

National Center for Therapeutics Manufacturing



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What is Biomanufacturing?



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Recombinant Proteins

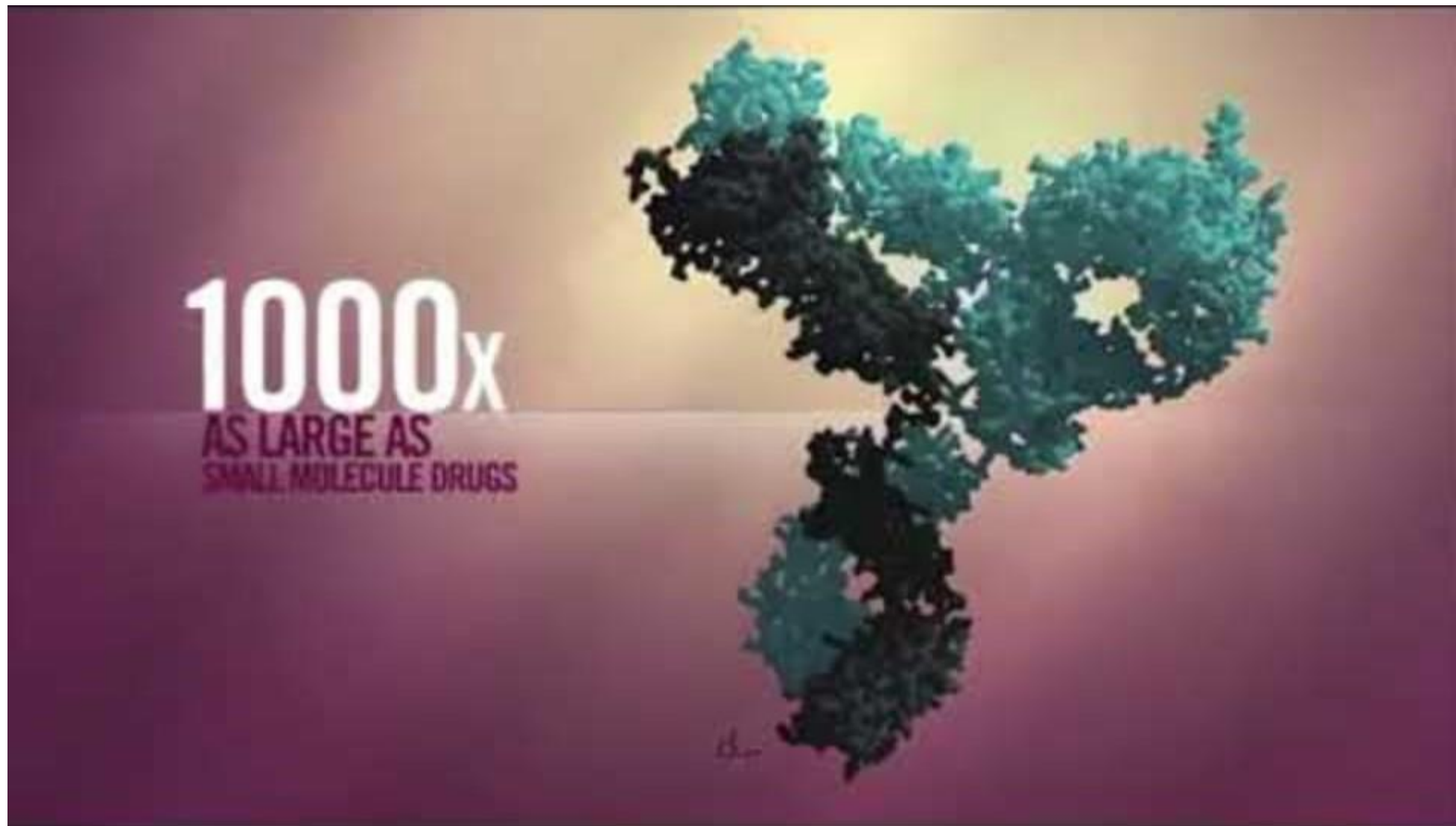
Vaccines



Gene Therapy

Cell Therapy

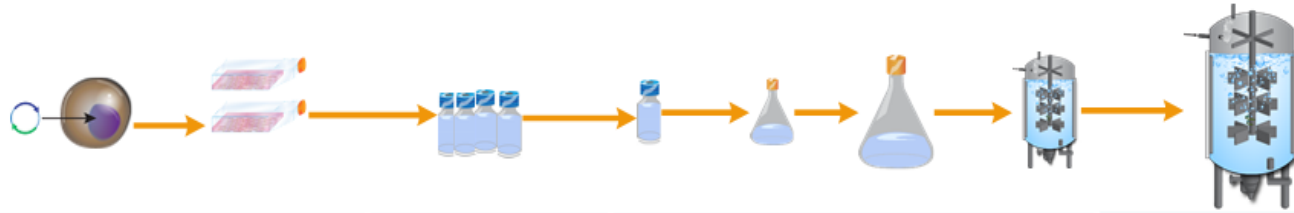




How do we make Biologics?



Upstream Workflow



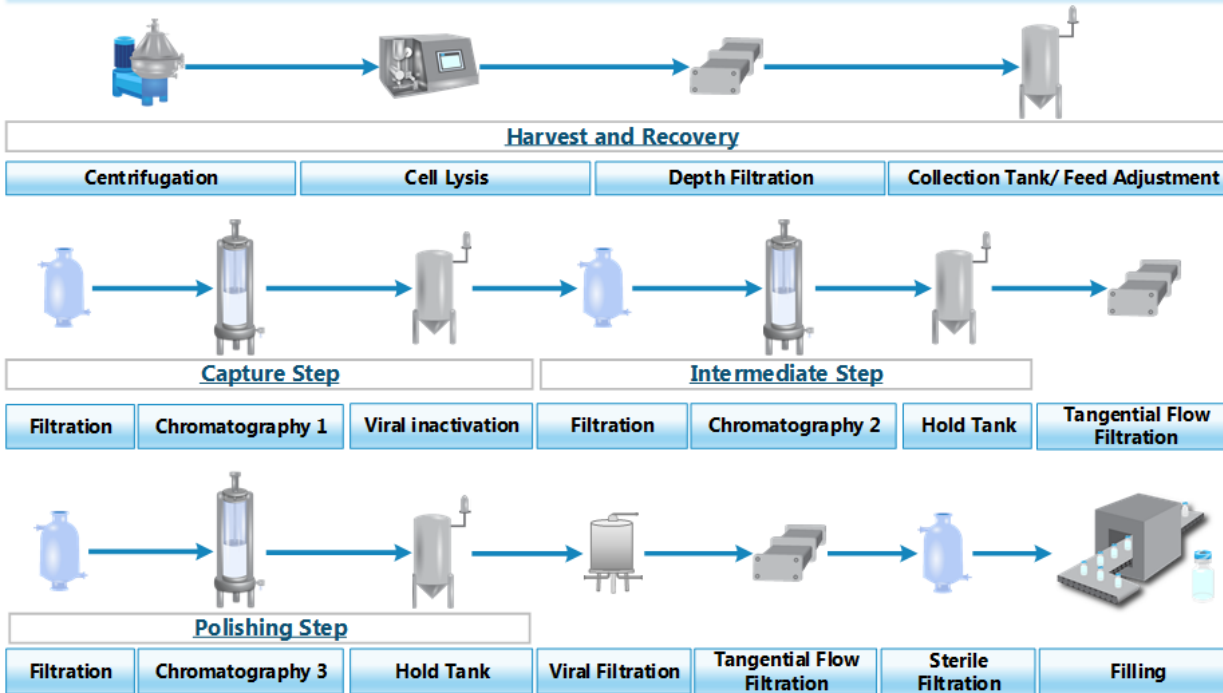
Cell Line Development/ Growth Conditions

Cell Banking

Thaw and Cell Expansion

Production/ Monitoring

Downstream Workflow



Well-trained staff

Written procedures

Addressing deviations

Process validation

Qualified equipment

Assigning CAPA

Validated analytical methods

Effective equipment cleaning

Testing of intermediates and drug product

Cleaning validation

Quality Product

Biomanufacturing Jobs



- No college degree needed for entry level technicians
- Average entry level salary \$50-60k
- Average annual wages for biomanufacturing companies \$90-100k
- Highly regulated work environment, specialized skills needed
 - cGMP: Current Good Manufacturing Practice
 - Documentation
 - Cleaning



Ian Dake



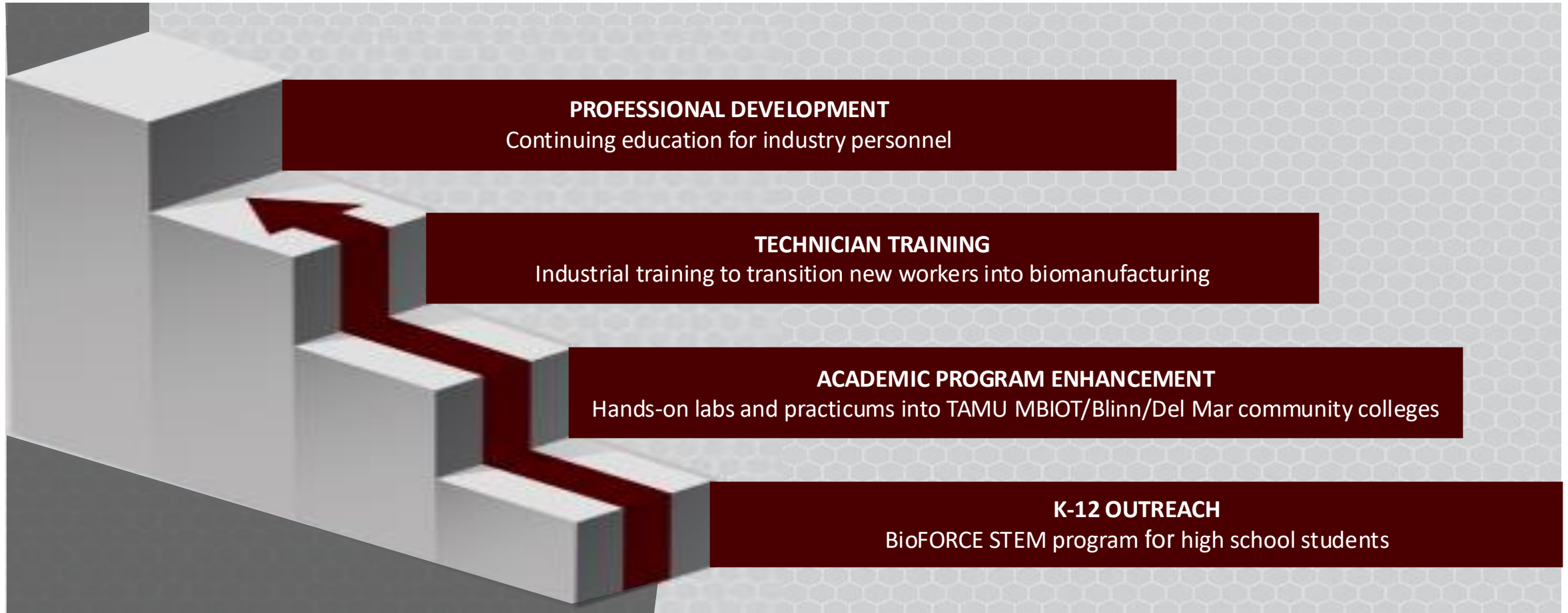
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Creating a Highly-Skilled Workforce



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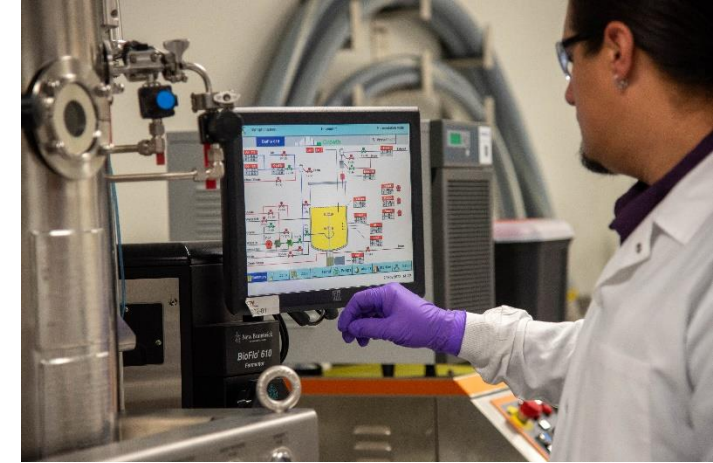


NCTM's Simulated cGMP Facility



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- Lab renovations for simulated cGMP facility
 - Gowning areas with air locks and unidirectional flow
 - Mock production facility
 - Aseptic passthroughs
- Cleanroom processing suites include:
 - Central services
 - Fermentation and recovery
 - Purification
 - Formulation and filling suite
 - Additional suites for cell culture and QC
- Pilot and manufacturing-scale skids
 - Both single-use and stainless equipment



NCTM Major Accomplishments



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- World-class, simulated cGMP training facility
 - Training provider for the WHO, PAVM, DCVMN and other international LMIC vaccine manufacturers
 - 29 organizations across 16 countries served
- Rapidly onboarded over 350 FDBT employees during Operation Warpspeed
- 39 courses developed
 - Over 300 training modules developed
- NCTM training has been disseminated to 5 states
- Over 2500 individuals trained
 - Military veterans
 - Industry professionals
 - High school, college, and university students
 - BARDA: 11 individuals, 5 online courses each
- Developed the US's first (and only manufacturing-scale) hands-on mRNA vaccine training program
- TAMU core facility and contract service provider for process development and scale-up support



World Health
Organization

DCVMN
INTERNATIONAL
Developing Countries Vaccine
Manufacturers Network International



PAVM

PARTNERSHIPS
FOR AFRICAN VACCINE
MANUFACTURING

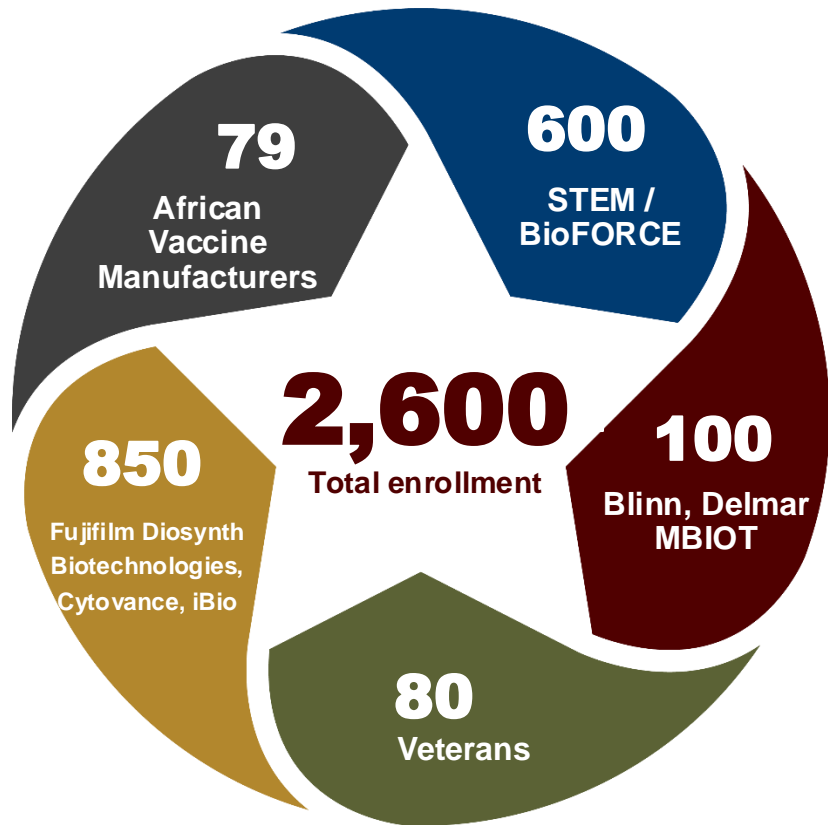


NCTM Customer Locations

Trainees from 2012 to Date



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Biopharma Bootcamp Origins

Rapid **5-day** training for entry level positions or people unfamiliar with the biopharma industry

Focuses on basics of upstream and downstream bioprocessing

- Also covers general lab skills, solution prep, environmental and in-process monitoring, etc.

Allows familiarity with the entire manufacturing process

- Works well for employees who would not normally see production areas or who might not understand the science

COVID CASE STUDY

Fujifilm Diosynth Biotechnologies Texas (FDBT) asked NCTM to onboard **hundreds** of new manufacturing personnel

Within 3 weeks, NCTM customized a hands-on training program based on FDBT's internal manufacturing processes

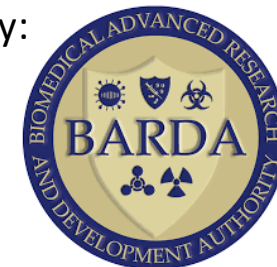
Allows continued operations of FDBT, avoiding productivity interruptions and **greatly reducing internal costs** of on-the-job training

NCTM has trained more than **350 individuals** through this initiative, ranging from service workers/waitstaff to university students to career changers

- **First hands-on mRNA training course in the U.S.**
 - IVT reaction through cold chain
 - Developed with a wide-range of industry partners
- **70% hands-on activities, 30% lecture**
- **Simulated cGMP environment**
- **Manufacturing-scale equipment**
- **Single-use and hard-piped systems**
- **Launched Fall 2023**



Sponsored by:



- Previous NCTM Veteran Training programs: Military Veterans Manufacturing Vaccines
 - Wagner Peyser (Texas Workforce Commission): Trained two, 12-person cohorts
 - NIIMBL: Military Veterans: Trained 41 participants across the nation (5 training cohorts)
 - Collaboration with NC Biotech
 - Guaranteed interviews with project partners Merck and Pfizer
- Currently working on federal appropriations through the FY25 Military Construction and Veterans affairs Bill.



Candace Laguna



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Veteran Scholarships/Resources



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Scholarship/Fund	Recipient	Application Window	Amount	Website
My Career Advancement (MyCAA)	Active duty spouses	Year-round	\$4000	https://mycaa.militaryonesource.mil/mycaa/
Folds of Honor	Dependents and/or spouses of fallen or disabled service members	Feb 1-March 31	\$5000 (\$2500 per term)	https://foldsofhonor.org/scholarships/military-scholarships/
Semper Fi & America's Fund	Wounded service members	Year-round	Need-based, up to \$5000	https://thefund.org/our-programs/transition-program/education-and-career-assistance/
Pat Tillman Foundation	Active duty service members, veterans, military spouses	Dec 1-Feb 1	\$1000	https://pattillmanfoundation.org/apply/scholar-benefits/
Chief Petty Officer Scholarship Fund	Child or spouse of Navy service member	Jan 1-April 1	\$2000 or \$5000	https://www.cposf.org/scholarship

Getting there:

- Campus Buses: Line 3 (Yell Practice)
- Driving: 100 Discovery Drive
 - Park in one of the Visitor parking spots at the front of the building

Tour information:

- Meet in the NCTM lobby at 4:15pm
- Will have team members standing by for tours through 4:45pm in the lobby





Questions?



TRIBEC: Texas Regional Industrial Biomanufacturing Education Certification



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- Consortium of 11 colleges and universities across Texas
- Aiming to create a harmonized biomanufacturing training program, offered concurrently at several locations across the state
- Using this collaboration to seek funding from the state for hands-on capstones for all TRIBEC participants at NCTM
- Tied into Registered Apprenticeship program in Biomanufacturing

