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COURSE SNAPSHOT

Drug Manufacturing

biotechPrimer
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Drug Manufacturing

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Understanding Biomanufacturing

ONE-DAY MASTER COURSE LIVE, ONLINE

OVERVIEW

Understanding Biomanufacturing is a one-day journey that delves into all aspects of large molecule drug production. Developed specifically for the non-scientist, this live, online course keeps participants engaged through its interactive activities and discussions. Topics include the process of drug production, the science of manufacturing, common cell lines used, and an overview of safety regulations including the role of GMP. Learn from a biomanufacturing professional who offers real-life insights into drug-derived product manufacturing

Five Takeaways

1. Understand the steps for large molecule drugs production campaigns.
2. Learn the important considerations when scaling upstream, midstream, and downstream.
3. List the testing and handling requirements for master and working cell banks.
4. Discuss the pros and cons of different production platforms and cell lines.
5. Learn the types of equipment, controls, utilities and facilities needed.

AGENDA

Biological Basis Biomanufacturing
9:00-10:00
Cells and viruses
DNA and genes
DNA replication
Gene expression

Break 10:00-10:15

The Regulatory Component 10:15-11:15
FDA guidance documents: CFRs
Overview of GXPs
Basic drug components
Chemistry, manufacturing and controls
Role of QA and QC
cGMP facilities and environmental monitoring
FDA adverse events reporting systems
Top reasons for drug recall and shortages

Break 11:15 – 11:30

Biomanufacturing Overview 11:30-12:15
Manufacturers: sponsors and CMOs
Manufacturing process: unit operations
Key equipment: function and validation
Cell lines
Cell banks: master and working
Cell bank testing requirements

Lunch 12:15-1:00

Biomanufacturing Overview continued
1:00-2:00
Continuous manufacturing principles
Upstream and downstream processes
Biologics formulation
Biologics stability and analytical testing
Fill and finish

Break 2:00-2:15

Immuno and Cellular Therapies 2:15-3:15
Immunoproteins: mAbs and cytokines
Formulation and manufacture
Cellular immunotherapies
Engineering CAR-T, NKCAR, macrophage CARs
CAR-T production
Quality expectations for cells
CAR-T formulation and release criteria

Wrap-Up 3:15-3:30

On-Demand, Online Classes

Learn anywhere, at your own pace. Designed for individuals, customized for organizations.

LEVELS

Each on-demand, online class is given a level to help individuals choose the appropriate class based on their background and needs. For all level 2 and 3 classes 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

Each individual on-demand, online class: **$150** BIO member price: **$120**

Bulk discount pricing:

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

**For BIO member companies only*

CORPORATE ACCOUNTS

Need to train an entire department or company? We offer two options.

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

LTI Bridge: Connect your organizations LMS to Biotech Primer's LMS. Individuals log into their company's LMS and take our classes.

Contact Stacey Hawkins at stacey@biotechprimer.com to learn more.

Biomanufacturing

45-MINUTE ONLINE CLASS | LEVEL 2 | SUGGESTED PREREQUISITES:
THE BIOLOGY OF BIOTECH, INTRODUCTION TO GENETIC ENGINEERING

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

Pharmaceutical Manufacturing

40-MINUTE ONLINE CLASS | LEVEL 2

SUGGESTED PREREQUISITE: THE BIOLOGY OF BIOTECH

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.

AAV Gene Therapy Manufacturing

45-MINUTE ONLINE CLASS | LEVEL 2

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

OVERVIEW

AAV Gene Therapy Manufacturing 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 characteristics of the naturally occurring Adeno-associated virus
2. Discuss the features of a mature AAV vectors
3. Describe the four primary platforms used to create AAV vectors
4. Explain how each of the following are characterized with respect to viral vectors: Safety, Identity, Potency, Quality, and Purity
5. Explain key regulatory considerations for AAV manufacturing

AGENDA

- **Adeno-Associated Virus Overview** provides an overview of the properties of the naturally occurring Adeno-associated virus including its origin and characteristics
- **AAV Vectors** describes how the adeno-associated virus is utilized in gene therapy using AAV vectors, including the composition of AAV viral vectors as well as the general characteristics of the types of genes that can be transfected using these vectors**.**
- **AAV Manufacturing and Control** discusses AAV Manufacturing and control including an introduction to manufacturing, the four primary platforms for AAV production, the characterization of AAV manufacturing products, and the regulation of AAV production.

WHAT PEOPLE ARE SAYING

"I got the job, and I couldn't wait a couple of months to get the learning I needed. I needed to get up to speed quickly so I took a few (Biotech Primer) online courses and hit the ground running."
– Technology Licensing Director