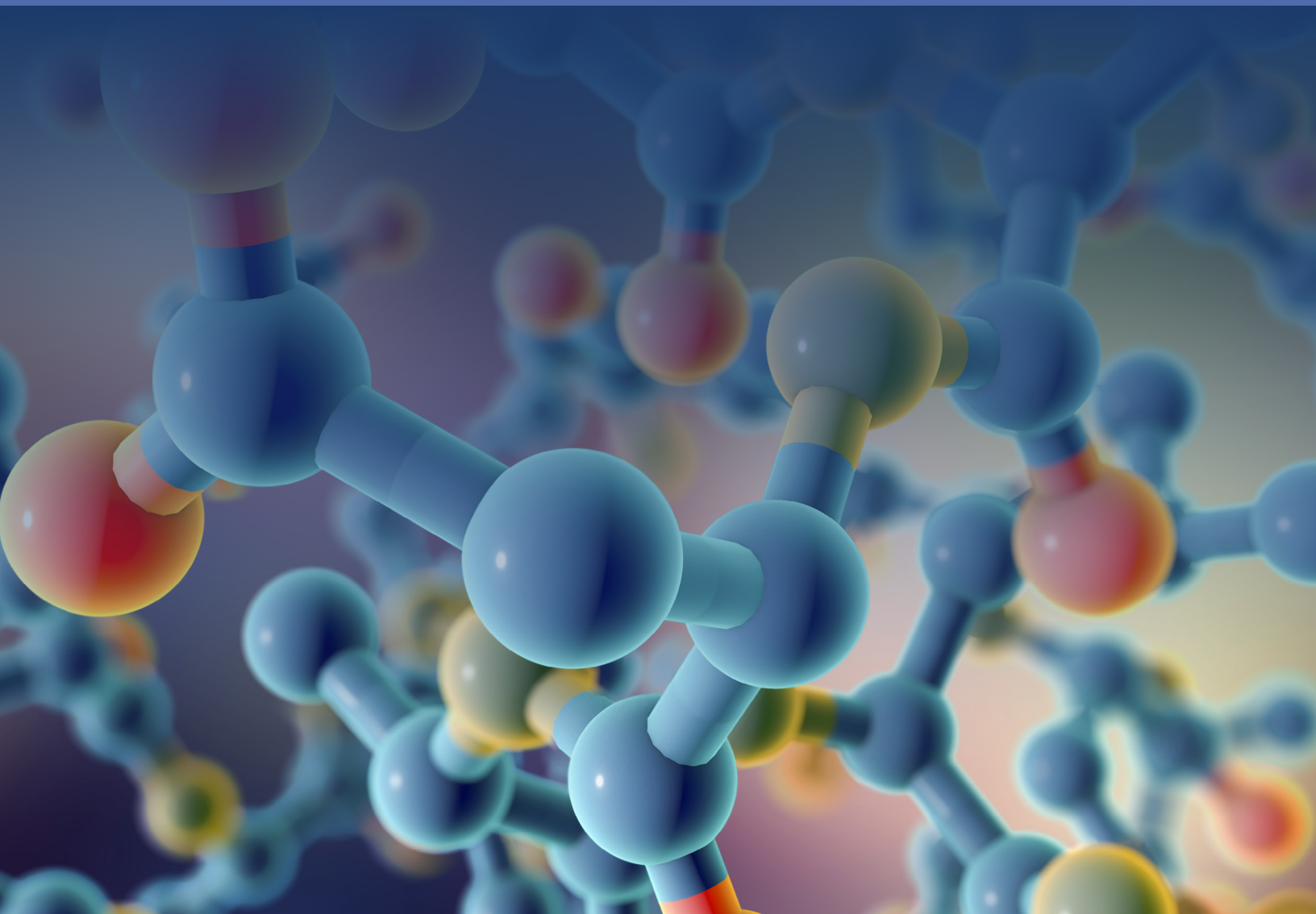
BIO DIGITAL STUDENT PASS + Bio Online Learning POWERED BY BIOTECH PRIMER

ONLINE COURSE BUNDLES



Biotech Primer Online Courses

Learn any time, anywhere, at your own pace.

Explore a week in the world of biotech at **BIO Digital June 8 – 12**, apply at bio.org/student-pass to unlock course bundle discounts, receive free access to BIO Digital education program, special student sessions, networking opportunities and more!

You are invited to take part in **BIO Digital Student Pass** which allows pre-approved students to purchase Biotech Primer's online course bundles within the months of May and June 2020 at a greatly reduced price. Each bundle features four interactive, on-demand courses that focus on a specific part of the biopharma industry, these bundles include:

Biotech for the Non-Scientist | Drug Discovery | Drug Development | Manufacturing

Molecular Diagnostics | Medical Device | Biosafety

LEVELS

Each online course is given a level to help individuals choose the appropriate course. For all level 2 and 3 courses a suggested prerequisite will be given but is not mandatory to take.

Level 1: Foundational	For non-scientists new to biopharma and for those who need a refresher on the fundamental science driving the health care 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 and biopharma industry

PRICING

Within the months of June and July 2020 only, this special BIO Digital offer entitles you to purchase as many bundles as you'd like. Each bundle is $99, a savings of $500.

What you can expect:

1. Four courses developed by an industry expert.
2. Downloadable course materials.
3. End of course quiz to document your increase in knowledge.
4. Downloadable course certificate.
5. Ability to update your education profile on LinkedIn with Biotech Primer coursework.

BIO DIGITAL STUDENT PASS

Biotech Primer Online Courses

Learn any time, anywhere, at your own pace for only $99 a course bundle. Purchase one or all.

Biotech for Non-Scientists Bundle

Drug Discovery & Preclinical Development Bundle

Drug Development Bundle

Molceular Diagnostic Bundle

BIO DIGITAL STUDENT PASS

Medical Device Bundle

Manufacturing Bundle

Biosafety Bundle

BIO DIGITAL STUDENT PASS

Biotech for Non-Scientists Bundle

The Biology of Biotech

85-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

The Biology of Biotech provides an overview of the most important biological molecules and systems used in biotechnology to make novel therapies and diagnostics. The Biology of Biotech online course lays the groundwork for the biopharma industry by focusing on cells, DNA and proteins and how these are manipulated by researchers to discover new products. If you are a non-scientist who wants to better understand the science driving research and discovery, this course is the perfect place to start.

Five Takeaways:

1. Knowledge of cell structure functions and how those functions are manipulated by scientists to develop new products.
2. Understanding of protein synthesis and how this cellular process is optimized to create therapeutics.
3. Correlation between genetic mutations and disease.
4. Fluency in genetic variation and its role in disease diagnosis and treatment.
5. Exploration of significantly important molecules and their role in health and disease.

AGENDA

- **The Cell: The Biotech Advantage** demonstrates how biotechnology takes advantage of processes that already exist in the human body to create new products.
- **DNA and Proteins: The Biotech Workhorses** correlates the relationship between DNA and proteins, and how the cellular process of protein synthesis is used to create medicines.
- **Genetic Variation: Understanding Disease** explains how mutations lead to genetic variation which sometimes triggers disease. Knowledge of genetic variation is the first step to improving disease diagnosis and treatment.

BIO DIGITAL STUDENT PASS

Biotech for Non-Scientists Bundle

Immunology 101

40-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITES: THE BIOLOGY OF BIOTECH

OVERVIEW

Immunology 101 provides an overview of how the human immune system works. Understanding how the human body naturally fights disease is often the first step in creating novel therapeutics. Many of today's blockbuster biologics are modifications of our immune system's molecules and cells, including antibodies, T-cells, B-cells and cytokine inhibitors. If you are a non-scientist who wants to better understand the amazing immunotherapies that will play a large role in the next health care wave, Immunology 101 is the perfect place to start.

Four Takeaways:

1. Explain the functions of the cells and tissues of the human immune system.
2. Describe how the immune system naturally mitigates disease.
3. Discuss the relationship between the naturally occurring immune system and the immune-inspired therapies created by the biopharma industry.
4. Differentiate between the non-specific and specific immune system and how each has implications in drug discovery and development.

AGENDA

- **Immune System Overview** describes how the immune system's cells and tissues work and makes the connection between what occurs naturally to the immune-inspired therapies created by the biopharma industry.
- **Disease** lists how the broad categories of disease are caused and how the immune system recognizes and fights each category. By mimicking the immune system's "illness-fighting game plan" researchers build better therapies.
- **Components of the Immune System** differentiates the two distinct immune systems, the non-specific immune system and the specific immune system, which has implications in drug discovery and development.

BIO DIGITAL STUDENT PASS

Biotech for Non-Scientists Bundle

Immunology 201

55-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITES: THE BIOLOGY OF BIOTECH, IMMUNOLOGY 101

OVERVIEW

Immunology 201 online course builds on Immunology 101 course to give a detailed description of the two types of immune system, the non-specific and the specific immune systems. This course will put all the details of the immune system into practice, taking you on a journey from how disease occurs to how your body fights disease. By understanding this complex process, you will have a better understanding of how these steps are exploited by the biopharma industry to create cutting-edge immunotherapies in biotechnology.

Five Takeaways:

1. List of immune response functions.
2. Explanation of how the non-specific immune system recognizes, responds to and eliminates a pathogen.
3. Road map of the specific immunity cell types, each of their functions and how they eliminate disease.
4. Knowledge of how immune system memory works to fight reinfection.
5. Process of the immune response from pathogen recognition to elimination.

AGENDA

- **Non-Specific Immunity** explains how your body recognizes, responds to, and eliminates a pathogen. To understand how vaccines, antiviral drugs, and antibiotics work, you must first understand your body's initial response to pathogenic infection.
- **Specific Immunity** (activation of B-cells and T-cells) occurs when pathogens have successfully compromised your non-specific immunity, infected your body, and made you sick. Biopharma has mimicked the best that B-cells and T-cells have to offer to amass a trove of medications. Learn how medications work by learning how specific immunity fights disease.
- **Immune System Activation: Putting It All Together** describes the immune response in its entirety so you can better understand pharmacology, the branch of biopharma concerned with uses, effects and modes of action of drugs.

BIO DIGITAL STUDENT PASS

Biotech for Non-Scientists Bundle

Antibodies

52-MINUTE ONLINE COURSE | LEVEL 3

SUGGESTED PREREQUISITES: THE BIOLOGY OF BIOTECH, IMMUNOLOGY 101, IMMUNOLOGY 201

OVERVIEW

Antibodies examines the versatile role of antibodies in current biotechnology applications. It takes an in-depth look at antibody production for biotech applications and offers specific examples of antibodies used in research, therapeutic and diagnostic applications. To understand the biotechnology industry, you must appreciate the important and diverse role antibodies continue to play in health care.

Five Takeaways:

1. Antibody structure and function.
2. Knowledge of how and why the antibody-antigen interaction occurs and its importance to understanding drug targets.
3. Steps of antibody production in the immune system.
4. Compare and contrast polyclonal, monoclonal and humanized antibody lab production and uses.
5. Description of antibody versatility and use as a therapeutic and diagnostic.

AGENDA

- **Antibody Structure and Function** lists the general structure and function of antibodies, describing how and why the antibody-antigen interactions occur. The antibody-antigen interaction is the basis upon which therapeutics fight disease.
- **Antibodies As Therapeutics** discusses the process of antibody production in the lab, including polyclonal, monoclonal and humanized antibodies and how each is used by the biopharma industry.
- **Antibody Diagnostics** describes how anitbodies are used in diagnostics including ELISA assays and bead immunoassays.

BIO DIGITAL STUDENT PASS

Drug Discovery & Preclinical Development Bundle

Drug Discovery of Small Molecules

55-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Drug Discovery of Small Molecules explains the steps involved in discovering new therapeutics. This process includes early screening for targets, target validation, lead optimization, and determining when a target should be transitioned from discovery to development. Learn how new drugs are discovered and optimized prior to being tested in preclinical and clinical trials.

Five Takeaways:

1. In-depth knowledge of the drug discovery process.
2. Survey of typical discovery platforms.
3. Understanding of how to identify and validate a drug target.
4. Performance of lead optimization activities.
5. Criteria for advancement of development candidates.

AGENDA

- **Drug Discovery Overview** explains the steps involved in drug discovery and how drug discovery fits into the entire process of bringing a new therapeutic to market.
- **Early Screening** describes common drug discovery platforms, explains target identification processes and screening considerations, and discusses the need for high throughput screening of molecules in drug discovery.
- **Target Validation** defines target validation processes and target selection and discusses some common questions that need to be answered about target-drug interactions.
- **Lead Optimization Criteria** explains lead optimization activities, discusses drug design methods defines ADMET, and gives an example of a screening pathway.
- **Discovery To Development Transition Criteria** lists the typical criteria for advancement of potential drug development candidates.

BIO DIGITAL STUDENT PASS

Drug Discovery & Preclinical Development Bundle

Drug Discovery of Biologics

45-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Drug Discovery of Biologics explains the steps involved in discovering new biologics, with a special focus on therapeutic antibodies. Learn the criteria used by researchers to for early target screening, select, validation, optimization, and determining when a drug target should be transitioned from discovery to development. Bonus content includes information on antibody diversity, affinity maturation, and key CMC challenges and how to overcome them.

Five Takeaways:

1. List the steps of discovery and lead optimization for biologics.
2. Explain target ID and selection considerations.
3. Explain how affinity maturation is tied to pharmaceutical liabilities.
4. Describe antibody diversity, IgG subtypes, and alternative formats.
5. Discuss the typical criteria for advancement of development candidates.

AGENDA

- **Overview** lists the steps of the drug discovery, development and commercialization process, including activities, costs and timing generally associated with each stage.
- **Early Selection, Target ID, & IgG Subtypes** compares and contrasts properties of both small and large molecule drugs. This section also reviews antibody production, selection, and humanization. It ends with target identification processes and antibody screening considerations.
- **Affinity Maturation & Pharmaceutical Liabilities** delves into the importance of affinity maturation and its key CMC liabilities. This section concludes with an explanation on how to overcome these CMC challenges.
- **Antibody Diversity & Alternative Formats** explains antibody therapeutic classes, includes immune checkpoint inhibitors, and explains why these medications are important.
- **Discovery To Development & Transition Criteria** lists the typical criteria for advancement of potential biologic development candidates.

BIO DIGITAL STUDENT PASS

Drug Discovery & Preclinical Development Bundle

Preclinical Development

55-MINUTES ONLINE COURSE | LEVEL 1

OVERVIEW

Preclinical Development focuses on both small and large molecule drug safety assessments and regulatory requirements. This course also explains how clinical starting dose levels are estimated. Learn what preclinical criteria is needed to support first-in-human clinical trials.

Five Takeaways:

1. In-depth knowledge of the preclinical development process.
2. Understanding of the Animal Rule and how animal models enable clinical trials.
3. Ability to estimate clinical starting dose levels by interpreting preclinical results.
4. Knowledge of how to integrate preclinical data into the Common Technical Document.
5. Fluency of criteria necessary to support first-in-human clinical trials.

AGENDA

- **Preclinical Development Overview** describes timing and costs for the major drug development steps by reviewing industry statistics.
- **Pharmacology** discusses the key data generated during pharmacology studies and how that information is used to move from animal studies to human studies. In addition, specific challenges in assessing pharmacology in biologics and small molecule drug candidates is explored.
- **Pharmacokinetics** demonstrates how pharmacokinetics is used to characterize the exposure-response relationship for a drug candidate, discusses the typical endpoints calculated, and describes bioanalytical assay and validation criteria.
- **Toxicology** describes the importance of toxicity studies and how the information obtained helps select compounds, establishes safety parameters of those compounds and influences animal model choice, dose selection, and routes of administration for the candidate drug. Concepts such as therapeutic margins and subjectivity in making conclusions based on sample study data are explored.
- **Nonclinical IND/CTA** explains what to include and how to complete the Common Technical Document.

BIO DIGITAL STUDENT PASS

Drug Discovery & Preclinical Development Bundle

Working With Animals

30-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Working With Animals focuses on the special considerations of working safely with laboratory animals. A detailed look into animal laboratory equipment and animal laboratory best practices will be covered.

Four Takeaways:

1. Identify hazards associated with work involving biohazards in the vivarium (animal laboratory).
2. Describe the Animal Biosafety Levels as described in the CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition.
3. List the engineering controls and practices used within the vivarium.
4. Explain safe operating practices in the vivarium.

AGENDA

- **Animal Biohazard Considerations** identifies hazards associated with work involving biohazards in the vivarium (animal laboratory).
- **Animal Facilities** explains the Animal Biosafety Levels as described in the CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition and identifies the engineering controls and practices used within the vivarium.
- **Emergency Procedures** explains safe operating practices in the vivarium.

BIO DIGITAL STUDENT PASS

Drug Development Bundle

Clinical Development 101: General Principles

55-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Clinical Development 101: General Principles sets the stage for the entire clinical development process. Learn who conducts trials, how trials are conducted and the various regulatory elements that must be performed throughout Phases I-IV trials.

Five Takeaways:

1. Understanding of the purposes for which clinical studies are conducted.
2. Fluency in clinical trial concepts such as control group, bias, binding, randomization, and endpoints.
3. Knowledge of the study design criteria.
4. Required regulatory studies and data to enable follow-on studies.
5. Familiarity of the various clinical trial participants and their roles.

AGENDA

- **Clinical Development Introduction** describes the key milestones for drug development, specifically focusing on clinical development. Important terms including evidence-based medicine, translational medicine, and patient-centric clinical trials are explained. Finally, the purposes for which clinical trials are conducted are explored.
- **Clinical Trials: Basic Principles** explains how risk management is approached in terms of scientific method, Good Clinical Practices (GCPs), and trial design. Bias, blinding, randomization and endpoints are all explained in detail.
- **Conducting Clinical Trials** explains the various clinical trial participants and their roles, identifies the basics elements of a clinical trial protocol, describes informed consent, discusses inclusion/exclusion criteria, lists the steps in data management and reporting, and reviews the concept of clinical trial transparency.

BIO DIGITAL STUDENT PASS

Drug Development Bundle

Clinical Development 201: Phase I

50-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITE: CLINICAL DEVELOPMENT 101

OVERVIEW

Clinical Development 201: Phase I explores the prerequisites, purpose, design, and conduct of Phase I trials. Topics such as bioequivalence, pharmacokinetics, pharmacodynamics, endpoints, selection of dose, and more are explained in detail.

Five Takeaways:

1. Requirements for and maintenance of an Investigational New Drug (IND) application and a Clinical Trials Application (CTA).
2. Purpose of, and characteristics of Phase 0 and Phase I clinical trials.
3. Expectations related to clinical benefit in early clinical trials for standard development programs, and development of treatments for conditions associated with serious unmet medical needs.
4. Typical endpoints assessed in Phase I clinical trials.
5. Steps to take at the conclusion of the Phase I clinical study.

AGENDA

- **Clinical Trial Prerequisites** identifies the CMC, preclinical safety, and pharmacology prerequisites for entering early phase clinical trials. Learn the requirements needed for the IND application and how ethics committees and Institutional Review Boards (IRBs) must review the protocols prior to a drug entering humans for the first time.
- **Phase 0/I Study Designs and Objectives** describes the purpose of, and characteristics of Phase 0 and Phase I clinical trials and the general approach associated with bioequivalence studies. Compares and contrasts the expectations related to clinical benefit in early clinical trials.
- **Phase I Conducting the Clinical Study** explains how dosage is determined using maximum tolerated dose (MTD), single ascending dose (SAD), and multiple ascending dose (MAD), pharmacokinetics, and pharmacodynamics data. Discusses typical endpoints assessed in Phase I clinical trials and how and why clinical trial phases are sometimes combined. This section also describes the requirements for Clinical Trial Safety Reports associated with adverse events and what steps take place at the conclusion of the clinical study.

BIO DIGITAL STUDENT PASS

Drug Development Bundle

Clinical Development 301: Phase II/III

55-MINUTE ONLINE COURSE | LEVEL 3

SUGGESTED PREREQUISITES: CLINICAL DEVELOPMENT 101, CLINICAL DEVELOPMENT 201

OVERVIEW

Clinical Development 301: Phase II/III considers the purpose, design, and conduct of Phase II and III clinical trials. Learn the various trial design approaches, endpoint choices, statistical considerations, and special regulatory designations.

Five Takeaways:

1. Key differences between early stage (Phase I) and late-stage (Phase II/III) clinical trials.
2. Regulatory significance of clinical endpoint, primary endpoint, secondary endpoint, and surrogate endpoint.
3. Fluency in Phase II and Phase III clinical trial nuances.
4. Basic statistical analysis completed in late-stage trials.
5. Description of specialized and expedited development cycles for rare disease, orphan drugs, and therapies for unmet medical needs.

AGENDA

- **Phase II/III Introduction** identifies the principle elements of a well-controlled Phase I/II clinical trial with an in-depth look at study design, endpoints, and statistical analysis. The concepts of a null hypothesis, p-value, type 1 error, type 2 error, power, variability, and treatment size effects are explained.
- **Phase II/III Objective and Design** compares the general characteristics of Phase II and Phase III clinical trials. Defines pivotal study, adaptive trial, basket trial, and umbrella trial. Discusses the function and types of recommendations the Data Safety Monitoring Boards provides.
- **Phase II/III Special Designations** focuses on rare disease and serious unmet medical need designations in both the US and Europe. Explains the challenges with clinical studies associated with rare disease and provides examples of flexible clinical development approaches for application to rare diseases. Lastly, the relationship between clinical trial endpoints and approved labeling claims are explained.

BIO DIGITAL STUDENT PASS

Drug Development Bundle

Clinical Development 401: Phase IV

50-MINUTE ONLINE COURSE | LEVEL 3

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

OVERVIEW

Clinical Development 401: Phase IV surveys the ongoing post-approval clinical assessments required by regulatory agencies. Learn how drug risk management is accomplished through detecting, assessing and reporting adverse effects using real-world data.

Five Takeaways:

1. Purpose of Phase IV studies.
2. Key limitations of pre-market studies and why post-market studies are an important complement to Phase I-III studies.
3. Role of regulatory safety information reporting programs including MedWatch in US and EudraVigilance in Europe.
4. In-depth look at Real-World Data (RWD) and Real-World Evidence (RWE) and their impact on safety.
5. Identification of important real-world data sources.

AGENDA

- **Phase IV Studies** explains the purpose of Phase IV studies and takes an in-depth look at numerous study examples including long-term safety and pharmacoeconomic studies.
- **Pharmacovigilance and Post-Marketing Safety Follow-Up** explains important regulatory terms such as pharmacovigilance, safety signal, signal detection and signal analysis. The purpose of regulatory safety information reporting programs such as MedWatch in US and EudraVigilance in Europe is thoroughly reviewed. The section ends by describing the post-marketing regulatory actions that may be taken in response to emerging knowledge of safety risks.
- **Real-World Evidence** discusses how regulatory authorities, such as FDA, are increasingly using real-world evidence to improve regulatory decisions. Important sources of real-world data are identified.

BIO DIGITAL STUDENT PASS

Molecular Diagnostic Bundle

Diagnostics' Role In Medicine Today

41-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Diagnostics' Role In Medicine Today introduces the ever-expanding molecular diagnostics industry. Diagnostics save lives by helping to pinpoint the exact cause and location of disease. Learn the purpose of each type of diagnostic, the science behind personalized medicine, and how companion diagnostics help doctors prescribe medication and dosage correctly the first time. If you are new to this area of health care, Diagnostics' Role in Medicine Today will provide a solid foundation on which to build your diagnostic acumen.

Five Takeaways:

1. Cite how biomarkers are used in molecular diagnostics.
2. Describe the types of measurements employed by diagnostics.
3. Identify the main purposes of each diagnostic category.
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** explains how biomarkers are used in molecular diagnostics to measure patient body chemistry and function that may or may not lead to disease.
- **Uses of Diagnostics** explains how diagnostics are used in health care today. Purposes include screening, diagnosis, prognosis, drug selection, drug treatment, monitoring, and disease management.
- **Types of Diagnostics** states the purpose for the different types of diagnostics including chemistry, immunochemistry, hematology, cytology, microbiology, infectious disease, imaging, and molecular testing.
- **The Science Behind Molecular Diagnostics** links DNA mutations and disease to the development and workings of companion diagnostics.
- **Selecting a Treatment** illustrates how companion diagnostics inform physicians on the best course of treatment for patients, including medication and dosage choice. This medication specificity is called personalized medicine.

BIO DIGITAL STUDENT PASS

Molecular Diagnostic Bundle

How Diagnostics Work: DNA-Based Diagnostics

44-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITE: DIAGNOSTICS' ROLE IN MEDICINE TODAY

OVERVIEW

How Diagnostics Work: DNA-Based Diagnostics explains the molecular science and technology used in a common set of diagnostic tools, including the various types of PCR, SNP chips, next-generation sequencing and microRNA techniques. Gain entry to the fast-paced field of molecular diagnostics by taking this course.

Five Takeaways:

1. Summarize the uses of DNA probes in diagnostics.
2. Describe the use of polymerase chain reaction in diagnostic applications.
3. Explain how microarray technology is exploited in diagnostic applications.
4. Cite the importance of next-generation sequencing technologies in the diagnostics industry.
5. Discuss how microRNA technology could lead to advancements in diagnostic technology.

AGENDA

- **Polymerase Chain Reaction (PCR) Technology** summarizes the use of DNA probes and how PCR technology works as a diagnostic. PCR is the tool that enabled the biotech revolution.
- **Microarray Technology** explains SNP chip technology and discusses the use of SNP chips in diagnostic applications.
- **Next Generation Sequencing Technology** looks at various next-generation sequencing tools and discusses the omnipotent diagnostic applications these machines offer.
- **microDiagnostics Technology** summarizes how microRNA works and its application in diagnostics development.

WHAT PEOPLE ARE SAYING

"The Biotech Primer webinars on diagnostics are an outstanding educational resource for professionals in the med device industry." – Training Specialist

BIO DIGITAL STUDENT PASS

Molecular Diagnostic Bundle

How Diagnostics Work: Protein-Based Diagnostics

40-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITE: DIAGNOSTICS' ROLE IN MEDICINE TODAY

OVERVIEW

How Diagnostics Work: Protein-Based Diagnostics focuses on antibodies: what they are, where they come from and how they work. Various antibody-based diagnostics, such as sandwich and bead immunoassays, multiplexed assays, lateral flow assays and chromatography are explained in detail. Develop an understanding of these diverse tools and how to interpret results, knowledge that can be applied in research, drug development, and patient care.

Five Takeaways:

1. Define the various types of protein-based diagnostics.
2. An improved ability to explain how biomarkers are used in diagnostics.
3. Explain how antibodies are used in diagnostics.
4. Understand the fundamental science of protein-based diagnostics.
5. Interpret the information gained from the following assays: antibody diagnostics, ELISA, bead immunoassays, lateral flow assays, and chromatography diagnostics.

AGENDA

- **Defining Protein-Based Diagnostics** introduces protein-based diagnostics by explaining the importance of biomarkers in diagnostics. A biomarker is a measurable molecule indicative of disease.
- **Antibody Technology** explains the importance of antibody structure and how that structure contributes to its function. Antibody structure and function are exploited by the medical device industry for diagnostic use.
- **Enzyme-Linked Immunosorbent Assays (ELISA) Technology** demonstrates the technology and how to interpret results of the widely-used screening test known as an ELISA.
- **Bead Immunoassay Technology** extends your ELISA knowledge by showing how ELISA technology can be adapted into more high throughput techniques, such as multiplexed bead assays.
- **Lateral Flow Assay Technology** explains how lateral flow immunochromatographic assay works, its applications and how to interpret its results.
- **Chromatography Technology** describes the applications of column chromatography in diagnostics and how to interpret its results.

BIO DIGITAL STUDENT PASS

Molecular Diagnostic Bundle

Statistical Features of Diagnostics

47-MINUTE ONLINE COURSE | LEVEL 3

SUGGESTED PREREQUISITES: DNA-BASED DIAGNOSTICS, PROTEIN-BASED DIAGNOSTICS

OVERVIEW

Statistical Features of Diagnostics surveys the measurements used to assess a diagnostic's accuracy. Diagnostics must achieve a certain level of accuracy before receiving regulatory approval. Learn the meaning of variability, sensitivity and specificity and how each is calculated. Learn how these measurements are used to determine false negative and false positive percentages. If you are new to diagnostic development and need a primer on the measurements needed to achieve regulatory approval this course is for you.

Five Takeaways:

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

AGENDA

- **Introduction to Measurements and Determining Unknowns** introduces the concept of measurements and discusses the process of producing, using and interpreting a standard curve when attempting to determine the results of a diagnostic test.
- **Measures: Variability and Distributions** explains how a diagnostic's variability measurements determine if a patient falls into a normal or abnormal distribution for a disease.
- **Examples of Test Distributions** shows how the analysis of various bi-modal distributions determine if patients fall within the normal or abnormal range for a disease and how to identify an ideal distribution for a specific diagnostic.

Continued

- **Measurement Considerations** reviews the concept of sample and instrument variability and best practices in reducing variability. It also describes how to choose the correct measurement to determine the disease state of a patient.
- **Accuracy of a Measurement** explains how precision and bias measurements determine the accuracy of a diagnostic.
- **Specificity and Sensitivity** contrasts sensitivity and specificity and explains how to calculate and interpret these measurements.
- **Positives and Negatives** describes how to calculate and interpret false positive and false negative percentages.
- **Risks of Diagnostics** defines positive predictive value and discusses how to calculate and interpret it. Additionally, it explains how to use a receiver operating characteristic (ROC) curve to interpret the strength of a diagnostic.
- **Examples of Diagnostics: Mammogram and PSA Testing** highlights the risks associated with screening for low prevalence diseases.

BIO DIGITAL STUDENT PASS

Medical Device Bundle

Medical Device Overview and Regulation

57-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Medical Device Overview and Regulation explores the diversity of the medical device industry by highlighting its various sectors, top companies and major regulatory bodies worldwide. Device classification and each classification's differing approval pathways are outlined in detail. The course concludes with a look at the quality system regulations and risk management plans you must follow. If you are new to medical device, Medical Device Overview and Regulation will provide an understanding of the industry's regulatory breadth.

Five Takeaways:

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

AGENDA

- **Overview of Medical Device Types** identifies the major medical device sectors and describes the history of medical device regulation.
- **FDA Medical Device Classification** explains how to classify medical devices into Class I, Class II, or Class III based on risk assessment.
- **FDA Approval Pathways for Medical Device** maps the medical device approval pathways, including how approval of a product can be obtained if a new device is being compared to a predicated device.
- **FDA Regulatory Compliance for Medical Device** surveys various compliance laws including the Code of Federal Regulations, Good Lab Practices, Good Clinical Practices, and current Good Manufacturing Practices as they relate to medical devices.
- **Medical Device Risk Management Plans** demonstrates how to develop a risk management plan for a medical device.
- **Medical Device Regulatory Bodies Worldwide** lists the worldwide regulatory bodies for medical devices.

BIO DIGITAL STUDENT PASS

Medical Device Bundle

Medical Device Development

57-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITE: MEDICAL DEVICE OVERVIEW AND REGULATION

OVERVIEW

Medical Device Development provides a detailed look at the five stages of medical device development including market opportunity evaluation, concept evaluation, engineering design, verification/validation and manufacturing transfer. If you are an engineer, manufacturer, information technologist, investor or someone who finds themselves in development, Medical Device Development will broaden your knowledge of the entire development process.

Five Takeaways:

1. Understand the importance of the five phases of medical device development.
2. How to evaluate market opportunity.
3. Determine the manufacturing feasibility based on a medical device's design.
4. Learn the required prototype specifications needed in device design, documentation and testing.
5. Appreciate the process of device scale-up production.

AGENDA

- **Market Opportunity Evaluation** explains how to evaluate the value and opportunity of the product, the user and the market.
- **Concept Evaluation** determines the feasibility of the medical device's conceptual design and how that blueprint is used to map out the key steps in product design.
- **Engineering Design** discusses how required medical device prototype specifications are designed, documented and tested.
- **Verification and Validation** advocates for a process of verification and validation in engineering builds, packaging, labeling, human factors testing and manufacturing.
- **Manufacturing Transfer** shows the arduous process of how to move from small scale to large scale production.

BIO DIGITAL STUDENT PASS

Medical Device Bundle

Medical Device Approval and Commercialization

55-MINUTE ONLINE COURSE | LEVEL 3 | SUGGESTED PREREQUISITES: MEDICAL DEVICE OVERVIEW AND REGULATION, MEDICAL DEVICE DEVELOPMENT

OVERVIEW

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

Five Takeaways:

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

AGENDA

- **Clinical Trials for Medical Device** discusses how to choose the appropriate level of clinical trial for a medical device based on that device's risk assessment to the patient.
- **Investigative Device Exemption** explains the process of obtaining approval to initiate human clinical trials, including how to identify a reference device and the importance of testing a new device against the reference device when seeking FDA approval.
- **Regulatory Submission for Medical Device** reviews the time cycle for submission approvals.
- **Business Decisions for Medical Device Launch** helps you think through the challenges of a product launch in terms of marketing, sales, reimbursement, and manufacturing.
- **Manufacturing Scale-Up for Medical Device** highlights the challenges involved in scaling up manufacturing in preparation for product launch and lists the time cycle for manufacturing scale-up.
- **Reimbursement for Medical Device** demonstrates how to outline a reimbursement strategy for coverage, coding and payment.
- **Medical Device Product Launch** lists the various pre-launch preparations and shows how to write a post-launch assessment and surveillance protocol. It concludes with a look at the mandatory medical device reports required by the FDA.

BIO DIGITAL STUDENT PASS

Medical Device Bundle

Diagnostic Development and Approval

50-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Diagnostic Development and Approval describes the regulatory pathways for different categories of diagnostics, emphasizing the differences between in vitro diagnostics and laboratory-developed tests. Quality system regulations are extensively reviewed. The course ends with a discussion on the economic evaluation of novel diagnostics. Diagnostic Development and Approval helps anyone in the diagnostics industry expand their diagnostics development acumen.

Five Takeaways:

1. Discuss the differences in diagnostic oversight by the FDA and the CMS.
2. Explain the US regulatory process for in vitro diagnostics with laboratory developed tests.
3. Recognize FDA's Class I, Class II, and Class III diagnostics.
4. Summarize the EU diagnostics approval process.
5. Discuss the challenges in receiving diagnostic reimbursement in the US.

AGENDA

- **Diagnostics: Regulation of New Clinical Tests** summarizes the regulatory pathways for different categories of diagnostics and explains the differences in oversight from the Center of Medicare and Medical Services with the FDA.
- **Approval Process for Laboratory Developed Tests** compares the regulatory differences between in vitro diagnostics and laboratory developed tests.
- **Diagnostic Regulatory Pathways** describes the regulatory burden of Class I, II, and III diagnostics and how to assess a diagnostic's class based on its risk profile. The FDA's 501(k), de nova 510(k), and premarket approval regulatory pathways are explained.
- **Quality Control of Diagnostics** highlights the application of quality system regulations for diagnostics.
- **European Union Approval Pathways for Diagnostics** provides a synopsis of the EU's diagnostic approval process.
- **Reimbursement for Diagnostics** describes the methodology for economic evaluation and reimbursement of novel diagnostics. Lastly, the US standard reimbursement codes for diagnostics are reviewed.

BIO DIGITAL STUDENT PASS

Manufacturing Bundle

Biomanufacturing

45-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Biomanufacturing introduces the intricacies and difficulties involved in manufacturing biologics. Biologics are produced in living cells, unlike small molecule drugs that are synthesized in glasswear. To understand the biopharma industry, you need know how biologic medicines are produced. Biomanufacturing is for everyone in the biopharma industry, especially for those new to drug production, drug development or product launch.

Five Takeaways:

1. List the types of products produced in biomanufacturing.
2. Explain how cell lines are developed.
3. Cite the need for cell banks and the process of cell bank production.
4. Describe in detail the steps of a biomanufacturing campaign.
5. Explain the testing protocols that ensure product quality.

AGENDA

- **Cell and Cell Banks** explains cell line development and the process of cell bank production.
- **The Manufacturing Process** discusses in detail the steps used to make biologics, specifically bulk upstream and bulk downstream processing.
- **Harvesting and Purification** highlights the nuances involved in harvesting and purifying a therapeutic protein from cell culture and explains the testing protocols that ensure drug product quality.
- **Emerging Technologies** explores some of the new technologies that companies are using to reduce costs and increase yield of the drug product. These include continuous bioprocessing, continuous chromatography, and single-use systems.

WHAT PEOPLE ARE SAYING

"I was eager to take the (online) biomanufacturing course because the subject matter is interesting to me. Once I took the first one, it made me want to take more." -Director of External Innovation

BIO DIGITAL STUDENT PASS

Manufacturing Bundle

Pharmaceutical Manufacturing

40-MINUTE ONLINE COURSE | LEVEL 2

OVERVIEW

Pharmaceutical Manufacturing introduces the complex processes of manufacturing, packaging and transporting small molecule drugs. Drug manufacturing is highly regulated by governments to ensure patients receive safe and effective medications. If you are new to drug production, drug development or product launch, Pharmaceutical Manufacturing provides you with the knowledge to understand how to get a small molecule drug from the production line to the patient and remain in regulatory compliance.

Five Takeaways:

1. Diagram the key steps of small molecule drug production on a large scale.
2. List the main ingredients that make up a small molecule drug.
3. Explain the ways regulators ensure manufacturing quality control through supplier, production, packaging and shipping validation.
4. Compare and contrast the four most common pharmaceutical formulations: tablets, capsules, suspensions and emulsions.
5. Describe the pharmaceutical supply chain considerations including the prevention of drug counterfeiting.

AGENDA

- **Chemical Synthesis** explains the types of reactions used to synthesize small molecule drugs.
- **API Purification** goes over the various purification methods for small molecule drug production and explains how supplier validation ensures manufacturing quality.
- **Formulation** compares the four most common pharmaceutical formulations: tablets, capsules, suspensions and emulsions.
- **Packaging** discusses pharmaceutical packaging and shipping regulations, including cold chain management, shipping validation and best practices to prevent drug counterfeiting.

BIO DIGITAL STUDENT PASS

Manufacturing Bundle

Adeno-Associated Virus CMC

65-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH, INTRODUCTION TO GENETIC ENGINEERING

OVERVIEW

Adeno-Associated Virus CMC explains the design, function, and features of adeno-associated virus (AAV) systems, details on specific platforms used for transfection, and methods of validation and purification after the gene therapy product is created.

Five Takeaways:

1. Describe the components of an AAV vector and AAV platform.
2. Detail the cDNA characteristics that can be packaged in AAV.
3. Discuss specifics of the following AAV platforms: Transfection into HEK293 cells, Sf9/rBV, HSV/BHK, and Producer Cell Line (such as HeLa or HEK cell line).
4. Describe the downstream techniques for purification of an AAV product as well as the techniques for potency, purity, and safety testing.
5. Discuss the regulatory considerations for AAV CMC.

AGENDA

- **AAV Design, Function, and Features** describes the components of an AAV capsid and the cDNA characteristics that an AAV system can package.
- **Gene Therapy Manufacturing Platforms** provides a basic overview of different gene therapy manufacturing platforms and gives a detailed account of the following platforms:
  - Transient Transfection into HEK293 cells
  - Sf9/rBV
  - HSV/BHK
  - Producer Cell Line (such as HeLa or HEK cell line)
- **Downstream Purification and Testing** describes the purification techniques used to ensure high quality and quantity of a gene therapy product with regards to potency and purity. Details on safety testing requirements and regulatory considerations for AAV CMC are provided.

BIO DIGITAL STUDENT PASS

Manufacturing Bundle

Biosimilars

50-MINUTE ONLINE COURSE | LEVEL 2

OVERVIEW

Biosimilars provides an overview of the science, biomanufacturing technology, and regulatory requirements for receiving approval to market biosimilar products. The course begins by taking an in-depth look at the science, specifically how a therapeutic protein's structure dictates its function. With this foundational knowledge, users understand how biomanufacturing conditions can alter a biosimilar, causing it to function differently than its reference product. The course ends with some tested approaches to demonstrating biosimilarity that have been acceptable to the FDA and EMA.

Five Takeaways:

1. Understanding how a protein's structure dictates its function.
2. Ability to discuss how post-translational modifications can change a protein's intended function.
3. A comprehensive understanding of how biosimilars may differ from its reference product once it has been manufactured.
4. FDA and EMA requirements for biosimilar approval and the underlying scientific/quality/regulatory principles involved.
5. General considerations of animal/clinical/in vitro studies, as well as the FDA's Totality-of-the-Evidence approach.

AGENDA

- **Protein Function** reinforces a deep understanding of proteins by describing their various cellular functions through examples. Biosimilars are proteins.
- **Protein Synthesis** explains protein structure and the steps involved in making a protein. By understanding that a protein's structure influences its functions, one can begin to understand how a reference product and biosimilar may not be identical.
- **Post-Translational Modifications** points out that both genes and cells influence the type of post-translational modification and the degree to which the protein is modified. This modification determines if a therapeutic will work or not work.

continued

- **Biologics** list the functions of therapeutic proteins and compares and contrasts biologics with small molecule drugs.
- **Introduction to Biosimilars** reviews the EMA and FDA definitions of biosimilars.
- **The Product Is the Process** lists the steps of biomanufacturing explaining the goal of each step. This section identifies where variations can occur between two identical production campaigns, demonstrating how a biosimilar may not be identical to the reference product. Itemize key formulation parameters and examples of where protein stability testing are highlighted.
- **Biosimilars Safety and Regulation** takes an in-depth look at immunogenicity, a main safety concern of biosimilars. A discussion of how companies test for immunogenicity and predict immune response to a therapeutic protein is given. The course ends by explaining how companies gain approval for a biosimilar.

BIO DIGITAL STUDENT PASS

Biosafety Bundle

Biosafety Basics

68-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Biosafety Basics provides the introductory framework to the practices and principles when working with infectious biological agents. Focus is placed on an introduction to infectious agents, assessment of biological hazards and risks, overview of laboratory safety, risk mitigation via personal protective equipment and biosafety cabinets, program management, and biosafety guidelines and regulations.

Five Takeaways:

1. Explain the risk factors involved in working with a biological agents.
2. Explain why personal protective equipment (PPE) is used, and what PPE is appropriate for the work area.
3. Describe the differences between a biological safety cabinet (BSC), a fume hood, and a laminar flow clean air center.
4. List the basic design differences between Biosafety Labs (BSL)-1, 2, 3,
5. Explain how the various Federal regulatory agencies affect the practice of biosafety.

AGENDA

- **Introduction to Infectious Agents** identifies certain diseases caused by prions, viruses, bacteria, fungi, and parasites and explains the different ways that diseases can be transmitted.
- **Assessing Biological Hazards and Biorisks** explains the risk factors involved when working with a biological agent and discusses how an infection can be prevented my modifying the agent itself or how that agent is handled.
- **Laboratory Safety Overview: Common Lab Hazards and Basic Safety** Thinking identifies the hierarchy of controls for working with biological hazards, underlines the difference between engineering controls and work practice controls, and explains how to eliminate or replace sharps in the workplace.
- **Biorisk Mitigation: Personal Protective Equipment (PPE)** first explains why personal protective equipment is used. Next, it discusses the limitations of each PPEs, and discusses how to select appropriate PPE based on tasks, work area, temperature, organisms, and chemicals used. Lastly, this section explains the difference between masks and respirators and which respirator is appropriate for a certain application.

continued

- **Biorisk Mitigation: Biological Safety Cabinets (BSC)** defines the term primary containment and explains the difference between a biological safety cabinet (BSC), a fume hood, and a laminar flow clean air center.
- **Biorisk Mitigation: Laboratory Facility Considerations** explains how the risk group of an organism influences the design of the laboratory where it will be handled, describes how a risk group corresponds to the biosafety level of a facility, and finally elucidates the design differences between Biosafety Labs (BSL) – 1, 2, 3, and 4.
- **Biorisk of Bioaerosols** first explain bioaerosols, how they can be present in the workplace, and the types of laboratory manipulation that can produce an aerosol. Next, the section discussed why aerosols present a high risk to workers, and lastly compares the differences between a disease spread by droplets and one spread by the aerosol or droplet nuclei route.
- **Biosafety Program Management** first lists the elements of a good biosafety program and the basic topics that a biosafety manual should cover. Second, the section discusses why an occupational health program is important and what types of concerns should be addressed by this program. Third the section lists the responsibilities of the Institutional Biosafety Committee (IBC). Lastly, the section explains when a biosafety officer is required per NIH guidelines and what procedures an emergency response plan should cover.
- **Biosafety Regulations and Guidelines** lists some of the primary US biosafety-related regulations and explains how the various federal regulatory agencies affect the practice of biosafety.

BIO DIGITAL STUDENT PASS

Biosafety Bundle

Elements of a Biorisk Management Program

53-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Elements of a Biorisk Management Program summarizes the major practices and principles, as well as the tools necessary for organizations to integrate biological safety and biorisk management techniques into their existing laboratory operations and programs.

Five Takeaways:

1. Describe the early steps involved in developing a biosafety program.
2. List the roles of various personnel in a Biorisk Management Program.
3. Implement a biosafety or Biorisk program in your institution.
4. Identify laboratory operations that pose potential biological risks.
5. Explain why procedures need to be established in biosafety programs.

AGENDA

- **Starting a Biosafety Program** describes the early steps involved in developing a biosafety program.
- **Operations** describes the roles various personnel working in an occupational health program, including biosafety committee members and biosafety officers, laboratory, facility, and security management workers, as well as lab workers and animal care workers.
- **Implementation** explains the implementation of a biosafety or Biorisk program in your institution.
- **Operation Control** identifies the laboratory operations that pose potential biological risks and explains why procedures need to be established in biosafety programs.

BIO DIGITAL STUDENT PASS

Biosafety Bundle

Introduction to Biosafety Cabinets

44-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Introduction to Biosafety Cabinets provides an overview of biosafety cabinets (BSCs), including different types, safe operation and work practices, proper decontamination methods, and a review of the NSF/ANSI 49 Standard.

Five Takeaways:

1. Define the function of a biosafety cabinet (BSC).
2. Describe the types of BSCs and explain why they are different.
3. Define what class II and III cabinets protect.
4. State how often a BSC should be certified.
5. Describe the primary method of decontamination and list the types of decontaminants approved by ANSI.

AGENDA

- **Air Filtration** defines the function of a biosafety cabinet (BSC), explains the features and functions of a HEPA filter, and lists the differences in retaining particle sizes for HEPA, ULPA, and SULPA filters.
- **Types of Biosafety Cabinets** describes the types of BSCs and explains why they are different.
- **Working in the Biosafety Cabinet** defines what class II and class III cabinets protect and explains why UV lights are not recommended for use in a BSC.
- **NSF/ANSI 49** explains how often BSCs should be certified and describes the different functional tests for BSCs.
- **Biosafety Cabinet Decontamination** first describes the primary method of decontamination, lists the types of decontaminants approved by ANSI, and describes the two components that are critical during any method of decontamination. Lastly, this section explains what indicators are used to validate decontamination.

BIO DIGITAL STUDENT PASS

Biosafety Bundle

Basic Disinfection Practices for Tissue Culture Laboratories

40-MINUTE ONLINE COURSE | LEVEL 1

OVERVIEW

Basic Disinfection Practices for Tissue Culture Laboratories introduces disinfection methods for laboratories working with infectious agents. Emphasis is placed on common sources of contamination, choosing the right type of disinfectant, best practices for tissue culture laboratories, and how to clean the laboratory and equipment.

Five Takeaways:

1. Identify the biosafety level to be used handling human tissues.
2. Describe what personal protective equipment should be used in different scenarios.
3. Define which laboratory processes require a written standard operating procedure.
4. Explain how often floors, bench-tops, and other laboratory equipment can be cleaned/disinfected.
5. Describe the appropriate means to clean/dispose of contaminated flasks, bottles, trays, etc.

AGENDA

- **Introduction: Tissue Culture and Contamination** identifies the biosafety level to be used when handling human tissues and describes how most contamination happens in a tissue culture lab.
- **Choosing a Disinfectant** defines decontamination, identifies where to find a list of approved disinfectants, and describes the appropriate use of alcohol for cleansing.
- **Best Practices for Tissue Culture Laboratories** describes what personal protective equipment (PPE) should be used in different scenarios and explains methods for decreasing/eliminating cross contamination.
- **Standard Operating Procedures** defines which laboratory processes require a written standard operating procedure and discusses special considerations of laboratory water baths as sources of contamination.
- **Cleaning and Waste Disposal** explains how often floors, bench-tops, and other laboratory equipment should be cleaned/disinfected and describes the appropriate means of cleansing/disposing of contaminated flasks, bottles, trays, etc.