This catalog provides a comprehensive overview and description of the National Center for Therapeutics Manufacturing’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.
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, computer-based and hands-on learning to expose students 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 startups 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.

Our Mission:
To advance workforce education and applied research for the biopharmaceutical industry.

To learn more visit: nctm.tamu.edu
For program inquiries email: programs@nctmmail.tamu.edu
INTRODUCTION TO PHARMACEUTICAL MANUFACTURING
UNDERSTANDING THE SCIENCE OF THE BIOPHARMACEUTICAL INDUSTRY
CURRENT GOOD MANUFACTURING PRACTICES (cGMP) PROCEDURES AND DOCUMENTATION
PHARMACEUTICAL FACILITY OPERATIONS
SAFETY IN THE BIOPHARMACEUTICAL INDUSTRY
THERAPEUTICS MANUFACTURING: PAST, PRESENT and FUTURE

DISTANCE LEARNING

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 GCP, quality assurance and control and finishes with an exploration of career paths within the pharmaceutical manufacturing industry.

MODULE 1
- Pharmaceutical Manufacturing Basics
- Drug Categories and 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.
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 R&D, manufacturing and qualification/validation.
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.
SAFETY IN THE BIOPHARMACEUTICAL INDUSTRY

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.

MODULE 1
- 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
- Industrial Hygiene
- Government Regulations
- Occupational Safety and Health Administration (OSHA) Standards
- Controlling Hazards
- Evaluation
- Risk Assessment
- Industrial Hygiene Controls

MODULE 3
- Risk Assessment Hazardous Operations Evaluations (HAZOP) Risk Analysis
- Risk Evaluation Risk Management

MODULE 4
- 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.
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

This weeklong 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.

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

UPSTREAM
- 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
- Buffer Preparation and Sterile Filtration
- Filter Integrity Testing
- Tangential Flow Filtration
- Intro to Chromatography
- Ion Exchange Chromatography
- Hydrophobic Interaction Chromatography
- Column Cleaning and Sanitization
This weeklong, 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.
UPSTREAM MANUFACTURING OF BIOLOGICS

This weeklong, 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.
This weeklong, 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 includes 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.
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.
BIOMANUFACTURING OF VECTORS FOR GENE THERAPY

This four-day continuing education course provides hands-on training in the production of vectors for gene therapy products using AAV2-GFP 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.

GENE THERAPY OVERVIEW
- Products
- Vectors
- Processes and Equipment
- Introduction to cGMP and Biosafety

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

ANALYTICAL
- AAV Methods of Quantification
- qPCR
- SDS-PAGE
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.

ADVANCED DOWNSTREAM

PROTEINS
- Protein Overview
- Protein Structure
- Protein Properties

UNICORN SOFTWARE
- Software Overview
- Method Editor
- System Control

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

CHROMATOGRAPHY
- 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
UPSTREAM BIOMANUFACTURING & CELL CULTURE TECHNIQUES

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 toward the development of optimal strategies to improve productivity and efficiency.
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.
FLEX TRAINING

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)

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.

MODULE 1
- Understanding CAPAs
- Regulatory Expectations
- Deviations
- Out of Specifications
- Investigation Initiation

MODULE 2
- 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

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.

MODULE 1
• Systems Engineering Fundamentals
• Humans and Sociotechnical Systems
• Cognitive Human Factors
• Human-Technology Interaction

MODULE 2
• 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
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 APIs, 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.
REGULATORY COMPLIANCE IN THE PHARMACEUTICAL INDUSTRY

This course targets research, medical and biotechnology professionals who require an understanding of the Food and 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 and vendor qualifications, as well as international and other regulating bodies.

MODULE 1
- FDA Background
- Major Laws/Regulations
- Guidance vs. Regulation
- Organizational Structure
- Types of Submissions
- Drug Development Cycle

MODULE 2
- 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

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.

MODULE 1

• 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

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

- For open enrollment training opportunities, check NCTM’s calendar: nctm.tamu.edu/events
- To enroll in our online courses, visit: nctm.tamu.edu/training
- For contract training needs, email: programs@nctmmail.tamu.edu

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

Debbie Oakes
NCTM Senior Administrative Coordinator
Catalog Content Development

Jenny Ligon
NCTM Associate Director
Catalog Content Development

Logan Ardrey
NCTM Technologist
Catalog Content Development

Sarah Manning
Texas A&M AgriLife Program Coordinator
Catalog Design & Layout
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.