

NCTM

NATIONAL CENTER FOR
THERAPEUTICS MANUFACTURING



Texas A&M Engineering
Experiment Station

PERFORMANCE REPORT

2021

*Advancing workforce education and applied
research for the biopharmaceutical industry.*

***“IT IS NOT OFTEN THAT A MAN CAN
MAKE OPPORTUNITIES FOR HIMSELF.
BUT HE CAN PUT HIMSELF IN SUCH
SHAPE THAT WHEN OR IF THE
OPPORTUNITIES COME HE IS READY.”***

THEODORE ROOSEVELT

It is with great pride that we share this recap of our 2021 activities and historical journey from our inception in 2012. I have never been more proud of our team for their tireless efforts to train more than 200 individuals in upstream and downstream bioprocessing and analytical methods this year alone. In addition to our training activities, our scientists completed a small-scale production of spike proteins for a federal COVID-19 project and are currently investigating bioprocessing options for novel recombinant protein-based materials.

- Zivko Nikolov, PhD, NCTM Director

ABOUT OUR CENTER

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 academic and industrial researchers ranging from media screening to improve cell line productivity through protein expression and purification. We offer a variety of expression systems including bacteria, yeast, mammalian, and insect lines and can perform process development and optimization, as well as analytical methods development and characterization.

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MAJOR MILESTONES

220 TRAINEES

consisting of industry new hires, Masters of Biotech students, and military veterans, completed NCTM's hands-on training courses.

120 NEW HIRES

were onboarded for Fujifilm Diosynth Biotechnologies Texas in preparation for COVID-19 vaccine manufacturing.

2 NEW COURSES

were developed: "Advanced Downstream" a hands-on continuing education course and "Therapeutics Manufacturing: Past, Present and Future" a 3-hour online course.

OUR VISION FOR 2022

NCTM will continue to offer customizable training modules to fit any company's needs, from technical onboarding programs to advanced continuing education courses. Our curricula provides hands-on experience in every unit operation from cell culture to purification, including analytics throughout.

Celebrating our 10th anniversary in 2022, NCTM has trained more than 1,700 professionals and secured more than \$27 million in funding and contract work.



**PROGRAMS
& ACTIVITIES**

COLLABORATION

NCTM successfully piloted a 4-day hands-on cGMP Biomanufacturing of Vectors for Gene Therapy continuing education course at North Carolina State University's Biomanufacturing Training and Education Center. The new curricula will allow NCTM to serve the cell and gene therapy industries and workforce.

Under a project awarded from the National Institute for Innovation in Manufacturing Biopharmaceuticals, NCTM will be able to purchase single-use equipment to train next-generation manufacturing associates, initiating the development of a new training program to address the future needs of biopharma.

RESEARCH & INNOVATION

Our major 2021 research projects included:

- Scale-Up of Mesenchymal Stem Cell (hMSC) Bioprocessing
 - In collaboration with the Texas A&M Department of Molecular and Cellular Medicine and Biomedical Engineering, NCTM worked on the development and scale up of mesenchymal stem cell (hMSC) bioprocessing to demonstrate the process robustness and manufacturing of hMSC using gelatin microcarriers.
- COVID-19 Spike Proteins
 - To expedite the development of therapeutic antibodies and diagnostics, NCTM scientists developed robust protein purification strategies and delivered hundreds of milligrams of high-quality spike proteins to the Army Research Lab and Houston Methodist Hospital.
- Production of Novel Protein Polymers
 - Funded by Bondwell Technologies, this project focused on the development of materials for a low-cost, single-use purification of therapeutic antibodies through the production of novel protein polymers.

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The National Center for Therapeutics Manufacturing is a member of the Texas A&M Engineering Experiment Station (TEES). TEES is a state research agency that solves problems through applied engineering research and development and collaboration with industry, government and academia. As part of The Texas A&M University System, TEES is connected with world-class researchers and facilities throughout the Texas A&M System.



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