

NCTM

PARTICIPANT HANDBOOK

Published March 2024



National Center for
Therapeutics Manufacturing

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WELCOME

Welcome to the National Center for Therapeutics Manufacturing (NCTM)! Thank you for selecting NCTM for your continuing education and professional training. NCTM develops and delivers customizable instructor-led, computer-based, and hands-on learning to train students in several areas of biomanufacturing including cell culture, fermentation, aseptic processing, microbiology, cGMP operations, downstream processing, and quality control (QC) methods.

NCTM prides itself on providing a valuable experience through hands-on training in our state-of-the-art educational facilities, and interactive curriculum. What we take the most pride in, however, is the quality of our instructional staff. These professionals have keen knowledge of the subject matter and are committed to your professional growth and advancement.

Our centers' mission is to make a difference by providing the training needed to succeed in the rapidly growing biopharmaceutical manufacturing business. This is more than our mission; this is our culture, and this is why you will see us go the extra mile to help you succeed.

So, let's begin as we work together on the path of training and education. We have a proven track record of high-quality trainees and industry placement, and look forward to partnering with you to grow your career.

Baley Reeves, NCTM Interim Director

NCTM

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GENERAL INFORMATION

ABOUT THE HANDBOOK

The NCTM Participant Handbook is designed to provide information, rules, and procedures for participants that attend NCTM sponsored events. Training programs may have additional information and policies that can be found within the NCTM Course Catalog.

HISTORY OF TEES/NCTM

TEES was established on Aug. 25, 1914, by the Agricultural and Mechanical College of Texas' board of directors to conduct engineering research to help build a better society. Its mission was to undertake research that would produce answers to urban difficulties, as well as disseminate information related to such problems, thus enhancing the quality of life in Texas.

Since its inception, TEES has continued to direct its efforts to the utilization of natural resources and the improvement of industrial processes for over 100 years. It is the state's leader in innovation engineering and enables the government and industry partners to deliver advanced technology solutions to key market segments.

TEES boasts a proud history of:

- Serving as a catalyst for collaborations that produce quality research that addresses the needs of our evolving society.
- Transferring emerging technology to the private industry;
- Supporting the state's workforce development through continuing and professional education.
- Established in 2010, The National Center for Therapeutics Manufacturing (NCTM) is a first-of-its-kind, multi-disciplinary workforce education institution and biopharmaceutical manufacturing center, located at Texas A&M University in College Station, Texas.

INSTITUTIONAL OWNERSHIP

The Texas A&M Engineering Experiment Station (TEES) was established in 1914 and incorporated within The Texas A&M University System in 1948. TEES is also recognized as a state agency in the Texas Education Code (Sec. 88.001(5)). TEES is under the direction and control of the Board of Regents of TAMUS.

INSTITUTIONAL OWNERSHIP CONT.

The TAMUS Board of Regents (as of January 2024) are listed below.

- Bill Mahomes, Chairman
- Robert Albritton, Vice Chairman
- David Baggett
- John Bellinger
- James R “Randy” Brooks
- Jay Graham
- Michael A “Mike” Hernandez III
- Michael J. Plank
- Sam Torn
- Elizabeth “Annie” Valicek, Student Regent

The Texas A&M Engineering Experiment Station (TEES) Operations Office:

- Oversees research compliance and research administration.
- Coordinates and implements strategic, enterprise risk management and business continuity plans.
- Sets goals for operational efficiency and increased productivity.
- Coordinates efforts to maximize efficiency and interdepartmental collaboration.
- Manages organization and crisis communications.
- Coordinates TEES Advisory Board interactions.

NCTM ADVISORY BOARD

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.

Current members of NCTM External Advisory Board Members as of January 2024:

NAME	TITLE	COMPANY	LOCATION
Koey Keylon	Executive Director	OKC Innovation District Biomanufacturing WTC	Oklahoma City, OK
Dale Baker	Associate Director, Learning & Development	Fujifilm Diosynth Biotechnologies Texas	College Station, TX
Gary Gilleskie	Director	NCSU BTEC	Raleigh, NC
Ricardo Jimenez	Senior VP, Technical Operations	Neurogene Inc.	Pearland, TX
Jesse McCool	Co-Founder & CEO	Wheeler Bio	Oklahoma City, OK
Angela Consani	Co-Founder & CEO	Bioscience Core Skills Institute	Olathe, KS
Linnea Fletcher	Biotech Department Chair	Austin Community College	Austin, TX
Shell Ip	Client Learning & Scientific Content Manager	Precision NanoSystems Inc.	Vancouver, B.C. Canada
Rob Morrison	Director	Pfizer	Chesterfield. MO
Josh Henkin	Senior Program & Portfolio Manager	Tunnell Consulting, Contractor Supporting BARDA	Washington, DC

VISION

NCTM is an innovative workforce development and research center making a difference in the biopharmaceutical and vaccine industry worldwide.

MISSION

NCTM's mission is to bolster the U.S. and global biopharmaceutical and vaccine industries by training highly-skilled workers to enter the manufacturing workforce and supporting research innovations to bring products to market.

CORE VALUES

Quality, Commitment, Respect, Teamwork, Adaptability, Innovation, Safety

NONDISCRIMINATION STATEMENT

NCTM/TEES is committed to providing safe and nondiscriminatory learning, and work environments for all members of the NCTM/TEES community. NCTM/TEES provides equal opportunity in all programs, activities, education and employment to all persons regardless of race, color, sex, religion, national origin, age, disability, genetic information, veteran status, sexual orientation, gender identity, or any other classification protected by federal, state, or local law. All complaints of discrimination, harassment (including sexual harassment), complicity and related retaliation based on a protected class will be promptly, thoroughly, and fairly investigated and resolved in accordance with System Regulation 08.01.01, TEES Rule 08.01.01.E1, Texas A&M University Rule 08.01.01.M1, and applicable federal and state laws. In accordance with Title IX and its implementing regulations, TEES does not discriminate on the basis of sex in any educational program or activity, or employment. The response to allegations of discrimination, harassment, complicity, and related retaliation will be conducted by Texas A&M University Office of Civil Rights Equity & Investigations (TAMU CREI) and will be 1) prompt, thorough, and equitable; 2) intended to prevent the recurrence of any harassment; and 3) intended to remedy its discriminatory effects, as appropriate. A substantiated allegation of such conduct may result in disciplinary action, up to and including separation from employment. Visitors, contractors, and third parties who commit discrimination, harassment, complicity, or related retaliation may have their relationships with TEES terminated and/or their privileges of being on TEES premises withdrawn. The procedures for responding to allegations of discrimination, harassment, complicity, and related retaliation against students, faculty, staff, and third parties are detailed in System Regulation 08.01.01, TEES Rule 08.01.01.E1 and Texas A&M University's SAP 08.01.01.M1.01. Questions should be directed to Jennifer Smith, Title IX Coordinator at civilrights@tamu.edu

PARTICIPANT PRIVACY

Participants may inspect and review their training records maintained by NCTM. Participants may also request changes to their records when those records are inaccurate or misleading. The requests must be in writing to the NCTM Records Custodian at Programs@NCTMmail.tamu.edu. If the record custodian determines that the records do not need to be amended, the participant may place a statement with their record setting forth the participant's view of the contested information.

NCTM may release directory information without participant written consent. NCTM defines the following participant items as directory information: name, address (local and/or permanent), telephone number (local and/or permanent), email address, affiliation/employer name, affiliation/ employer address (local and/or permanent), affiliation/employer telephone number (local and/or permanent), Training courses attended, Dates of attendance, Certificates, CEUs, and/or certifications received.

Participants may place a directory hold on their information by contacting the NCTM Programs Office Programs@NCTMmail.tamu.edu. Once the participant has placed a hold on their directory information, this information may not be released without the prior, written consent of the participant.

NCTM will not permit access to or release of personally identifiable information (PII) without prior written consent from the participant, except to NCTM or TEES personnel needing access for legitimate educational duties, officials of other institutions to which the participant seeks to transfer credits, persons needing information for scholarship or third party education loans, state/federal/accrediting agencies as required, and/or appropriate TEES personnel in cases of health or safety emergencies.

LOCATION AND FACILITY

National Center for Therapeutics Manufacturing

100 Discovery Drive, 4482 TAMU

College Station, Texas 77843-4482

Email: Programs@NCTMmail.tamu.edu

Our headquarters house an office suite for staff and center business operations as well as classrooms and laboratory spaces for training and research.

BIOPROCESS LABS

NCTM offers a variety of well-equipped laboratory spaces for on-site training and applied research. Our four primary bioprocess labs are dedicated to cell culture, analytical methods, upstream, and downstream manufacturing with each lab housing a unique set of instruments designed to simulate every unit operation utilized in biomanufacturing facilities. Our skilled staff and stocked laboratories allow us to perform cutting-edge workforce development, process development and process scale-up to support the next generation of the biomanufacturing industry.

COURSE REGISTRATION INFORMATION

COURSES OFFERED

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.

For the most up-to-date course listing and class schedules, visit the digital course catalog at: <https://nctm.tamu.edu/training/>

COURSE REGISTRATION

NCTM offers open enrollment course registration online through the TEES EDGE portal and well as contracted trainings and education programs for the U.S. and global biopharmaceutical industry. Participants should refer to teesedge.tamu.edu for information and instructions on the online registration system. Course delivery dates can be found on TEES EDGE as well as the NCTM events link on the NCTM website.

Prerequisites or registration requirements will be identified within the course description found on the TEES EDGE website.

PARTICIPANT PHOTO IDENTIFICATION AND BACKGROUND CHECK REQUIREMENTS

All participants must complete a DPS background check prior to arrival at NCTM. The DPS verification form will be sent via email to participants upon receipt of their registration. Forms must be returned to NCTM not later than 72 hours prior to the start of the course.

PARTICIPANT PHOTO IDENTIFICATION AND BACKGROUND CHECK REQUIREMENTS CONT.

Participants attending face-to-face classroom training events will be required to provide photo identification. Your identification will be verified by a NCTM designated representative the morning of the first day of class. The proof of identification you bring should include your full name and photograph. The following are acceptable forms of photo identification*:

- State-issued IDs such as a Driver's License or Identification Card
- United States or Foreign Passports National Identity Card
- US military card (front and back)
- Military dependent's ID card (front and back)
- Permanent Resident Card Certificate of Citizenship Certificate of Naturalization
- Employment Authorization Document Employee ID or badge with photo

** Courses delivered online do not require photo identification.*

If you forget to bring your identification the first day of class, you have until the beginning of the second day to provide it. If you cannot provide your identification, you will be dismissed from the class (without a refund). Participants attending classes that are one day or less and are unable to provide photo identification by the end of class will not receive credit for the class (or a refund).

ATTENDANCE REQUIREMENTS

Class attendance is an essential part of the education process and participants in NCTM courses are expected to attend all class sessions and lab exercises. Attendance and participation are components of successful course completion. In addition, some courses may require a form of assessment. Participants who do not complete the required minimum attendance hours and other course completion requirements (when applicable) will not receive a NCTM course completion certificate. Class instructors will track attendance during the course delivery through a sign-in sheet. Participants will be able to review their attendance records during the course. Participants are expected to be present and ready for instruction at the scheduled time. Tardiness is defined as a late arrival 15 minutes or more after the scheduled start time; an early departure is leaving more than 15 minutes before the instructor releases the class. The instructor will monitor and counsel participants on their tardiness/early departure to ensure participants comply with the stated attendance policy.

The time a participant misses due to tardiness and/or early departures is tracked by the class instructor. To avoid an incomplete status in the course, the time missed cannot violate the minimum hours of attendance required by the course attendance policy.

ATTENDANCE REQUIREMENTS CONT.

NCTM courses do not allow for excused absences. If a participant misses a portion of the course, it is the participant's responsibility to contact the instructor before the end of the course they are attending to determine if and/or how missed work can be made up. The instructor will evaluate, on a case-by-case basis, whether or not the missed instruction can be made up. In some cases, make-up work will not be available (due to equipment/facility needs) and the hours missed will be deducted from the attended hours. CEU's will be adjusted accordingly.

Make up work must not interfere with the other scheduled class hours/activities and must be completed by the end of the course or within the maximum timeframe identified by the instructor.

LEAVE OF ABSENCE

NCTM does not allow participants to apply for a leave of absence during a course. If a participant is unable to complete a course, they can withdraw from the course and retake it at a later time.

INSTRUCTOR DISCLOSURE

Instructor(s) must disclose any conflicts of interest(s) applicable to the course subject matter or materials (e.g., proprietary interest in products, instruments, or devices) at the start of each course delivery.

COURSE COMPLETION

NCTM courses have varying requirements for completion. Participants should review the individual course descriptions found in NCTM Course Catalog for completion requirements prior to enrolling in a course. In addition, the class instructors will review completion requirements at the start of each course.

FINANCIAL INFORMATION

COURSE FEES

NCTM will publish course fees in the course descriptions found on the TEES Edge registration portal and the NCTM Course Catalog. If a course does not have a price listed, or if you have questions about the pricing, contact the program representative listed within the course description. Full fee payment is required at the time of registration or per contract, when applicable.

FUNDING OPTIONS

NCTM does not provide financial assistance. NCTM does not issue 1098 Forms because we are not considered an eligible institution by the U.S. Department of Education. An eligible institution is one that provides student financial aid and NCTM does not. Participants are encouraged to seek out third party support on their own to cover all or some course expenses

VETERANS SERVICES

From service with the Army, Marine Corps, Navy, Air Force or Coast Guard, the path for veterans looking for a new career begins with training in one of the many face-to-face certificate programs offered by NCTM each year. NCTM will work with veterans to determine the best course options and payment options.

REFUNDS

If a NCTM participant is unable to attend a class for which they have registered, they must contact the program representative found on the course description or course confirmation in advance to either transfer or cancel the registration.

CANCELLATIONS

Participants who cancel within 14 calendar days of the start of class for classes with a tuition that is \$50.00 or less will not receive a refund. For classes with a tuition over \$50.01, participants will be charged a \$50.00 registration fee or 10% of the class tuition, whichever is greater, not to exceed \$500.00.

CANCELLATIONS CONT.

Participants that cancel prior to 14 calendar days of the class start date will receive a full refund. Participants will receive their refund, less applicable fees, within 45 calendar days of the date of cancellation. If NCTM cancels a course, participants will be refunded all monies or transferred to another course delivery. If NCTM determines that an applicant is ineligible to enroll or if a prospective international participant has their visa application denied, a full refund of all monies paid will be made to the applicant,

NO SHOWS

Participants considered no shows for classes with a tuition that is \$50.00 or less will not receive a refund. For classes with a tuition over \$50.01, participants will be charged a \$50.00 registration fee or 10% of the class tuition, whichever is greater, not to exceed \$500.00. Participants who no show will receive their refund, less applicable fees, within 45 calendar days of the last scheduled day of class.

ONLINE COURSES

Refunds are not available for online courses once a participant has logged into the course. Online courses cannot be transferred from one participant to another. Participants who cancel the online course prior to logging in will be refunded in accordance with the cancellation policy above.

WITHDRAWAL

Participants who begin a training class and withdraw before the completion of the class are not eligible for refunds.

DISMISSAL

Participants who begin a class and are dismissed by NCTM before the completion of the class are not eligible for refunds.

VETERANS

Cancellations or refunds for veterans must follow the current Veteran Administration requirements.

PARTICIPANT APPEAL REFUND AMOUNT

If the refunded amount issued is in conflict with the participant refund policies stated above, a report may be filed at Programs@nctmmail.tamu.edu. NCTM will work with the participant and TEES accounts receivable to resolve the dispute.

PARTICIPANT SERVICES

PARTICIPANT SERVICES

The services that NCTM provides to participants includes the following:

- The class instructor will inform participants of available services at the location where the class is being held, when applicable, such as Wifi access, etc.
- Participants that would like copies of their completion certificates or training records should contact Programs@nctmmail.tamu.edu with their request. Electronic copies of available records will be provided.
- Participants are responsible for retaining their own housing/lodging unless NCTM has created a room block for a contracted training course. Information concerning room blocks will be provided to participants during the registration process.
- International participants wishing to attend NCTM courses in the United States should contact their local U.S Embassy or Consulate about other non-immigrant visa options. NCTM is not able to provide visa advice or assist with visa issues for these courses. All international participants must provide the necessary documents to clear US Export Controls to include a copy of the participants C.V. and passport photo page a minimum of 2 weeks prior to the beginning of training.

DISABILITY RESOURCES

In compliance with the Americans with Disability Act (ADA) of 1990, NCTM will make reasonable accommodations for participants with disabilities.

To ensure NCTM is able to make reasonable accommodations, participants should communicate their needs at least two weeks prior to attending a course or activity. Documentation may be required. To initiate the review process, participants should read the information found on

<https://tees.tamu.edu/engr-hr/workplace-notices/americans-with-disabilities-act-ada-as-amended.html>

and complete the ADA Request form found at

https://tees.tamu.edu/engr-hr/_files/_documents/ada-request-accommodation-form.pdf

For additional questions or to check on the status of your request please contact programs@nctmmail.tamu.edu

Participants requiring accommodation through the ADA must review their approved accommodations with the instructor on the first day of class.

PARTICIPANT SAFETY

Safety of our participants is a core value for NCTM. Emergency service contact information posted in the classrooms and labs. Many NCTM staff members are certified in CPR/AED and First Aid. The class instructor should review safety procedures at the beginning of class.

Participants that have fever (100°F or higher) or other symptoms of acute illness are highly encouraged to refrain from attending class to prevent the spreading of illness to classmates and NCTM staff. Participants that come to class with a fever may be asked to leave.

NCTM POLICES AND EXPECTATIONS

PARTICIPANT CODE OF CONDUCT

Participants attending NCTM sponsored events are expected to comply with the NCTM Participant Code of Conduct. Failure to follow this code may result in disciplinary action.

Participant Code of Conduct:

- Follow NCTM policies and local, state, or federal laws.
- Comply with directions of NCTM instructors, administrators, or authorized personnel.
- Respect fellow participants and NCTM staff by not discriminating or harassing individuals on the basis of race, color, national or ethnic origin, religion, sex, disability, age, sexual orientation, or veteran status.
- Support a safe and healthy learning environment.
- Avoid participating in hazing or conduct that threatens or endangers the mental or physical health or safety of others.
- Do not participate in academically dishonest actions such as cheating, plagiarizing, fabricating or falsifying work, or impersonating another in training/testing environment.

DISCIPLINARY PROCEDURES

Participants who violate the NCTM Participant Code of Conduct may be subject to disciplinary action. Disciplinary actions may include verbal reprimand, written reprimand, or dismissal from a training program or NCTM.

Participants found responsible for any violation may file an appeal within thirty (30) calendar days from the sanction date.

If NCTM becomes aware that a participant may have violated the law, NCTM will report the circumstance to law enforcement.

PARTICIPANT COMPLAINT AND APPEAL PROCESS

Complaints can be sent to the Programs email and/or the center director, who will respond to complaints or escalate to the appropriate governing body (TEES leadership and/or law enforcement) as appropriate.

REPORTING AN ACCIDENT, INJURY OR ILLNESS

Participants who witness an accident, are personally injured, or become ill while attending a NCTM sponsored event, should report the accident, injury, or illness to the instructor or other member of the NCTM staff as soon as possible.

DOING THE RIGHT THING

The Texas A&M University System is dedicated to adhering to the highest ethical standards and principles. If you have factual information suggestive of fraudulent, wasteful or abusive activities, we want you to report it. Examples of reportable issues include fraud; misuse of resources or information; violations of safety rules; inappropriate conduct, harassment or discrimination.

We encourage you to report such issues through the Risk, Fraud & Misconduct Hotline, a telephone and web-based reporting system, by calling 1-888-501-3850 or selecting “file a report” at the top of the page at ethicspoint.com. The hotline is independently operated and available 24 hours a day,

The EthicsPoint hotline is managed by the Texas A&M University System. The individuals listed below are the respective leads for their System departments:
Janet Gordon, System Ethics and Compliance Officer
Charlie Hrcir, Chief Auditor

TOBACCO PRODUCTS AND DEVICES

All forms of smoking and tobacco products including but not limited to cigarettes, cigars, pipes, smokeless tobacco, snuff and chewing tobacco, and electronic cigarettes (includes vapors, personal vaporizers, tanks and other electronic nicotine delivery system) are prohibited in all NCTM facilities and properties. Facilities means all grounds, buildings and structures, sidewalks and walkways, parking structures, and all vehicles owned, leased, or otherwise controlled by NCTM.

CARRYING WEAPONS

A handgun license holder under Chapter 411, Texas Government Code, may carry a concealed handgun on or about their person while the license holder is on NCTM property. There is no open carry allowed on NCTM property. Licensed peace officers are authorized by law to carry firearms.

CARRYING WEAPONS CONT.

In Texas, licensed handgun holders must follow any legally posted restrictions (Chapter 411 30.06, 30.07), whether concealed or open carry, on non-NCTM property or at NCTM special events. Other state laws will apply when training is held in another state.

DRUG USAGE

NCTM prohibits the use, sale, attempted sale, conveyance, distribution, manufacturing, cultivation, dispensation, purchase, attempted purchase, and possession of illicit drugs, intoxicants, or controlled substances, at any time and in any amount or in any manner. Additionally, NCTM prohibits the use of medications for which the participant does not have a valid prescription or the use of prescription medication in a manner inconsistent with the prescription. A participant taking any medication that may limit his/her ability to fully or safely participate in a NCTM course or activity should inform their instructor.

COPYRIGHT GUIDELINES

Participants are required to comply with the copyright guidelines found within the materials distributed during a course. Courses that use NCTM-produced materials are subject to copyright protection and do not allow for the publications to be reproduced, distributed, or transmitted in any form or by any means without prior written approval from NCTM. Unauthorized use of materials may be subject to legal action.

PERSONAL BELONGINGS

Participants are responsible for securing their personal belongings while attending NCTM sponsored events. NCTM is not responsible for the loss or theft of personal belongings.

LAB DRESS CODE

Participants must wear closed-toed shoes, long pants, and pull their hair back.

CELL PHONE AND ELECTRONIC DEVICES

Cell phones and other electronic devices will not be allowed to pose as a distraction to other participants or the instructor of the course. Participants may be asked to silence device(s) at the beginning of class and/or excuse themselves from class to make/receive phone calls. Participants should follow the direction of their instructor on usage of electronic devices during the course.

USE OF CAMERAS AND RECORDING DEVICES

Participants are not permitted to record or photograph NCTM training or activity without prior approval by appropriate NCTM personnel, such as the class instructor or center director.

NCTM TRAINING RESOURCES

NCTM provides consumable and/or equipment resources for use during hands-on training classes. Participants are expected to use these resources in accordance with the prescribed guidelines provided by the instructor. Failure to follow the usage guidelines may result in the removal of the NCTM property from the participant and/or holding the participant financially responsible for damages.

NCTM

Texas A&M Engineering Experiment Station

1111 RELIS Parkway, Suite 5226, Bryan, TX 77807
(979) 317-3800
tees.tamu.edu

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