BIOTECH PRIMER

COURSE SNAPSHOT

Drug Manufacturing

biotechPrimer
Life Science Training From Industry Experts

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ABOUT US

Biotech Primer Inc. develops and delivers training to help professionals understand the science, business, and regulatory processes essential to the biotechnology, pharmaceutical, molecular diagnostics and medical device industries. Our industry experts continuously create, update and deliver the most engaging instruction anywhere. We have the experience and expertise needed to prepare companies to make strategic business decisions, navigate important regulatory hurdles, and move healthcare products from the bench to the bedside. To accomplish these goals, we offer a diverse range of learning opportunities, ensuring participants retain and put into practice what they learn.

- Integrate your science and business operations
- Bring in-depth knowledge to your sales force
- Help your team converse more effectively with industry clients, colleagues, and scientists
- Enable your entire staff to recognize new opportunities

OUR SUBJECT EXPERTISE

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

OUR DELIVERY PLATFORMS

Our training is offered using multiple platforms to better fit your learning preferences and scheduling constraints

- **Live Customized Courses** Tailored training delivered to organizations worldwide live online or live onsite. You can modify the master course agendas to meet your specific learning needs.
- **Live Master Courses** Prescheduled courses for individuals or schedule a master course for your organization.
- **Recorded Master Courses** Offers the same content, exercises and workbook as the live master course, with the ability to take the course on-demand, online when your schedule permits.

- **On-Demand, Short Classes** Short interactive 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.
  - Certificate available upon successful class completion.
  - Ability to upload certificate to your LinkedIn education profile.
  - Two corporate account options available for on-demand, short classes
    - **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. No extra cost.
    - **LTI Bridge:** Connect your organizations LMS to Biotech Primer's LMS. Participants log into their company's LMS and take our classes. Integration costs apply.

OUR PRICING

- **Live Customized Courses** The cost of tailored training depends on content, length of course, and number of participants. Discounts given to multiple classes purchased within one year.
- **Live Master Courses** Prescheduled two-day courses for individuals range from $1495-$1695 US.
- **Recorded Master Courses** These courses are 3-12 hours in length and cost $895 US. Participants are given three months to complete each course.
- **On-Demand, Short Classes** Each class is $150 US. BIO members receive special pricing of $120 US per class. Participants are given two weeks to complete the class.

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*

OUR COURSE LEVELS

- **Level 1: Foundational** For non-scientists new to biopharma and 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 therapeutics mitigate disease in this easy-to-read 170-page book. Books available for purchase on Amazon.
- **The WEEKLY**
  White papers that explain the science behind the headlines.

OUR INSTRUCTORS

Biotech Primer instructors offer extensive industry experience. By drawing on their various backgrounds, these seasoned professionals are well-informed on the real-world situations you face. They have developed drugs, diagnostics, and medical devices for companies ranging from multinational corporations to start-ups.

Biotech Primer courses are on point, thorough and taught by one dedicated industry educator, not a patchwork of invited academic lecturers.

You can expect:

- Limited class size so all your questions are answered
- Hands-on labs, thought-provoking case studies, and dynamic discussions so you practice what you learn
- Industry war stories to help you avoid lessons hard learned by others

biotechPrimer
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LIVE MASTER COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

Understanding Biomanufacturing

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, standard 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. Explanation of steps taken during large molecule drug production campaigns.
2. Considerations for upstream processing, downstream processing, and formulation.
3. List of the testing and handling requirements for master and working cell banks.
4. Pros and cons of different production platforms and cell lines.
5. Survey of equipment, controls, utilities, and facilities needed.

AGENDA

Biological Basis Biomanufacturing
60 minutes
Cells and viruses
DNA and genes
DNA replication
Gene expression

Break 15 minutes

The Regulatory Component 60 minutes
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 15 minutes

Biomanufacturing Overview 45 minutes
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 45 minutes

Biomanufacturing Overview continued
60 minutes
Continuous manufacturing principles
Upstream and downstream processes
Biologics formulation
Biologics stability and analytical testing
Fill and finish

Break 15 minutes

Immuno and Cellular Therapies 60 minutes
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 15 minutes

Biomanufacturing

OVERVIEW

Biomanufacturing introduces the intricacies and challenges involved in manufacturing biologics. Biologics are produced in living cells, unlike small molecule drugs that are synthesized in glassware. To understand the biopharma industry, you must know how biological 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. Explain the process of bacterial and mammalian cell line development.
2. List the process steps used to make a master cell bank and a working cell bank.
3. Describe, in detail, the steps of upstream and downstream bioprocessing.
4. Explain the testing protocols that ensure product quality.
5. Cite the benefits and risks of 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

OVERVIEW

Pharmaceutical Manufacturing introduces the complex processes of manufacturing, packaging, and transporting small molecule drugs. Governments highly regulate drug manufacturing to ensure patients receive safe and effective medications. 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.
2. List the main ingredients that make up a small molecule drug and the purposes for each.
3. Explain how regulators ensure manufacturing quality control through the 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 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

AAV Gene Therapy Manufacturing For Non-Scientists

OVERVIEW

AAV Gene Therapy Manufacturing For Scientists explains the features and functions of AAV viral vector platforms, focusing on Triple Transient Transfection. An explanation of the upstream bioprocessing, cell harvesting, downstream bioprocessing, fill and finish and packaging of AAV gene therapy products is given. The class ends with a review the CMC regulatory component of AAV manufacturing.

Five Takeaways:

1. Fluency in the structures and functions of AAV.
2. Knowledge of how AAV serotypes influence tissue tropism.
3. Compare and contrast the four primary AAV vector platforms.
4. Understanding the manufacturing workflow's purpose: upstream bioprocessing, cell harvesting, downstream bioprocessing, fill and finish, and packaging.
5. Survey of the key guidances for CMC testing 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

AAV Gene Therapy Manufacturing For Scientists

OVERVIEW

AAV Gene Therapy Manufacturing For Scientists uses scientific vocabulary and concepts that require the learner have an excellent command of molecular biology. This class explains the features, functions, and design of four AAV viral vector platforms, followed by an in-depth explanation of the upstream and downstream AAV manufacturing process. The class reviews the CMC regulatory component of AAV manufacturing, highlighting the analytical and comparability of manufacturing platforms. A quick review of the AAV manufacturing facility and the workflows round out this course.

Five Takeaways:

1. Description of the structures and functions of the AAV viral vector and how this influences tropism.
2. Listing of the AAVs serotypes and how new serotype genomes are designed.
3. Compare and contrast four primary AAV vector platforms, including their precursor materials, critical raw materials, and CMC considerations.
4. Explanation of how each of the following is characterized concerning viral vectors: safety, identity, potency, quality, and purity.
5. Discussion of key regulatory considerations for AAV manufacturing.

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

AAV Manufacturing And Controls
(continued)

- 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