

National Career Pathways Network Conference October 15-16, 2020

Credentialing and Careers in the Bioscience Industry



Biotechnician



Tamara Mandell M.Ed. Director, UF Biotility tmandell@cerhb.ufl.edu



University of Florida Center of Excellence for Regenerative Health Biotechnology

Est. 2003 (Florida Biologix & Biotility) Mission:

- Economic development for State of Florida
- Improve climate and expand infrastructure for translational research
- Develop courses for workforce training







Building the Workforce







Florida Partnership for Industrial Biotechnology

- Develop & deliver curricula for industrial biotechnology (short-course) training
- Ensure programs within educational institutions are relevant & meet industry's needs & standards
- HS Industrial Biotechnology Program
 - Blended CTE/Academic Credit
 - "Equally Rigorous" Science
- Articulation Agreements
- Teacher Professional Development



High School Industrial Biotechnology I, II, III

- Comprehensive sequence covering skills used by industrial, medical, agricultural and research facilities
 - Biotech I & II Students earn 0.5 each of Academic (elective science) and CTE credit
 - Biotech III earns 1 full CTE credit
 - Performance and Sunshine State Standards (Next Generation) assigned to each benchmark
- Provides *multiple* career paths
 - Articulation into A.S. degree/Certificate
 - University
 - Entry level employment



Secondary Industrial Biotechnology

Biotech I # 3027010 History, Benefits, Careers Safety Procedures Solution Preparation **Basic Chemistry Basic Equipment Cell Structure & Function** Culturing Microorganisms Sterile Technique Experimental Design DNA Isolation/Analysis **Environmental Monitoring** Data Analysis Law & Ethics Documentation Communication

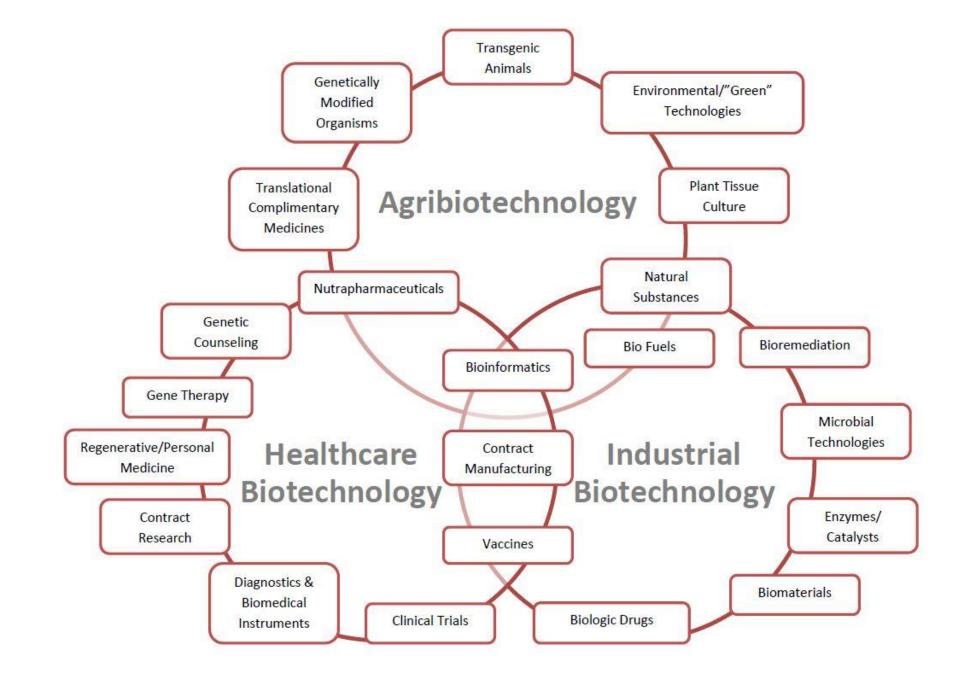
Biotech II #3027020 Transformation Culture Scale-up **Recombinant Proteins Production of Proteins** Protein Quantification Filtration & Purification ELISA PAGE Immunoblotting PCR Assay Development Quality Control Quality Assurance **Regulatory Affairs Product Marketing**

Biotech III #8736030 CTE Credit Only Independent design and implementation of student projects, simulating employment in a biotechnologybased industry and utilizing industry partners



Comprehensive sequence covering skills used by industrial, medical, agricultural and research facilities





Industry Career Opportunities

- Research & Development
- Manufacturing
- Quality Control (QC)
- Quality Assurance (QA)



Technician Level

- Process Technician
- Quality Control Tech
- Quality Assurance Tech
- Manufacturing Tech
- Research Tech

Plus Education/Experience

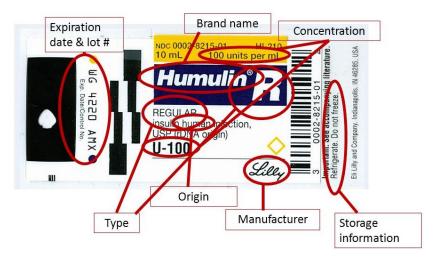
- Process Development
- Quality Control Asst./Assoc.
- Quality Assurance Asst./Assoc.
- Validation Specialist
 - Research Asst./Assoc./Scientist

© UF/CERHE

Research & Development (R&D)

- Find/develop a potential product with commercial value
 - Develop processes to make the product
- Characterize the properties of the product
 - Composition, physical & chemical properties
 - Effect, strength, potency
 - Purity
 - Stability & shelf life
 - Product applications
 - Safety concerns (use and production)
- Establish product specifications
- Develop methods to test the product

Insulin – LABELS



https://slideplayer.com/slide/4583246/

© UF/CERHE

Manufacturing/Production Unit

- Operate (large-scale) equipment
 - Bioreactors, Purification Systems, Filtration Systems, Fill-Finish
- Preparation of supporting materials
- Routine production environment control
- Monitor process parameters
 - Implement corrective actions
- Facility Maintenance
 - Maintenance & repair of equipment & facility
 - Calibration
- Receiving and Shipping
 - Insure proper routing of incoming raw materials
 - Shipment of finished products





Quality Control

Demonstrate Product Safety through the testing of:

- Raw materials
- Components
- In-Process samples/materials
- Finished product

Demonstrate product lot consistency

Demonstrate product stability

Environmental Monitoring

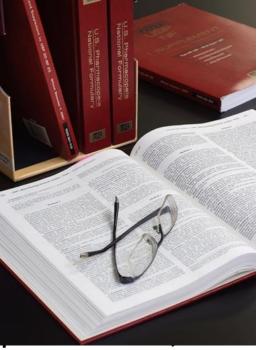






Quality Assurance

- Ensure compliance with cGMPs, cGLPs, cGCPs
 - Independent
 - Control, prepare and issue documents
 - Training oversight
 - Inspections/Audits
 - Review customer complaints
 - Review and Approve all Records, Reports, written specifications
 - Ultimate authority to release/reject raw materials and product lots





Rigorous Programs of Study (2008)

- US Office of Career, Technical, and Adult Education (OCTAE)
 - FL DOE to UF-CERHB: Florida's Biotechnology Articulation consortium (FBAC)
 - Develop and promote a rigorous program of study
 - Implement a statewide articulation agreement (secondary to associate degree) in the area of Biotechnology









Florida's Career and Professional Education Act: §1003.491

Purpose: to provide a statewide planning partnership between the business and education communities in order to attract, expand and retain targeted, high-value industry and to sustain a strong, knowledge-based economy.

- Improve academic performance through rigorous & relevant curricula
- Provide rigorous and relevant career-themed courses
- Opportunities to articulate to *postsecondary coursework* <u>and</u> *earn industry certifications*





Based on foundational concepts and skills required in biotechnology-based workplace settings

- Written & Practical exam
 - Aligned w/Academic and Performance Standards
- Industry recognition via BioFlorida
 - Relevance, Accuracy, Alignment to Standards



- Approved by Florida's Board of Education, Jan., 2012 for statewide articulation (A.S.) Biotechnology
- Approved by Florida's Agency for Workforce Innovation

© UF/CERH

Knowledge Exam Subjects

BIOLOGICAL SYSTEMS

- Cells (general)
- Cell Structures and Function
- Genetics/Model Organisms
- Central Dogma of Molecular Biology
- Immune System

CHEMISTRY/BIOCHEMISTRY

- Bonds
- Cell Respiration
- Chemistry, Molecules & Macromolecules
- DNA Structure & Function
- Enzymes & Reactions
- Periodic Table
- Protein Structure & Function
- Reaction Rates
- Translation (Gene Expression)

RESEARCH & SCIENTIFIC METHOD

- Experimental Design
- Scientific Method
- Analyze/Interpret Data
- Maintain Lab Book
- Communicating Scientific Research

LABORATORY SKILLS/APPLICATIONS

- Culturing Microorganisms
- Aseptic Technique
- DNA Isolation, Purification, Quantitation
- Restriction Enzymes/Digests/Cloning
- Transformation & Transfection
- Protein Expression, Purification and Quantitation
- Agarose & PAGE Electrophoresis
- Polymerase Chain Reaction (PCR)
- Spectrometry, pH, Microscopy
- Immunoassays
- Equipment Maintenance, Calibration, Validation
- Scientific Notation, Significant Figures, Decimals

GENERAL TOPICS IN BIOTECHNOLOGY

- Historical and Current
- Applications, Benefit to Society, Ethics
- Biotech Careers
- Regulatory Compliance
- Workplace/Safety



BACE Practical Exam Subjects

APPLIED MATHEMATICS

- Scientific Notation, Significant Figures, Decimals, Correct Units
- Graphing, Axis Scaling & Limits
- Standard Curves, Beer's Law
- Interpreting Data
- Volume/Volume Calculations
- Weight /Volume Calculations
- Molarity Calculations
- Serial Dilutions, & from Concentrate **BIOTECHNOLOGY SKILLS**
- Culturing Microorganisms
- Aseptic/Sterile Technique
- Electrophoresis
- Accurate Weight and Volume Measurement
 - Pipetting (Macro and Micro)
- Measuring/Adjusting pH
- Preparing Solutions, Buffers, Media
- Spectrophotometry, Centrifugation

LABORATORY EQUIPMENT

- Electrophoresis Equipment
- Spectrophotometer
- pH Meter
- Micro/Macropipettors
- Balances
- Fume Hoods and Biosafety Cabinets
- Microscope
- Stirrers, Shakers, Vortex
- Water Bath, Incubator, Autoclave
- Glassware

WORKPLACE SAFETY & BEHAVIOR

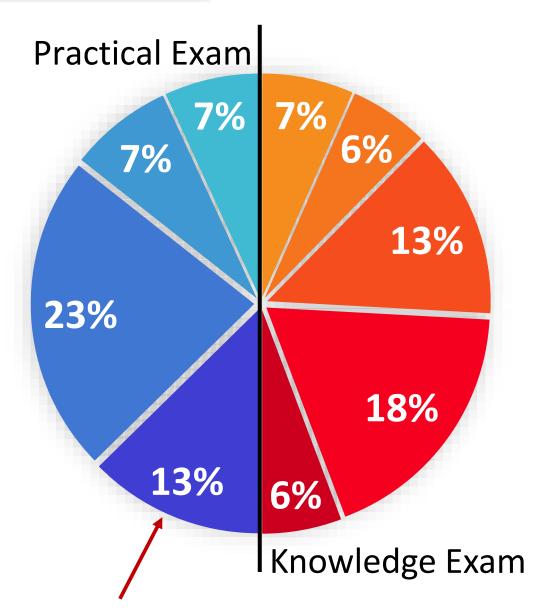
- Identify Safety Symbols
- Laboratory Safety Protocols/Handling Waste
- Using Safety Data Sheets (SDS)
- Personal Protective Equipment (PPE)
- Proper Labeling
- Regulatory Compliance, Documentation

1

© UF/CERHB

Identify Acceptable Work Habits

2020 BACE Category Distribution: Percentage of Points Per Category



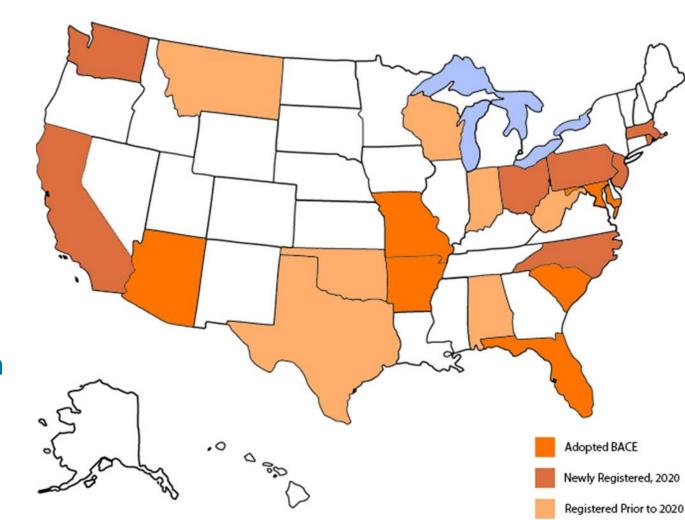
- 1.0 BIOCHEMISTRY/CHEMISTRY
- 2.0 BIOLOGICAL SYSTEMS
- 3.0 GENERAL TOPICS IN BIOTECHNOLOGY
- 4.0 LABORATORY SKILLS/APPLICATIONS
- 5.0 RESEARCH & SCIENTIFIC METHOD
- 6.0 Applied Mathematics in Biotechnology
- 7.0 Biotechnology Skills
- 8.0 Laboratory Equipment
- 9.0 Workplace Safety & Behavior



Expanding the Opportunity

Traditional Biotech

Alabama Arizona **Arkansas Florida** Indiana Maryland Missouri Montana Oklahoma **South Carolina** Texas West Virginia



PLTW

Alabama **Arkansas** Florida Indiana Maryland Missouri Montana Oklahoma **South Carolina** Texas West Virginia

Brazil

Wisconsin

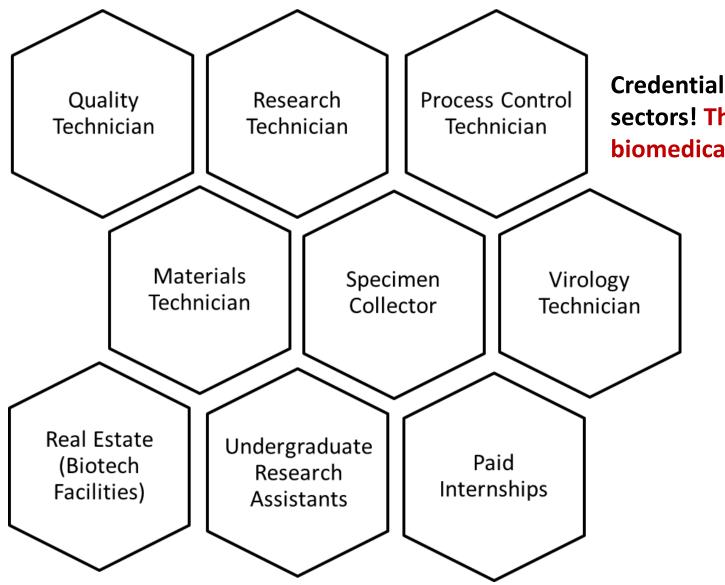
Credential Earner Employers

- ANDRITZ
- Applied Genetic Technologies, Corp.
- Avidyne
- Bayer
- Bureau of Public Health
- Cutrale, Inc.
- Foundry Commercial
- GE Aviation
- Massachusetts General Hospital
- Mayo Clinic
- Mérieux NutriSciences
- MIT Lincoln Laboratory
- MIT Teaching Systems Lab
- Monsanto
- Nobel Research Institute
- Nothrop Grumman
- Novabone, Inc.

- NYU Langone Health
- Ology, Inc.
- OPharmatech, Inc
- RTI-Surgical, Inc.
- Southern Earth Sciences
- Syngenta, Inc.
- Tallahassee Memorial Healthcare
- The Selling Factory
- Thermo-Fisher Scientific
- UF College of Dentistry
- UF College of Medicine
- Ultimate Nutrition, Inc.
- United Juice Companies of America
- University of Utah Health
- USDA
- IFAS, MIT, Koch Institute, Paid internships

© UF/CERHB

Positions



Credential earners work in a variety of industry sectors! These include agriculture, food science, biomedical, medical device, and many more.

© UF/CERHB

National Advisory Board

| COMPANY | TITLE | STATE |
|------------------------------------|---|----------------|
| ACell, Inc. | Senior Product Manager | Maryland |
| AGTC | Scientist, Preclinical & Clinical Assays, R&D | Florida |
| Akron Biotech | Manager, Strategic Alliances | Florida |
| AxoGen, Inc. | Product Development Engineer | Florida |
| Boehringer Ingelheim Animal Health | Principal Scientist | lowa |
| ELISA Technologies | Scientific Director | Florida |
| Encoded Therapeutics, Inc. | Director, Process Development & Manufacturing | California |
| Georgia Bio | VP, Operations | Georgia |
| K2M, Inc. | Director, Clinical Affairs | Virginia |
| Merck & Co. | Associate Director, Engineering | Pennsylvania |
| PCM Trials | Director, Clinical Operations | Colorado |
| QuickStart | Director, Georgia BioScience Training Center | Georgia |
| StrideBio, Inc. | VP, Preclinical Development | North Carolina |
| Yukon Medical, LLC | Senior Director, Product Development | North Carolina |



New edition! Biotechnology: A Laboratory Skills Course, Second Edition

By J. Kirk Brown



AVAILABLE LATE SUMMER 2018

Put the power and excitement of Biotechnology at your students' fingertips

Biotechnology: A Laboratory Skills Course is a ready-to-go solution for your biotechnology course, or to start a new one right away! This laboratory textbook provides you and your students with background information about the methods and techniques used in today's exciting research and manufacturing laboratory environments.

BACE Registration

http://biotility.research.ufl.edu/bace



Scroll to learn more about BACE and Begin the Registration Process





Remote Testing - Honorlock

- Remote testing for the BACE became available April 20th, 2020 and is board-approved to July 15th, 2021.
- During this window, candidates are permitted to take both the Knowledge and Practical portions of the BACE from their home or any other location of their choice. These changes have been approved by the National Advisory Board.
- Below are links to two documents, one for you and one for students, which contain the detailed information needed to take the BACE.
- BACE Remote Testing Procedures
- <u>Candidate Information Bulletin</u>



Candidate Enrollment Process

 Unique candidate enrollment links emailed to Site Coordinators

During first login, candidates create an account by:

- Registering through an existing external identity (Gmail, LinkedIn, or Facebook)
 - Provide Name, Birthdate, email address, phone number
 - Verify email address
- Free Practice Exam
- BACE Knowledge Exam



Fee Structure & Testing Window

- The BACE is now available year round (excluding holidays). All Exams and Exam Retakes must be completed by the end of each calendar year.
- 1st Attempt (includes Knowledge and Practical Exams)
- Knowledge Exam 2nd Attempt
- Practical Exam 2nd Attempt
- Knowledge Exam 3rd Attempt
- Practical Exam 3rd Attempt

Includes materials for Practical Exam

\$150.00 \$25.00 \$25.00 \$25.00 \$25.00



BACE Results: Program Growth and Passing Rate

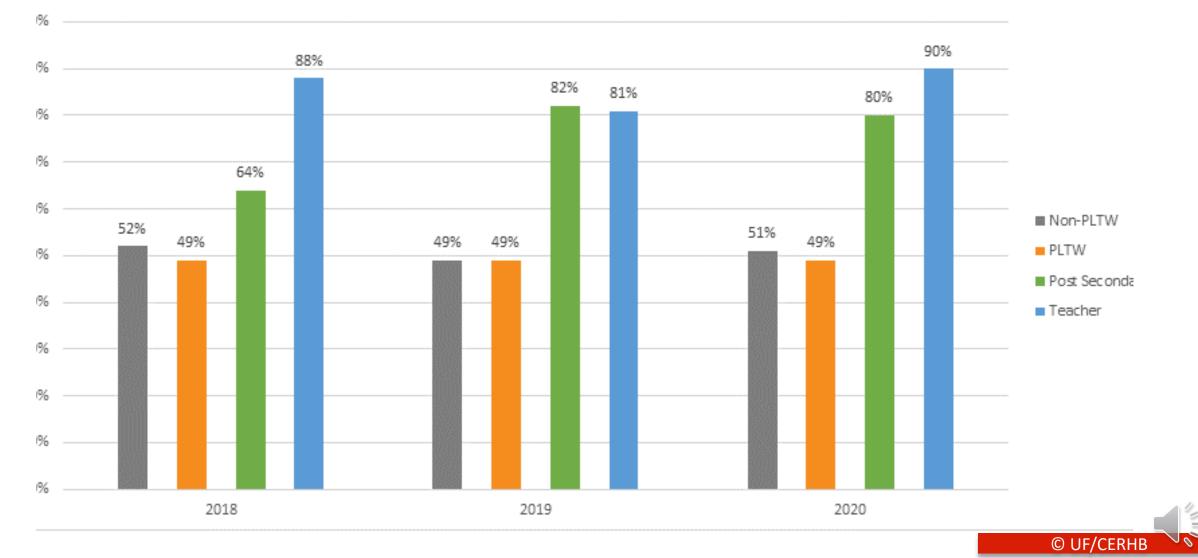
| Year | Participating Sites | Candidates | Passing Candidates | Passing Rate |
|------|---------------------|------------|--------------------|--------------|
| 2012 | 5 | 55 | 38 | 69% |
| 2013 | 7 | 100 | 63 | 63% |
| 2014 | 17 | 338 | 182 | 54% |
| 2015 | 26 | 417 | 286 | 69% |
| 2016 | 32 | 592 | 373 | 63% |
| 2017 | 50 | 1063 | 638 | 60% |
| 2018 | 60 | 1236 | 639 | 52% |
| 2019 | 80 | 1461 | 728 | 50% |

*2020 outcomes are in the process of being finalized. Pass Rate to date is 51%



BACE Pass Percentage Results

Program Passing Rate by Year



1

Instructor Professional Development

Industrial Biotechnology Teacher Experience (IBTE)

- Provides experience with the skills, techniques, and knowledge within context of working in the industry.
- Design, development, testing, and manufacture of a biopharmaceutical product.
- Participants develop an understanding of the departmental roles, careers, and criteria associated with working in this highly regulated environment.

Know Your ABCS: Applications of Biotechnology for the Classroom

- Presents multiple interactive modules for use in the classroom
- Dengue outbreak in Key West, Florida (2009). Participants perform clinical tests and take on role of diagnostic laboratories.
- Overview of bacteriology and proteomics, covering:
 - Aseptic technique
 - structure and function of proteins, using SDS-PAGE and mass spectrometry.
- Practice working in a regulated environment.

Contact Information

Tamara Mandell, M. Ed. (Director) <u>tmandell@cerhb.ufl.edu</u> (386) 462-6397

Lisa Mrozinske (Credentialing Specialist) Imronzinske@cerhb.ufl.edu

Houda Pruitt, Ph.D. (Senior Training Specialist) hpruitt@cerhb.ufl.edu

Stephanie DeMarco, M.Ed. (Educational Support Specialist) <u>demarcos@cerhb.ufl.edu</u>

Biotility website http://biotility.research.ufl.edu

THANK YOU!!!

