National Center for Therapeutics Manufacturing

# VOCATIONAL PROGRAM CATALOG 2025

Printed in the United States of America

# PROGRAM CATALOG

This catalog provides a comprehensive overview and description of NCTM's training courses. With the exception of our online courses, all training courses are customizable to fit any organization's needs. Pricing is based on the level of customization and the number of cohort participants.

NCTM

# PROGRAMS


National Center for Therapeutics Manufacturing

# ABOUT

The National Center for Therapeutics Manufacturing (NCTM) is an interdisciplinary workforce education and research center serving the global biopharmaceutical and vaccine manufacturing industries. A member of the Texas A&M Engineering Experiment Station, the NCTM develops and delivers customizable instructor-led, hands-on, and computer-based learning to expose the student to various aspects of cell culture and basic molecular biology, aseptic processes and microbiology, upstream and downstream processing of biological materials including viruses, monoclonal antibodies, and other recombinant proteins, as well as industrial bioanalytical methods.

NCTM also provides enabling technologies to medical researchers, and start-ups through its blended infrastructure of academic, scientific, and industrial expertise and complete range of bench-to-pilot and Phase I scale bioprocess and analytical equipment.

## ENHANCING THE BIOPHARMACEUTICAL WORKFORCE.

**Our Mission:**

*To advance workforce education and applied research for the bio-pharmaceutical industry.*

To learn more visit:
**nctm.tamu.edu**

For program inquiries email:
**programs@nctmmail.tamu.edu**

@NCTMtamu


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# HANDS-ON COURSES

These courses provide practical, hands-on training to anyone wanting to enter or expand their knowledge about topics in the biopharmaceutical manufacturing industry.

# BIOPHARMA BOOTCAMP

This week-long, hands-on short course provides an overview and hands-on lab activities of general, upstream and downstream operations within the biomanufacturing industry. Participants will learn about working in a controlled environment, aseptic technique, and how to operate basic laboratory equipment. Participants will then produce a model protein during a series of upstream activities including bioreactor assembly, culture media preparation, batch cultivation, offline analysis and harvesting. Participants will also learn a series of downstream techniques to purify protein by performing ion exchange chromatography, hydrophobic interaction chromatography, and column cleaning and sanitization.

## TARGET AUDIENCE

Individuals seeking an understanding of the primary unit operations and process of biologics manufacturing.

## COURSE CALENDAR

**Open Enrollment**

**March 24-28, 2025**
**September 8-12, 2025**

## COURSE COST

**Tuition:** $4800

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 3.5 Continuing Education Credits (CEU's).**

# MODULES/TOPICS

| DAY 1 : | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:15 | Sign In/Orientation |
| 8:15 | 8:45 | Lecture: Introduction Biomanufacturing Processes |
| 8:45 | 9:15 | Lecture: Biological Laboratory Safety Overview |
| 9:15 | 10:00 | Lecture: Introduction to Analytical Laboratory Equipment |
| 10:00 | 12:30 | Lab: Operation of Analytical Equipment |
| 12:30 | 1:30 | *LUNCH BREAK* |
| 1:30 | 2:15 | Lecture: Controlled Environments |
| 2:15 | 2:30 | *AFTERNOON BREAK* |
| 2:30 | 3:30 | Lecture: Aseptic Technique |
| 3:30 | 4:30 | Lab: Aseptic Technique in the Biological Safety Cabinet |

**UPSTREAM BIOMANUFACTURING PROCESSES**

| DAY 2 : | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:30 | Lecture: Introduction to Upstream Bioprocessing |
| 8:30 | 9:00 | Lecture: Overview of Cell Biology |
| 9:00 | 9:45 | Lecture: Bioreactor Preparation and Set-up |
| 9:45 | 10:00 | *MORNING BREAK* |
| 10:00 | 12:00 | Lab: Bioreactor Assembly and Configuration Overview |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 1:45 | Lecture: Culture Media Preparation Overview (Mock BPR and Calculation) |
| 1:45 | 3:15 | Lab: Culture Media Preparation and Vessel Sterilization |
| 3:15 | 3:30 | *AFTERNOON BREAK* |
| 3:30 | 4:45 | Lab: Cultivation of Seed Culture |

| DAY 3 : | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 9:00 | Lecture: Monitoring and Sampling / Offline Analysis |
| 9:00 | 10:30 | Lab: Inoculation of BioFlo 320 Fermentor |
| 10:30 | 10:45 | *MORNING BREAK* |
| 10:45 | 12:00 | Lab: Batch Fermentation/Sample Collection and Analysis |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 1:30 | Lab: Sample Collection and Analysis |
| 1:30 | 3:00 | Lab: Cell Observation and Counting |
| 3:00 | 3:15 | *AFTERNOON BREAK* |
| 3:15 | 3:45 | Lab, continued: Sample Collection and Analysis |
| 3:45 | 5:00 | Lecture: Intro to Downstream Processing and Primary Recovery |
| 5:00 | 5:10 | Lab, continued: Sample Collection and Analysis |

**DOWNSTREAM BIOMANUFACTURING PROCESSES**

| DAY 4 : | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 10:00 | Lab: Harvest and Storage of Biomass |
| 10:00 | 10:15 | *MORNING BREAK* |
| 10:15 | 11:15 | Lecture: Introduction to Buffers and Molarity |
| 11:15 | 12:00 | Lecture: Normal/Tangential Flow Filtration |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 2:00 | Lecture: Normal/Tangential Flow Filtration |
| 2:00 | 3:00 | Lab: Buffers and Solution Preparation |
| 3:00 | 3:15 | *AFTERNOON BREAK* |
| 3:15 | 4:15 | Lab: Sterile Filtration and Sampling |
| 4:15 | 4:45 | Lab: Filter Integrity Testing |

| DAY 5: | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 11:30 | Lab: Tangential Flow Filtration Activity |
| 11:30 | 12:30 | *LUNCH BREAK* |
| 12:30 | 1:30 | Lecture: Introduction to Chromatography/Column Sanitization and Cleaning |
| 1:30 | 2:15 | Lab: Ion Exchange Chromatography: System and Method Preparation |
| 2:15 | 2:30 | *AFTERNOON BREAK* |
| 2:30 | 3:30 | Lab: Ion Exchange Chromatography: Method and Results |
| 3:30 | 4:45 | Lab: Hydrophobic Interaction Chromatography/Anion Exchange Column Cleaning & Sanitization |
| 4:45 | 5:00 | Closing Discussion |

# ADVANCED CERTIFICATE IN BIOPHARMACEUTICAL MANUFACTURING

Participants of this program complete NCTM online courses, then attend 2 weeks of hands-on training at NCTM. This course provides lectures and hands-on lab activities of upstream, downstream, and analytical operations within the biomanufacturing industry. Participants will learn how to work in a controlled environment, aseptic technique, and how to operate basic laboratory equipment. Participants will then produce a model protein during a series of upstream activities including plating, bioreactor assembly, culture media preparation, seed culturing, sterilization, inoculation, batch cultivation, and harvesting. Participants will also learn a series of downstream techniques to purify protein by performing homogenization, centrifugation, solution preparation, sterile filtration, tangential flow filtration, column packing, column cleaning and sanitization, ion exchange chromatography,and hydrophobic interaction chromatography. Finally, participants will perform a small set of analytical techniques including OD and metabolite measurements, BCA assay, and membrane integrity testing.

Online courses required include 1101/1201, 1102, 1103, 1104, and 1105. See pages 39-48 for additional details. Course cost includes enrollment in online courses and hands-on component.

## TARGET AUDIENCE

Entry level biomanufaturing technicians who want an overview of all aspects of the manufacturing process , while having an interest in earning a certificate.

## COURSE CALENDAR

**Contract training cohort of 10 participants as available upon request**

## COURSE COST

**Tuition:** $9,195 per p**articipant** assumes cohort of 10 participants

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 9.6 Continuing Education Credits (CEU's).**

# MODULE/TOPICS

| DAY 1 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:45 | Sign In/Orientation |
| 8:45 | 9:15 | Lecture: Introduction Biomanufacturing Processes |
| 9:15 | 9:45 | Lecture: Biological Laboratory Safety Overview |
| 9:45 | 10:00 | *MORNING BREAK* |
| 10:00 | 11:00 | Lecture: Introduction to Analytical Equipment |
| 11:00 | 12:00 | Lab: Operation of Analytical Equipment |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 2:15 | Lab: Operation of Analytical Equipment cont. |
| 2:15 | 2:30 | *AFTERNOON BREAK* |
| 2:30 | 3:30 | Lecture: Cell Culture Basics |
| 3:30 | 4:00 | Lab: Aseptic Technique on the Bench |
| 4:00 | 5:00 | Lab: Aseptic Technique in the Biological Safety Cabinet |
| **DAY 2 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 10:00 | Lecture: Quality Assurance |
| 10:00 | 10:15 | *MORNING BREAK* |
| 10:15 | 11:15 | Lecture: Controlled Environments |
| 11:15 | 12:00 | Lecture: Introduction to Gowning and De-gowning |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 2:45 | Lab: Cleanroom Gowning and Air/Surface Monitoring Sample |
| 2:45 | 3:15 | Lab: Surface Monitoring Sample Preparation / Total Air Particle Results |
| 3:15 | 3:30 | *AFTERNOON BREAK* |
| 3:30 | 4:30 | Lecture: Fermentation Overview |
| **DAY 3 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:30 | Lecture: Overview of Cell Biology |
| 8:30 | 9:00 | Lecture: BioFlo 310 Fermetor Overview |
| 9:00 | 10:00 | Lab: BioFlo 310 Fermentor Assembly |
| 10:00 | 12:00 | Lab: BioFlo 310 Fermentor Controller |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 1:45 | Lecture: Culture Media Preparation Overview (Mock BPR and Calculation) |
| 1:45 | 2:30 | Lab: Media Preparation BPR |
| 2:30 | 2:45 | AFTERNOON BREAK |
| 2:45 | 3:30 | Lab: Steam & Filter Sterilization |
| 3:30 | 4:30 | Lab: Cultivation of Seed Culture |
| **DAY 4 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 9:30 | Lecture: Offline Analysis |
| 9:30 | 10:30 | Lab: Inoculation of BioFlo 310 Fermentor |
| 10:30 | 10:45 | *MORNING BREAK* |
| 10:45 | 12:00 | Lab: Batch Cultivation/Sample Collection and analysis |

| | | |
|---|---|---|
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 1:30 | Lab: Sample Collection and Analysis |
| 1:30 | 2:15 | Lecture: Recombinant E. coli in the Biopharmaceutical Industry |
| 2:15 | 2:40 | Lab: Sample Collection and Analysis |
| 2:40 | 2:55 | *AFTERNOON BREAK* |
| 2:55 | 3:55 | Lecture: Advanced Bioreactors & Feeding |
| 3:55 | 4:30 | Lab: Sample Collection and Analysis |
| **DAY 5 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 10:00 | Lab: Harvest and Storage of Biomass |
| 10:00 | 10:30 | Lab: Summary of Fermentation Run |
| 10:30 | 10:45 | *MORNING BREAK* |
| 10:45 | 11:30 | Lecture: Mammalian Cell Culture |
| 11:30 | 12:30 | *LUNCH BREAK* |
| 12:30 | 2:30 | Lab: Counting and Passaging of Eukaryotic Cells |
| 2:30 | 2:45 | *AFTERNOON BREAK* |
| 2:45 | 3:15 | Lab: Surface and Air Monitoring Results |
| 3:15 | 4:00 | Course Review and Quiz |
| 4:00 | 4:15 | Survey and Final Q/A |
| **DAY 6 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:15 | Sign in/Orientation |
| 8:15 | 8:45 | Lecture: Introduction Biomanufacturing Processes |
| 8:45 | 9:15 | Lecture: Biological Laboratory Safety Overview |
| 9:15 | 9:30 | *MORNING BREAK* |
| 9:30 | 10:30 | Lecture: Introduction to Analytical Equipment |
| 10:30 | 11:30 | Lab: Operation of Analytical Equipment |
| 11:30 | 12:30 | *LUNCH BREAK* |
| 12:30 | 1:45 | Lab: Operation of Analytical Equipment cont. |
| 1:45 | 2:30 | Lecture: Introduction to Downstream Processing |
| 2:30 | 2:45 | *AFTERNOON BREAK* |
| 2:45 | 3:45 | Lecture: Protein Chemistry Overview |
| 3:45 | 5:00 | Lecture: Primary Recovery |
| **DAY 7 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 9:30 | Lecture: Introduction to Buffers and Molarity |
| 9:30 | 9:45 | *MORNING BREAK* |
| 9:45 | 10:45 | Lab: Buffer prep activity |
| 10:45 | 11:30 | Lab: Sterile Filtration and Sampling |
| 11:30 | 12:30 | *LUNCH BREAK* |
| 12:30 | 1:30 | Lecture: Normal Flow Filtration |
| 1:30 | 2:15 | Lecture: Membrane Integrity Testing |
| 2:15 | 2:30 | *AFTERNOON BREAK* |
| 2:30 | 3:15 | Lab: Membrane integrity testing |
| 3:15 | 4:30 | Lecture: Demo on Single use connections and assemblies, Tube Sealing and Welding |

| DAY 8 - | | |
|---|---|---|
| Start Time | End Time | Activity |
| 8:15 | 8:45 | Lab:  Cell cake suspension |
| 8:45 | 9:15 | Lecture: Cell Lysis |
| 9:15 | 10:30 | Lab: Homogenization |
| 10:30 | 10:45 | *MORNING BREAK* |
| 10:45 | 11:00 | Lab: Centrifugation of Feed Material |
| 11:00 | 12:00 | Lecture:  Introduction to Chromatography |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 1:30 | Lecture: Introduction to Column Packing and Qualification |
| 1:30 | 3:00 | Lab:  Column Packing |
| 3:00 | 3:15 | *AFTERNOON BREAK - flexible timing* |
| 3:15 | 3:45 | Lab: Column Packing Calculations |
| 3:45 | 4:30 | Lab: Evaluation of Column Packing using software and hand calculations |
| **Day 9 -** | | |
| Start Time | End Time | Activity |
| 9:00 | 9:30 | Lecture: Introduction to Ion Exchange Chromatography |
| 9:30 | 10:15 | Lab: Preparation of Feed Material |
| 10:15 | 10:30 | *MORNING BREAK* |
| 10:30 | 11:45 | Lab: Introduction to AKTA Pilot Chromatography System and Unicorn Software Overview |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 2:30 | Lab: Ion Exchange Chromatography and Analysis of Results |
| 2:30 | 3:00 | Lecture: Column Cleaning and Sanitization |
| 3:00 | 3:15 | *AFTERNOON BREAK* |
| 3:15 | 4:30 | Lab: Column Cleaning and Sanitization |
| **Day 10 -** | | |
| Start Time | End Time | Activity |
| 8:00 | 9:00 | Lecture:  Tangential Flow Filtration |
| 9:00 | 10:30 | Lab: Tangential Flow Filtration with Hollow Fiber Cartridges |
| 10:30 | 11:15 | Lab: Tangential Flow Filtration: Diafiltration and Sample Recovery |
| 11:15 | 12:00 | Tangential Flow Filtration: Analysis of Samples and Mass Balance Calculations |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 1:30 | Lecture: Introduction to Hydrophobic Interaction Chromatography |
| 1:30 | 3:00 | Lab: Hydrophobic Interaction Chromatography Method |
| 3:00 | 3:15 | *AFTERNOON BREAK* |
| 3:15 | 4:00 | Course Quiz and Review |

# HANDS-ON CGMP BIOMANUFACTURING OF VECTORS FOR GENE THERAPY

This 4-day continuing education course provides hands-on training in the production of vectors for gene therapy products using an AAV2-GFP model system in a Sf9/Baculovirus system. Engage in upstream operations (suspension cell culture, vector production scale-up in single-use bioreactors); downstream operations (cell lysis, product recovery via depth filtration, purification using chromatography, and ultrafiltration for concentration and buffer exchange); and analytical technologies, such as qPCR and SDS-PAGE, as well as discuss strategies and issues around scale-up, tech transfer, and adherent vs. suspension cultures.

## TARGET AUDIENCE

Industry professionals who have some background in traditional biomanufacturing and are interested in expanding their knowledge on viral vectors and gene therapy applications.

## COURSE CALENDAR

**Open Enrollment:**

**February 4-7, 2025**
**May 6-9, 2025**
**October 27-30, 2025**

**Contract training cohort of 10 participants as available upon request.**

## COURSE COST

**Tuition:** $4,466 per p**articipant** assumes cohort of 10 participants

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 3.7 Continuing Education Credits (CEU's).**

# MODULE/TOPICS

| DAY 1 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:15 | Lecture 1: Course Orientation |
| 8:15 | 9:15 | Lecture 2: Gene Therapy Products and Process |
| 9:15 | 10:15 | Lecture 3: Intro to Current Good Manufacturing Practice and Biosafety |
| 10:15 | 10:30 | *MORNING BREAK* |
| 10:30 | 11:30 | Lecture 4: Methods to Produce Gene Therapy Vectors |
| 11:30 | 12:15 | *LUNCH BREAK* |
| 12:15 | 2:00 | Lab 1: Construction of $P_0$ Baculovirus Stocks/Infection of F3 Cells |
| 2:00 | 2:45 | Lecture 5: Single-Use Bioreactors |
| 2:45 | 3:00 | *AFTERNOON BREAK* |
| 3:00 | 5:00 | Bioractor Orientation & Rocker Bag Set-Up |

| DAY 2 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 9:30 | Lab 3: Rocker Bag Inoculation and Lysis |
| 9:30 | 9:45 | *BREAK* |
| 9:45 | 11:45 | Lecture 6: Cell Growth in Bioreactors, Process Control, and Critical Process Parameters |
| 11:45 | 12:15 | Lecture 7: Overview of Downstream Processing of Viral Vectors |
| 12:15 | 1:15 | *LUNCH BREAK* |
| 1:15 | 2:45 | Lecture 8: Vector Harvest (Centrifugation, Cell Lysis, and Depth Filteration) |
| 2:45 | 3:00 | *AFTERNOON BREAK* |
| 3:00 | 5:00 | Depth Filtration for Lysis Clarifcation |

| DAY 3 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 9:00 | Lecture 9: Chromatography for Purification of Viral Vectors |
| 9:00 | 10:00 | Lecture 10: Ultrafiltration (UF) for Vector Concentration and Buffer Exchange |
| 10:00 | 10:15 | *MORNING BREAK* |
| 10:15 | 11:30 | Lab 5: Chromatography for AAV2 Purification |
| 11:30 | 12:30 | *LUNCH BREAK* |
| 12:30 | 1:15 | Lab 5: Chromatography for AAV2 Purification |
| 1:15 | 3:45 | Lab 6: Ultrafiltration (UF) for Vector Concentration and Buffer Exchange |
| 3:45 | 4:00 | *AFTERNOON BREAK* |
| 4:00 | 5:00 | Lecture 11: Analytical Principles of Gene Therapy |

| DAY 4 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:45 | Lecture 12: AAV Methods of Quanification |
| 8:45 | 9:00 | *MORNING BREAK* |
| 9:00 | 11:00 | Lab 7: qPCR for Viral Genome Quanification |
| 11:00 | 12:00 | Lecture 13: SDS-PAGE for Identifaction and Quantitation of AAV |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 1:45 | Lecture 14: Advanced AAV Analytics |
| 1:45 | 3:15 | Workshop: Multi-Attribute Quantification for Gene Therapy |
| 3:15 | 3:30 | *AFTERNOON BREAK* |
| 3:30 | 4:00 | Disscussion: qPCR Data Analysis |
| 4:00 | 4:30 | Wrap Up & Course Evaluation |

# ADVANCED UPSTREAM PROCESSES: DESIGN AND OPTIMIZATION

This 5-day, hands-on course will cover basic cell culture and fermentation techniques; principles of scale up and optimization for large scale cell culture and fermentation; Single-use bioreactor set-up, operation and maintenance; 100 Liter bioreactor operation; continuous flow disc stack centrifuge operation; PID control loops; feeding strategies; and maintenance and operation of metabolite analyzer and cell counters.

## TARGET AUDIENCE

Industry professionals who are looking to deepen their knowledge about upstream processing, going in depth about feeding strategies and optimization, process control, and scale up for fermentation and cell culture in a variety of bioreactors (single-use, stainless steel, wave platform, and stirred tank).

## COURSE CALENDAR

**Open Enrollment:**

**March 3-7, 2025**
**August 25-29, 2025**
**December 8-12, 2025**

**Contract training cohort of 10 participants as available upon request**

## COURSE COST

**Tuition: $6205 per participant assumes cohort of 10 participants**

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 3.8 Continuing Education Credits (CEU's).**

# MODULES/TOPICS

| DAY 1 - | | |
|---|---|---|
| Start Time | End Time | Activity |
| 8:00 | 8:30 | Orientation and Lecture 0: Lab Safety Overview |
| 8:30 | 9:30 | Lecture 1: Principles of Cell Culture |
| 9:30 | 10:30 | Lecture 2: Cell Banking |
| 10:30 | 10:45 | *MORNING BREAK* |
| 10:45 | 12:00 | Lab 1: Cell Banking |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 2:00 | Lecture 3: Principles of Scale Up |
| 2:00 | 2:15 | *AFTERNOON BREAK* |
| 2:15 | 3:30 | Lecture 4: Single Use Bioreactors |
| 3:30 | 5:00 | Lab 2: Single Use Rocking Bioreactor Set-up |
| **DAY 2 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 9:30 | Lab 3: Inoculation of a Rocking Bioreactor |
| 9:30 | 9:45 | *MORNING BREAK* |
| 9:45 | 10:45 | Lecture 5: Offline Analysis of Mammalian Cells or Lab 4: Single Use Stirred Tank Bioreactor Set-up |
| 10:45 | 12:15 | Lab 5: Maintenance of Offline Analysis Equipment (ViCell & BioFlex2) or Lab 4: Single Use Stirred Tank Bioreactor Set-up (cont.) |
| 12:15 | 1:15 | *LUNCH BREAK* |
| 1:15 | 2:15 | Lecture 5: Offline Analysis of Mammalian Cells or Lab 4: Single Use Stirred Tank Bioreactor Set-up |
| 2:15 | 3:45 | Lab 5: Maintenance of Offline Analysis Equipment (ViCell & BioFlex2) or Lab 4: Single Use Stirred Tank Bioreactor Set-up (cont.) |
| 3:45 | 4:00 | *AFTERNOON BREAK* |
| 4:00 | 5:00 | Lecture 6: Calculations for Transfection and Infection of Cell Culture |
| 3:30 | 3:30 | Lecture 8: Issues and Troubleshooting in Cell Culture |
| 4:30 | 5:00 | Lab 4: Growth Monitoring |

| **DAY 3 -** | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 9:00 | Lecture 7: Feeding Strategies and Growth Monitoring |
| 9:00 | 9:15 | *MORNING BREAK* |
| 9:15 | 11:15 | Lab 6: Fed-Batch Fermentation Set-up |
| 11:15 | 12:00 | Lab 7: Offline Analysis of Mammalian Cells and Analyte Data Interpretation |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:15 | 1:45 | Lab 8: Growth Monitoring |
| 1:45 | 2:15 | Lecture 8: Bioflo 610 Orientation |
| 2:15 | 2:30 | *AFTERNOON BREAK* |
| 2:30 | 5:00 | Lab 9: 100L Bioreactor Set up: Bioflo 610/Lab 8 Growth Monitoring |
| **DAY 4 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:30 | Lab 8: Growth Monitoring (cont.) |
| 8:30 | 10:00 | Lab 10: 100L Bioreactor Inoculation: Bioflo 610 |
| 10:00 | 11:00 | Lecture 9: PID Loops |
| 11:00 | 11:30 | Lab 11: PID control/Lab 4: Growth Monitoring (cont.) |
| 11:30 | 12:30 | *LUNCH BREAK* |
| 12:30 | 1:00 | Lab 7: Offline Analysis of Mammalian Cells and Analyte Data Interpretation |
| 1:00 | 1:30 | Lab 8: Growth Monitoring (cont.) |
| 1:30 | 2:30 | Lecture 10:Proper Passaging of Suspension and Adherent Cells |
| 2:30 | 2:45 | *AFTERNOON BREAK* |
| 2:45 | 3:15 | Lab 8: Growth Monitoring (cont.) |
| 3:15 | 4:15 | Lecture 11: Issues and Troubleshooting in Cell Culture |
| 4:15 | 4:45 | Lab 8: Growth Monitoring (cont.) |
| **Start Time** | **End Time** | **Activity** |
| **DAY 5:** | | |
| 8:00 | 11:00 | Lab 12: Bioflo 610 Harvest with Whisperfuge or Disc Stack Centrifuge |
| 11:00 | 12:00 | Lab 13 Clarification of Mammalian cells by Depth Filtration |
| 12:00 | 12:45 | LUNCH BREAK |
| 12:45 | 2:45 | Lab 14: Passaging of Suspenion and Adherent Cells |
| 2:45 | 4:45 | Lab 9: CIP Demo |
| 4:45 | 5:00 | Wrap up |

# ADVANCED DOWNSTREAM

In this course we will cover advanced topics in downstream processing. Chromatography will be covered in great detail, ranging from fundamental principles of mass transport within chromatography equipment to determining operating conditions for chromatography runs based on the resin selected. Process development studies will be executed to demonstrate process optimization, and scale up calculations will be performed. Tangential flow filtration (TFF) will also be covered. Process development methodology for TFF will be covered, as well as other related topics including membrane cleaning and lifetime studies.

## TARGET AUDIENCE

Industry professionals who are looking to deepen their knowledge about downstream processing, learning about process development and optimization for chromatography and Tangential Flow Filtration.

## COURSE CALENDAR

**Open Enrollment:**

**January 21-24, 2025**
**April 21-24, 2025**
**October 13-16, 2025**

**Contract training cohort of 10 participants as available upon request.**

## COURSE COST

**Tuition: $4,578** per **participant** assumes cohort of 10 participants

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 2.3 Continuing Education Credits (CEU's).**

# MODULES/TOPICS

| DAY 1 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:15 | 8:30 | Orientation and Lecture 0: Laboratory Safety Overview |
| 8:30 | 9:00 | Lecture 1: Protein Structure and Properties |
| 9:00 | 10:30 | Lecture 2: Chromatography Basics, Part I |
| 10:30 | 10:45 | *MORNING BREAK* |
| 10:45 | 12:30 | Lab 1: Introduction to UNICORN and Methods |
| 12:30 | 1:30 | *LUNCH BREAK* |
| 1:30 | 2:00 | Lecture 3: Column Packing and Evaluation |
| 2:00 | 3:30 | Lab 2: Column Packing |
| 3:30 | 4:00 | Activity: Column Packing Evaluation |
| **DAY 2 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 9:15 | Lecture 4: Viral Clearance |
| 9:15 | 10:30 | Lecture 5: Chromatography Step Design |
| 10:30 | 10:45 | *MORNING BREAK* |
| 10:45 | 11:45 | Lab 3: Binding Capacity Measurement |
| 11:45 | 12:15 | Activity: Binding capacity determination and load volume calculations |
| 12:15 | 1:15 | *LUNCH BREAK* |
| 1:15 | 3:00 | Lab 4: Step vs. Gradient Elutions for GFP Capture Step with AEX Column |
| 3:00 | 3:15 | *AFTERNOON BREAK* |
| 3:15 | 4:00 | Activity: Data Analysis from AEX Runs and HIC DBC data review |
| **DAY 3 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 9:30 | Lecture 6: Chromatography Scale-Up |
| 9:30 | 11:00 | Lab 5: Packed Bed vs. Monolith Chromatography for Intermediate Purification of GFP Using HIC |
| 11:00 | 12:15 | Activity: Data Analysis from HIC Runs and Chromatography Scale Up |
| 12:15 | 1:15 | *LUNCH BREAK* |
| 1:15 | 2:45 | Lecture 7: Membrane Selection and Process Development for TFF |
| 2:45 | 3:00 | *AFTERNOON BREAK* |
| 3:00 | 4:00 | Lab 6: NWP Measurement, Generating Flux vs. TMP Curves for TFF Optimization |
| **DAY 4 -** | | |
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 10:30 | Lab 6: NWP Measurement, Generating Flux vs. TMP Curves for TFF Optimization |
| 10:30 | 11:30 | Lab 7: Comparing the Effect of Cleaning Procedures on NWP Recovery |
| 11:30 | 12:30 | *LUNCH BREAK* |
| 12:30 | 1:00 | Lab 7: Comparing the Effect of Cleaning Procedures on NWP Recovery (continued) |
| 1:00 | 2:00 | Activity: TFF Data analysis |
| 2:00 | 2:30 | Closing Discussion |

# HANDS-ON MANUFACTURING OF mRNA VACCINES & THERAPEUTICS

In this course we cover topics related to the manufacturing of mRNA vaccines in a simulated cGMP environment. Participants will perform manufacturing unit operations and quality control testing of a model mRNA vaccine. Laboratory modules will utilize bench scale unit operations to establish process parameters. Participants will then get hands-on experience with commercial scale equipment for the in vitro transcription reaction, chromatography and UF/DF unit operations. This course also provides participants with hands-on QC testing to supplement learning on drug substance and drug product critical quality attributes and release testing.

## TARGET AUDIENCE

Industry professionals with experience in biomanufacturing who are interested in the new modality of mRNA vaccine and therapeutics manufacturing and quality control testing.

## COURSE CALENDAR

**Open Enrollment:**

**February 17-21, 2025**
**May 19-23, 2025**
**November 10-14, 2025**

## COURSE COST

**Tuition: $6,500** per p**articipant** assumes cohort of 10 participants

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 3.7 Continuing Education Credits (CEU's).**

# MODULES/TOPICS

| DAY 1 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:15 | Orientation and Lecture 0: Laboratory Safety Overview |
| 8:15 | 9:15 | Lecture 1: Overview of mRNA Vaccines |
| 9:15 | 9:30 | *MORNING BREAK* |
| 9:30 | 11:15 | Lecture 2: Overview of cGMP and Product Quality |
| 11:15 | 11:50 | Lecture 3: In Vitro Transcription Reaction for mRNA Production |
| 11:50 | 12:30 | Lab 1: Small Scale IVT Reaction (Set-Up) |
| 12:30 | 1:15 | *LUNCH BREAK* |
| 1:15 | 2:00 | Lab 2: Documentation |
| 2:00 | 3:30 | Lab 1: Small Scale IVT, continued/Lab 3: Large Scale IVT Reaction (Set-Up) |
| 3:30 | 5:00 | Lab 1: Small Scale IVT, continued/Lab 3: Large Scale IVT Reaction (Set-Up) |

| DAY 2 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 9:15 | Lecture 4: Filtration |
| 9:15 | 10:15 | Lecture 5: LNP Delivery System |
| 10:15 | 11:30 | Lab 4: Encapsulation of mRNA LNPs |
| 11:30 | 12:30 | *LUNCH BREAK* |
| 12:30 | 2:00 | Lab 5: Bench-scale UF/DF |
| 2:00 | 2:30 | Lecture 6: Chromatography for mRNA Vaccine Production |
| 2:30 | 5:00 | Lab 6: Chromatography OR Lab 7: Gowning and Lab 8: Large Scale TFF |

| DAY 3 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 9:00 | Demo: Quantoom IVT |
| 9:00 | 11:30 | Lab 6: Chromatography OR Lab 7: Gowning and Lab 8: Large Scale TFF |
| 11:30 | 12:15 | Lecture 7: Cold Chain |
| 12:15 | 1:15 | *LUNCH BREAK* |
| 1:15 | 2:00 | Lecture 8: Analytical and QC Methods for mRNA Vaccines |
| 2:00 | 2:45 | Lab 9A and 9B: mRNA Quantification via RT-ddPCR and RT-qPCR |
| 2:45 | 4:00 | Lecture 8: Analytical and QC methods for mRNA Vaccines, continued |
| 4:00 | 5:00 | Demo: Bulk Filling and Freezing |

| DAY 4 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:00 | 8:45 | Lab 10: Denaturing Agarose Gel for mRNA Visualization |
| 8:45 | 9:30 | Lab 11: Sequence Verification via Capillary Electrophoresis |
| 9:30 | 9:45 | *MORNING BREAK* |
| 9:45 | 12:00 | Lab 9A and 9B: mRNA Quantification via RT-ddPCR and RT-qPCR, continued |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 1:30 | Lab 11: Sequence Verification via Capillary Electrophoresis, continued |
| 1:30 | 2:30 | Lab 12: HPLC |
| 2:30 | 3:45 | Lab 11: Sequence Verification via Capillary Electrophoresis, continued |
| 3:45 | 4:00 | *AFTERNOON BREAK* |
| 4:00 | 4:30 | Lab 10: Denaturing Agarose Gel for mRNA Visualization, continued |
| 4:30 | 5:00 | Lab 12: continued, Analysis Discussion of HPLC Results |

| DAY 5 - | | |
|---|---|---|
| **Start Time** | **End Time** | **Activity** |
| 8:30 | 9:00 | Lab 9A and 9B: continued, Analysis Discussion of RT-ddPCR and RT-qPCR Results |
| 9:00 | 9:30 | Lab 11: continued, Analysis Discussion of Capillary Electrophoresis results |
| 9:30 | 9:45 | *MORNING BREAK* |
| 9:45 | 11:00 | Lecture 9: Regulatory Standards for mRNA Vaccines |
| 11:00 | 11:30 | Lab 13: LNP Analysis with DLS |
| 11:30 | 12:30 | *LUNCH BREAK* |
| 12:30 | 2:00 | Lab 14: mRNA Quantification with RiboGreen |
| 2:00 | 3:00 | Discussion and Wrap up |

# HANDS-ON COURSES

# ADDITIONAL INFORMATION

## PAYMENT DETAILS

- Credit Card or Electronic Check - Please have payment ready to apply during registration.
- Request Approval for Invoicing / Wire Transfer
- Payment for the course must be received prior to the course start date.
- Please note that if you plan to apply payment via a wire transfer, a standard $30 fee will apply.

## PARTICIPATION REQUIREMENTS

While there are no formal prerequisites for any of our courses, 1-2 years of experience in the biomanufacturing industry or completion of the Biopharma Bootcamp course is recommended.

Students must wear long pants, close toed shoes, and tie back long hair in the laboratory.

## ENROLLMENT REQUIREMENTS AND PROCESS

Contract Training arranged by Workforce Training Agreement with TEES/NCTM.

Open Enrollment registration is handled online through the TEES EDGE Portal

***https://teesedge.tamu.edu/courses/biomanufacturing-industry/***

## REQUIREMENTS FOR SUCCESSFUL COMPLETION

**To receive CEUs and a completion certificate for this course, participants must be present for >90% of the course. While we understand that a student may need to step out of the course at times, if absences account for more than 10% of the total course time, CEUs cannot be issued. Attendance is documented on a daily sign-in sheet. Scheduled breaks are incorporated into the daily schedule that allow participants to tend to personal matters.**

## PROGRAM CONTACT INFORMATION

NCTM Programs

- **programs@nctmmail.tamu.edu**

# FLEX TRAINING

NCTM also offers courses on specialty topics in biomanufacturing. These lecture-based courses incorporate case studies and cover advanced theoretical concepts within the biopharmaceutical industry. Training can be delivered either in person or virtually through a video call platform, depending on the needs of the client. Offerings for these courses are available by request.

# CORRECTIVE AND PREVENTATIVE ACTIONS (CAPA)

This course provides an in-depth examination of effective root cause analysis and failure investigation, deviation management and documentation, corrective actions, and other elements of risk mitigation. The course explains the regulatory environment surrounding CAPA, how the CAPA system works, the basics of an investigation, and how an investigation is performed. Case studies, exercises and group activities allow participants to gain knowledge from the instructor, as well as peers.

## TARGET AUDIENCE

Industry Professionals

## COURSE COST

**Tuition: $1,950 per participant. Minimum of 5 participants required.**

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 1.6 Continuing Education Credits (CEU's).**

# MODULES/TOPICS

| DAY 1 - | | |
|---|---|---|
| Start Time | | MODULE 1: Basic CAPA Concepts |
| 8:30 A.M. | | 1.1 - Understanding CAPAs |
| | | 1.2 - Regulatory Expectations |
| | | *MORNING BREAK* |
| | | Activity 1 - Edge Pharmaceuticals Case Study |
| | | Activity 2 - Sanquin Plasma Products Case Study |
| | | 1.3 - Common CAPA Sources: Deviation |
| | | *LUNCH* |
| | | 1.4 - Common CAPA Sources: Out of Specifications (OOS) |
| | | *AFTERNOON BREAK* |
| | | MODULE 2: CAPA Investigations |
| | | 2.1 - When to Initiate an Investigation |
| 5:00 P.M. | | DAY 1 ADJOURNED |
| **DAY 2 -** | | |
| 8:30 A.M. | | 2.2 - Investigation Skills |
| | | *MORNING BREAK* |
| | | MODULE 3: CAPA Tools & Challenges |
| | | 3.1 - CAPA Tool *MORNING BREAK* s Overview |
| | | 3.2 - Quality Data Analysis |
| | | Activity 4 - Fishbone Diagram |
| | | Activity 5 - Is-Is Not Analysis |
| | | *LUNCH* |
| | | 3.3 - Root Cause Analysis |
| | | 3.4 - Risk Management |
| | | *AFTERNOON BREAK* |
| | | 3.4 - Risk Management, cont. |
| | | 3.5 - CAPA Challenges |
| 5:00 P.M. | | DAY 2 ADJOURNS |

# HUMAN ERROR AND RESILIENCE IN BIOMANUFACTURING SYSTEMS

This course examines how human error impacts the safety and quality of operations in biomanufacturing processes. Reason's error classification model and the Skill-Rule-Knowledge behavioral modes are reviewed in order to highlight how individual breakdowns may lead to error within a system. Case studies are presented to illustrate how environmental and human factors, such as workload, stress, and time pressure interact to significantly affect the outcome of processes. Discussion of strategies including error prediction and analysis, operator practices and training, and system design is included to explore how Biomanufacturing systems can be built safer and more resilient.

## TARGET AUDIENCE

Industry Professionals

## COURSE COST

Tuition: $1,950 per p**articipant**. Minimum of 5 participants required.

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 1.6 Continuing Education Credits (CEU's).**

# MODULES/TOPICS

| DAY 1: | | |
|---|---|---|
| **Start Time** | **End Time** | **Topic** |
| 9:00 | 9:30 | Sign In/ Orientation |
| 9:30 | 10:15 | Module 1 - Topic 1: Systems Engineering Fundamentals |
| 10:15 | 11:00 | Module 1 - Topic 2: Humans and Sociotechnical Systems |
| 11:00 | 11:15 | *MORNING BREAK* |
| 11:15 | 12:00 | Module 1 - Topic 3: Cognitive Human Factors |
| 12:00 | 1:30 | *LUNCH BREAK* |
| 1:30 | 2:45 | Module 1 - Topic 3: Cognitive Human Factors (cont.) |
| 2:45 | 3:00 | *AFTERNOON BREAK* |
| 3:00 | 4:30 | Module 1 - Topic 4: Human-Technology Interaction |
| **DAY 2:** | | |
| **Start Time** | **End Time** | **Topic** |
| 9:00 | 10:00 | Module 2 - Topic 1: Introduction to Human Error Management: Describing Error as a System Prioirity |
| 10:00 | 10:45 | Module 2 - Topic 2: Rasmussen's Skill-Rule Knowledge Framework |
| 10:45 | 11:30 | Module 2 - Topic 3: Reason's Human Erro Classifications |
| 11:30 | 1:00 | *LUNCH BREAK* |
| 1:00 | 1:45 | Module 2 - Topic 4: Error Prediction and Analysis Techniques |
| 1:45 | 2:30 | Module 2 - Topic 5: System Design Strategies for Error Management |
| 2:30 | 2:45 | *AFTERNOON BREAK* |
| 2:45 | 3:30 | Module 3 - Topic 1: Fundamentals of Resilience and Systems Safety |
| 3:30 | 4:15 | Module 3 - Topic 2: Lessons from High Reliability Organizations |
| 4:15 | 4:30 | Questions/Surveys |

# SUPPLY CHAIN MANAGEMENT FOR PHARMACEUTICAL MANUFACTURING

This course presents how supply chain concepts can be used to improve the product quality and reduce consumer risks throughout the life-cycle of a pharmaceutical product while maintaining sustainable business performance. Emphasis will be given to the manufacturing of API's, registered intermediates and critical raw materials. Fundamental supply chain concepts will be presented in the context of the pharmaceutical regulatory environment; topics include supply chain fundamental concepts, inventory management, supplier relationship management, cold chain, and supply chain integration concepts. Class instruction will be complemented with case studies, interactive simulators, and team exercises that will provide opportunities to practice these concepts.

## TARGET AUDIENCE

Industry Professionals

## COURSE COST

Tuition: $1,950 per p**articipant**. Minimum of 5 participants required.

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 1.2 Continuing Education Credits (CEU's).**

# MODULES/TOPICS

| DAY 1: | | |
|---|---|---|
| **Start Time** | **End Time** | **Topic** |
| 8:30 | 9:30 | Introduction to Supply Chains |
| 9:30 | 11:00 | Supply Chain Fundamentals |
| 11:00 | 12:00 | Inventory and Demand Management |
| 12:00 | 1:00 | *LUNCH BREAK* |
| 1:00 | 2:00 | Forecasting |
| 2:00 | 2:30 | Inventory Criteria |
| 2:30 | 3:30 | Risk Pooling |
| 3:30 | 4:00 | A-B-C Classification |
| 4:00 | 4:30 | Inventory Models - Safety Stocks |
| 4:30 | 5:00 | Perishable Inventory |
| Homework: | | Read “After Heperin” Case Study |
| **Day 2** | | |
| **Start Time** | **End Time** | **Topic** |
| 8:30 | 9:00 | Pharmaceutical Supplier Relationship Management (PSRM) |
| 9:00 | 10:00 | PSRM Methodology |
| 10:00 | 11:30 | Cold Chain Logistics |
| 11:30 | 12:00 | IT System Components |
| 12:00 | 1:00 | Working Lunch: Push-Pull Boundary |
| 1:00 | --- | Adjourn |

# REGULATORY COMPLIANCE IN THE PHARMACEUTICAL INDUSTRY

This course targets research, medical, and biotechnology professionals who require an understanding of the Food & Drug Administration (FDA) and regulatory compliance. Includes FDA background: history, major laws and regulations, and guidance regulations; working with the FDA: types of regulatory submissions, meetings with FDA and preparations, and inspections and enforcement; Complying with FDA Regulations: GxPs and their related regulatory framework, documentation, vendor qualifications, internal quality audits, change control; International Regulatory Environment: conference on Harmonization, major regulatory agencies, organization for standardization.

## TARGET AUDIENCE

Industry Professionals

## COURSE CALENDAR

**Contract training only. Scheduled upon request with minimum class size of 5 participants**

## COURSE COST

**Tuition: $1,950 per participant. Minimum of 5 participants required.**

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 1.2 Continuing Education Credits (CEU's).**

# MODULES/TOPICS

| DAY 1 | | |
|---|---|---|
| Start Time | | **MODULE 1: Introduction to FDA** |
| 8:30 | | 1.1 - FDA Background |
| | | 1.2 - Major Laws and Regulations |
| | | Activity |
| 9:30 | | *MORNING BREAK* |
| | | 1.3 - Guidance and Regulation |
| | | Activity |
| | | 1.4 - FDA Organizational Stucture |
| | | **MODULE 2: Working with the FDA** |
| | | 2.1 - Types of Regulatory Submission |
| 12:00 | | *LUNCH BREAK* |
| | | 2.1 - Types of Regulatory Submission, cont. |
| 3:30 | | *AFTERNOON BREAK* |
| | | 2.1 - Types of Regulatory Submission, cont. |
| | | 2.2 - Drug and Device Development Cycle |
| 5:00 | | DAY 1 ADJOURNED |
| **DAY 2** | | |
| 8:30 A.M. | | 2.3 - Meeting Between FDA and Sponsors/Applicants |
| | | 2.4 - Meeting Preparation |
| | | Activity |
| | | *2.5* - FDA Inspection |
| 10:00 | | *MORNING BREAK* |
| | | 2.6 - FDA Enforcement |
| | | Activity |
| | | **MODULE 3: Overview of GxPs** |
| | | 3.1 - Good Laboratory Practice (GLPs) |
| | | 3.2 - Good Manufacturing Practices (GMPs) |
| 12:00 | | *LUNCH BREAK* |
| | | 3.3 - Good Clinical Practices (GCPs) |
| | | **MODULE 4: Complying with FDA Regulations** |
| | | 4.1 - Documentation |
| | | 4.2 - Supplier Qualification |
| | | Activity |
| | | 4.3 - Internal Quality Audit |
| | | 4.4 - Quality Policy and Management Oversight |
| | | 4.5 - Quality and Drug Development |
| | | 4.6 - Change Control |
| 3:30 | | *AFTERNOON BREAK* |
| | | **MODULE 5: International Regulatory Environment** |
| | | 5.1 - International Conference on Harmonisation |
| | | 5.2 - Major International Regulatory Agencies |
| | | 5.3 - International Organizational for Standardization (ISO) |
| | | 5.4 - Regulation of Foreign Trade |
| 5:00 | | DAY 2 ADJOURNED |

# VACCINOLOGY 101

A continuing education course that reviews the biological basis of vaccination as a strategy to control infectious diseases. The course addresses the molecular basis of pathogenesis; with emphasis placed on virus structure/function relationships; host cell interactions; recovery from disease; the immune system and how vaccines work to create immunity; and the essential features of the host-pathogen interaction. Specific examples of important bacterial and viral pathogens along with select agents will be covered and case studies will be provided to promote discussion.

## TARGET AUDIENCE

Individuals that have completed basic biology or chemistry and want to learn more about the immune system and vaccines.

## COURSE COST

**Tuition: $1,950 per participant. Minimum of 5 participants required.**

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 1.6 Continuing Education Credits (CEU's).**

## MODULES/TOPICS

| DAY 1 |
| --- |
| Viral agents, Bacterial agents, Epidemiology, Biothreats, Immune system, Antigen processing/presentation, T Cells, B Cells and Antibodies, Techniques for cultivation and quantification of microbes, Examine history, Present state, and Future of vaccine development |
| **DAY 2** |
| Immunological memory and vaccine effectiveness, Anti-microbial resistance, Conjugate vaccines, Vaccine delivery, Adjuvants |

# FLEX TRAINING

# ADDITIONAL INFORMATION

## PAYMENT DETAILS

- Credit Card or Electronic Check - Please have payment ready to apply during registration.
- Request Approval for Invoicing / Wire Transfer
- Payment for the course must be received prior to the course start date.
- Please note that if you plan to apply payment via a wire transfer, a standard $30 fee will apply.

## COURSE CALENDAR

Contract training only. Scheduled upon request with minimum class size of 5 participants

## PARTICIPATION REQUIREMENTS

This course can be delivered in person or virtually on a distance learning.
Must have access to a computer and internet.

## ENROLLMENT REQUIREMENTS AND PROCESS

Contract Training arranged by Workforce Training Agreement with TEES/NCTM.

## REQUIREMENTS FOR SUCCESSFUL COMPLETION

To receive CEUs and a completion certificate for this course, participants must be present for >90% of the course. While we understand that a student may need to step out of the course at times, if absences account for more than 10% of the total course time, CEUs cannot be issued. Attendance is documented on a daily sign-in sheet. Scheduled breaks are incorporated into the daily schedule that allow participants to tend to personal matters.

## PROGRAM CONTACT INFORMATION

NCTM Programs

- programs@nctmmail.tamu.edu

# ONLINE COURSES

These courses offer a comprehensive review of the major components and guiding principles of the pharmaceutical manufacturing industry, with specific focus on biologics manufacturing. They are completely self-paced and can be accessed online on the TEES Edge platform at all times.

# INTRODUCTION TO PHARMACEUTICAL MANUFACTURING

This online course comprehensively discusses the fundamental elements associated with the development and manufacture of pharmaceutical products.

Training modules discuss the categories of pharmaceutical products, phases of pharmaceutical discovery, development, approval, and varying manufacturing processes (chemical or biological). The curriculum also reviews regulatory agencies and their roles, current Good Manufacturing Practice (cGMP) and GXP, quality assurance and quality control, and finishes with an exploration of career paths within the pharmaceutical manufacturing industry.

## COURSE COST & PAYMENT DETAILS

**Tuition:** $99

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 0.2 Continuing Education Credits (CEU's)**

# MODULES/TOPICS: 2HR ASYNCHRONOUS

| MODULE 1 |
| --- |
| Pharmaceutical manufacturing basics, drug categories, target site, drug products and drug substances, industry sectors, types of manufacturing companies |
| **MODULE 2** |
| Introduction to regulations, major legislation, FDA jurisdiction and enforcement, standards and guidelines |
| **MODULE 3** |
| Pharmaceutical development process, IND application, marketing application, FDA review through surveillance, licensing applications |
| **MODULE 4** |
| Manufacturing process, material and supplies, materials management, drug production process, upstream processes vs. downstream processes, equipment, master production record |
| **MODULE 5** |
| Current Good Manufacturing Practice (cGMP), quality system requirements, cGMP compliance overview, basic cleanroom requirements, dressing for cleanrooms, careers in pharmaceutical manufacturing, and job skills overview. |

# UNDERSTANDING THE SCIENCE OF THE BIOPHARMACEUTICAL INDUSTRY

This online course provides a pragmatic study in the scientific principles of microbiology, immunology, and basic biochemistry that create the foundation for developing and manufacturing biopharmaceutical products.

Curriculum covers biological macromolecules, an intensive study of infectious and non-infectious diseases, immune system structure and function, pathogenesis, and categories, uses, and development process of biotherapeutics and vaccines.

## COURSE COST

**Tuition:** $299

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 0.4 Continuing Education Credits (CEU's)**

## MODULES/TOPICS: 4HR ASYNCHRONOUS

| MODULE 1 |
| --- |
| Biopharmaceuticals history, manufacturing process, FDA mandates, structure and roles of biological molecules, infectious diseases, non-infectious diseases, genetic factors vs. environmental factors |
| **MODULE 2** |
| Immune system, innate vs. adaptive immune system, NK cells, antigen presentation, antibodies, active vs. passive immunity, primary vs. secondary immune response, pathogenesis, and routes of entry |
| **MODULE 3** |
| Recombinant DNA technology, protein therapeutics and gene therapy, targeting activity, monoclonal antibodies, vaccine types, whole vs. partial organism vaccines, DNA overview, vaccine effectiveness, duration of immune memory, cost of development, and biosimilars. |

# PHARMACEUTICAL FACILITY OPERATIONS

This online course provides an overview of pharmaceutical manufacturing facilities, including design/layout, utilities, and equipment. Participants will study clean room design, classification, and structure, and understand the many processes that are implemented to ensure a sterile environment, including aseptic technique, gowning, environmental monitoring, and sanitization. Management of chemical and biological waste, sterilization techniques, and equipment maintenance and calibration are also discussed alongside the importance of validation in a pharmaceutical facility.

## COURSE COST

**Tuition:** $199

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certi icate and 0.3 Continuing Education Credits (CEU's)**

## MODULES/TOPICS: 3HR ASYNCHRONOUS

| MODULE 1 |
| --- |
| Facility design overview (types of facilities, facility design/construction/complexities, utilities design, equipment, startup procedures, and maintenance) |
| MODULE 2 |
| Clean area design (contaminants, clean room design, clean room classifications, and controlling contamination) |
| MODULE 3 |
| Clean area operations (aseptic techniques, human and workplace contaminants, clean room supplies and storage, and environmental monitoring) |
| MODULE 4 |
| Sanitization and sterilization (cleaning and disinfection, types of sanitization, reasons to sterilize, sterility assurance Levels, and sterilization responsibilities) |

# cGMP PROCEDURES & DOCUMENTATION

This online course explains the expectations of and reasoning behind proper documentation protocols mandated in current Good Manufacturing Practice (cGMP) environments, like pharmaceutical production facilities.

Topics include principles of data and information entry, technical writing, recording guidelines, document control, and process documentation, including laboratory notebooks, logbooks, standard operating procedures (SOPs), and batch production records (BPRs). Participants will understand the entire documentation pathway from R&D to commercialization of product, including corporate, R&D, manufacturing and qualification/validation.

## COURSE COST & PAYMENT DETAILS

**Tuition:** $299

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 0.2 Continuing Education Credits (CEU's)**

## MODULES/TOPICS: 4HR ASYNCHRONOUS

| MODULE 1 |
| --- |
| Introduction to regulations in the pharmaceutical industry, Food and Drug Administration, history and legislation, current Good Manufacturing Practices (cGMP), cGMP requirements, Title 21 CFR, federal documents, FDA enforcement, correspondence for nonconformance, importance of documentation, GMP records, "documentation pyramid", regulatory pathway of drug development, stages, measurable claims |
| **MODULE 2** |
| Document control, legal requirements for record maintenance, features of controlled documents, system integrity, change control, recording guidelines for entering data/making corrections/signing data/reporting deviations/Corrective and Preventative Actions, reporting to FDA, identifiers and samples, internal auditing, risk levels, employee documentation and training |
| **MODULE 3** |
| R&D documents/development protocol/records/reports/procedures, log books, Standard Operating Procedures (SOP), SOP development/types/writing/flowchart use/forms, batch records, qualification documentation/activities, validation documentation/plan |
| **MODULE 4** |
| Fundamentals of technical writing, recording original data, data collection, making entries in lab notebook, recording laboratory procedures/inventions/ideas, attachments, referencing and blank space cGMP compliance overview, basic cleanroom requirements, dressing for cleanrooms, careers in pharmaceutical manufacturing, and job skills overview. |

# SAFETY IN THE BIOPHARMACEUTICAL INDUSTRY

This online course covers environmental health and safety (EHS) issues specifically related to the pharmaceutical industry, including environmental safety, process and product safety, biosafety levels, industrial hygiene, and physical and chemical properties. Participants will receive an overview of product development stages and vaccine production, and will learn about toxicology, drug safety and evaluation, pharmacokinetics and toxicokinetics, as well as risk assessment and analysis. Case studies, historically significant accidents, and lessons learned are incorporated throughout to provide real-life relevance.

## COURSE COST & PAYMENT DETAILS

**Tuition:** $199

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 0.3 Continuing Education Credits (CEU's)**

## MODULES/TOPICS: 3HR ASYNCHRONOUS

| MODULE 1 |
| --- |
| Introduction to workplace safety, safety responsibilities, risks and hazards, exposure and routes, toxicity (local and systemic) and effects, types of hazards, case studies, hazardous waste and proper handling |
| **MODULE 2** |
| Industrial hygiene, government regulations for the pharmaceutical industry, OSHA standards 29 CFR 1910 (subpart D-J / K-Z), controlling hazards, evaluation, risk assessment, industrial hygiene controls |
| **MODULE 3** |
| Risk Assessment, processes, hazardous operations evaluations (HAZOP), risk analysis, risk evaluation, risk management |
| **MODULE 4** |
| Basics of laboratory safety, biosafety defined, biosafety levels, CDC lesson, standard microbiological practices, safe storage of toxic materials, lab security, BSLs 1-3, clean benches, biosafety scenarios, case studies |

# THERAPEUTICS MANUFACTURING: PAST, PRESENT & FUTURE

This asynchronous online course provides a complete review of therapeutic products manufacturing, including small molecule drugs and large molecule biologics. Instructional modules discuss dosage forms and routes of administration, drug substance and drug product, a history of small molecule medicines and their manufacturing process, as well as a chronology of biologics and upstream and downstream manufacturing. Also covered are vaccines, cell and gene therapies, and devices, as well as the regulatory environment, the process from research and development to commercialization, and a review of various types of companies.

## COURSE COST

**Tuition:** $199

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

**Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certi icate and 0.3 Continuing Education Credits (CEU's)**

## MODULES/TOPICS: 3HR ASYNCHRONOUS

| MODULE 1 |
| --- |
| What are therapeutics? Includes target site, dosage form, dose and dosage, routes of administration and classes of therapeutics |
| **MODULE 2** |
| Small molecule therapeutics. Includes history of small molecule therapeutics, start of mass production, active pharmaceutical ingredient, drug substance vs. drug product, excipients, small molecule manufacturing process/production diagram, synthesizing API, and formulating the final product |

| MODULE 3 |
| --- |
| Large molecule therapeutics. Includes background, biologics today, antibodies, manufacturing process, recombinant DNA technology, manufacturing facilities, overview of upstream and downstream, transition point, upstream manufacturing stage, cell line development/host cell selection, mammalian cell lines usage, cell banking, cellular growth, biomass accumulation processes, fermentation, mammalian cell culture, harvest, product recovery, downstream manufacturing, product location, trapped product release, biomass clarification, initial purification, intermediate processing steps, bulk fill/formulation and final fill. |
| MODULE 4 |
| Vaccines. Includes history of vaccination, Edward Jenner, smallpox vaccination, how vaccination became widely available, effectiveness and duration, antigen ID and categories, types (whole organism, live attenuated, inactivated whole, partial organisms, toxoid, subunit, conjugate, nucleic acid-based, DNA, recombinant vector and RNA), vaccine manufacturing process, whole organism manufacturing and nucleic acid-based manufacturing. |
| MODULE 5 |
| Other therapeutics. Includes cell-based therapy, gene therapy, diagnostics and treatment of infections. |
| MODULE 6 |
| Development-to-market process. Includes FDAs role, new therapeutic development process, R&D phase, pre-clinical phase, IND application, clinical trials (phases 1-3), marketing application, other licensing applications, scale-up manufacturing, manufacturing and surveillance, getting a therapeutic to market, license period, biosimilars and additional exclusivity. |
| MODULE 7 |
| Producing therapeutics. Includes overview of the manufacturing process, research & development, pilot-scale run, commercial-scale run, other production activities, materials management, chain of custody, procuring materials and cold chain. |
| MODULE 8 |
| Types of pharmaceutical companies. Includes different types of companies, Genentech case study, large manufacturing companies and characteristics, contract manufacturing organizations (CMOs), outsourced manufacturing, project management department, clinical trial materials and small/start-up pharma companies. |

# ONLINE COURSES

# ADDITIONAL INFORMATION

## COURSE CALENDAR

Offered online (anytime)

## PAYMENT DETAILS

Credit Card or Electronic Check - Please have payment ready to apply during registration. Request Approval for Invoicing/Wire Transfer
- Please note that if you plan to apply payment via a wire transfer, a standard $30 fee will apply.

Courses are non-refundable

## REQUIRED MATERIALS

Must provide/have access to a computer and internet.

## ENROLLMENT REQUIREMENTS AND PROCESS

Registration is handled online through the TEES EDGE Portal
*https://teesedge.tamu.edu/courses/biomanufacturing-industry/*

## REQUIREMENTS FOR SUCCESSFUL COMPLETION

To receive a certificate, you must complete each selected course within 60 days of registration.

## CERTIFICATE RECEIVED UPON SUCCESSFUL COMPLETION

Participants that successfully complete the course will receive a Texas A&M Engineering Experiment Station Completion Certificate and 0.3 Continuing Education Credits (CEU's)

## PROGRAM CONTACT INFORMATION

NCTM Programs
- programs@nctmmail.tamu.edu


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# CUSTOMIZED TRAINING

NCTM can tailor a customized training program based on a company's unit operations using content from our repository of more than 200+ course modules. Train-the-trainer cohorts and curriculum licensing is also available. For more information on our customized training options contact NCTM Programs at programs@ntcmmail.tamu.edu.

The National Center for Therapeutics Manufacturing is a member of the Texas A&M Engineering Experiment Station (TEES). TEES is a state research agency that solves problems through applied engineering research and development and collaboration with industry, government, and academia.

As part of The Texas A&M University System, TEES is connected with world-class researchers and facilities throughout the Texas A&M System.

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