

# Florida's Statewide Biotechnology Program of Study *Opening Doors to Careers in Biotechnology*

**National Careers Pathway Network  
October 2<sup>nd</sup>, 2009**

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# Overview

- What is Biotechnology?
- Careers
- Biotechnology Curricula
- Articulation
- Outcomes

# *Biotechnology*

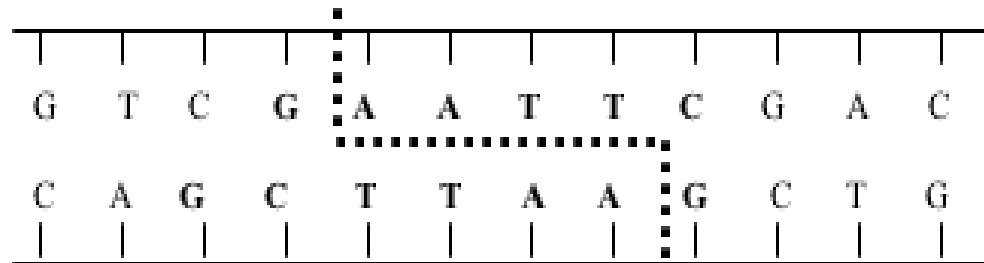
***Using processes that already exist in nature to make or create something new***

- Health Care
  - **Biopharmaceuticals**
  - Diagnostics
  - Medical Devices
- Agriculture/Aquaculture
  - Crop Yields
  - Pesticides
  - Fertilizers
- Waste Management
  - Wastewater Treatment
  - Bio-Remediation
- BioFuels
- Forensics

# Genetic Engineering

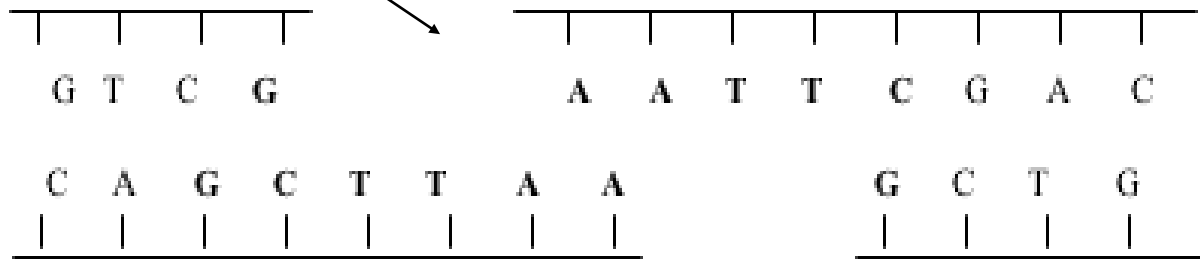
restriction enzyme *EcoR*1

DNA  
double  
helix



New DNA sequence goes here

DNA cut  
into  
fragments



New DNA sequence = New Protein

# The Power of Biotech



[http://www.nbsc.com/bioflopro\\_cc.aspx](http://www.nbsc.com/bioflopro_cc.aspx)

- Human gene for insulin
- Expression system
  - Humalog (E.coli)
  - Novolin (Yeast)



[http://www.humalog.com/patient/humalog\\_insulins.jsp](http://www.humalog.com/patient/humalog_insulins.jsp)



<http://en.wikipedia.org>

# Biotechnology in the U.S.



Nature Biotechnology 23: 175-179; E+Y insert

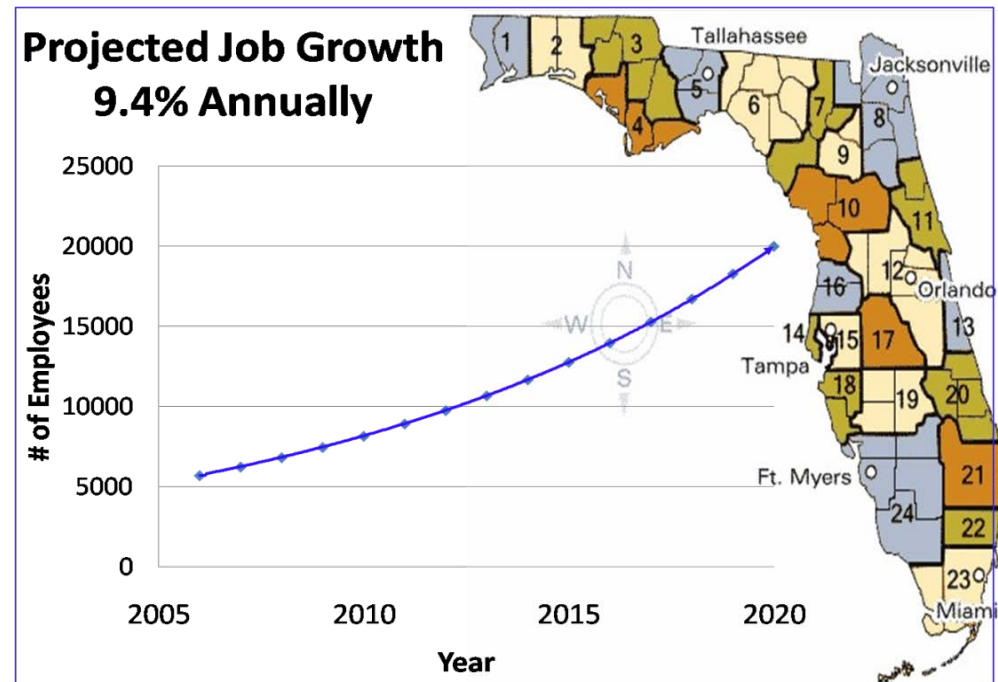
 Companies

 Investment

# Industrial Biotechnology in Florida

## Adding Value to Florida!

- ❖ UF's Center of Excellence for Regenerative Health Biotechnology
- ❖ Scripps Florida
- ❖ Torrey Pines Institute
- ❖ Max Planck Florida Institute
- ❖ Oregon Health & Science
- ❖ Burnham Institute
- ❖ Mann Research Center



# Job Opportunities!

- **Research & Development**
- **Manufacturing**
- **Quality Control (QC)**
- **Quality Assurance (QA)**
- **Regulatory Affairs**
- **Facilities**
- **Business**
  - Market analysis, Sales, Advertising, Bus. Development
- **Administration**

# Research & Development (R & D)

Finding/developing a product with commercial value.

- Develop processes to make the product
- Determine raw materials and equipment required & establish their specifications
- Develop plan for production of the product
- Characterize the properties of the product
  - Composition
  - Effect, strength, potency, purity, safety
  - Stability & shelf life
  - Product applications
- Establish product specifications
- Develop methods to test the product



# Manufacturing/Production Unit

- Responsible for making the product
  - Operating equipment
  - Preparation of supporting materials
  - Routine production environment control
  - Monitoring processes associated with making the product
  - Implementing corrective actions in the event of a problem
  - Routine calibration & maintenance of equipment
  - Completing forms, labeling, filling in logbooks, maintaining other required documents



# Manufacturing/Facilities

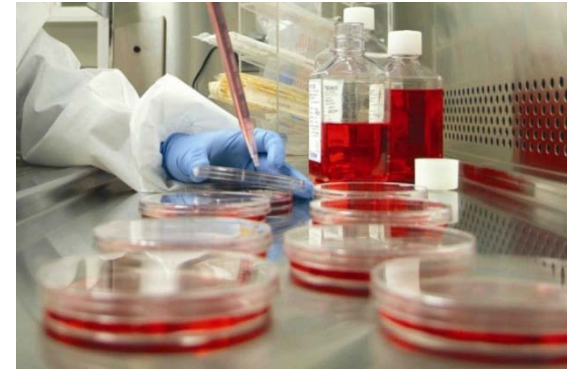
- Engineering (Facilities Management)
  - Proper operation of building systems
  - Proper installation/operation of large equipment
- Facility Maintenance & Housekeeping
  - Maintenance & repair of equipment & facility
  - Calibration
- Receiving and Shipping
  - Insure proper routing of incoming raw materials
  - Finished products go to proper destination



# Quality Control

## Demonstrate Product Safety

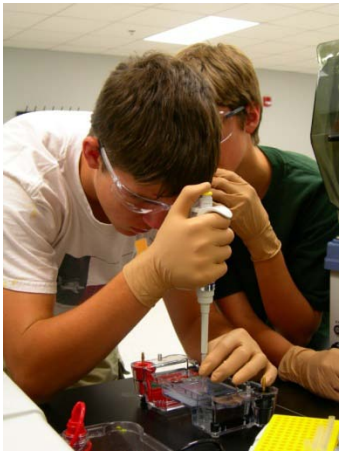
- Characterize product
  - Test samples of the product and materials used to make product
- Demonstrate product lot consistency
- Demonstrate product stability
  - Historical
  - Concurrent with clinical trial
- Environmental Monitoring



# Quality Assurance

- **Oversight – ensure compliance with GMPs, GLPs, GCPs**
  - Review and Approve all Records, Reports, written procedures, specifications
  - Audit methods, results, systems and processes
  - Store, prepare and issue documents
  - Training oversight
  - Vendor Qualification & Inspections
  - Validation plans
  - Review customer complaints
  - ❖ Ultimate authority to release/reject raw materials and product lots





# Career Options



## Entry Level

- Process Technician
- Manufacturing Prep Technician
- Formulation/Fill Tech
- Packaging Technician
- Instrument/Calibration
- Environmental Tech

## Plus Education/Experience

- Process Engineer
  - Development & Manufacturing
- Quality Control Asst./Associate
- Quality Assurance Asst./Associate
- Validation Specialist
- Maintenance Engineer
- Environmental Engineer
- Research Asst./Associate

# Manufacturing Technician

## **JOB REQUIREMENTS:**

- Prepare solutions, culture media and equipment for use
- Document data in batch records
- Work in clean room
- Monitor/maintain equipment during production.
- Assist in facility and equipment cleaning.
- Assist in reviewing batch records and SOPs as necessary.
- Assist in the generation of SOPs, production batch records

# Manufacturing Technician

**Qualifications:** (0-2) years experience in laboratory or manufacturing, detail-oriented, strong written and verbal communication skills, ability to work independently, within prescribed guidelines, or as a team member. In addition, he/she will have the ability to follow detailed directions in a laboratory/manufacturing environment. Entry level requires a HS Diploma and some experience with basic lab techniques such as filtration, glassware washing, micropipetting, pipetting, reagent preparation and weighing, or an A.S. degree from a Biotechnology program.

- Salary Range: \$28,000-\$40,000 based on education and experience

# Quality Control Associate

## JOB REQUIREMENTS:

- Perform **gel electrophoresis** and data analysis on Manufacturing and stability samples including drug product, drug substance, and intermediates
- Perform **PCR** to test for residual DNA on drug substance
- Provide analytical support to Manufacturing and Development, as needed
- Perform **ELISA** tests on products and Clinical Research samples
- Analyze data for documentation and reporting of test results
- Maintain documentation for regulatory compliance

# Quality Control Associate

## Qualifications:

- A.S. degree in Biotechnology, or B.S. in Biology or Chemistry
- 2-5 years of experience in a Pharmaceutical (Biologics), Biopharmaceutical, and/or Biotechnology environment
- Prior training in current Good Manufacturing Practices (cGMP) and experience working in a cGMP environment is a plus
- Solid organization and written skills
- Ability to work independently as well as an part of a cohesive team

**Salary Range:** \$30,000-60,000 per year, depending on education and experience

# Assay Development Scientist

## **JOB REQUIREMENTS:**

- Assay development including real-time PCR, cell-based assays, ELISA, and gel electrophoresis
- Assay Validation
- Testing samples to support process development and preclinical studies
- Documentation and assay transfer to Quality Control Labs
- Monitoring of and support to Quality Control Laboratories
- Interface with QA and regulatory personnel to ensure product compliance
- Manage the transfer of validated assays from early R&D to product development
- Technical report writing

# Assay Development Scientist

## Qualifications:

- Ph.D. in biochemistry or other life science field with functional knowledge in biochemistry, immunochemistry, infectious diseases and microbiology.
- Significant assay development experience in the field of in-vitro diagnostics
- At least 5 years work experience including experience in a cGMP environment is required.
- Strong laboratory and organizational skills, capability for independent problem-solving as well as teamwork, and excellent communication skills are essential. Technology transfer experience would be a plus.
- Salary Range: \$75,000.00 to \$100,000.00 annually

# UF CERHB Complementing Programs



*Industrial Biotechnology*

- Develop & deliver curricula for industrial biotechnology training
- Ensure programs within educational institutions are relevant & meet industry's needs & standards
- Promote economic development in biotechnology industry
- Curricula for a 3-year high school Program/ Academy
- Curricula for an A.S. degree in Industrial Biotech
- Articulation between high school and community college courses
- Teacher Training/Prep

# UF's Center of Excellence for Regenerative Health Biotechnology



- Thank you to our Partners!
  - Collaborating Institutions
  - Government Partners
  - University of Florida Partners
  - Florida Educational Partners
  - Florida Industry Partners



# Process

- Advisory Council
  - Industry Leaders
  - Workforce Boards
  - Economic Development Agencies
- Industry Focus Groups
  - Statewide, to assess regional hiring & training needs
- Needs Assessment/Pipeline Study
- Developed and Implemented Curricula

# High School Industrial Biotechnology I, II, III

- Added to the FL DOE Course Code Directory (Dec. 2006)
- Comprehensive sequence covering skills used by industrial, medical, agricultural and research facilities
- Students earn 0.5 ea of Academic **and** CTE credit for Biotech I & II
  - 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

# Program Overview

## 8736000

### **Biotech I**

# 3027010

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

### **Biotech II**

#3027020

Transformation  
Culture Scale-up  
Recombinant Proteins  
Production of Proteins  
Protein Quantification  
Filtration & Purification  
ELISA  
PAGE  
Western/Southern Blot  
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  
biotechnology-based  
industry and utilizing  
industry partners



# Gold Seal Scholarship

## Special Course Equivalencies

Biotechnology I (3027010) or Biotechnology II (3027020) will earn:

- 0.5 science credit for the Gold Seal Vocational Scholars award and the grade can be calculated in the academic GPA; and
- 0.5 practical arts credit for the Gold Seal Vocational Scholars award, and the grade can be calculated in the academic GPA; and

Students may also use the course to satisfy one credit of the vocational program completion requirements for the Gold Seal Vocational Scholars award, and the grade can be calculated in the vocational GPA.

**3 vocational credits in one vocational program:**

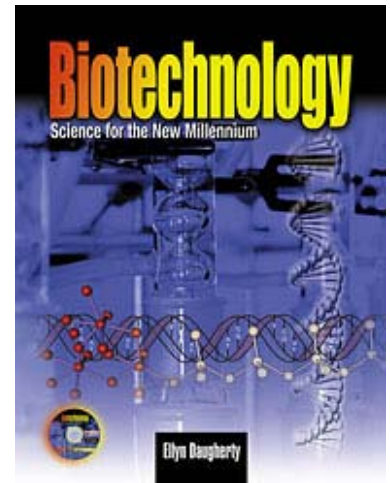
- **Biotechnology Technician (Program 8736000)**

<b>Biotechnology 1</b>	<b>3027010</b>	<b>.5 sci/.5 voc</b>	<b>1.0 credit</b>
<b>Biotechnology 2</b>	<b>3027020</b>	<b>.5 sci/.5 voc</b>	<b>1.0 credit</b>
<b>Biotechnology 3</b>	<b>8736030</b>	<b>1.0 vocational</b>	<b>1.0 credit</b>

**3.0 credits**

- Courses **not** used in Florida Academic or Medallion Scholars award evaluations.
- NOTE: The student will receive only one credit each for Biotechnology I (3027010) and/or Biotechnology II (3027020) for graduation purposes.
- <file:///U:/Academy%20Curriculum/Credit%20for%20Bright%20Futures%20Program.htm>

# Text Book



## © “Biotechnology: Science for the New Millennium”

› Elyn Daugherty

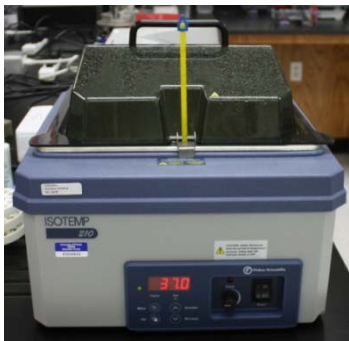
- Biotech I: Chapters 1-4, 10,11,13
- Biotech II: Chapters 5-9, 12,13,14
- Paradigm Publishers
- Bruce Ayscue [bayscue@emcp.com](mailto:bayscue@emcp.com) (770) 822-5653

# Start Up Cost

Power supply unit  
Electrophoresis  
chambers  
Micro-centrifuges  
Protein gel boxes  
Vortexer  
Water bath  
Rocking platform  
Thermal cycler (PCR  
Machine)

Incubation oven  
pH Meter  
Spectrophotometer  
Centrifuge  
Balance  
10 2-20ul micropipets  
10 20-200 micropipets  
10 100-1000 micropipet

\$20,000+



# Teacher Certification -Emerging Industry



- District Certification Program – Banner Center
  - 80 hour (2-week) “Industry Experience” Workshop
  - Provides industry experience in the context of the HS curriculum, including preparative steps
- Master’s Program (Graduate Certificate)
  - UF CPET’s HHMI funded “Interdisciplinary Center for Ongoing Research/Education”
    - 12 Credits: 3 credits/2 wk summer program, 3 credits/advanced workshops, 6 credits on-line

# Florida's Biotechnology Articulation Consortium (FBAC)

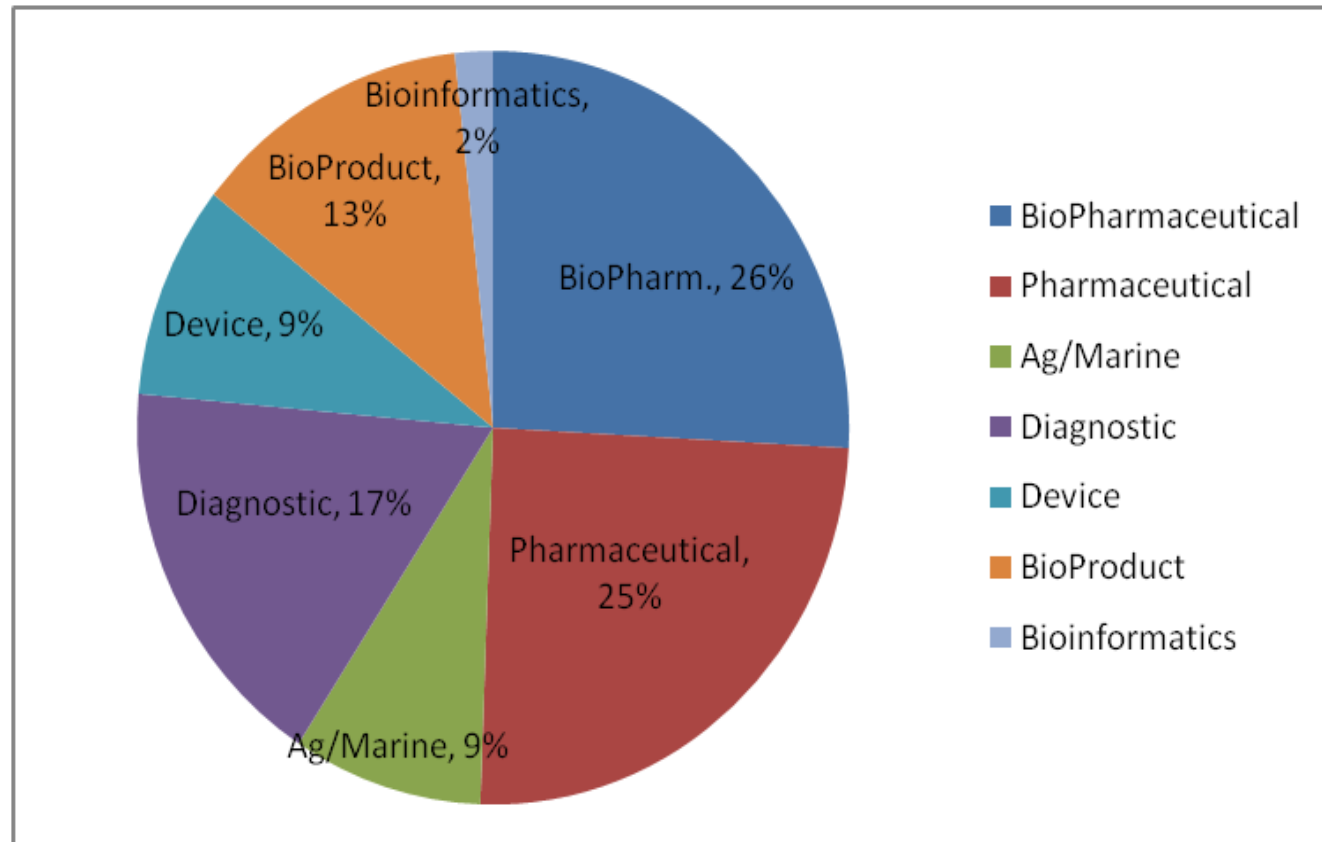
- Awarded a two-year grant by the US Department of Education's Office of Vocational and Adult Education (OVAE)
- Develop and promote a rigorous program of study through the implementation of a statewide articulation agreement (secondary to associate degree) the area of Biotechnology

# Phase I - Research

- Analysis of current and emerging occupations in biotechnology
- Identification of foundational knowledge and skills applicable to broad range of biotechnology-based occupations
- Review existing core competencies in secondary/post-secondary curricula

# Florida's Industrial Biotechnology by Classification

FBAC identified 174 companies, up 25% from Banner Center survey in 2007  
Over 50% are in Start-up or Growth Phase



# Employee Education Level

**Figure 5:  
Current Employee Education Level**

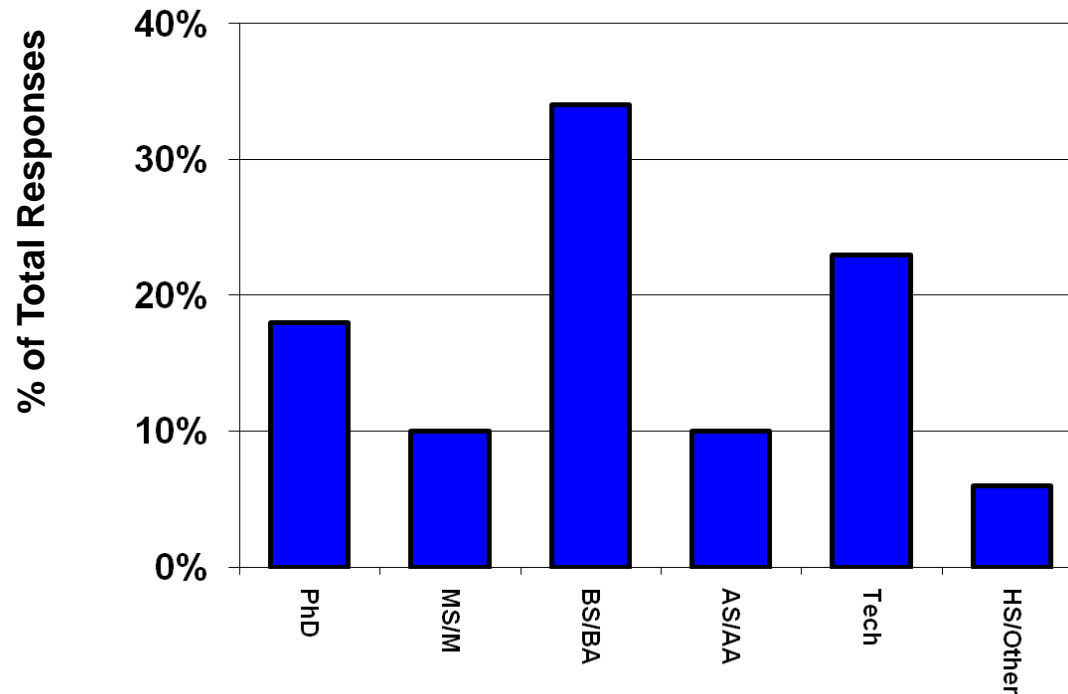
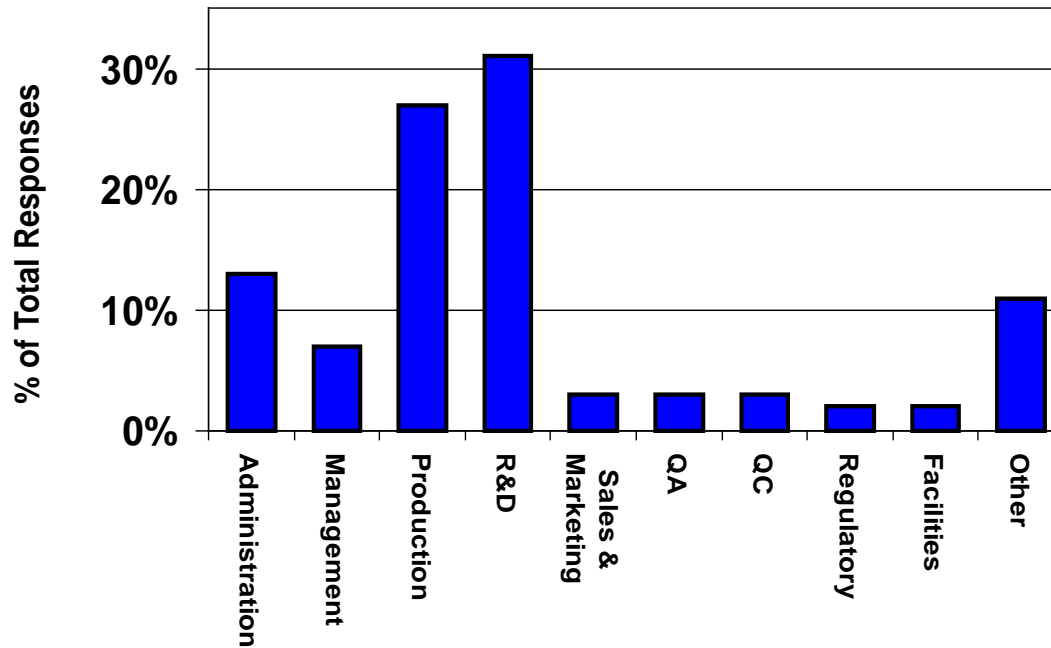


Figure 5: We asked companies to report the number of employees in each education level. Not all companies could respond for all employees in their companies. The percent is not of the total employees, but the total number of employees that they were able to classify.

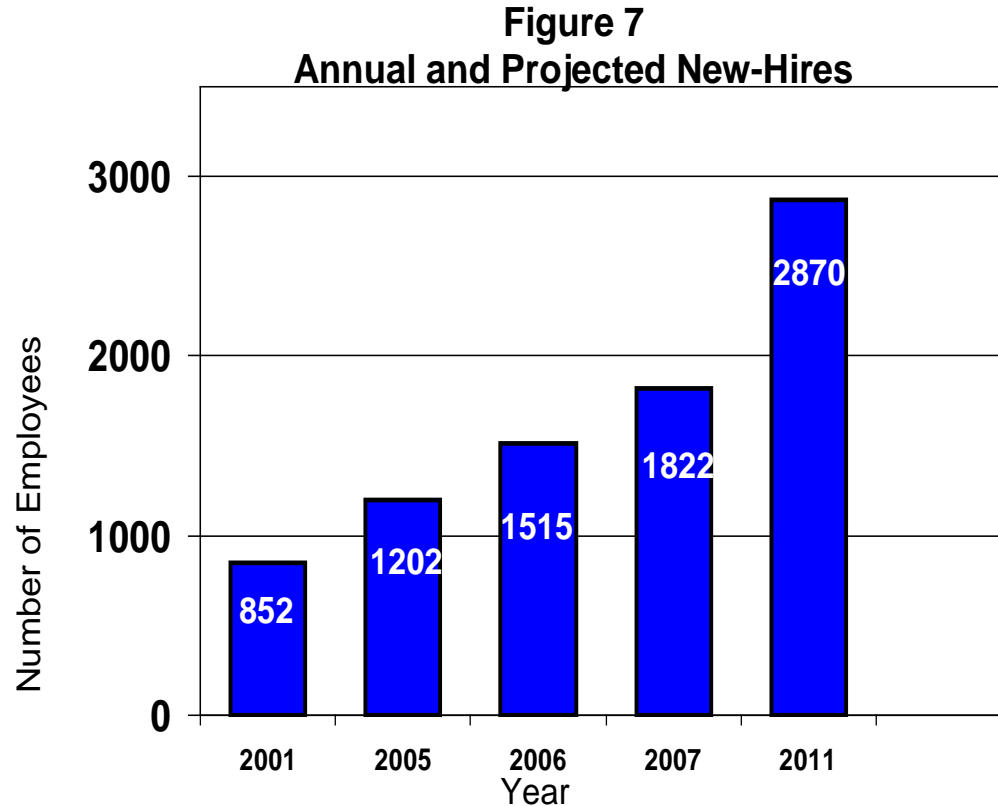
# Distribution by Job Type

**Figure 6:  
Current Workers by Job Type**



Companies were asked to give the number of employees for defined job types. Not all companies could respond and in some companies, employees have overlapping duties. The percent is not of the total employees, but the total number of employees that they were able to classify.

# Career Opportunity Growth



The 2006 value is based on the total number of employees stated by the companies. We asked companies how many employees they had hired in the last year, and last 5 years, then subtracted that number from the total current employees to derive the 2001 and 2005 values. We asked companies to predict how many new employees would be hired in the next year, and next 5 years, then added that number to the total 2006 employee number to derive the 2007 and 2011 values.

# Prioritized Positions

- Entry-level
  - Laboratory Technician, Quality Control Technicians, Quality Assurance Technicians, and Bioinformatics Technicians
- Mid-level
  - Quality Control and Quality Assurance personnel
- Senior-level
  - Senior Scientists for Process and Assay development, Manufacturing, and Regulatory Affairs

# Alignment of Standards (Performance, Next Generation Sunshine State, National) to Industry

1. History, Career Fields, Benefits of Biotech
2. **Safety** Procedures
3. Quality Control and Regulatory Guidelines
4. Communication/Interpersonal Skills
5. Scientific Inquiry, **Calculations**, Analysis
6. Organism Structure & Function
7. Materials Processing/SOP's for Biotech
8. Biotech Materials Analysis
9. Basic Chemistry Applied to Biotech Procedures
10. Microbiology and Blood Borne Diseases
11. **Legal** and Ethical Responsibilities
12. Literacy and Computer Skills applied to Biotech
13. Employability Skills

# Post-Secondary Biotechnology Alignment

- Comparison of standards to post-secondary program Biotechnology courses
  - Syllabi, course descriptions, Florida's SCNS, Instructor communications
- Introduction to Biotechnology
  - FSCJ, IRSC, SFC, TCC = BSC 1421
  - PBC = BSC 2421
- Introduction to Biotechnology Methods (Lab)
  - FSCJ, SFC, TCC = BSC 1404C
  - IRSC = BSC 1421L
  - PBC = BSC 2421L

# Academic Course Alignment

- Validation of secondary/post-secondary standards
  - Ensure consistency at each level
- Alignment of secondary/post-secondary programs
- Course Analysis (LA, Math, Science, Social Studies)
  - For inclusion into POS, additional post-secondary credit, and ensure success at post-secondary level

## Accelerated Credit Options

Secondary Course	Score	Post-Secondary Course	Credit	
<b>Credit by Exam</b>				
AP Biology	4,5	BSCX010C Principles of Biology I & Lab	4	4
AICE Biology A-Level	A-E	BSCX010C Principles of Biology I & Lab	4	
AP Chemistry	4	CHM1045C General Chemistry 1 & Lab	4	4
AP Chemistry	5	CHM1046C General Chemistry 2 & Lab	4	
AICE Chemistry A-Level	A-E	CHM1045C General Chemistry 1 & Lab	4	
AP Eng. Composition	3,4,5	ENC1101 College Composition 1	3	3
AICE English A or AS Level	A-E	ENC1101 College Composition 1	3	
CLEP, English Composition		ENC1101 College Composition 1	3	
AICE Psychology AS level	A-E	PSYX012 Introduction to Psychology	3	3
AP Statistics	3,4,5	STAX023 Statistics	3	3
CLEP, College Algebra	50	MACX105 College Algebra	3	3
CLEP Precalculus	50	MACX140 Precalculus	3	
<b>Dual Enrollment/Articulation</b>				
Biology		BSCX010C Principles of Biology I & Lab	4	4
Chemistry		CHM1045C General Chemistry 1 & Lab	4	Counted Above
English		ENC1101 College Composition 1	3	
Math		MAC105 College Algebra	3	
Math		STAX023 Statistics	3	
Introduction to Biotechnology		Introduction to Biotechnology & Lab	4	4
Total Accelerated Credits Possible				28

## **2009 FL Statute Title XLVIII, Chapter 1007 Articulation and Access (1007.271)**

- Demonstrate readiness for college-level coursework to enroll in college courses, and readiness for career-level coursework for enrollment in career courses.
- Common placement examination
- 3.0 un-weighted GPA for enrollment in college credit dual enrollment courses
- 2.0 un-weighted GPA for enrollment in career certificate dual enrollment courses

# Secondary POS Recommendations

## Program Entrance

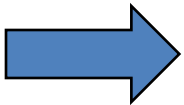
- Entrance Requirements
  - Letters of Recommendation
    - Math Teacher
    - Science Teacher
  - Minimum GPA of 2.0
  - FCAT score of 3 or higher
- Pre/Co-Requisite
  - Algebra I (8<sup>th</sup> or 9<sup>th</sup> grade)
  - Biology (ninth grade)
  - Chemistry (10<sup>th</sup> grade)

## Program Completion

- Minimum Maintained GPA
  - Biotechnology 3.0
  - Overall 3.0
- Completion
  - Above requirements met
  - Grade of “B” or higher on industry-recognized exam for certification

# Articulation

- Alachua & Marion Counties w/Santa Fe College Biotechnology Program, and St. John's county w/Florida State College Jacksonville
    - Grade of “B” or higher in Biotech I and 2
    - Score 80% or higher on comprehensive exam
- Credit for “Intro. to Biotechnology Methods” (3), and  
“Intro. to Biotechnology” (1)



# In-Progress

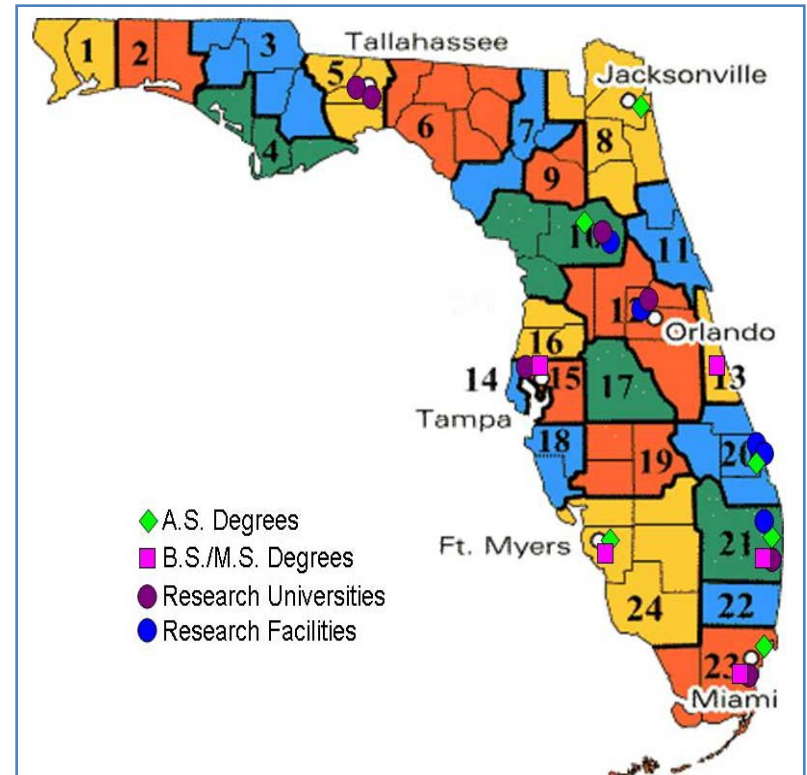
- Industry Certification
  - The Florida Career and Professional Education (CAPE) Act
- Development of rubric for comprehensive exam/practical skills
- Mechanism for credit transfer, maximum credits, admission requirements, etc.

# Growth & Dissemination

- **Alachua County, Santa Fe HS Science Academy for 2008/09**
- **Marion County, North Marion HS**
- **St. John's County, Ponte Vedra High School Academy of Biotechnology and Medical Research**
- **Palm Beach County, Seminole Ridge HS**
- **Palm Beach County, Palm Beach Lakes HS**
- **Palm Beach County, Spanish River HS**
- **Putnam County, Interlachen HS**
- **Seminole County, Lake Brantley HS**
- **Polk County, Lake Gibson HS,**
- **Pinellas County**
- **Brevard, Columbia, Levy, & St. Lucie Counties**
- **A total of 620 students and growing**
- **First program graduates in 2010**

# Statewide Articulation

Santa Fe College, Gainesville  
Florida State College Jacksonville  
Hillsborough Community College  
Palm Beach College, Palm Beach  
Miami-Dade College, Miami  
Indian River State College,  
Ft. Pierce  
Seminole CC (Dual Enrollment)  
Tallahassee (complete at SFC)



# Thank you!

## **University of Florida**

Dr. Richard O. Snyder (PI)

Dr. Mary Jo Koroly

Lori Wojciechowski

## **Santa Fe College**

Dr. Linda Nichols

Dr. Kelly Gridley

## **Florida State College Jacksonville**

Dr. Kathryn Birmingham

Dr. Kevin Pegg

## **Indian River State College**

Dr. Henri Sue Bynum

Dr. Robin Willoughby

## **International Society**

### **for Pharmaceutical Engineers**

Beth Potter

Ali Montes

## **Alachua County School District**

Dr. David Edwards

Bill Herschleb

June Camerlengo

## **Marion County School District**

Dee Reedy

Jill Stephens

## **Palm Beach County School District**

Fred Barch

Lynn Slygh

Tom Hession

## **Florida Department of Education**

Kathleen Taylor

Loretta Costin

Eric Owens

## **Banner Center for Career Academies**

Dr. Frank Fuller