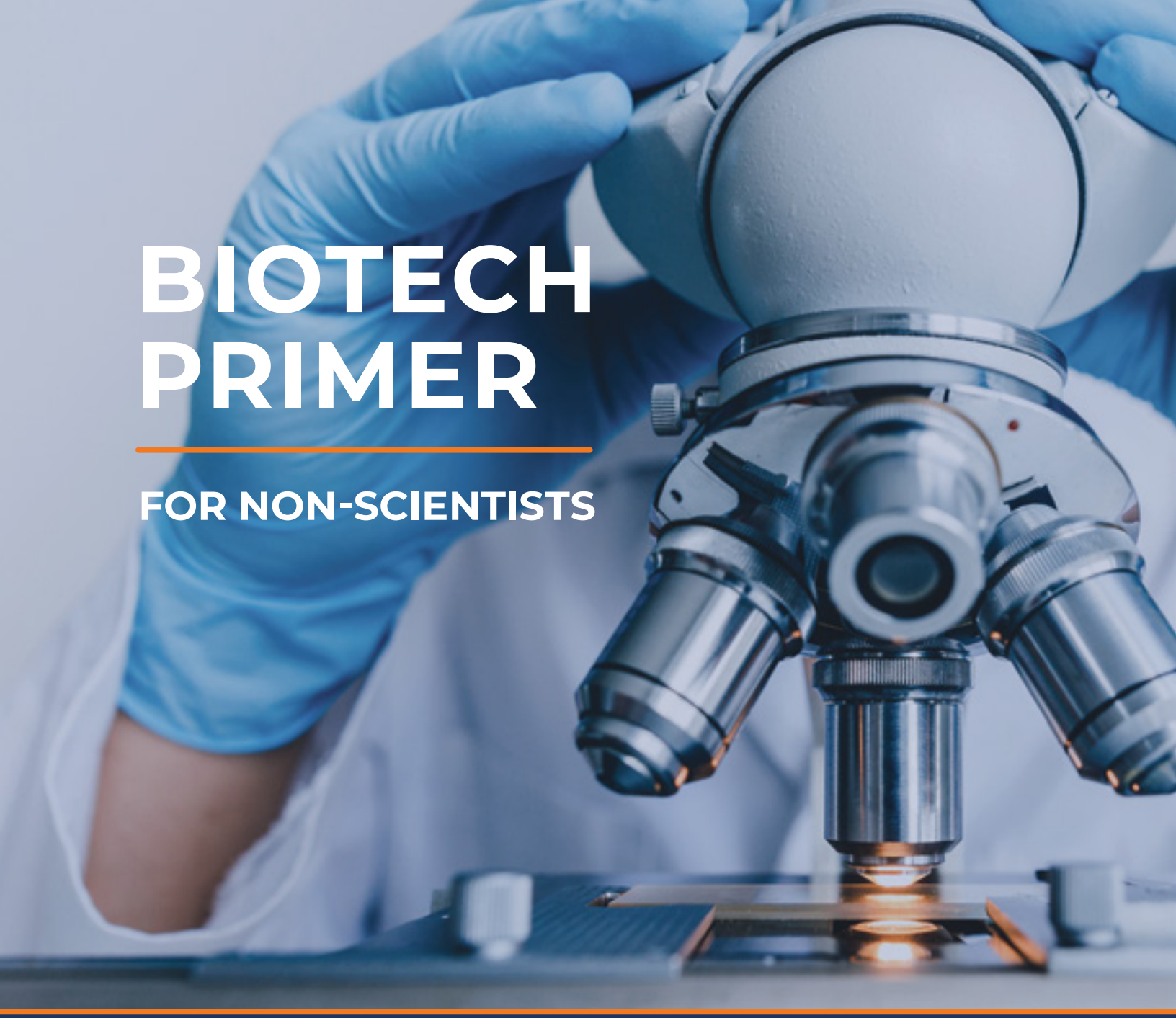

BIOTECH PRIMER

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

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BIOTECH PRIMER
ABOUT US

Biotech Primer is your go-to source for interactive training across the biotechnology, pharmaceutical, molecular diagnostics, and medical device sectors.

We specialize in making complex scientific concepts accessible and engaging, ensuring that all participants, regardless of their scientific background, can fully retain and apply what they learn in real-world scenarios. With the perfect blend of scientific expertise, business acumen, and regulatory know-how, our life science Industry Experts painstakingly craft and deliver the most captivating and informative training available.

Our approach is focused on breaking down barriers to understanding, making our courses ideal for those looking to gain a comprehensive understanding of the life sciences without a scientific background.

We offer a diverse range of learning opportunities to ensure participants retain and apply what they learn in real-world scenarios.

We help:

- **Integrate your science and business operations**
- **Bring in-depth knowledge to your sales force**
- **Enhance communication with clients, colleagues, and scientists in the industry**
- **Enable your entire staff to recognize new opportunities**

Our Subject Expertise

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

BIOTECH PRIMER
OUR ADVANTAGE

Our small woman-owned company takes pride in being highly responsive to our customers' needs and requests.

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 not only witnessed but actively participated in shaping the ever-evolving landscape of biotechnology and medical devices.

Drive Individual and Organizational GrowthOur

Highly Experienced Instructors with decades of industry expertise

Our training specialization focuses exclusively on the biopharmaceutical and medical device sectors.

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Our content delivery options are designed to adapt to your busy schedule. Choose between live sessions and on-demand access to customized training modules.

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Over 150,000 individuals trained since 2001

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OUR DELIVERY PLATFORMS

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Live Courses

Live Signature Courses: Prescheduled 1-2 day signature courses delivered onsite throughout the USA and Canada or delivered online worldwide in partnership with membership organizations.

Live In-House Training: Tailored training delivered to organizations worldwide live onsite or online by our industry experts. Don't know where to start? Modify our signature course agendas to meet your organization's specific learning needs.

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On-Demand Recorded Signature Courses: Our 1-2 day signature courses delivered online as a recording. These recordings offer the same content as the live signature course, with one-year access to complete.

On-Demand Micro Classes: Interactive, animated hour-long classes for individuals or bulk purchased for organizations.

- Class transcripts and subtitles available in 9 languages including English, Japanese, Chinese, Spanish, French, French Canadian, Hindi, Arabic, and Russian. (Available for Micro Classes)
- Certificates available upon successful class completion with the ability to upload to your LinkedIn education profile. (Available for Micro and Recorded Signature Classes)

On-Demand Micro Classes Corporate Account Options

Enterprise

Manage your own company account within our Learning Management System (LMS) Assign classes and view individual's progress. Enterprise is intuitive and easy-to-manage.

Integration Bridge

Instantly expand your company's online training curriculum. Seamlessly connect your organization's LMS to Biotech Primer's LMS.

*** All Learning Management Systems and private websites quality for Biotech Primer's Web Hosted Integration Bridge allowing companies to maintain absolute privacy and autonomy during course participation and management.**

BIOTECH PRIMER
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Life Science Training From Industry Experts

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- Earn certificates and add to LinkedIn

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- Unlimited access to over 60 hours of life science training
- Earn certificates and add to LinkedIn

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Additional $400 OFF

- Includes all Micro Classes Recorded Signature Courses
- Unlimited access to over 100 hours of life science training
- Earn certificates and add to LinkedIn

Class Pricing

- **In-House Training:** The cost of tailored training depends on content, length of course, and number of participants.
- **Live Signature Courses:** Prescheduled two-day courses for individuals range from $1595-$1795 USD.
- **On-Demand Recorded Signature Courses:** These courses are 8-12 hours in length and cost $895 USD. Participants are given one year access to complete the course.
- **On-Demand Micro Classes:** Each class is $190 USD. BIO members receive special pricing of$160 USD per class. Participants are given one year access to class content.

Number of total classes	Discount per class	Price per class
10-20	25%	$152
21–100	30%	$133
101–250	40%	$114
251–500	50%	$95
500 and up	70%	$57

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REFERENCES

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Our Course Levels

Level 1

Foundational For individuals new to biopharma or for those who need a refresher on the fundamental science driving the healthcare industry.

Level 2

General For individuals who possess a general understanding of science basics.

Level 3

Advanced For individuals who have a good grasp of the science.

Our Publications

The Biotech Primer One: The Science Driving Biopharma Explained
Learn the basic science driving the biopharma industry in this fully illustrated 120-page book.

The Biotech Primer Two: Next Generation Therapies Explained
Learn how vaccines, therapeutic antibodies, cell therapy, gene therapy, and RNA therapeutic mitigate disease in this easy-to-read 170-page book.

The Primer: Science Made Simple
Read Biotech Primer's blog, The Primer, where science is explained simply.

BIOTECH PRIMER

BIOTECHNOLOGY FOR NON-SCIENTISTS

COURSE CATALOG

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Life Science Training From Industry Experts

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Life Science Training From Industry Experts

SIGNATURE COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

BioBasics 101

The Biology of Biotech for the Non-Scientist

OVERVIEW

BioBasics 101: The Biology of Biotech for the Non-Scientist offers a fascinating exploration of the fundamental scientific principles that underpin the life sciences. It delves into the crucial roles of the FDA, NIH, academia, and drug sponsors and how they interact to promote 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 details the genetic basis of diseases, highlighting the devastation of mutations and the impact of genomics and proteomics on personalized medicine. This course 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 course—register today!

Five Takeaways:

1. Master the essential terminology of the life science industry.
2. Identify the crucial roles of the FDA, NIH, academia, and research support companies and state how they work together to promote scientific breakthroughs.
3. Describe DNA, RNA, and protein structure and function and explain how these molecules interact in healthy and diseased tissue.
4. Discuss the genetic basis of diseases and the impact of genomics and proteomics on personalized medicine.
5. Explain the principles of genetic engineering and how this technology is used for research and biomanufacturing purposes.

AGENDA

DAY ONE

Introductions 15 minutes

Industry Overview: Setting the Stage 75 minutes

Biopharma US 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
Industry application: epigenetic medicines
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

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SIGNATURE COURSE | LEVEL TWO
SUGGESTED PREREQUISITE: BIOBASICS 101

Immunotherapy Immersion:

A Non-Scientist Guide to Immune-Based Medicine

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 class 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 course highlights the pivotal roles, mechanisms of action, and next-generation innovation of each revolutionary treatment. Grab your spot today and unlock the secrets of immunology and biopharma's cutting-edge innovations!

Five Takeaways:

1. Explain the mechanisms of the human immune system used to safeguard our health against cancer and autoimmune threats.
2. List vaccine platforms and discuss how they harness the power of immunological memory to protect us against infectious agents.
3. Examine the rationale behind therapeutic antibody mechanisms of action and cite the diverse approaches of monoclonal antibodies, antibody-drug conjugates, bispecific antibodies, and checkpoint inhibitors.
4. Contrast gene therapy and gene editing and analyze the unique features of each approach.
5. Describe how cell therapies are being used to treat liquid and solid tumors.

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 CLTA-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: Luxtuma and Zolgensama
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
CAR-T, CAR-NK, CAR-MA, CAR-Til
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 this approach
Next-generation CARs

Course Wrap-Up and Evaluation 15 minutes

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SIGNATURE COURSE | LEVEL TWO
SUGGESTED PREREQUISITE: **BIOBASICS 101**

Regenerative Medicine Immersion:

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

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 class 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. Secure your spot in our newest signature course by signing up today!

Five Takeaways:

1. State the characteristics and describe the differences between types of stem cells, including induced pluripotent stem cells.
2. Summarize the risks and medical challenges associated with gene therapy.
3. Explain the structure and function of the cell therapy CAR receptor and provide an overview of CAR-T, CAR-NK, CAR-MA, and CAR-Til's mechanisms of action.
4. Compare the various gene editing techniques, such as Zinc-Finger Nucleases (ZFN), CRISPR, BASE editing, and PRIME editing.
5. List 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
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: Luxtuma and Zolgensama
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
CAR-T, CAR-NK, CAR-MA, CAR-Til
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 this approach
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

RECORDED SIGNATURE COURSE | LEVEL ONE | 8 HOURS

SUGGESTED PREREQUISITE: NONE

Recorded BioBasics 101

The Biology of Biotech for the Non-Scientist

OVERVIEW

This is the recorded BioBasics 101 course with the same content, interactive exercises, and course materials that are given in the live version. You have one year access to this course.

Recorded BioBasics 101: The Biology of Biotech for the Non-Scientist offers a fascinating exploration of the fundamental scientific principles that underpin the life sciences. It delves into the crucial roles of the FDA, NIH, academia, and drug sponsors and how they interact to promote 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 details the genetic basis of diseases, highlighting the devastation of mutations and the impact of genomics and proteomics on personalized medicine. This course culminates with a survey of immunotherapies, which sets the scene for BioBasics 201, a follow-on course that expertly examines all therapeutic drug classes. Get ready to revolutionize your understanding of the life science industry in this interactive course—register today!

Five Takeaways:

1. Master the essential terminology of the life science industry.
2. Identify the crucial roles of the FDA, NIH, academia, and research support companies and state how they work together to promote scientific breakthroughs.
3. Describe DNA, RNA, and protein structure and function and explain how these molecules interact in healthy and diseased tissue.
4. Discuss the genetic basis of diseases and the impact of genomics and proteomics on personalized medicine.
5. List types of immunotherapies and summarize how each mitigates disease.

AGENDA

WEEK 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

WEEK 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

WEEK 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

WEEK 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

WEEK FIVE

Genetic Engineering 55 minutes

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

WEEK 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

WEEK 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

WEEK 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

Course Evaluation 20 minutes

RECORDED SIGNATURE COURSE | LEVEL TWO | 9 HOURS

SUGGESTED PREREQUISITE: BIOBASICS 101

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Recorded BioBasics 201

Targeted Therapeutics Explained for the Non-Scientist

OVERVIEW

This is the recorded BioBasics 201 course with the same content, interactive exercises, and course materials that are given in the live version. You have one year access to this course.

Recorded 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 class 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. Grab your spot today and unlock the secrets of immunology and biopharma's cutting-edge innovations!

Five Takeaways:

1. Explain the mechanisms of the human immune system used to safeguard our health against cancer and pathogenic threats.
2. List vaccine platforms and discuss how they harness the power of immunological memory to protect us against infectious agents.
3. Examine the rationale behind therapeutic antibody mechanisms of action and cite the diverse approaches of monoclonal antibodies, antibody-drug conjugates, bispecific antibodies, and checkpoint inhibitors.
4. Contrast DNA-based and RNA-based therapies and analyze the unique features of each approach.
5. Describe how cell therapy, including cell-based immunotherapies, stem cell-based therapies, and gene therapies, are being used to treat liquid and solid tumors.

AGENDA

WEEK 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

WEEK 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 CLTA-4

Industry application: tumor suppression of T-cells

WEEK THREE

Targeted Biologics: Vaccines 80 minutes

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

WEEK FOUR

Focus On: Oncology 25 minutes

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

WEEK FIVE

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

WEEK 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: CAR treatment for autoimmunity

WEEK 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

WEEK 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: Luxtuma
Industry application: Zolgensa
AAV neutralizing antibodies
Gene therapy and biomarkers
Durability of effect
RMAT designation
Risks and challenges

WEEK 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
- CRISPR babies activity
- CRISPR as RNA editor
- CRISPR diagnostics
- Industry application: SHERLOCK and DECETR

WEEK 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

ON-DEMAND MICRO CLASS | LEVEL ONE | 85-MINUTES

SUGGESTED PREREQUISITE: NONE

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Life Science Training From Industry Experts

The Biology of Biotech

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. Develop a comprehensive understanding of DNA, RNA, and proteins in the context of biotechnology.
2. Become well-versed in the process of gene expression.
3. Demonstrate knowledge of cell structure and function and how scientists manipulate cells to develop new products.
4. Define genetic variation and explain its role in disease.
5. Explore the connection between genetic mutations and diseases and acquire valuable insights into disease diagnosis and treatment.

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 funcitons

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

ON-DEMAND MICRO CLASS | LEVEL TWO | 50-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH

biotechPrimer
Life Science Training From Industry Experts

Genetic Engineering Primer

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. Explain how an organism's DNA is modified for research, discovery, development, and biomanufacturing.
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 proteins defined
- Recombinant proteins synthesis in bacterial cells
- Recombinant proteins 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

ON-DEMAND MICRO CLASS | LEVEL TWO | 40-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH

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Life Science Training From Industry Experts

Immunology Primer 101

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. Highlight the differences between non-specific and specific immunity.
2. Name the cells and the tissues of the immune system.
3. Compare how the immune system distinguishes between self and non-self when fighting disease.
4. Summarize the general steps of the non-specific immune system to combat disease.
5. Discuss the relationship between the naturally occurring immune system and the immune-inspired therapies created by the biopharma industry.

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

ON-DEMAND MICRO CLASS | LEVEL THREE | 55-MINUTES

SUGGESTED PREREQUISITE: IMMUNOLOGY PRIMER 101

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Immunology Primer 201

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. List in meticulous detail the intricate processes of the specific immune response.
2. Explain how the specific immune system recognizes, responds to, and eliminates cancer and infection.
3. Describe how the immune system's memory B-cells and T-cells fight reinfection.
4. Summarize the role of cytokines and why/how cytokine storms may occur due to some medications.
5. Explore the use of immune responses to develop novel immunotherapies and vaccines to combat cancer and infections.

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: Putting It All Together

- 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

ON-DEMAND MICRO CLASS | LEVEL THREE | 70-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH, IMMUNOLOGY PRIMER 101

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Life Science Training From Industry Experts

Antibody Primer

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. Explain how the unique structure of antibodies can be manipulated to change its function for therapeutic and diagnostic use.
2. Compare and contrast polyclonal, monoclonal, and humanized antibody uses and production methods.
3. Discuss how and why the antibody-antigen interaction occurs and its importance to clinical and medical device applications.
4. Analyze the mechanisms of action of innovative biologics such as monoclonal antibodies, antibody-drug conjugates, bispecific antibodies, and checkpoint inhibitors to understand how each fights disease.
5. Gain proficiency in foundational diagnostic techniques that use antibodies, such as ELISA, bead immunoassays, and lateral flow immunochromatographic assays.

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
- 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

ON-DEMAND MICRO CLASS | LEVEL TWO | 65-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH

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Life Science Training From Industry Experts

Biosimilars Primer

OVERVIEW

Biosimilars Primer explains the science, manufacturing technology, and regulatory requirements for receiving approval to market biosimilar products. Beginning with an overview of protein structure, function, and production, this class hones in on different types of biologics and how each fights disease. This class highlights how production conditions can alter a biosimilar, causing it to function differently than its reference product. The course ends with a Safety and Regulation section that examines immunogenicity and approaches to demonstrating biosimilar safety and efficacy that have been acceptable to the FDA and EMA. Four real-world case studies illustrate the complexity and versatility of biosimilars in treating various medical conditions. Enroll today!

Five Takeaways:

1. Discuss how post-translational modifications can change a biosimilar's intended function.
2. Conclude how biosimilars may differ from their reference product due to the biomanufacturing process.
3. Justify the EMA's and FDA's Totality-of-the-Evidence requirements for biosimilar approval and the underlying scientific, quality, and regulatory principles involved.
4. Emphasize the rigorous safety standards required in clinical trials due to the potential of biosimilars triggering immunogenicity.
5. Analyze real-world case studies to understand the complexity and versatility of biosimilars in treating different medical conditions.

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
- Same gene can produce a different protein
- Upstream process: cell culture seeding and scale-up
- Downstream processing: harvesting and purification
- 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

ON-DEMAND MICRO CLASS | LEVEL TWO | 90-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH

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Gene Therapy Primer

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. Command the scientific principles and regulatory intricacies behind gene therapy technologies.
2. Gain proficiency in the mechanics of viral vectors, including the amounts of genetic material each vector type delivers and the cell types of each target.
3. Analyze the key factors determining the diseases' suitability for gene therapy intervention.
4. Critique proven and new approaches to offset gene therapy adverse reactions in the clinic.
5. Evaluate the FDA approval process and the rigorous standards employed to assess the safety and effectiveness of gene therapies.

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
- 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

ON-DEMAND MICRO CLASS | LEVEL TWO | 45-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH AND GENE THERAPY PRIMER

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Cell Therapy Primer

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. Identify stem cell therapies and list their applications in regenerative medicine.
2. Explain the general mechanism of action for Chimeric Antigen Receptors (CARs).
3. Evaluate the commercial viability of CAR-T cell therapy to predict its real-world impact to transform medicine.
4. Explore ongoing innovations and potential use of CARs with cell types other than T-cells for solid tumors.
5. Paraphrase the steps used in manufacturing CAR-T for use in patients.

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

BIOTECH PRIMER

DRUG DEVELOPMENT FOR NON-SCIENTISTS

COURSE CATALOG

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SIGNATURE COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

Drug Development Immersion

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 course 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. This class 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. Become proficient in the terminology and acronyms used in preclinical and clinical development.
2. State the roles of regulatory agencies worldwide and list the tools they use to ensure approved drugs are safe and efficacious.
3. Cite the testing criteria in preclinical development that ensure a candidate drug is safe and supports first-in-human clinical trials.
4. Explore the rationale, study design, and special considerations for both traditional and non-traditional clinical trial phases.
5. Discuss 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
US 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 studies
Combining Phase I/II trials

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 15 minutes

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SIGNATURE COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

Biopharmaceutical Commercialization Immersion

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 course 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. Enroll today for an immersive learning experience and uncover the strategies for successful launch planning, building competitive advantage, and thriving in a rapidly evolving marketplace!

Five Takeaways:

1. Identify key commercialization success factors and their value as a core, differentiating competency.
2. Access a commercialization "toolbox" that can be immediately and practically applied.
3. Gain a comprehensive understanding of the product launch process.
4. Recognize key issues, opportunities, and challenges of effective commercialization strategy and tactics.
5. Discover tools needed to build compelling and effective 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

Course Evaluation 15 minutes

Course Wrap-Up 15 minutes

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SIGNATURE COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: DRUG DEVELOPMENT IMMERSION

Commercialization Readiness from Preclinical to First Launch: The First Time Biotech CEOs Playbook

OVERVIEW

Commercialization Readiness from Preclinical to First Launch will equip early-stage biotechnology leaders with the commercialization knowledge they need to strategically position their organizations for financing success and meeting critical Commercial and Medical Affairs milestones.

The drug development process is complex and multifaceted, and understanding the commercialization considerations at each phase is vital. From preclinical to first product launch, this one-day course will help biotech executives make informed strategic choices for long-term success.

Beginning with Phase I, this interactive course 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. *Note these early commercial flows inform the corporate and partnering strategy at emerging biotech companies.*

Five Takeaways:

1. Discover how defensible revenue forecasts and meaningful clinical differentiation are the underpinnings of value creation at Preclinical to Phase I companies.
2. Access and review McKinsey, IQVIA, and Syneos data illustrating why most commercial launches fail (and how to prevent that).
3. Recognize the value of the Commercialization Roadmap and how it impacts both commercial and corporate strategy.
4. Identify key commercialization success factors and their value as a core, differentiating competency that impacts strategy and spending.
5. Gain a comprehensive understanding of the product launch process and understand the scope of work your CCO is responsible for heading to a successful launch.

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

Commercial and Medical Affairs Imperatives: Phase II–Phase III (pre-data) 40 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

Commercial and Medical Affairs Imperatives: Positive Data Readout to Launch 40 minutes

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

Medical Affairs Imperatives 40 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 15 minutes

Course Wrap-Up and Evaluation 15 minutes

RECORDED SIGNATURE COURSE | LEVEL ONE | 9 HOURS

SUGGESTED PREREQUISITE: NONE

Recorded Drug Development Immersion

OVERVIEW

This is the recorded Drug Development Immersion course with the same content, interactive exercises, and course materials that are given in the live version. You have one year access to this course.

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

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AGENDA

WEEK 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

WEEK 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
US patents and market exclusivity

WEEK 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

WEEK FOUR

General Principles: Ethics and Risk 25 minutes

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

WEEK 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

WEEK 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

WEEK 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

WEEK 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 studies

Combining Phase I/II trials

WEEK 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

WEEK 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

WEEK ELEVEN

Clinical Development Phase IV

15 minutes

Real-world evidence initiatives

Launch and lifecycle management

Drug safety and pharmacovigilance

Course Evaluation 20 minutes

Recorded Biopharmaceutical Commercialization Immersion

OVERVIEW

This is the recorded Biopharmaceutical Commercialization Immersion course with the same content, interactive exercises, and course materials that are given in the live version. You have one year access to this course.

Recorded 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 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. Enroll today for an immersive learning experience and uncover the strategies for successful launch planning, building competitive advantage, and thriving in a rapidly evolving marketplace!

Five Takeaways:

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

AGENDA

WEEK 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

WEEK 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

WEEK 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

WEEK FOUR

Creating the Value Proposition 97 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

WEEK 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

WEEK SIX

In-Line Planning 83 minutes

Key performance indicators (KPI)
Post launch threats
Building and sustaining competitive advantage
Lifecycle management challenges
Risk management strategies
Multichannel marketing
Developing key brand performance measures
Lose of exclusivity (LOE) commercialization planning
LOE timing considerations
LOE strategies
Market dynamics
Regulatory challenges

ON-DEMAND MICRO CLASS | LEVEL ONE | 55-MINUTES

SUGGESTED PREREQUISITE: NONE

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Small Molecule Drug Discovery Primer 101

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 demonstrates how scientists refine small molecule drugs before they undergo preclinical and clinical trials. Discover how proven techniques like computational modeling, in vitro testing, and animal studies are crucial 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 the terms drug target, drug candidate, and small molecule drug.
2. Acquire a foundational understanding of the drug discovery process for small molecules.
3. Compare and contrast the most common drug targets exploited by the pharmaceutical industry.
4. Gain insights into the known methods of identifying, validating, and selecting a drug target.
5. State the importance of identifying, validating, optimizing, and selecting a drug candidate.

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
- 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

ON-DEMAND MICRO CLASS | LEVEL TWO | 55-MINUTES

SUGGESTED PREREQUISITE:

SMALL MOLECULE DRUG DISCOVERY PRIMER 101

biotechPrimer
Life Science Training From Industry Experts

Small Molecule Drug Discovery Primer 201

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. Acquire an in-depth understanding of the rigorous drug discovery process for small molecules.
2. Explore the impact and results of typical drug development discovery platforms.
3. Master the art of performing lead optimization activities and learn the strategies that lead to remarkable outcomes.
4. Unlock the secrets to successfully advancing development candidates by understanding and applying the essential criteria for success.
5. Make well-informed decisions by justifying and selecting the most effective testing methods at each critical stage of the drug discovery process.

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

ON-DEMAND MICRO CLASS | LEVEL ONE | 45-MINUTES

SUGGESTED PREREQUISITE: NONE

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Life Science Training From Industry Experts

Drug Discovery of Biologics Primer 101

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. List the five steps of drug discovery and state each purpose.
2. Explain the methodologies of target identification and validation.
3. Discuss the selection considerations for a large molecule to become a drug candidate.
4. Describe the assays and the results needed to select a drug candidate.
5. Explain the importance of lead candidate optimization before preclinical development.

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

ON-DEMAND MICRO CLASS | LEVEL TWO | 45-MINUTES

SUGGESTED PREREQUISITE: DRUG DISCOVERY OF BIOLOGICS PRIMER 101

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Drug Discovery of Biologics Primer 201

OVERVIEW

Drug Discovery of Biologics Primer 201 builds upon the foundational knowledge of Drug Discovery of Biologics Primer 101, focusing on systematic insights into therapeutic antibody discovery. This course begins with the significance of antibody screening and structure-based affinity maturation, emphasizing antibody Chemistry, Manufacturing, and Controls (CMC) liabilities. Covering four therapeutic antibody classes, including immune checkpoint inhibitors, this class showcases the factors that influence early drug candidate selection. The data and transition criteria essential for advancing candidate drugs from the discovery phase to preclinical development are also covered. Enroll today to deepen your therapeutic antibody drug discovery knowledge!

Five Takeaways:

1. Master the drug discovery workflow and align specific goals for successful development.
2. Analyze the early drug candidate selection criteria and consider therapeutic antibody properties in the selection process.
3. Utilize in silicon, in vitro, and in vivo models to investigate functional pharmacological activity.
4. Demonstrate proficiency in the drug discovery considerations needed for the four distinct classes of antibody therapeutics.
5. Investigate pharmacology data and transition criteria to determine which drug candidates are progressing into preclinical development.

AGENDA

Drug Discovery Workflow

- Drug target identification and validation
- Drug candidate identification
- Lead candidate selection and optimization
- Preclinical and clinical development

Affinity Maturation and CMC Liabilities

- Structure-based affinity maturation
- Targeted diversification methods
- Chain shuffling
- Formulation
- CMC liabilities
  - Aggregation
  - Solubility
  - Immunogenicity
  - Glycationt

Early Drug Candidate Selection

- Drug size and complexity
- Drug target interaction
- Discovery process criteria
- In silico, in vitro, and in vivo models
- Human immunoglobulin functions and structures
- Fc and Fab regions

Antibody Diversity

- Therapeutic antibody classe
  - Canonical blocking antibodies
  - Antibody-drug conjugates
  - Antibody-like molecules
  - Reactivators of the immune response
  - Antibody-like molecules
- Cell banking
  - Master cell banks
  - 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

ON-DEMAND MICRO CLASS | LEVEL ONE | 55-MINUTES

SUGGESTED PREREQUISITE: NONE

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Preclinical Development Primer 101

OVERVIEW

Preclinical Development Primer 101 guides you through the essential steps of early-stage drug development and the efficacy and safety standards that must be met prior to beginning clinical trials. This class integrates the key disciplines of pharmacology, pharmacokinetics/ pharmacodynamics, and toxicology to showcase the attributes that make a compelling drug candidate. This primer finishes by revealing the regulatory steps to file an Investigational New Drug (IND) application required to initiate clinical trials. This 101 class equips you with the foundational knowledge needed to understand the basics of preclinical development. Join now and gain a command of the preclinical process!

Five Takeaways:

1. List in order the crucial steps involved in preclinical development and state the purpose of each.
2. Compare the objectives of pharmacology and toxicology in preclinical development.
3. Contrast the data received in pharmacodynamics and pharmacokinetic studies.
4. Explain how to estimate starting does in animals using data from in silico and in vitro testing.
5. State the importance of integrating data collected during pharmacology and toxicology studies into the Common Technical Document for an IND submittal.

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 assay
- Potency assay
- Dose-response curves
- Receptor occupancy assay
- Efficacy assay

Pharmacokinetics and Pharmacodynamics

- Pharmacokinetics explained
- Measuring pharmacokinetics
- Pharmacokinetics: absorption
- Pharmacokinetics: 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
- Concordance of animal and human toxicities
- 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

ON-DEMAND MICRO CLASS | LEVEL TWO | 55-MINUTES

SUGGESTED PREREQUISITE: PRECLINICAL DEVELOPMENT PRIMER 101

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Preclinical Development Primer 201

OVERVIEW

Preclinical Development Primer 201 builds upon the established knowledge in Preclinical Development Primer 101, utilizing real-world examples and case studies to delve deep into the specific tests and data required to file a successful Investigational New Drug (IND) application. The class focuses first on efficacy, centered around pharmacology studies, including binding and potency assays, and second on safety, including ADME, hERG, DART, PK/PD, mutagenicity, and carcinogenicity testing. This primer examines each preclinical test's goals and outcomes, evaluating data results to determine therapeutic margin, side effects, and optimal drug concentration. Finally, the class describes the workflow, timeline, and standards for validating and qualifying these tests. Don't miss this opportunity to understand preclinical development—secure your spot today!

Five Takeaways:

1. State the FDA criteria necessary to support first-in-human clinical trials.
2. List the required pharmacology assays, explain their purposes, and outline the criteria to move the candidate drug onto clinical trials.
3. Analyze dose-response curves to estimate clinical starting dose levels.
4. Name the required toxicology assays, list their purposes, and state the criteria to move the candidate drug onto clinical trials.
5. Evaluate tissue culture and animal testing data to assess the drug candidate's impact on safety

AGENDA

Overview

- Drug development metrics: chances of success, timelines, and costs
- Preclinical development overview
- Investigational new drug (IND)
- Clinical trial application (CTA)
- Pre-IND: pharmacology, pharmacokinetics, toxicology

Pharmacology

- Pharmacology defined
- Binding assay: Law of Mass Action
  - Equilibrium dissociation (Kd)
  - Association /affinity (Ka) constants
- Potency assay: dose-response curves
- Efficacy assay: full, partial, inverse agonist and antagonist drugs
- Antagonist drug mechanism of action
- Agonist drug mechanism of action
- Product design: ROA, acute vs chronic, dose, container
- Animal model challenges

Pharmacokinetics

- Pharmacokinetics defined
- ADME
- Regulatory agencies
- GXP compliance: GLP, GMP, GCP
- Bioanalytical assay: API concentration
- Bioanalytical assay workflow and timeline
- Validation and qualification criteria
- Pharmacokinetics and pharmacodynamics measurements

Toxicology

- Animal model/species selection
- Animal research: replace, reduce, refine
- Concordance of animal and human toxicities
- Differences between animals and humans: subjects, doses, diagnostic procedures
- Preclinical testing: mutagenicity, hERG, acute/chronic toxcity, 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

ON-DEMAND MICRO CLASS | LEVEL ONE | 60-MINUTES

SUGGESTED PREREQUISITE: NONE

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Drug Approval Primer

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 class. Grab your spot today to gain insights into the process of bringing new drugs to market!

Five Takeaways:

1. Discuss the essential components and timing of Investigational New Drug (IND) applications in the United States and Clinical Trials Application (CTA) in the European Union.
2. Explain the purpose and impact of the PDUFA legislation.
3. Explore the criteria for various expedited drug approval pathways and how these designations can significantly speed up the timing of the regulatory process.
4. Gain insight into the intricacies of filing for a New Drug Application (NDA) or Biologics License Application (BLA) in the United States and a Marketing Authorisation Application (MAA) in the European Union.
5. Compare the approval pathways for generic drugs and biosimilars, highlighting each case's unique considerations and challenges.

AGENDA

Introduction to the Regulatory Process

- Organization and mission of the FDA and EMA
- Global harmonization drug testing requirements

IND/CTA Filing

- IND applications and CTA
- 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
- Pathways employed by the EMA

Market Approval

- NDA and BLA in the US and lists the different
- Paths to approval in the EU
- Generics and biosimilars approval pathways

ON-DEMAND MICRO CLASS | LEVEL ONE | 55-MINUTES

SUGGESTED PREREQUISITE: NONE

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Clinical Development 101: General Principles

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:

1. Enumerate the clinical trial phases in order, explain the purpose of each, and list their milestones.
2. Identify the key individuals and groups involved in clinical trials and explain their roles in detail.
3. Define foundational drug development concepts to control bias, such as control groups, blinding, and randomization.
4. Choose the appropriate study design criteria to reduce bias and ensure patient safety.
5. Compile a list of regulatory studies and the data each collects to enable follow-on studies.

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
- Ethics committees and institutional review boards
- Clinical trial data management and reporting

ON-DEMAND MICRO CLASS | LEVEL TWO | 50-MINUTES

SUGGESTED PREREQUISITE: CLINICAL DEVELOPMENT 101

Clinical Development 201: Phase I

OVERVIEW

Clinical Development 201: Phase I provides insights into Phase 0 and Phase I clinical trials, including their purpose and regulatory requirements. This class, the second in the Biotech Primer Clinical Development series, 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. Evaluate the purposes and critical differences between Phase 0 and Phase I clinical trials.
2. Enumerate the types of endpoints used to assess efficacy in Phase I studies.
3. Compare the dosing strategies of Single Ascending Dose (SAD) and Multiple Ascending Doses (MAD) and explain when each is employed.
4. Describe the vital steps sponsors take upon completion of Phase I clinical development.
5. Emphasize the significance of Clinical Trial Safety Reports in evaluating the safety and overall success of Phase I clinical trials.

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 and 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

ON-DEMAND MICRO CLASS | LEVEL THREE | 55-MINUTES

SUGGESTED PREREQUISITE: CLINICAL DEVELOPMENT 101, CLINICAL DEVELOPMENT 201

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Clinical Development 301: Phase II/III

OVERVIEW

Clinical Development 301: Phase II/III focuses on the purpose and critical differences between well-controlled Phase II and III studies. This class 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. Evaluate the purposes and key differences between Phase II and III clinical trials.
2. Contrast the regulatory significance of clinical endpoints, primary endpoints, secondary endpoints, and surrogate endpoints.
3. List the special designations that can accelerate the drug candidates' development.
4. Explain the basic statistical analysis completed in late-stage trials.
5. State the critical role data safety monitoring boards play in patient safety.

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

ON-DEMAND MICRO CLASS | LEVEL THREE | 50-MINUTES

SUGGESTED PREREQUISITE: CLINICAL DEVELOPMENT 101, CLINICAL DEVELOPMENT 201,CLINICAL DEVELOPMENT 301

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Clinical Development 401: Phase IV

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. Highlight the significance of Phase IV clinical trials in monitoring a drug's real-world performance and safety.
2. Identify the limitations associated with Phase I-III clinical trials in representing the broader patient population and detecting rare side effects.
3. Appreciate the importance of pharmacovigilance in post-marketing drug safety follow-up.
4. Illustrate the role of regulatory actions in mitigating risks associated with approved drugs and safeguarding public health.
5. Identify two government-run reporting programs used to report adverse reactions to approved medicines.

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

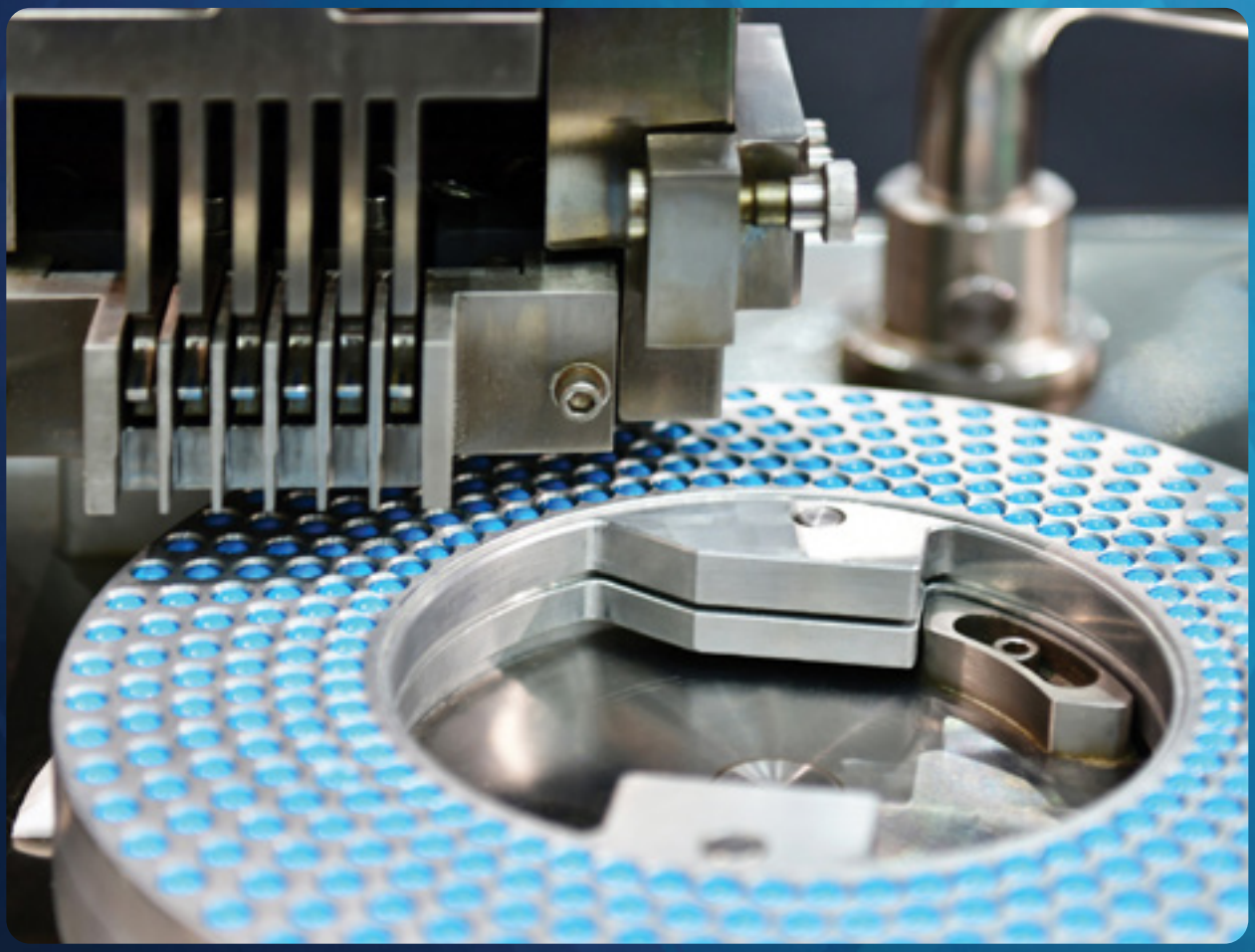
- Drug safety: pharmacovigilance
- Signal detection and analysis
- Regulatory actions: post-approval risk mitigation

Real-World Evidence

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

BIOTECH PRIMER

DRUG MANUFACTURING FOR NON-SCIENTISTS



COURSE CATALOG

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ON-DEMAND MICRO CLASS | LEVEL ONE | 45-MINUTES

SUGGESTED PREREQUISITE: NONE

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CMC Primer

OVERVIEW

CMC Primer explores the essential considerations in drug development known as Chemistry, Manufacturing, and Controls (CMC). It starts by explaining the critical importance of CMC implementation using the Common Technical Document to ensure patient safety. The course then analyzes in detail the significance of CMC across every stage of drug development, from discovery to preclinical and clinical development, ending with post-launch considerations. Furthermore, CMC Primer focuses on the key aspects of CMC, such as Chemistry, Manufacturing, and Controls, through three practical case studies. The course ends by showcasing CMC's regulatory implications, post-approval measures, and common challenges encountered in the field. Enroll today and gain insight into CMC's pivotal role in drug development, manufacturing, and patient safety.

Five Takeaways:

1. Discuss the purpose of CMC in drug development and manufacturing.
2. List the three CMC components and provide an in-depth explanation of their focus.
3. Specify what CMC data is found in the Common Technical Document (CTD) and its importance.
4. State three reasons CMC is critical to patient safety.
5. Identify and compare Control studies for CMC, including the study establishing drug product shelf life and studying degradation over time.

AGENDA

CMC: Drug Development Considerations

- What is CMC?
- Chemistry, Manufacturing, Controls components overview
- CMC implementation in the common technical document
- CMC in drug discovery
- CMC in preclinical and clinical development
- CMC in post-launch
- The importance of CMC

CMC: In Action

- Purpose of the Chemistry component
- CMC Chemistry assessments
  - Studies in API identification, formulation, compatibility, stability, impurity, polymorphism, solubility, morphology, etc.
- Case study: Zantac
- Purpose of the Manufacturing component

CMC: In Action *(continued)*

- CMC Manufacturing assessments
  - Validation, batch records, facility design, quality control, environmental monitoring, scale-up, process validation, etc.
- Case study: Children's Dimetapp
- Purpose of the Controls component
- 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 and accountability, risk management
- CMC data considerations
- CMC in post-marketing surveillance
  - Batch consistency, stability monitoring, change control, regulatory compliance, adverse events monitoring
- Five CMC measures post-approval
- Common CMC challenges
  - Process variability and regulatory changes
- Case study: Vioxx

ON-DEMAND MICRO CLASS | LEVEL TWO | 50-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH, GENETIC ENGINEERING PRIMER

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cGMP Primer

OVERVIEW

cGMP Primer introduces the benefits and challenges of current Good Manufacturing Practices. The first section sets the stage with the regulatory bodies that enforce cGMP worldwide and the laws that pertain to it. This class takes a deep dive into the six cGMP pillar requirements, including Quality Management System (QMS), Premises and Equipment, Personnel Training, Materials Management, Documents and Records, and Validation and Qualification. This primer ends with a focus on regulatory audits, the Establishment Inspection Report (EIR), non-compliance, and remediations such as a 483. Two real-world case studies provide the opportunity to showcase your newfound knowledge by identifying the non-compliance and determining the corrective action. Take your spot for this introductory cGMP course!

Five Takeaways:

1. Gain a comprehensive understanding of cGMP by exploring its definition, importance, and historical context.
2. Identify the global regulatory bodies that enforce cGMP and familiarize yourself with the laws and publications governing this crucial manufacturing practice.
3. State the specific requirements of each cGMP pillar.
4. Explain the challenges involved in implementing cGMP and list the strategies to overcome them.
5. Analyze real-world case studies to identify non-compliance issues and develop effective corrective actions to ensure compliance in manufacturing operations.

AGENDA

Understanding cGMP

- cGMP defined
- Importance of cGMP
- History of cGMP
- Global regulatory bodies who enforce cGMP
- Global regulatory 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
  - Appropriate qualifications
  - Personal protective equipment (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*

ON-DEMAND MICRO CLASS | LEVEL TWO | 50-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH, GENETIC ENGINEERING PRIMER

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Biomanufacturing Primer

OVERVIEW

Biomanufacturing Primer introduces the ever-evolving world of biomanufacturing. It gives a scientific overview of essential topics such as the intricacies driving cell lines, cell banks, upstream/downstream bioprocessing, and the latest advancements in this dynamic field. The class compares the fascinating differences between bacterial and mammalian cell lines and explains which drug products each can and cannot produce. The concept of cell banks, both master and working cell banks, and their critical manufacturing roles are explained in detail. This primer outlines the art of upstream bioprocessing (optimizing cell growth and scale-up) and downstream bioprocessing (harvesting and purifying protein drug products). The class ends by highlighting incredible advancements such as continuous bioprocessing, single-use technologies, and critical quality attributes. Register today for this informative class and gain a foundational understanding of biomanufacturing!

Five Takeaways:

1. Explain the process of bacterial and mammalian cell line development.
2. Compare the roles of a master cell bank and the working cell bank.
3. Describe, in detail, the steps of upstream and downstream bioprocessing and how to optimize cell growth for maximum productivity.
4. Discuss the highly regulated testing protocols that ensure product quality.
5. Cite the benefits and risks of game-changing advancements in biomanufacturing, including continuous bioprocessing and single-use technologies.

AGENDA

Cell Lines

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

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

Pharmaceutical Manufacturing Primer

OVERVIEW

Pharmaceutical Manufacturing Primer covers essential aspects of small molecule drug production. It begins with the unique ingredients incorporated into these medications, emphasizing the roles of active pharmaceutical ingredients (API) and excipients. Various chemical synthesis methods are demonstrated, including organic, linear, convergent, and stereoselective approaches. The intricate purification process and stringent regulatory aspects of API production are explained, along with supplier validation requirements. This foundational class continues with formulation goals and dosage form characteristics, such as tablets and capsules. It ends with a deep dive into packaging considerations, highlighting fill and finish methodology, regulations, tamper resistance measures, anti-counterfeit technologies, and supply chain management, including cold chain logistics. Grab your spot today for this comprehensive class that provides insight into the intricate manufacturing processes of small molecule drugs!

Five Takeaways:

1. Diagram the essential stages involved in the production of small molecule drugs.
2. List the primary components that constitute a small molecule drug and state the functions of each.
3. Clarify regulators' methods to guarantee quality control during supplier selection, production, packaging, and shipping validation.
4. Explore the similarities and differences between the four prevalent forms of pharmaceutical formulations: tablets, capsules, suspensions, and emulsions.
5. Detail the factors to be considered in the pharmaceutical supply chain, including measures to prevent drug tampering and counterfeiting.

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

ON-DEMAND MICRO CLASS | LEVEL TWO | 50-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH, GENETIC ENGINEERING PRIMER, BIOMANUFACTURING PRIMER

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Gene Therapy Manufacturing Primer 101

OVERVIEW

Gene Therapy Manufacturing Primer 101 is a foundational class that ventures into the essential AAV production platforms, comparing four different approaches and dissecting the key elements of the AAV cassette. This class illustrates the basic upstream/downstream bioprocessing stages, contrasting suspension and adherent cell lines. Bioreactors, such as hyperstacks and iCellis, are examined for their role in this cutting-edge process. This primer ends by summarizing the role of CMC in AAV development, giving an overview of identity, potency, purity, and sterility testing required by the regulatory authorities. Grab your seat today for this introductory course and become conversant in gene therapy manufacturing!

Five Takeaways:

1. Gain mastery in the structure and function of AAV.
2. Describe how AAV types affect tissue targeting and give examples.
3. Compare and contrast common AAV vector systems.
4. List in order the general steps of AAV gene therapy production.
5. Investigate the main regulatory guidelines for conducting CMC evaluations of AAV viral vectors.

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 overview

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

ON-DEMAND MICRO CLASS | LEVEL THREE | 65-MINUTES

SUGGESTED PREREQUISITE: GENE THERAPY MANUFACTURING PRIMER 101

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Gene Therapy Manufacturing Primer 201

OVERVIEW

Gene Therapy Manufacturing Primer 201 is a deep dive into cGMP manufacturing processes for AAVs. This class explores in detail the science and regulatory controls of AAV gene therapy manufacturing. It begins by elucidating the critical steps in upstream vector cGMP production platforms, including Transient Transformation (TT), Baculovirus Expression (rBV/Sf9), Herpes Simplex Expression (HSV/BHK), and Producer Cell Lines (PCL). It continues by focusing on CMC strategies and precursor materials for each production platform. Purification strategies, AAV vector product characterization, analytical testing for safety and quality, viral vector manufacturing facility design, and regulatory considerations for AAV vectors are considered in detail. Take the next step and learn the highly technical aspects of AAV gene therapy manufacturing. Enroll today!

Five Takeaways:

1. Explain how the structure and functions of the AAV virus influence its tissue tropisms.
2. Analyze the challenges faced in manufacturing recombinant AAV gene therapy vectors.
3. Identify the strengths and weaknesses of the different AAV vector production platforms Transient Transformation (TT), Baculovirus Expression (rBV/Sf9), Herpes Simplex Expression (HSV/BHK), and Producer Cell Lines (PCL).
4. Examine downstream bioprocessing strategies, including CMC strategies and precursor materials, for each production platform (TT, rBV/Sf9, HSV/BHK, PCL).
5. Assess the key considerations in viral vector manufacturing facility design and regulatory requirements for AAV vectors, ensuring compliance with safety, identity, potency, quality, and purity testing.

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 strategies
- TT GMP precursor materials
- TT critical raw materials: fetal bovin serum, polyethylenine, benzonase
- rBV/sF9 CMC strategies
- rBV/sF9 GMP precursor materials and raw materials
- HSV/BHK CMC strategies
- HSV/BHK GMP precursor materials and raw materials
- PLC CMC strategies
- PLC GMP precursor materials and raw materials
- 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

ON-DEMAND MICRO CLASS | LEVEL ONE | 60-MINUTES

SUGGESTED PREREQUISITE: NONE

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Laboratory Worker Biosafety Primer

OVERVIEW

Laboratory Worker Biosafety Primer introduces the biosafety guidelines that keep workers, the environment, and the public safe. It uses the World Health Organization (WHO) process and framework to explain how to identify and assess infectious agent risk, so this content is appropriate for science workspaces worldwide. This class focuses on the hierarchy of controls, including the elimination/substitution of dangerous protocols and equipment, engineering controls, administrative controls, and personal protective equipment (PPE). Proper laboratory design is also crucial in ensuring containment and control measures are in place, so a bonus section on facility design is included. The Laboratory Worker Biosafety Primer is a need-to-have course for all who work in a science space- register today and stay safe!

Five Takeaways:

1. Explain the WHO risk assessment frameworks and processes for identifying and assessing infectious agents.
2. Discuss ways to lower exposure to infectious biological agents through engineering controls.
3. State the administrative controls used in lab safety regulations and the role each plays.
4. Identify the most common personal protective equipment (PPE) and explain the rationale for each.
5. Provide examples of facility design elements that protect workers, the environment, and the public from accidental exposure or unintentional release of infectious biological agents and toxins.

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
- World Health Organization (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
  - US 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

ON-DEMAND MICRO CLASS | LEVEL ONE | 40-MINUTES

SUGGESTED PREREQUISITE: NONE

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Implementing a Biosafety Program Primer

OVERVIEW

Implementing a Biosafety Program Primer discusses the principles, practices, and personnel related to biosafety and biosecurity programs. This class explains the identification principles of biologic and select agents, categorizing them into four risk levels. It breaks down the practices involving various techniques, such as targeted diversification, chain shuffling, and formulation, which aim to address CMC liabilities. This primer discusses the roles of personnel involved in biosafety programs, including the institutional biosafety committee, biosafety officer, and biosecurity director. It ends with a detailed look at workplace controls and how to report/ investigate breaches should they occur. Grab your spot today and ensure a robust biosafety and biosecurity program in your organization!

Five Takeaways:

1. Become fluent in the fundamental principles required to establish a biosafety and biosecurity program.
2. Identify the potential risks involved in operating a facility that deals with biological agents.
3. State the guidelines, inventory systems, training, and communication protocols to manage biosafety and biosecurity risks effectively.
4. Describe the workplace controls commonly implemented to control and mitigate risks in a biosafety and biosecurity program.
5. Investigate the various roles and organizational structures within a biosafety and biosecurity program.

AGENDA

Principles

- Biosafety and biosecurity programs
- Biological and select agents
- Four biosafety risk levels
- Infectious agents

Practices

- Structure-based affinity maturation
- Targeted diversification methods
- Chain shuffling
- Formulation
  - CMC liabilities
  - Aggregation
  - Solubility
  - Immunogenicity
  - Glycation

Personnel

- Institutional biosafety committee (IBC)
- Biosafety program roles
  - Biosafety officers
  - Chief scientific officers
  - Principal investigators
  - Ancillary workers
  - Biohazard workers
  - Head of facility
  - Biosecurity director
  - Animal care and handling director

Controls

- Risk assessment considerations
- Change management programs
- Work practice controls
- Personal protective equipment (PPE)
- Decontamination and disposal
- Facility and equipment
- Biosecurity
  - Physical
  - Information
- Incident reporting and investigation
- Transport
- Occupational health
- Emergency plans
- Inventory
- Control reviews

ON-DEMAND MICRO CLASS | LEVEL ONE | 45-MINUTES

SUGGESTED PREREQUISITE: NONE

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OSHA Bloodborne Pathogen Standard Primer

OVERVIEW

OSHA Bloodborne Pathogen Standard Primer focuses on preventing the spread of infectious diseases by managing the chain of infection and handling biohazardous materials safely. This class sets guidelines for employers and employees on safe practices when dealing with potentially infectious materials. The standard covers biosafety levels, personal protective equipment, waste management, and disinfection procedures. Additionally, this primer explains the OSHA Emergency Response Procedures, including spill protocols, emergency response plans, and incident follow-up, which are crucial for worker safety. Compliance documents such as a biosafety manual and exposure control plan are also reviewed. Register today and become compliant with the OSHA Bloodborne Pathogen Standard!

Five Takeaways:

1. Identify common bloodborne biohazardous materials in the laboratory, clinical setting, and manufacturing facility.
2. Explain in detail the biosafety responsibilities and expectations of employers and employees as stated by the OSHA Bloodborne Pathogen Standard.
3. State the standard operating procedures for common microbiological work practices to avoid infections.
4. List the necessary documents required by a facility handling bloodborne pathogens and discuss the purpose of each.
5. Paraphrase the special considerations for sharps and various waste streams outlined by the OSHA Bloodborne Pathogen Standard.

AGENDA

Biosafety Basics

- Chain of infection
- Biohazardous material
- Human body fluids
- Infectious clinical specimens
- Infected animals
- Infected 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
- Biohazard lables
- 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

BUSINESS OF BIOTECH FOR NON-SCIENTISTS

COURSE CATALOG

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SIGNATURE COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

Biopharmaceutical Commercialization Immersion

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 course 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. Enroll today for an immersive learning experience and uncover the strategies for successful launch planning, building competitive advantage, and thriving in a rapidly evolving marketplace!

Five Takeaways:

1. Identify key commercialization success factors and their value as a core, differentiating competency.
2. Access a commercialization "toolbox" that can be immediately and practically applied.
3. Gain a comprehensive understanding of the product launch process.
4. Recognize key issues, opportunities, and challenges of effective commercialization strategy and tactics.
5. Discover tools needed to build compelling and effective 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

Course Evaluation 15 minutes

Course Wrap-Up 15 minutes

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SIGNATURE COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: DRUG DEVELOPMENT IMMERSION

Commercialization Readiness from Preclinical to First Launch: The First Time CEOs Playbook

OVERVIEW

Commercialization Readiness from Preclinical to First Launch will equip early-stage biotechnology leaders with the commercialization knowledge they need to strategically position their organizations for financing success and meeting critical Commercial and Medical Affairs milestones.

The drug development process is complex and multifaceted, and understanding the commercialization considerations at each phase is vital. From preclinical to first product launch, this one-day course will help biotech executives make informed strategic choices for long-term success.

Beginning with Phase I, this interactive course 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. *Note these early commercial flows inform the corporate and partnering strategy at emerging biotech companies.*

Five Takeaways:

1. Discover how defensible revenue forecasts and meaningful clinical differentiation are the underpinnings of value creation at Preclinical to Phase I companies.
2. Access and review McKinsey, IQVIA, and Syneos data illustrating why most commercial launches fail (and how to prevent that).
3. Recognize the value of the Commercialization Roadmap and how it impacts both commercial and corporate strategy.
4. Identify key commercialization success factors and their value as a core, differentiating competency that impacts strategy and spending.
5. Gain a comprehensive understanding of the product launch process and understand the scope of work your CCO is responsible for heading to a successful launch.

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

Commercial and Medical Affairs Imperatives: Phase II–Phase III (pre-data)
40 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

Commercial and Medical Affairs Imperatives: Positive Data Readout to Launch 40 minutes
Updated commercial assessment (revenue forecast)
Product strategy and marketing
Market access, pricing, and reimbursement (MAPR)
Health economics and outcomes research (HEOR)
Sales force
Distribution
Commercial ops and analytics
Training

Medical Affairs Imperatives 40 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 15 minutes

Course Wrap-Up and Evaluation 15 minutes

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SIGNATURE COURSE | LEVEL TWO
SUGGESTED PREREQUISITE: NONE

Revenue Forecasting and Epidemiology Immersion

OVERVIEW

Revenue Forecasting and Epidemiology Immersion showcases the intersection of epidemiology, revenue forecasting, and drug valuation. It details global market perspectives, tactical competitive assessments, market share analysis, drug pricing strategies, and the impact of demographics. These financial considerations are juxtaposition against epidemiology, including real-world disease rates, projections, and patient populations. This interactive course includes data source exercises, case studies, and revenue forecast activities. This engaging course equips you with the knowledge and skills to navigate the complex landscape of revenue forecasting using the science of epidemiology. Don't miss this opportunity to broaden your understanding and enhance your decision-making prowess. Enroll today and unlock the secrets to maximizing a drug's valuation!

Five Takeaways:

1. Explain how revenue forecasts are developed to drive strategic decision making and investment in the biopharma industry.
2. List the core elements of revenue forecasting and explain the role of each.
3. Discuss how revenue forecasting varies across geographies and cite the considerations that need to be accounted for.
4. Discuss the logical process (workstreams) that leads to effective, defensible revenue forecasting and the interpretation of its findings.
5. Generate insights and actionable decisions from the forecasting process.

AGENDA

DAY ONE

Revenue Forecasting Context 45 minutes

Forecasting's strategic and tactical roles
External and internal factors
Market perspectives: an art and science
Forecasting utilization in product lifecycle
Forecasting approaches
Market assessment, product forecast, in-line product support

Competitive Assessments 60 minutes

Determining indication, geography, time frame, resources
Defining scope: target product profile
Defining indication: databases
How to mine data for in clinicaltrials.gov
How to perform a technical review of data
How to determine if an agent is or is not a competitor
Netting out the competitive set
Competitive assessments with rare and genetic diseases
Adjusting risk when competitor is determined

Break 15 minutes

Market Share Assignment 60 minutes

Significance of market share
Measuring market share
Key factors: therapeutic value, number of competitors, launch speed
Market share models: advantages and disadvantages of each
McKinsey/MIT and Schulze/Rigel
McKinsey and Company/EvaluatePharma market share analysis

Lunch 45 minutes

Drug Pricing Today: What Every Biopharma Executive Should Know 75 minutes

Today's drug pricing environment
US drug pricing legislation
Different proposals to modify drug pricing
Drug pricing definitions
US payers: Medicare, Medicaid, CMS, private
Role of the pharmacy benefit manager (PBM)
Elements of pricing: clinical value, HEOR, pharmacoeconomic models, MAPR, GTN, rare disease
Pricing outside the US
Pricing references and resources
Annual price increases
Generics
Additional forecasting assumptions: duration of therapy, compliance, gross-to-net discoun

Break 15 minutes

Revenue Forecasting Elements: Epidemiology 60 minutes

Basic epidemiology terminology
Prevalence as a rate
Types of prevalence measures
Incidence as a rate
Relationship between prevalence and incidence
Using survival data
Epidemiology study designs
Cross-sectional study design
Cohort study design
Case-control study design

Wrap-Up 15 minutes

DAY TWO

Epidemiology: Disease Rates 60 minutes

How and why disease rates are used

Types of disease rates

World standard rates, crude rates, age specific rates, age-adjusted rates

Case Study: Japan vs Philippines Renal Cell Carcinoma Disease Rates

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Epidemiology: Role of Demographics in Epidemiological Projections 60 minutes

Data used in epidemiological projections

Prevalence and incidence: specific age and gender profiles

Example: cancer epidemiology profiles

Case Study: Japan vs Philippines: Demographic Changes Influence Future Trends

How to use disease rates to project future patients

Break 15 minutes

Epidemiology: The Process of Determining Patient Populations 60 minutes

Quantitative epidemiology process overview

Defining the patient

Defining level of patient's epidemiology

How to build the patient tree

Literature acquisition and data sources

How to process, analyze, and interpret data

How to create results: epidemiology calculations and meta-analysis

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Lunch 45 minutes

Epidemiology: Basic Sources of Epidemiological Data 45 minutes

Peer reviewed scientific/medical literature

PRISMA

Rare/orphan disease sources

Disease registries

Government health databases worldwide (US, Japan, Korea, China, Canada, EU, UK)

Case Study: Oncology Data Sources

Revenue Forecast Assumptions Summary 45 minutes

How to run a SEER query

Case Study: Epidemiology of AML

Case Study: Start Up CEO 45 minutes

Wrap-Up 15 minutes

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SIGNATURE COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

Drug Pricing, Policy, and Utilization Immersion

OVERVIEW

Drug Pricing, Policy, and Utilization Immersion exposes the complexities of the United States healthcare market by detailing how competing forces, including the US Federal government, the insurance industry, and healthcare providers influence formulary systems, which in turn determines 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 class 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 course is a must for anyone new to healthcare policy and pricing—grab your seat today!

Five Takeaways:

1. List the different types of information used to inform drug policy.
2. Utilize various types of analysis to determine drug prices.
3. Evaluate the rationale behind drug placement on formularies and their impact on patient outcomes.
4. Explain the intricacies of the product lifecycle and supply chain issues in pricing, marketing, and reimbursement.
5. Discuss the interconnected relationship between manufacturers, policymakers, pharmacies, and patients and how this influences access to medications.

AGENDA

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

Drug Placement Into Formularies 30 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

Break 15 minutes

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

Lunch 45 minutes

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

Break 15 minutes

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

Activity: Start-Up CEO 30 minutes

Wrap-Up 15 minutes

RECORDED SIGNATURE COURSE | LEVEL ONE | 8 HOURS

SUGGESTED PREREQUISITE: NONE

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Recorded Biopharmaceutical Commercialization Immersion

OVERVIEW

This is the recorded Biopharmaceutical Commercialization Immersion course with the same content, interactive exercises, and course materials that are given in the live version. You have one year access to this course.

Recorded 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 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. Enroll today for an immersive learning experience and uncover the strategies for successful launch planning, building competitive advantage, and thriving in a rapidly evolving marketplace!

Five Takeaways:

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

AGENDA

WEEK 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

WEEK 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

WEEK 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

WEEK FOUR

Creating the Value Proposition 97 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

WEEK 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

WEEK SIX

In-Line Planning 83 minutes

Key performance indicators (KPI)
Post launch threats
Building and sustaining competitive advantage
Lifecycle management challenges
Risk management strategies
Multichannel marketing
Developing key brand performance measures
Lose of exclusivity (LOE) commercialization planning
LOE timing considerations
LOE strategies
Market dynamics
Regulatory challenges

RECORDED SIGNATURE COURSE | LEVEL TWO | 7 HOURS

SUGGESTED PREREQUISITE: NONE

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Recorded Revenue Forecasting and Epidemiology Immersion

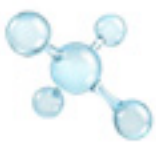
OVERVIEW

This is the recorded Revenue Forecasting and Epidemiology Immersion course with the same content, interactive exercises, and course materials that are given in the live version. You have one year access to this course.

Recorded Revenue Forecasting and Epidemiology Immersion showcases the intersection of epidemiology, revenue forecasting, and drug valuation. It details global market perspectives, tactical competitive assessments, market share analysis, drug pricing strategies, and the impact of demographics. These financial considerations are juxtaposition against epidemiology, including real-world disease rates, projections, and patient populations. This interactive course includes data source exercises, case studies, and revenue forecast activities. This engaging course equips you with the knowledge and skills to navigate the complex landscape of revenue forecasting using the science of epidemiology. Don't miss this opportunity to broaden your understanding and enhance your decision-making prowess. Enroll today and unlock the secrets to maximizing a drug's valuation!

Five Takeaways:

1. Explain how revenue forecasts are developed to drive strategic decision making and investment in the biopharma industry.
2. List the core elements of revenue forecasting and explain the role of each.
3. Discuss how revenue forecasting varies across geographies and cite the considerations that need to be accounted for.
4. Discuss the logical process (workstreams) that leads to effective, defensible revenue forecasting and the interpretation of its findings.
5. Generate insights and actionable decisions from the forecasting process.



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AGENDA

WEEK ONE

Revenue Forecasting Context 30 minutes

Forecasting's strategic and tactical roles
External and internal factors
Market perspectives: an art and science
Forecasting utilization in product lifecycle
Forecasting approaches
Market assessment, product forecast, in-line product support

WEEK TWO

Competitive Assessments 60 minutes

Determining indication, geography, time frame, resources
Defining scope: target product profile
Defining indication: databases
How to mine data for in clinicaltrials.gov
How to perform a technical review of data
How to determine if an agent is or is not a competitor
Netting out the competitive set
Competitive assessments with rare and genetic diseases
Adjusting risk when competitor is determined

WEEK THREE

Market Share Assignment 20 minutes

Significance of market share
Measuring market share
Key factors: therapeutic value, number of competitors, launch speed

WEEK FOUR

Market Share Models
40 minutes

Market share models: advantages and disadvantages of each
McKinsey/MIT and Schulze/Rigel
McKinsey and Company/EvaluatePharma market share analysis

WEEK FIVE

Drug Pricing Today 65 minutes

Today's drug pricing environment
US drug pricing legislation
Different proposals to modify drug pricing
Drug pricing definitions
US payers: Medicare, Medicaid, CMS, private
Role of the pharmacy benefit manager (PBM)
Elements of pricing: clinical value, HEOR, pharmacoeconomic models, MAPR, GTN, rare disease
Pricing outside the US
Pricing references and resources
Annual price increases
Generics
Additional forecasting assumptions: duration of therapy, compliance, gross-to-net discount

WEEK SIX

Basic Epidemiology Terminology
35 minutes

Prevalence as a rate
Types of prevalence measures
Incidence as a rate
Relationship between prevalence and incidence
Using survival data
Epidemiology study designs
Cross-sectional study design
Cohort study design
Case-control study design

WEEK SEVEN

Disease Rates 25 minutes

How and why disease rates are used

Types of disease rates

World standard rates, crude rates, age specific rates, age-adjusted rates

Case Study: Japan vs Philippines Renal Cell Carcinoma Disease Rates

WEEK EIGHT

Role of Demographics in Epidemiological Projections 15 minutes

Data used in epidemiological projections

Prevalence and incidence: specific age and gender profiles

Example: cancer epidemiology profiles

Case Study: Japan vs Philippines: Demographic Changes Influence Future Trends

How to use disease rates to project future patients

WEEK NINE

The Process of Determining Patient Populations 60 minutes

Quantitative epidemiology process overview

Defining the patient

Defining level of patient's epidemiology

How to build the patient tree

Literature acquisition and data sources

How to process, analyze, and interpret data

How to create results: epidemiology calculations and meta-analysis

WEEK TEN

Basic Sources of Epidemiological Data 60 minutes

Peer reviewed scientific/medical literature

PRISMA

Rare/orphan disease sources

Disease registries

Government health databases worldwide (US, Japan, Korea, China, Canada, EU, UK)

Case Study: Oncology Data Sources

WEEK ELEVEN

Revenue Forecast Assumptions Summary 20 minutes

How to run a SEER query

Case Study: Epidemiology of AML

Course Evaluation 20 minutes

RECORDED SIGNATURE COURSE | LEVEL ONE | 4.5 HOURS

SUGGESTED PREREQUISITE: NONE

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Recorded Drug Pricing, Policy, and Utilization Immersion

OVERVIEW

This is the recorded Drug Pricing, Policy, and Utilization Immersion course with the same content, interactive exercises, and course materials that are given in the live version. You have one year access to this course.

Recorded Drug Pricing, Policy, and Utilization Immersion exposes the complexities of the United States healthcare market by detailing how competing forces, including the US Federal government, the insurance industry, and healthcare providers influence formulary systems, which in turn determines 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 class 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 course is a must for anyone new to healthcare policy and pricing—grab your seat today!

Five Takeaways:

1. List the different types of information used to inform drug policy.
2. Utilize various types of analysis to determine drug prices.
3. Evaluate the rationale behind drug placement on formularies and their impact on patient outcomes.
4. Explain the intricacies of the product lifecycle and supply chain issues in pricing, marketing, and reimbursement.
5. Discuss the interconnected relationship between manufacturers, policymakers, pharmacies, and patients and how this influences access to medications.

AGENDA

WEEK ONE

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

WEEK 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

WEEK 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

WEEK 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

WEEK 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

ON-DEMAND MICRO CLASS | LEVEL ONE | 45-MINUTES

SUGGESTED PREREQUISITE: NONE

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Biopharma Business Acumen Primer

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. Identify and describe the basic financing vehicles used in the biopharma industry and explain when they are most appropriate to use in a company's life cycle.
2. Analyze key patent concepts to assess the value of a claim.
3. Distinguish between a supplemental new drug application and an abbreviated new drug application.
4. Outline and discuss the different methods employed by biopharmaceutical companies to prolong the lifecycle of a drug.
5. Discuss strategies for pricing a drug in a strategic manner.

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 US

Lifecycle Management of a Cure

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

Pricing a Cure

- US drug pricing explained
- US price influencers: insurance, PBMs, formularies
- Types of drug pricing
  - Value-based pricing
  - Strategic pricing

ON-DEMAND MICRO CLASS | LEVEL ONE | 40-MINUTES

SUGGESTED PREREQUISITE: NONE

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Applying for a Life Science Job

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. State the importance of a well-crafted resume and articulate its purpose.
2. Demonstrate proficiency in the ten-step process to write an effective resume.
3. Customize your resume to showcase your unique skills, experiences, and qualifications.
4. Write a compelling cover letter by following the nine-step process.
5. Apply customization techniques to craft a personalized resume and cover letter that captures the attention of potential employers.

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*

ON-DEMAND MICRO CLASS | LEVEL ONE | 40-MINUTES

SUGGESTED PREREQUISITE: NONE

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Life Science Training From Industry Experts

Interviewing for a Life Science Job

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. Analyze your personality to understand how it influences your interview performance.
2. Create a captivating digital profile on LinkedIn to enhance your professional image in the job market.
3. Utilize effective strategies to search job boards and find relevant job openings that align with your skills and interests.
4. List the documents that should be brought to the job interview.
5. Acquire six essential interview skills to excel in job interviews and secure your desired position.

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

MEDICAL DEVICE FOR NON-SCIENTISTS

COURSE CATALOG

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SIGNATURE COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

Medical Device Development Immersion

OVERVIEW

Medical Device Development Immersion showcases the fascinating aspect of medical device development. Beginning with an overview of the dynamic medical device industry, this course quickly navigates the changing regulatory environment and pathways devices undertake for FDA or EMA marketing approval. Throughout this course 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 course. Learn from an industry expert with 30 years of experience in both large and start-up medical device companies—register today!

Five Takeaways:

1. Master medical device terminology.
2. Create your own toolbox for designing a top-notch medical device prototype.
3. Paraphrase the steps of multiple approval pathways for each medical device class.
4. Conduct a risk mitigation exercise during the medical device development process.
5. Summarize the pain points of commercializing a medical device and including reimbursement.

AGENDA

DAY ONE

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

Break 15 minutes

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

Lunch 15 minutes

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

Medical Device Development 105 minutes
Phase I: market opportunity
Market analysis
Risk management plan
Phase II: concept evaluation
  Formulation steps
  Feasibility
Phase III: engineering design process
  Design
  Development
  Prototyping

Wrap-Up 15 minutes

DAY TWO

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

Break 15 minutes

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

Lunch 45 minutes

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

Break 15 minutes

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

Wrap-Up 15 minutes

RECORDED SIGNATURE COURSE | LEVEL ONE | 10 HOURS

SUGGESTED PREREQUISITE: NONE

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Recorded Medical Device Development Immersion

OVERVIEW

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1. Master medical device terminology.
2. Create your own toolbox for designing a top-notch medical device prototype.
3. Paraphrase the steps of multiple approval pathways for each medical device class.
4. Conduct a risk mitigation exercise during the medical device development process.
5. Summarize the pain points of commercializing a medical device and including reimbursement.

AGENDA

WEEK ONE

Medical Device Overview 40 minutes

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

WEEK TWO

Regulatory Approval Pathways 60 minutes

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

WEEK THREE

Medical Device Regulation 50 minutes

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

WEEK FOUR

Phase I: Market Opportunity Evaluation 20 minutes

Development process overview
Product development Gantt chart
Regulation of medical device design
Market opportunity evaluation key requirements
Activity: Bionic Walker Customer Requirements

WEEK FIVE

Phase II: Concept Evaluation 30 minutes

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

WEEK SIX

Phase III: Engineering Design 30 minutes

Engineering design key requirements
Specifications
Iterative design
Software design
Documentation

WEEK SEVEN

Phase IV: Verification and Validation 70 minutes

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

WEEK EIGHT

Phase V: Manufacturing 30 minutes

Manufacturing key considerations
Manufacturing transfer
Manufacturing scale-up

WEEK NINE

Medical Device Approval
80 minutes

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

WEEK TEN

Commercialization 15 minutes

Reimbursement strategy
CMS vs FDA
Issues affecting private payers

Course Evaluation 20 minutes

ON-DEMAND MICRO CLASS | LEVEL ONE | 41-MINUTES

SUGGESTED PREREQUISITE: NONE

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Diagnostics' Role In Medicine Today

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 biomarkers are used in molecular diagnostics.
2. Describe the qualitative and quantitative measurements used by diagnostics to assess disease.
3. List each diagnostic category and identify the primary purpose of each.
4. Explain how companion diagnostics take advantage of a patient's genetic variation.
5. Connect diagnostics to improved disease treatment through personalized medicine.

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

ON-DEMAND MICRO CLASS | LEVEL ONE | 41-MINUTES

SUGGESTED PREREQUISITE:

DIAGNOSTICS' ROLE IN MEDICINE TODAY

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Diagnostic Development Primer

OVERVIEW

Diagnostic Development Primer is a comprehensive guide to navigating the complex world of approval pathways. This class begins by examining the vital roles that various United States government agencies play in regulating In Vitro Diagnostics (IVD) and Laboratory-Developed Tests (LDTs). It provides a detailed description of the regulatory requirements for Class I, II, and III diagnostic approval pathways. A review of the internationally recognized Quality System Regulations (QSR) and how they impact the design and manufacturing of diagnostic products closes out section two. This primer wraps up by explaining the reimbursement process for Medicare, Medicaid, hospitals, and private payers, breaking down complex inpatient DRG codes and outpatient CPT codes. Enroll now in the Diagnostic Approval Primer and become well-versed in the approval process of molecular diagnostics. Let's start your journey today!

Five Takeaways:

1. Compare the diagnostic regulatory oversight by the FDA and the CMS.
2. Contrast the United States regulatory process for in vitro diagnostics and laboratory-developed tests.
3. Recognize the regulatory differences between the Class I, II, and III diagnostics.
4. Explain the purpose of quality system regulations (QSR), highlighting the design and manufacturing of QSRs.
5. Discuss the challenges in receiving diagnostic reimbursement in the United States.

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
- CMC LDT guidance

Diagnostic 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

ON-DEMAND MICRO CLASS | LEVEL THREE | 47-MINUTES

SUGGESTED PREREQUISITE:

DIAGNOSTIC DEVELOPMENT PRIMER, DNA-BASED DIAGNOSTICS PRIMER, PROTEIN-BASED DIAGNOSTICS PRIMER

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Diagnostic Measurements Primer

OVERVIEW

Diagnostic Measurements Primer unravels the importance of direct and indirect measurements and their vital role in obtaining regulatory approval. This class begins with the art of constructing and reading a standard curve to determine unknown analyte concentrations. The agenda extends to testing accuracy, focusing on the ins and outs of specificity, sensitivity, false positives/false negatives, and true positives/true negatives. These concepts are reinforced with a graphics exercise on distributions, exploring the varied factors contributing to data variability and bi-modal distribution. This class ends with two real-world case studies critiquing data from mammography for breast cancer and PSA diagnostics for prostate cancer. Learn what it takes to secure diagnostic approval by learning acceptable measurement thresholds. Register today!

Five Takeaways:

1. Produce and interpret a standard curve to analyze a diagnostic's results.
2. Recognize types of data distributions and how each is used to determine if a patient's condition falls in the normal or abnormal range.
3. Explain how precision, bias, specificity, and sensitivity measurements determine the accuracy of a diagnostic.
4. Discuss how false positive and false negative percentages and their comparison to the reference product determine regulatory approval for a novel diagnostic.
5. Choose the correct measurement to determine a patient's disease state.

AGENDA

Introduction to Measurements

- The gold standard
- Requirements for regulatory approval
- Types of diagnostic measurements
- Direct and indirect measurements
- Determining unknown analyte concentrations
- Standard curve estimations
- Constructing a standard curve
- Reading a standard curve
- Science of colorimetric assays

Variability of Measurements

- Variability defined
- Distribution of values
- Graphic display of distributions
- Bi-modal distribution
- Variability factors

Examples of Test Distributions

- Blood pressure and cholesterol
- Cholesterol predicts atherosclerotic disease
- Bi-model 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
- Example: mammograph for breast cancer
- Example: PSA diagnostic for prostate cancer

ON-DEMAND MICRO CLASS | LEVEL TWO | 44-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH, DIAGNOSTICS' ROLE IN MEDICINE TODAY, DIAGNOSTIC MEASUREMENTS PRIMER

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DNA-Based Diagnostics Primer

OVERVIEW

DNA-Based Diagnostics Primer is the ultimate guide to the molecular science behind 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. Enumerate the applications and summarize the use of DNA probes in diagnostics.
2. Explain the scientific principles underlying Polymerase Chain Reaction (PCR) in diagnostic applications.
3. State how to interpret microarray results for diagnosing diseases.
4. Cite the significance of Next-Generation Sequencing (NGS) technologies in the diagnostics industry.
5. Provide a comprehensive list of the advantages offered by microRNA diagnostic technology.

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

ON-DEMAND MICRO CLASS | LEVEL TWO | 40-MINUTES

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH, DIAGNOSTICS' ROLE IN MEDICINE TODAY, DIAGNOSTIC MEASUREMENTS PRIMER

biotechPrimer
Life Science Training From Industry Experts

Protein-Based Diagnostics Primer

OVERVIEW

Protein-Based Diagnostics Primer is an extensive tutorial on protein-based diagnostics commonly used in disease detection in the research and clinic setting. This engaging class covers various tools, including immunoassays, multiplexed assays, lateral flow assays, and chromatography. Get ready to explore the science of ELISA and bead immunoassays, two quantitative diagnostics that measure multiple proteins simultaneously. This course also takes a closer look at Lateral Flow Assay (LFA) technology, a rapid detection diagnostic for target-specific biomarkers. To round out the agenda, this primer ends with an in-depth exploration of chromatography technologies used for protein separation, purification, and analysis. Grab your spot today to gain a deep understanding of these different protein-based diagnostics and their practical implications!

Five Takeaways:

1. Discuss what makes antibodies uniquely appropriate for use in protein diagnostics.
2. List examples of protein-based diagnostics and state their uses.
3. Describe how biomarkers are used in diagnostics.
4. Summarize the fundamental science of protein-based diagnostics.
5. Analyze and interpret the findings from ELISA, bead immunoassays, lateral flow assays, and chromatography diagnostics.

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
- Science of ion exchange chromatography
- Science of affinity exchange chromatography
- Science of size exclusion chromatography
- Reading chromatography diagnostics
- Chromatography diagnostic examples

ON-DEMAND MICRO CLASS | LEVEL TWO | 57 MINUTES

SUGGESTED PREREQUISITE:

DIAGNOSTICS' ROLE IN MEDICINE TODAY, MEDICAL DEVICE APPROVAL PRIMER

biotechPrimer
Life Science Training From Industry Experts

Medical Device Development Primer

OVERVIEW

Medical Device Development Primer broadly explores the five pivotal stages of medical device development. This class focuses on the workflow at each step, from evaluating market opportunities and rigorously assessing concepts to crafting engineering designs and scaling manufacturing. This primer unlocks the secrets of FDA guidances pertaining to process design, qualification, and monitoring. It ends with a look at product risk assessment and reimbursement, summarizing their role in management's momentous "go"/"no go" decisions. Enroll today to embark on this exciting quest toward groundbreaking medical device development!

Five Takeaways:

1. List the five phases of medical device development in order.
2. Explain the techniques to effectively evaluate the market opportunity for a novel medical device.
3. Determine the manufacturing feasibility by analyzing a medical device's design.
4. Recommend required prototype specifications needed in medical device design, documentation, and testing.
5. Explain the FDA validation guidance for process design, qualification, and monitoring.

AGENDA

Market Opportunity Evaluation

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

Concept Evaluation

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

Engineering Design

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

Verification and Validation

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

Manufacturing Transfer

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

ON-DEMAND MICRO CLASS | LEVEL TWO | 57 MINUTES

SUGGESTED PREREQUISITE:

DIAGNOSTICS' ROLE IN MEDICINE TODAY

biotechPrimer
Life Science Training From Industry Experts

Medical Device Approval Primer

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:

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

AGENDA

Medical Device Overview

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

Medical Device Regulation

- Medical device regulation history
- FDA organizational structure
- Medical device classification and risk
- Class I risk and controls
- Class II risk and controls
- Class III risk and controls
- FDA approval pathways
- 510(k)
- De novo 510(k)
- Premarket notification (PMN)
- Premarket approval (PMA)
- Predicate device
- Regulatory compliance requirements
- Good laboratory practices (GLP)
- Good clinical practices (GCP)
- Good manufacturing practices (cGMP)
- Quality system regulations (QSR) requirements
  - Material controls
  - Production and process controls
  - Design controls
  - Corrective and preventative actions
  - Records and documents change controls
  - Facility and equipment controls

- QSR examples: hiring and product development
- Risk management plan
- Managing human factor risks
- Risk analysis plan process
- Global regulatory agencies
- European Union approval process

ON-DEMAND MICRO CLASS | LEVEL THREE | 55 MINUTES

SUGGESTED PREREQUISITE:

MEDICAL DEVICE APPROVAL PRIMER, MEDICAL DEVICE DEVELOPMENT PRIMER

biotechPrimer
Life Science Training From Industry Experts

Medical Device Commercialization Primer

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

AGENDA

Approval

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

Commercialization

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