

National Career Pathways Network Conference October 15-16, 2020

### **Credentialing and Careers** in the Bioscience Industry



Biotechnician



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#### 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

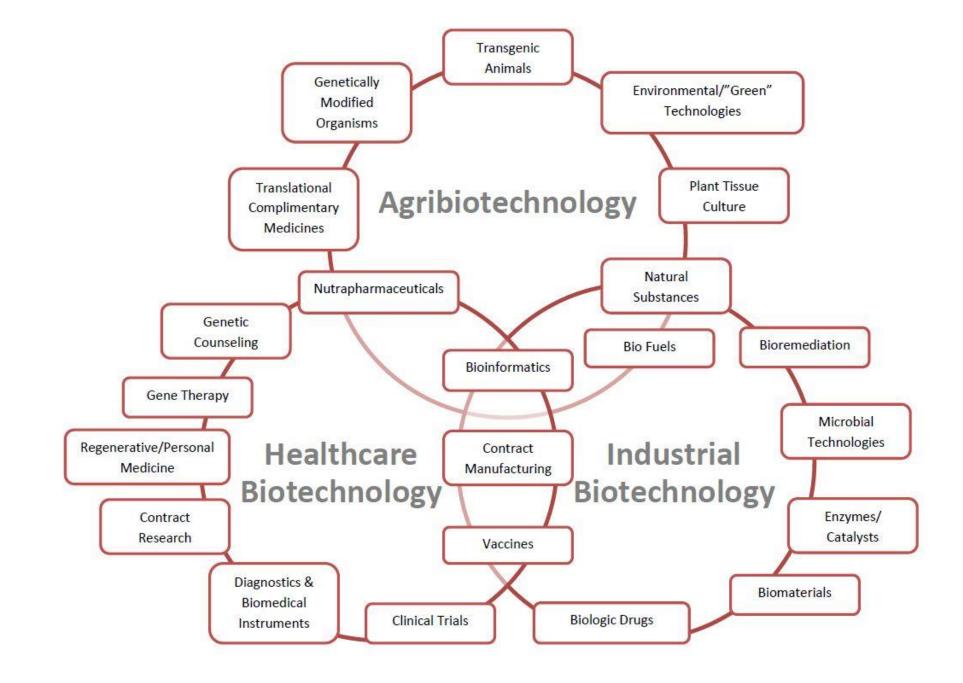
**Biotech II** #3027020 Transformation Culture Scale-up **Recombinant Proteins Production of Proteins** Protein Quantification Filtration & Purification ELISA PAGE Immunoblotting PCR Assay Development Quality Control Quality Assurance **Regulatory Affairs Product Marketing** 

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**

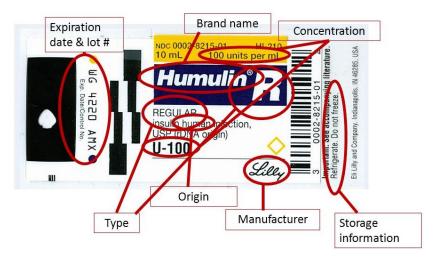
- Process Development
- Quality Control Asst./Assoc.
- Quality Assurance Asst./Assoc.
- Validation Specialist
  - Research Asst./Assoc./Scientist

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### **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/

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### **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** 

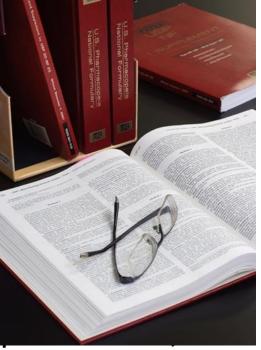






### **Quality Assurance**

- 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

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### **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**

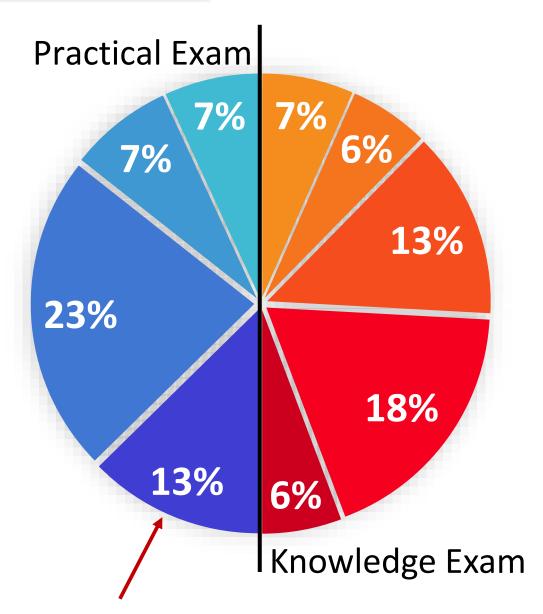
- Identify Safety Symbols
- Laboratory Safety Protocols/Handling Waste
- Using Safety Data Sheets (SDS)
- Personal Protective Equipment (PPE)
- Proper Labeling
- Regulatory Compliance, Documentation

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Identify Acceptable Work Habits

### **2020 BACE Category Distribution: Percentage of Points Per Category**



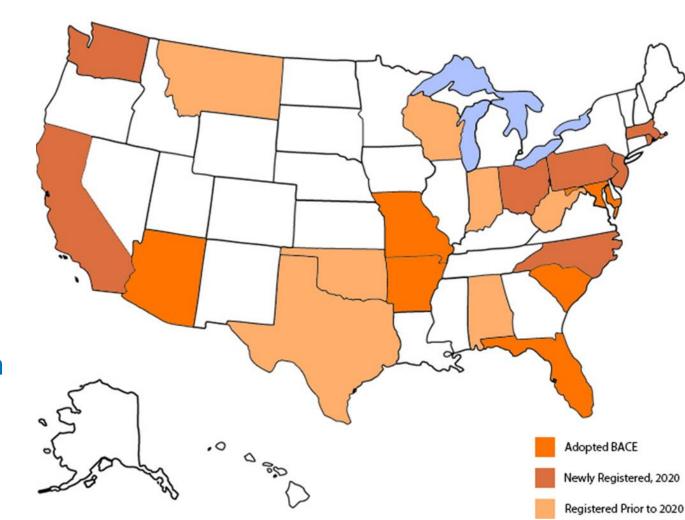
- 1.0 BIOCHEMISTRY/CHEMISTRY
- 2.0 BIOLOGICAL SYSTEMS
- 3.0 GENERAL TOPICS IN BIOTECHNOLOGY
- 4.0 LABORATORY SKILLS/APPLICATIONS
- 5.0 RESEARCH & SCIENTIFIC METHOD
- 6.0 Applied Mathematics in Biotechnology
- 7.0 Biotechnology Skills
- 8.0 Laboratory Equipment
- 9.0 Workplace Safety & Behavior



## **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

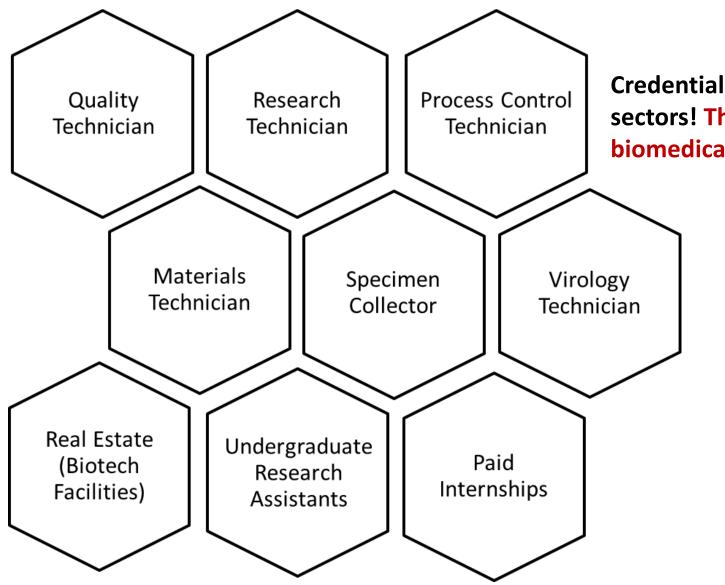
### **Credential Earner Employers**

- 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

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#### **Positions**



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

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### **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 20<sup>th</sup>, 2020 and is board-approved to July 15<sup>th</sup>, 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**

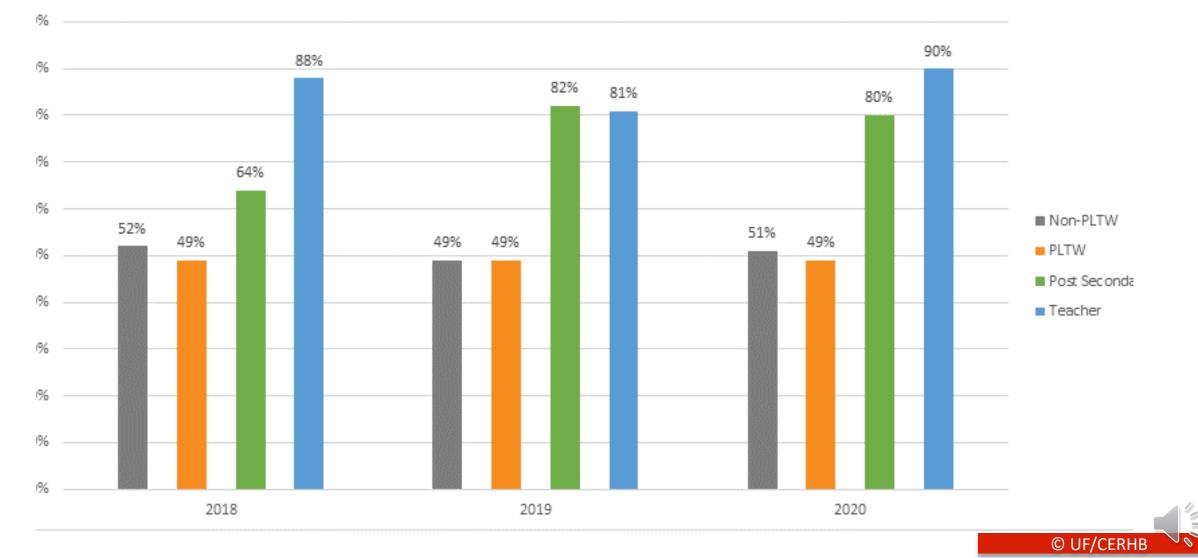
Year	Participating Sites	Candidates	Passing Candidates	Passing Rate
2012	5	55	38	69%
2013	7	100	63	63%
2014	17	338	182	54%
2015	26	417	286	69%
2016	32	592	373	63%
2017	50	1063	638	60%
2018	60	1236	639	52%
2019	80	1461	728	50%

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



#### **BACE Pass Percentage Results**

#### Program Passing Rate by Year



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### **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** 

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Biotility website <a href="http://biotility.research.ufl.edu">http://biotility.research.ufl.edu</a>

THANK YOU!!!

