

# NCTM

NATIONAL CENTER FOR  
THERAPEUTICS MANUFACTURING



Texas A&M Engineering  
Experiment Station

# COURSE CATALOG

# NCTM

## COURSE CATALOG

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

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Texas A&M Engineering Experiment Station

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# ABOUT

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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, computer-based, and hands-on 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  
biopharmaceutical industry.*

**f in @NCTMtamu**

To learn more visit:  
**[nctm.tamu.edu](http://nctm.tamu.edu)**

For program inquiries email:  
**[programs@nctmmail.tamu.edu](mailto:programs@nctmmail.tamu.edu)**



INTRODUCTION TO PHARMACEUTICAL  
MANUFACTURING

UNDERSTANDING THE SCIENCE  
OF THE BIOPHARMACEUTICAL  
INDUSTRY

CGMP PROCEDURES AND  
DOCUMENTATION

PHARMACEUTICAL FACILITY  
OPERATIONS

SAFETY IN THE BIOPHARMACEUTICAL  
INDUSTRY

THERAPEUTICS MANUFACTURING:  
PAST, PRESENT, AND FUTURE



# DISTANCE LEARNING

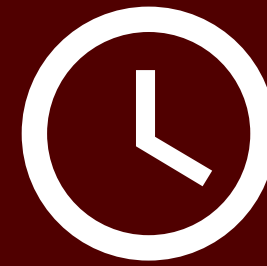
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These courses offer a comprehensive review of the major components and guiding principles of the pharmaceutical manufacturing industry, with specific focus on biologics manufacturing. They are completely self-paced and can be accessed online on the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

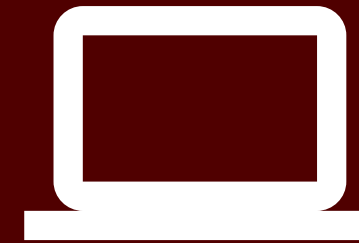
# INTRODUCTION TO PHARMACEUTICAL MANUFACTURING

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 Practices (cGMP) and GXP, quality assurance and control, and finishes with an exploration of career paths within the pharmaceutical manufacturing industry.



2 HOURS



ONLINE



TEES EDGE

## MODULE 1

- Pharmaceutical Manufacturing Basics
- Drug Categories
- Target Site
- Drug Products and 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
- Materials and Supplies
- Material Management
- Drug Production Process
- Upstream Processes vs Downstream Processes
- Equipment
- Master Production Record

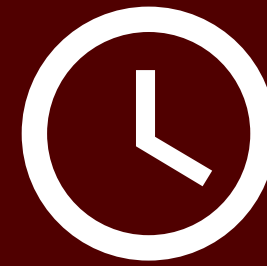
## MODULE 5

- Current Good Manufacturing Practices (cGMP)
- Quality System Requirements
- cGMP Compliance Overview
- Basic Cleanroom Requirements
- Dressing for Cleanrooms
- Careers in Pharmaceutical Manufacturing
- Job Skills Overview

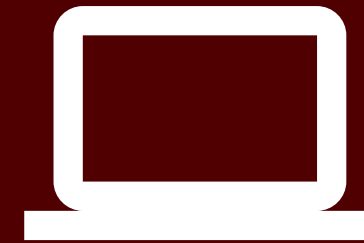
# UNDERSTANDING THE SCIENCE OF THE BIOPHARMACEUTICAL INDUSTRY

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, the immune system's structure and function, pathogenesis, and categories, uses, and development process of biotherapeutics and vaccines.



4 HOURS



ONLINE



TEES EDGE

## 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
- NK Cells
- Antigen Presentation
- Antibodies
- Active vs. Passive Immunity
- Primary vs. Secondary Immune Response
- Pathogenesis
- Routes of Entry

## MODULE 3

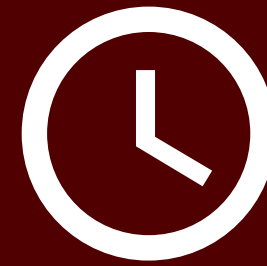
- Recombinant DNA Technology
- Protein Therapeutics and Gene Therapy
- Targeting Activity
- Monoclonal Antibodies
- Vaccine Types
- Whole vs. Partial Organism
- DNA Overview
- Effectiveness
- Duration of Immune Memory
- Cost of Development
- Biosimilars



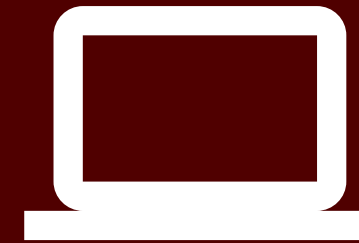
# CGMP PROCEDURES & DOCUMENTATION

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.



4 HOURS



ONLINE



TEES EDGE

## MODULE 1

- Regulations in the Pharmaceutical Industry
- Food and Drug Administration (FDA)
- FDA Enforcement
- Current Good Manufacturing Practices (cGMP)
- Importance of Documentation
- cGMP Records
- The Documentation Pyramid
- Regulatory Pathway of Drug Development

## MODULE 2

- Legal Requirements for Record Maintenance
- Controlled Documents and System Integrity
- Change Control and Data Entry
- Corrective and Preventative Actions
- FDA Reporting
- Internal Auditing
- Risk Levels
- Employee Documentation and Training

## MODULE 3

- R&D Documents
- Development Protocol
- Standard Operating Procedures (SOP)
- SOP Development, Types, Writing, Flowchart Use, and Forms
- Batch Records
- Qualification Documentation and Activities
- Validation Plans and Documentation

## MODULE 4

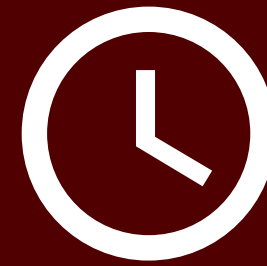
- Fundamentals of Technical Writing
- Data Collection and Recording
- Lab Notebook Entries
- Recording Laboratory Procedures
- Inventions, Ideas, and Attachments
- Referencing and Blank Space



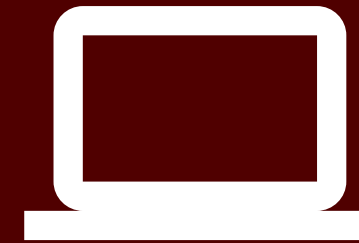
# PHARMACEUTICAL FACILITY OPERATIONS

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 practicing 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.



3 HOURS



ONLINE



TEES EDGE

## MODULE 1

- Facility Design Overview
- Types of Facilities
- Facility Design, Construction, and Complexities
- Utilities Design, Equipment, Startup Procedures, and Maintenance

## MODULE 3

- Clean Area Operations
- Aseptic Techniques
- Human and Workplace Contaminants
- Clean Room Supplies and Storage
- Environmental Monitoring

## MODULE 2

- Contaminants
- Cleanroom Design
- Cleanroom Classifications
- Cleanroom Controlling and Contamination

## MODULE 4

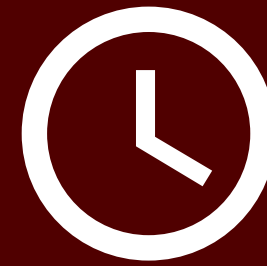
- Sanitization and Sterilization
- Cleaning and Disinfection
- Types of Sanitization
- Sterility Assurance Levels
- Sterilization Responsibilities

# SAFETY IN THE BIOPHARMACEUTICAL INDUSTRY

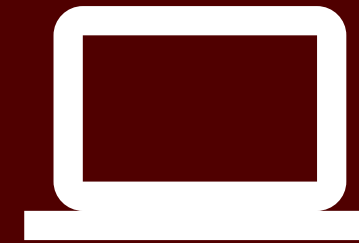
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This online course covers a wide range of safety, health and environmental (SHE) issues specifically related to the pharmaceutical industry, including environmental safety, process and product safety, biosafety levels, industrial hygiene, and physical and chemical properties.

Participants will receive an overview of product development stages and vaccine production, and will learn about toxicity, 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 relevancy.



3 HOURS



ONLINE



TEES EDGE

## MODULE 1

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- Introduction to Workplace Safety
- Safety Responsibilities
- Risks and Hazards
- Types of Hazards
- Exposure and Routes
- Toxicity
- Case Studies
- Hazardous Waste and Proper Handling

## MODULE 2

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- Industrial Hygiene
- Government Regulations
- Occupational Safety and Health Administration (OSHA) Standards
- Controlling Hazards
- Evaluation
- Risk Assessment
- Industrial Hygiene Controls

## MODULE 3

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- Risk Assessment
- Hazardous Operations Evaluations (HAZOP)
- Risk Analysis
- Risk Evaluation
- Risk Management

## MODULE 4

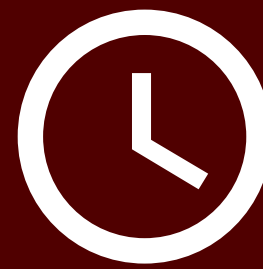
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- Basics of Laboratory Safety
- Biosafety Levels and Scenarios
- BSLs 1-3
- Centers for Disease Control and Prevention (CDC)
- Standard Microbiological Practices
- Storage of Toxic Materials
- Lab Security
- Clean Benches
- Case Studies

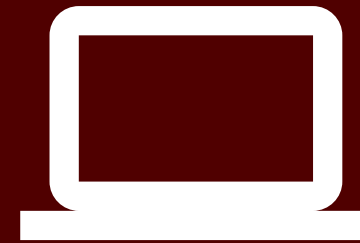
# THERAPEUTICS MANUFACTURING: PAST, PRESENT & FUTURE

This online course provides a complete review of therapeutic products manufacturing, including small molecule (chemical) drugs, and large molecule biologics.

Instructional modules discuss dosage forms and routes of administration, drug products and substances, small molecule medicine history, chronology of biologics, and upstream and downstream manufacturing. This course also covers vaccines, cell and gene therapies and devices, regulatory environments, the research to commercialization process, and manufacturing processes in various companies.



3 HOURS



ONLINE



TEES EDGE

## MODULE 1

- Therapeutics Defined
- Target Site and Dosage Forms
- Routes of Administration
- Classes of Therapeutics

## MODULE 2

- Small Molecule Therapeutics
- Ingredients
- Mass Production

## MODULE 3

- Large Molecule Therapeutics
- Manufacturing Facilities
- Upstream and Downstream Manufacturing

## MODULE 4

- History of Vaccination
- Types of Vaccines
- Vaccine Manufacturing Process

## MODULE 5

- Other Therapeutics
- Cell and Gene Therapies
- Diagnostics and Treatment

## MODULE 6

- Development to Market Process
- FDA Overview
- Manufacturing Regulations
- Licensing

## MODULE 7

- Producing Therapeutics
- Research and Development
- Supply Chain

## MODULE 8

- Pharmaceutical Companies
- Small-Scale and Large-Scale Manufacturing
- Contract Manufacturing Organizations

BIOPHARMA BOOTCAMP

QUALITY UNIT OPERATIONS

UPSTREAM MANUFACTURING  
OF BIOLOGICS

DOWNSTREAM MANUFACTURING  
OF BIOLOGICS



# TECHINICAL TRAINING

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These courses provide practical, hands-on training to anyone wanting to enter the biopharmaceutical manufacturing industry. While NCTM's online courses are excellent precursors to our technical courses, there are no prerequisites to taking these technical courses.

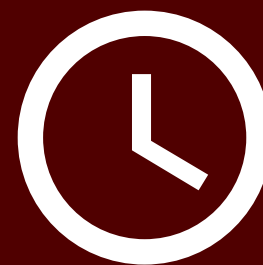


# BIOPHARMA BOOTCAMP

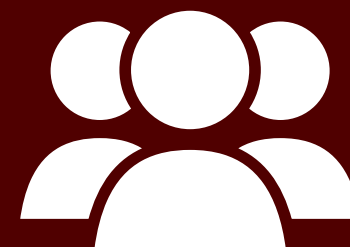
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This week long hands-on short course provides an overview and hands-on lab activities of general, upstream, and downstream operations within the biomanufacturing industry.

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 buffer preparation, tangential flow filtration, column cleaning and sanitization, ion exchange, and hydrophobic interaction chromatography.



5 DAYS



IN-PERSON



NCTM LAB

## GENERAL

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- Aseptic Technique
- Controlled Environments
- Biomanufacturing Process Overview
- Intro to Analytical Lab Equipment

## UPSTREAM

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- Overview of Cell Biology
- Bioreactor Assembly and Configuration
- Culture Media Preparation and Sterilization
- Seed Culture & Inoculation
- Batch Fermentation
- Sample Collection and Analysis
- Mammalian Cell Counting
- Harvest

## DOWNSTREAM

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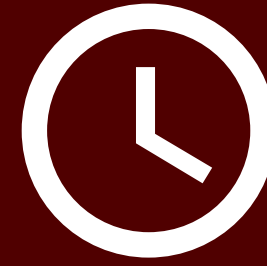
- Buffer Preparation and Sterile Filtration
- Filter Integrity Testing
- Tangential Flow Filtration
- Intro to Chromatography
- Ion Exchange Chromatography
- Hydrophobic Interaction Chromatography
- Column Cleaning and Sanitization

# QUALITY UNIT OPERATIONS

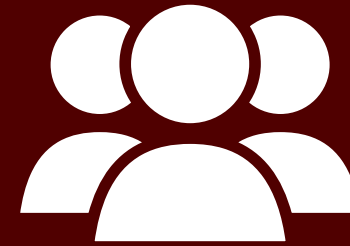
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This week long, hands-on course offers a comprehensive review of quality assurance systems and practices, quality control activities, and quality control assays that are relevant to biomanufacturing.

Participants learn about best documentation practices, environmental monitoring and microbial testing, as well as the types of products made in biotherapeutics manufacturing and how they are tested. Hands-on lab activities cover aspects of environmental monitoring such as gowning, surface monitoring, viable and total air particle sampling and total organic carbon sampling for water, as well as assays and analytical techniques that are used in the testing of biologics and other therapeutics, including bacterial endotoxin testing, SDS-PAGE assay, total protein assay, and high performance liquid chromatography



5 DAYS



IN-PERSON



NCTM LAB

## LAB SKILLS

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- Light Microscopy
- pH
- Conductivity
- Balances
- Pipetting
- Laboratory Safety

## CONTROLLED ENVIRONMENTS

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- Gowning
- Aseptic Technique in a Biosafety Cabinet
- Total Air Particle Monitoring
- Viable Air Particle Monitoring
- Surface Monitoring
- Total Organic Carbon Analysis

## ANALYTICAL METHODS

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- Bacterial Endotoxin Testing
- SDS-PAGE
- Western Blot
- Total Protein Assay
- Polymerase Chain Reaction
- Restriction Enzyme Digest
- Gel Electrophoresis
- High-Performance Liquid Chromatography
- Biomolecule Analysis

## REGULATIONS

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- cGMP Eefined
- Quality Assurance
- Quality Control

# UPSTREAM MANUFACTURING OF BIOLOGICS

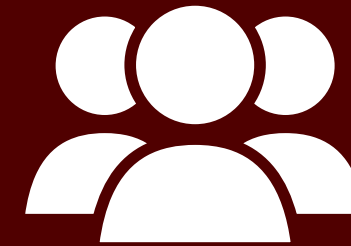
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This week long, hands-on course provides a comprehensive overview of the techniques and challenges involved in the upstream processes for manufacturing biologics.

Lectures and laboratories cover biologic products, upstream processes, biomass production, cell lines, bioreactors and their operation, and the analytics used to evaluate upstream production. Applied hands-on training includes preparation and proper labeling of reagents and media, aseptic technique, plasmid extraction, purification and quantitation, enzyme digestion and agarose gel electrophoresis, cell banking, counting and passaging, bioreactor assembly, sterilization, and operation, microbial cultivation and inoculation of seed culture, fed-batch, and batch fermentation.



5 DAYS



IN-PERSON



NCTM LAB

## CELL BIOLOGY

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- DNA, RNA, and Protein Overview
- Plasmid Components
- Bacterial Transformation
- Plasmid Purification and Analysis
- Cell Lines
- Cell Banking
- Cell Culture Basics
- Protein Chemistry Overview

## FERMENTATION

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- Seed train
- Culture Media Preparation
- Metabolites
- Harvest Storage
- Harvest Recovery
- Batch vs. Fed-batch Fermentation
- Counting and Passaging of Mammalian Cells

## BIOREACTOR OPERATION

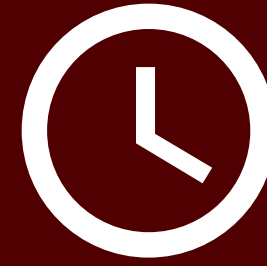
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- Assembly
- Controller
- Steam Sterilization
- Filter Sterilization
- Offline Analysis
- Types of Bioreactors

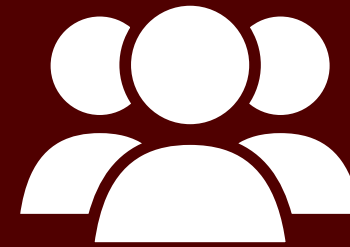
# DOWNSTREAM MANUFACTURING OF BIOLOGICS

This week long, hands-on course provides a thorough review of the most commonly utilized techniques involved in the downstream processes for manufacturing biologics.

Lectures and labs cover sterile buffer preparation, initial product clarification and recovery, various modes of filtration and column chromatography. Applied hands-on training include techniques in buffer preparation, sterile filtration, cell lysis, centrifugation, product clarification, tangential flow filtration, UNICORN chromatography software training, column packing, ion exchange and hydrophobic interaction chromatography.



5 DAYS



IN-PERSON



NCTM LAB

## BUFFER PREPARATION

- pH
- Molarity Calculations
- Buffer Preparation Activity
- Sterile Filtration
- Filter Integrity Testing

## TANGENTIAL FLOW FILTRATION

- Concentration
- Diafiltration
- Sample Analysis
- Mass Balance Calculations

## PRIMARY RECOVERY

- Cell Lysis Methods
- Homogenization Activity
- Centrifugation
- Depth Filtration

## CHROMATO- GRAPHY

- Liquid Chromatography Overview
- Column Packing
- Unicorn Software
- Ion Exchange Chromatography
- Hydrophobic Chromatography
- Column Cleaning and Sanitization



HANDS-ON CGMP  
BIOMANUFACTURING OF VECTORS  
FOR GENE THERAPY

ADVANCED DOWNSTREAM

HANDS-ON MANUFACTURING OF  
MRNA VACCINES & THERAPEUTICS

BIOSEPARATIONS AND DOWNSTREAM  
BIOPROCESSING

UPSTREAM BIOMANUFACTURING AND  
CELL CULTURE TECHNIQUES

# CONTINUING EDUCATION

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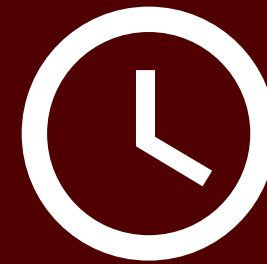
These courses provide opportunities for current pharmaceutical industry professionals to learn new or improve their existing skills to continue to meet the demands of this rapidly-changing industry. Training incorporates hands-on activities and case studies, as well as advanced theoretical concepts.

# Hands-on cGMP BIOMANUFACTURING OF VECTORS FOR GENE THERAPY

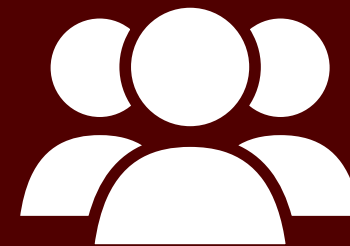
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This 4-day continuing education course provides hands-on training in the production of vectors for gene therapy products using an AAV2-GFP model system in a Sf9/Baculovirus system.

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, as well as discuss strategies and issues around scale-up, tech transfer, and adherent vs. suspension cultures.



4 DAYS



IN-PERSON



NCTM LAB

## GENE THERAPY OVERVIEW

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- Products
- Vectors
- Processes and Equipment
- Introduction to cGMP and Biosafety

## UPSTREAM

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- Transient Transfection of Sf9 cells
- Single Use Bioreactors
- Reusable Bioreactors
- Cell growth in Bioreactors
- Monitoring Bioreactors
- Methods to Produce Gene Therapy Vectors
- Production of AAV2-GFP using Baculovirus and Sf9 cells.

## DOWNSTREAM

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- Vector Harvest and Recovery
- Chromatography for AAV2 Purification
- Ultrafiltration for Concentration and Diafiltration

## ANALYTICAL

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- AAV Methods of Quantification
- qPCR
- SDS-PAGE

# ADVANCED DOWNSTREAM

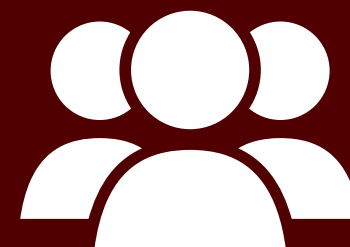
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In this course we cover advanced topics in downstream processing. Chromatography is covered in great detail, ranging from fundamental principles of mass transport within chromatography equipment to determining operating conditions for chromatography runs based on the resin selected.

Process development studies are executed to demonstrate process optimization, and scale up calculations will be performed. Tangential flow filtration (TFF), process development methodology for TFF, and other related topics including membrane cleaning and lifetime studies will be covered.



4 DAYS



IN-PERSON



NCTM LAB

## PROTEINS

---

- Protein Overview
- Protein Structure
- Protein Properties

## UNICORN SOFTWARE

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- Software Overview
- Method Editor
- System Control

## ULTRA- FILTRATION

---

- Membrane Selection
- TFF Process Development
- NWP Measurements
- GFP Concentration and Diafiltration
- Flux vs. TMP curves for TFF Optimization
- Cleaning Procedures for NWP Recovery

## CHROMATO- GRAPHY

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- AKTA Avant Overview
- Chromatography Basics
- Column Packing
- Chromatogram Evaluation
- Step Design
- Step vs. Gradient Elution
- Dynamic Binding Capacity Determination
- Viral Clearance
- Scale-Up
- Packed Bed vs. Monolith Chromatography
- Anion Exchange Chromatography
- Hydrophobic Interaction Chromatography

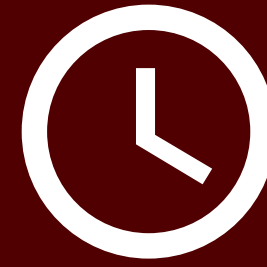


# Hands-on MANUFACTURING of mRNA VACCINES & THERAPEUTICS

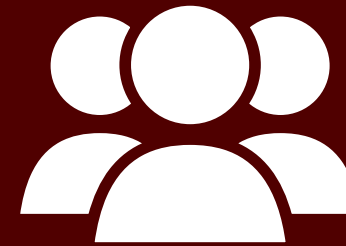
In this course we cover topics related to the manufacturing of mRNA vaccines in a simulated cGMP environment. Participants will perform manufacturing unit operations and quality control testing of a model mRNA vaccine.

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.



5 DAYS



IN-PERSON



NCTM LAB

## PLATFORM TECHNOLOGIES

- In Vitro Transcription
- Encapsulation
- Chromatography
- Ultrafiltration
- Diafiltration
- Cold Chain

## QUALITY CONTROL

- RT-qPCR
- RT-ddPCR
- Denaturing Gel for mRNA Visualization
- HPLC
- Capillary Electrophoresis
- Dynamic Light Scattering (DLS)
- RiboGreen Assay

## cGMP

- Overview of cGMP
- Documentation
- Gowning
- Regulatory Considerations

## COMMERICAL SCALE OPERATIONS

- IVT Reaction
- ÄKTA Process
- Millipore TF2S
- Quantoom Ntensify™ Midi
- Single Use Support RoSS.FILL
- Single Use Support RoSS.pFTU

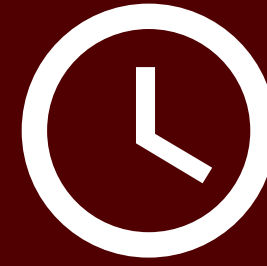


# UPSTREAM BIOMANUFACTURING & CELL CULTURE TECHNIQUES

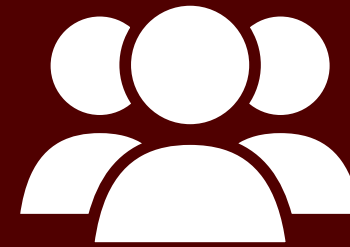
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This hands-on course covers the applications, platforms, equipment, and variables that are critical to upstream bioprocessing, including the steps needed to take a product from lab to pilot scale.

Topics include commonly-used industrial production platforms and bioreactor configurations, factors that affect biomanufacturing performance, observation of the effects selected parameters have over product formation, and real-time monitoring and trending of cell culture health. Ultimately, participants apply learned concepts towards the development of optimal strategies to improve productivity and efficiency.



3 DAYS



IN-PERSON



NCTM LAB

## CELL CULTURE

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- Cell Cultivation
- Media
- Seed Train

## BIOREACTORS

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- Critical Control Parameters
- Bioreactor Configurations and Processes
- Single Use Technology
- Inoculation
- Cultivation Run

## GUIDED CASE STUDIES

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- Bacterial
- Mammalian
- Insect

## SCALE-UP

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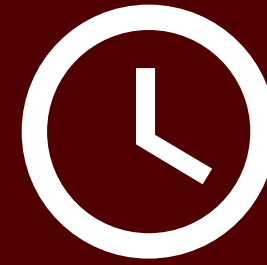
- Defining Operating Parameters
- Bioprocess Evaluation
- Upstream Biomanufacturing Key Points
- Future of the Industry

# BIOSEPARATIONS & DOWNSTREAM BIOPROCESSING

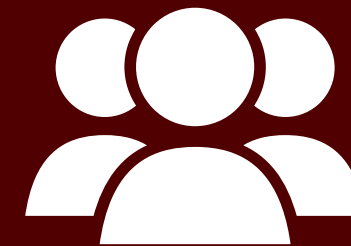
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This hands-on course exposes participants to the theory, operating principles and scale-up considerations of common downstream unit operations to better understand how they can be used together to form a robust and efficient process.

Topics include a survey of downstream bioprocesses and bio products, recovery of intracellular biomolecules, centrifugation separations, normal flow filtration, filter integrity testing, membrane separations utilizing TFF, column chromatography separations and calculations for each unit operation to aid in scale-up and product recovery.



3 DAYS



IN-PERSON



NCTM LAB

## RECOVERY

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- Cell Lysis
- Centrifuge Calculations
- Centrifuge Operations

## FILTRATION

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- Normal Flow Filtration
- Membrane Integrity Testing

## TANGENTIAL FLOW FILTRATION

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- Process Design
- Concentration
- Diafiltration
- TFF Calculations

## CHROMATO- GRAPHY

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- Principles of Chromatography
- Packed-Bed Column Dynamics
- Anion-Exchange Screening
- Column Scale-Up
- Developing Method in Unicorn
- Chromatogram Evaluation

CORRECTIVE & PREVENTATIVE  
ACTIONS (CAPA)

HUMAN ERROR AND RESILIENCE  
IN BIOMANUFACTURING SYSTEMS

PHARMACEUTICAL  
SUPPLY CHAINS

REGULATORY COMPLIANCE IN  
THE PHARMACEUTICAL INDUSTRY

VACCINOLOGY 101

# FLEX TRAINING

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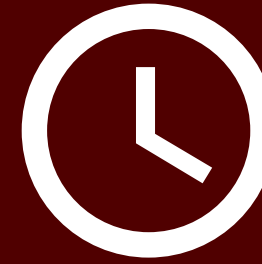
These lecture-based courses incorporate case studies and cover advanced theoretical concepts within the biopharmaceutical industry. Training can be delivered either in person at the NCTM laboratory or virtually through the TEES Edge platform, depending on the needs of the client.

# CORRECTIVE & PREVENTATIVE ACTIONS (CAPA)

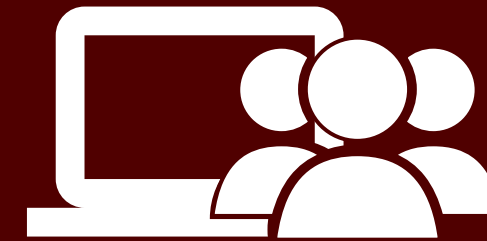
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This course provides an in-depth examination of effective root cause analysis and failure investigation, deviation management and documentation, corrective actions, and other elements of risk mitigation.

The course explains the regulatory environment surrounding corrective and preventative actions (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.



2 DAYS



IN-PERSON OR ONLINE



NCTM LAB

## MODULE 1

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- Understanding CAPAs
- Regulatory Expectations
- Deviations
- Out of Specifications
- Investigation Initiation

## MODULE 2

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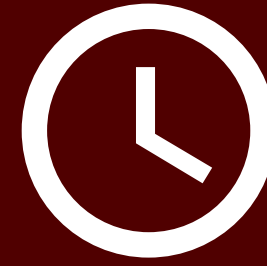
- Investigation Skills
- Effective CAPA SOPs
- CAPA Tools
- Quality Data Analysis
- Fishbone Diagram
- Is-Is Not Analysis
- Root Cause Analysis
- Risk Management
- CAPA Challenges



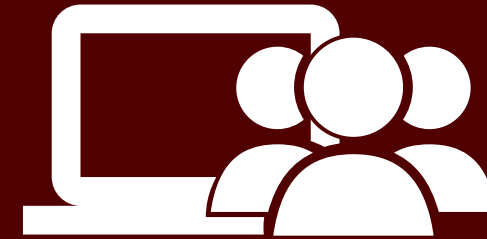
# HUMAN ERROR & RESILIENCE IN BIOMANUFACTURING SYSTEMS

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This course examines how human error impacts the safety and quality of operations in biomanufacturing processes. Models 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 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.



2 DAYS



IN-PERSON OR ONLINE



NCTM LAB

## MODULE 1

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- Systems Engineering Fundamentals
- Humans and Sociotechnical Systems
- Cognitive Human Factors
- Human-Technology Interaction

## MODULE 2

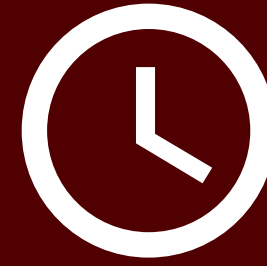
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- Introduction to Human Error and Error Management
- Rasmussen's Skill-Rule-Knowledge Framework
- Reason's Human Error Classifications
- Error Prediction and Analysis Techniques
- System Design Strategies for Error Management
- Fundamentals of Resilience and Systems Safety
- Lessons from High Reliability Organizations

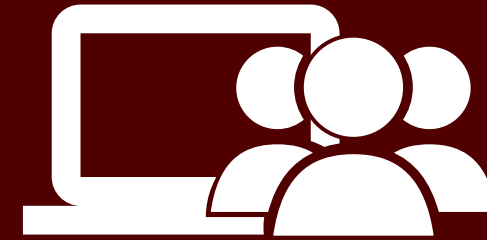
# PHARMACEUTICAL SUPPLY CHAINS

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 logistics systems, and supply chain integration concepts. Class instruction is complemented with case studies, interactive simulators, and team exercises that provide opportunities to practice these concepts.



2 DAYS



IN-PERSON OR ONLINE



NCTM LAB

## MODULE 1

- Fundamentals of Pharmaceutical Supply Chains
- Regulatory Environment
- Inventory Management for Delicate & Regulated Materials
- Supplier Selection and Qualification
- Security Assessments and Continuous Monitoring

## MODULE 2

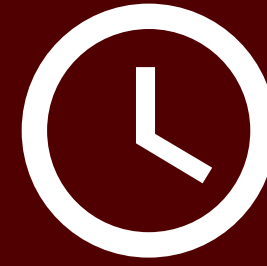
- Logistical Concepts
- Transportation
- Storage and Handling of Temperature Controlled Products
- Integration Concepts

# REGULATORY COMPLIANCE IN THE PHARMACEUTICAL INDUSTRY

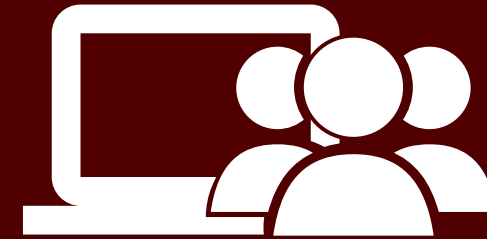
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This course targets research, medical, and biotechnology professionals who require an understanding of the Food & Drug Administration (FDA) and regulatory compliance.

Content includes FDA background, working with the FDA, types of regulatory submissions, meetings with FDA and complying with FDA Regulations. Also covered are GxPs and their related regulatory framework, documentation, vendor qualifications, as well as international and other regulating bodies.



2 DAYS



IN-PERSON OR ONLINE



NCTM LAB

## MODULE 1

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- FDA Background
- Major Laws/Regulations
- Guidance vs. Regulation
- Organizational Structure
- Types of Submissions
- Drug Development Cycle

## MODULE 2

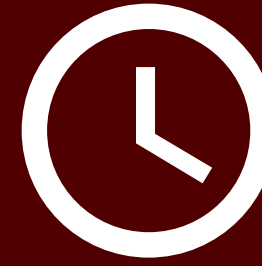
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- Meetings and Preparation
- FDA Inspections
- FDA Enforcement
- GLP/GMP/GCP
- Documentation
- Supplier Qualification
- Internal Quality Audits
- Quality Policy and Management
- Change Control
- ICH and Other Agencies
- ISO
- Regulation of Foreign Trade

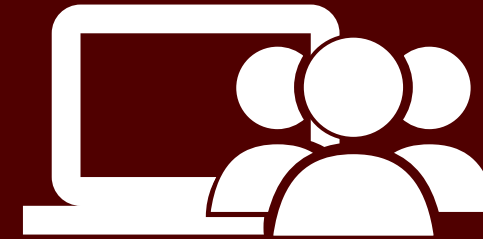
# VACCINOLOGY 101

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This course reviews the biological basis of vaccination as a strategy to control infectious diseases. Training 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 are covered and case studies are provided to promote discussion.



2 DAYS



IN-PERSON OR ONLINE



NCTM LAB

## MODULE 1

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- Viral and Bacterial Agents
- Epidemiology
- Biothreats
- Immune System
- Antigen Processing and Presentation
- T Cells, B Cells and Antibodies
- Techniques for Cultivation and Quantitation of Microbes
- History, Present state, and Future of Vaccine Development

## MODULE 2

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- Immunological Memory and Vaccine Effectiveness
- Anti-Microbial Resistance
- Conjugate Vaccines
- Vaccine Delivery
- Adjuvants



# RESOURCES

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- For open enrollment training opportunities, check NCTM's calendar: [nctm.tamu.edu/events/](https://nctm.tamu.edu/events/)
- To enroll in our online courses, visit: [nctm.tamu.edu/training](https://nctm.tamu.edu/training)
- For contract training needs, email: [programs@nctmmail.tamu.edu](mailto:programs@nctmmail.tamu.edu)

*Stay connected, follow us on Facebook and LinkedIn:*  
**@NCTMtamu**







# ACKNOWLEDGEMENTS

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