

# Biotechnology Department

## DEGREES:

Biomanufacturing (BS)

Industrial Biotechnology (AS)

## CERTIFICATES OF ACHIEVEMENT

Industrial Biotechnology

Biotechnology Laboratory Assistant

Stem Cells and Cell-Based Technologies

## COURSES:

BIOT (Biotechnology)

## CONTACT INFORMATION:

School of Mathematics and Sciences

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## P.A.C.E. - SCIENCE, TECHNOLOGY, ENGINEERING, AND MATHEMATICS - A PATHWAY FOR ACADEMIC AND CAREER EXCELLENCE AT SOLANO COMMUNITY COLLEGE

### ARE YOU THE KIND OF PERSON WHO...

- ...desires to observe, learn, analyze, evaluate, or solve problems?
- ...enjoys to question and explore physical or biological happenings?
- ...likes to work hands-on with objects, machines, tools, plants, or animals?
- ...is interested in math and/or thinking analytically to solve complex problems?

## P.A.C.E. - INDUSTRIAL AND APPLIED TECHNOLOGY - A PATHWAY FOR ACADEMIC AND CAREER EXCELLENCE AT SOLANO COMMUNITY COLLEGE

### ARE YOU THE KIND OF PERSON WHO...

- ...desires to work hands-on with objects, machines, tools, plants, or animals?
- ...enjoys work and play outside, including use your physical or athletic abilities?
- ...likes to follow directions to organize, plan and complete a project or task?
- ...is interested in attaining employment as soon as possible?

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## **Biomanufacturing**

*Bachelor of Science (Baccalaureate)*

Solano Community College is one of fifteen community colleges in the state of California to offer a pilot four year, or baccalaureate, degree. Solano Community College's degree is a Bachelor of Science in Biomanufacturing. In biomanufacturing scientists develop techniques to grow genetically engineered cells (bacterial, yeast, or animal cells) in large tanks called bioreactors and develop methods to purify the protein that the cells produce. Then technicians use analytical techniques to prove the purity of the isolated protein. In the future Biomanufacturing will be expanded to include the industrial production of biofuels, biomaterials, stem cells, and other products currently manufactured using chemical rather than biological techniques.

### **Program Description**

The Biomanufacturing program builds upon the Associate in Science in Industrial Biotechnology. In the baccalaureate program students gain knowledge in biology, chemistry, engineering, statistics, quality, regulatory affairs, and business. Students use biomanufacturing laboratory facilities to gain process development skills. Many of the courses have been designed with curriculum that aligns with the requirements of certifications from professional organizations.

The Bachelor of Science is awarded upon successful completion of a total of 120 units that include 60 lower-division units and ten upper-division major courses, three upper division general education courses, and electives. All courses in the major must be completed with a minimum grade of C.

### **Program Outcomes**

#### **Technology:**

1. Identify and critically analyze two viable options for a biomanufacturing process. The critical analysis will include the technical, financial, and environmental impact of the two options as well as the identification of the benefits and disadvantages of each.
2. Produce a professional report and presentation representing their opinion regarding the advantages of selecting a specific biomanufacturing process.

#### **Quality:**

3. Demonstrate the skills needed to conduct an investigation and analysis of an Out of Specification deviation that occurred during a production step in the manufacturing of a pharmaceutical protein. The student will be able to determine the impact of the OOS deviation on the batch of protein.
4. Produce a written Corrective Action Preventative Action report in a format standard to the industry. The report will include evidence to justify their conclusions and action plan.
5. Demonstrate the ability to apply Quality by Design (QbD) principles (understanding of the product, the process, and the process control) as adopted by the U.S. Food and Drug Administration (FDA) to design a robust, stable, and controlled manufacturing process for a protein pharmaceutical that can be carried out under current Good Manufacturing Practices (cGMPs). This includes the ability to predetermine values and potential ranges of the critical quality attributes (CQAs) of the product and the critical material attributes (CMAs) of the materials. Students will also be able to determine which parameters would benefit from a Design of Experiments (DoE) approach for their optimization, and construct a strategy for experimental planning and data analysis.
6. Use a quality risk assessment approach to perform a criticality assessment to determine the Critical Process Parameters (CPPs) that would need to be monitored and controlled.

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## Program Requirements and Courses

The program has been designed to follow a cohort model: all students take all of the courses in order.

### REQUIRED COURSES

First Semester	Units	Third Semester	Units
BIOT 401 Biomanufacturing Process Sciences.....	5	BIOT 405 Emerging Biomanufacturing Technologies.....	3
BIOT 407 Advanced Topics in Quality Assurance and Regulatory Affairs.....	4	BIOT 406 Supply Chain and Enterprise Resource Planning .....	3
ENGL 400 Advanced Technical Writing: Writing in the Scientific Professions.....	3	BIOT 408 Six Sigma and Lean Manufacturing .....	4
		PHIL 400 Bioethics .....	3
Second Semester	Units	Fourth Semester	Units
BIOT 402 Design of Experiments for Biomanufacturing .....	4	BIOT 409 Methods in Quality Improvements, Investigations and Audits .....	4
BIOT 403 Design of Biomanufacturing Facilities, Critical Utilities, Processes, and Equipment.....	4	BIOT 410 Emerging Trends in Biomanufacturing Quality .....	3
BIOT 404 Bioprocess Monitoring and Control .....	5	BUS 400 Project Management .....	3
		<b>Total Units .....</b>	<b>48 Units</b>

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## Biomanufacturing Program Eligibility Requirements

The Biomanufacturing Bachelor of Science program admits students once per year in the fall. Eligibility requirements, application process, and related information is available online at <http://www.solano.edu/biomanufacturing>.

All of the following requirements must be met in order to apply to the Biomanufacturing program. For any questions about these items, meet with an Academic Counselor. For counseling information, please visit

<http://www.solano.edu/counseling/>.

1. Overall cumulative grade point average (GPA) of 2.5 for ALL college coursework.
2. Completion of, or current Spring semester enrollment in Biomanufacturing Program  
Prerequisites:  
*Courses must be completed with a minimum grade of C and with a combined GPA of 2.5*  
BIO 002 Cell and Molecular Biology .....- 3. Completion of lower division IGETC or CSU General Education Breadth.  
5  
3  
3  
4  
4  
5  
4
- 4. Applicants who have attended college outside the United States must have transcripts evaluated by a National Association of Credential Evaluation Services (NACES) approved independent agency, demonstrating equivalency to the Program Eligibility requirements (1, 2, & 3).
- 5. One Statement of Interest, submitted with your application, explaining why you are interested in the program. Topic below:  
  
Write a Statement of Interest that explains why you would like to complete the Bachelor of Science degree in Biomanufacturing. In this essay, state how your background in the prerequisite courses and/or any job experience has prepared you to succeed in this rigorous program. Emphasize your laboratory background. Include any life experience, special circumstances or barriers that you had to overcome while completing the prerequisite courses.
- 6. Submit unofficial Transcripts

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## Steps for Completing the Application Process

### 1. New or Returning Solano Community College Students apply to SCC

*(Students currently enrolled in classes go to Step 2)*

- a. Students who have never attended Solano Community College or are former students (returning SCC students who are not currently enrolled in classes) must submit a current SCC application for admission. Access the SCC home page, [www.solano.edu](http://www.solano.edu), and click on the yellow "APPLY NOW!" button.
- b. After submitting the SCC application for admission, via CCCApply, allow 30 minutes for processing. An email will be sent to the email address provided in the application and will include the applicant's SCC ID number, username and password for their MySolano account. When completing a new application to Solano, if the applicant previously had an ID number, the system will re-activate that same ID number. The applicant will need their SCC ID number to complete the Biomanufacturing application.

### 2. Complete the Biomanufacturing Program Application

- a. The applicant must have their SCC ID number, unofficial transcripts (official transcripts will be required upon acceptance into the program), and Statement of Interest ready.
- b. All required information for admission to the Biomanufacturing Program must be submitted through the link provided on our webpage.

### 3. Once Biomanufacturing Program Application is Submitted

- a. All correspondence regarding the application status will be sent to the email address provided on the application. Applicants will not receive any paper or phone verification regarding their status. The applicant must update their information in MySolano if there is a change in email address.
- b. New student applications for fall semester enrollment will be evaluated beginning March 31st of each year. Incomplete applications will NOT be accepted.

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## Accepted Applicant Requirements

1. Once accepted to the Biomanufacturing program one original official transcript in a sealed envelope from each institution attended, including Solano Community College, must be submitted to the Office of Admissions and Records, prior to being granted permission to enroll and register for classes in the program.

Please send transcripts from institutions from within the US to :

**Solano Community College**

**Admissions and Records**

**Attn: Biomanufacturing Baccalaureate Admissions**

**4000 Suisun Valley Road**

**Fairfield, CA 94534-3197**

### **Foreign Transcripts:**

All foreign transcripts must be evaluated by a NACES agency for determining U.S. equivalency. **\*IF foreign courses were completed or degree earned**, the evaluation must state its equivalency to Program Eligibility requirements (1, 2, & 3). A list of approved agencies can be found in the Admissions and Records Office.

2. If the applicant received notification that they have been accepted into the program, a Biomanufacturing Admitted Student Information Session must be completed before their cohort program begins. A schedule will be made available through the School of Math and Science, Fairfield Campus.
3. Upon completion of the Admitted Student Information Session, the student must schedule an Advisement Session prior to registering for classes. Students will meet with an Academic Counselor to develop a Student Education Plan (SEP) during the Advisement Session.

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## Cost for Biomanufacturing Bachelor of Science Degree

Lower division courses (numbered 001-399/500+) cost \$46 per unit. Non-resident (out-of-state and International students) tuition fees cost \$304 per unit with an \$11.00 per unit nonresidential capital outlay fee.

Upper division courses (numbered 400-499) cost \$130 per unit. The additional fee for upper division units of \$84 cannot be covered by the California College Promise Grant (formerly BOG Fee Waiver).

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## Industrial Biotechnology

*Associate in Science*

### Program Description

This program prepares graduates to work in the biotechnology industry as production technicians. A production technician operates and maintains the equipment used to manufacture protein pharmaceuticals or other products. Students will grow bacterial, yeast, and mammalian cells and recover the proteins that they produce. They will follow good manufacturing practices by maintaining records in order to comply with quality assurance procedures and government regulations. Students in the program must be able to adjust their time to a flexible schedule.

The Associate in Science can be obtained upon completion of the 22-24 unit major, General Education, and electives as needed to complete a minimum of 60 units. All courses in the major must be completed with a minimum grade of C or a P if the course is taken on a Pass/No Pass basis.

### Program Outcomes

Students who complete the Industrial Biotechnology Associate in Science will be able to:

1. Explain how the structure and function of protein pharmaceuticals and evaluate which protein properties a production facility can exploit to purify a particular protein from other cellular components.
2. Construct a pathway analyzing how a drug or biologic is produced by genetically engineered cells and subsequently purified.
3. Explain how the manufacturer of pharmaceuticals is regulated by the Food and Drug Administration and other international regulatory agencies and how quality systems assure the safety, purity, identity, consistency, potency, and stability of a product.

<b>REQUIRED COURSES.....</b>	<b>Units</b>
BIOT 001 Principles of Biotechnology.....	3
BIOT 052 Business, Regulatory and Quality Practices in Biotechnology .....	3
BIOT 062 Cell Culture and Protein Recovery .....	4
BIOT 063 Biotechnology Instrumentation: Quality Control & Genetic Engineering.....	4
Select Option A or Option B .....	8-10
<b>Required Major Total Units.....</b>	<b>22-24</b>

<b>Option A .....</b>	<b>Units</b>
BIO 002 Principles of Cell and Molecular Biology.....	5
CHEM 001 General Chemistry I .....	5
<b>Option B .....</b>	<b>Units</b>
BIO 014 Principles of Microbiology .....	4
CHEM 010 Intermediate Chemistry.....	4

**NOTE: Prior knowledge and use of computers is advised, including word processing, spreadsheets, and databases.**

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## Industrial Biotechnology

### *Certificate of Achievement*

#### Program Description

This program prepares graduates to work in the biotechnology industry as production technicians. A production technician operates and maintains the equipment used to manufacture protein pharmaceuticals and other products. Students will grow bacterial, yeast, and mammalian cells and recover the proteins that they produce. They will follow good manufacturing practices by maintaining records in order to comply with quality assurance procedures and government regulations. Students in the program must be able to adjust their time to a flexible schedule.

The Certificate of Achievement can be obtained upon completion of the 18-24-unit major. Each course must be completed with a minimum grade of C or a P if the course is taken on a Pass/No Pass basis.

#### Program Outcomes

Students who complete the Industrial Biotechnology Certificate of Achievement will be able to:

1. Explain how the structure and function of protein pharmaceuticals and evaluate which protein properties a production facility can exploit to purify a particular protein from other cellular components.
2. In preparation to working at a biotechnology company, a successful student should be able to construct a pathway analyzing how a drug of biologic is produced by genetically engineered cells and subsequently purified.
3. Explain how the manufacturer of pharmaceuticals is regulated by the Food and Drug Administration and other international agencies and how quality systems assure the safety, purity, identity, consistency, potency, and stability of a product.

#### REQUIRED COURSES.....Units

BIOT 001 Principles of Biotechnology..... 3

BIOT 052 Business, Regulatory and quality Practices  
in Biotechnology ..... 3

BIOT 062 Cell Culture and Protein Recovery ..... 4

BIOT 063 Biotechnology Instrumentation:  
Quality Control & Genetic Engineering..... 4

Choose Option A, B or C ..... 4-10

**Required Major Total Units.....18-24**

#### Option A.....Units

BIO 002 Principles of Cell and Molecular Biology..... 5

CHEM 001 General Chemistry I ..... 5

#### Option B.....Units

BIO 014 Principles of Microbiology ..... 4

CHEM 010 Intermediate Chemistry..... 4

#### Option C.....Units

BIOT 160 Basic Concepts/Methods in  
Biotechnology ..... 4

**NOTE: Prior knowledge and use of computers is advised, including word processing, spreadsheets, and databases.**

This is a Gainful Employment Program. For additional information, please visit  
[http://www.solano.edu/gainful\\_employment/](http://www.solano.edu/gainful_employment/) and select "Industrial Biotechnology."

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## Biotechnology Laboratory Assistant

*Certificate of Achievement*

### Program Description

This program serves as a Bridge to Biosciences, enabling graduates to enter the Solano College Industrial Biotechnology program or to enter an entry level position in a biotechnology company. It serves as a stackable certificate that may be followed by the Industrial Biotechnology Certificate. A Laboratory Assistant may be hired by life science related companies to prepare buffers, prepare media, operate routine laboratory equipment, and to clean glassware.

The Certificate of Achievement can be obtained upon completion of the 14-unit major with a minimum grade of C or a P if the course is taken on a Pass/No Pass basis.

### Program Outcomes

Students who complete the Biotechnology Laboratory Certificate of Achievement will be able to:

1. Demonstrate the ability to perform routine laboratory techniques including buffer preparation, media preparation, and aseptic microbial culture.
2. Demonstrate the ability to perform mathematical (algebraic) operations required for calculations important in chemistry and biology.
3. Demonstrate the ability to read and write in a range of writing style categories typical of laboratory and scholarly environments, including lab reports, expository texts, and research-based arguments.

<b>REQUIRED COURSES.....</b>	<b>Units</b>
BIOT 160 Basic Concepts/Methods in Biotechnology ....	4
MATH 330 Elementary Algebra .....	5
ENGL 360 Focused English Fundamentals .....	5
<b>Total Units: .....</b>	<b>14</b>

This is a Gainful Employment Program. For additional information, please visit [http://www.solano.edu/gainful\\_employment/](http://www.solano.edu/gainful_employment/) and select "Biotechnology Laboratory Assistant."

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## Stem Cells and Cell-Based Technologies

*Certificate of Achievement*

### Program Description

This program trains students to enter the emerging fields of commercial stem cell production and other cell production technologies, such as CAR-T, cancer therapies, and other cell-based therapies.

The Certificate of Achievement can be obtained by completing the 24-29-unit major. All courses must be completed with a minimum grade of C or a grade of P if the course is taken on a Pass/No Pass basis.

### Program Outcomes

Students who complete the Stem Cells and Cell-Based Technologies Certificate of Achievement will be able to:

1. Apply knowledge of cell biology concepts to prepare and maintain cells in culture while maintaining sterility – stem cells must be able to be cultured in an undifferentiated state or induced to differentiate into different cell types.
2. Apply knowledge of the regulation of the Food and Drug Administration and other international regulatory agencies of cell-based therapeutic agents.
3. Follow the appropriate procedures to maintain controlled documents: In a research setting, students will keep a research laboratory notebook using a standard legal format. In a manufacturing setting, students will keep the appropriate controlled documents (batch production records) required to comply with current Good Manufacturing Practice

### REQUIRED COURSES ..... Units

BIOT 001 Principles of Biotechnology..... 3

BIOT 052 Business and Regulatory Practices in  
Biotechnology ..... 3

BIOT 057 Synthetic Biology and Algae Biotechnology .... 3

BIOT 060 Mammalian Cell Culture ..... 3

BIOT 061 Stem Cells and Cell-Based Technologies ..... 3

One course from Biomanufacturing List..... 1-4

One course from Biology List..... 4-5

One course from the Chemistry List ..... 4-5

**Total Units: .....24-29**

### Biomanufacturing: ..... Units

BIOT 062 Cell Culture and Protein Recovery ..... 4

BIOT 065 Biomanufacturing Fundamentals ..... 1

### Biology ..... Units

BIO 002 Cell and Molecular Biology ..... 5

BIO 014 Principles of Microbiology ..... 4

### Chemistry ..... Units

CHEM 001 General Chemistry ..... 5

CHEM 010 Intermediate Chemistry ..... 4

CHEM 012 Chemistry for the Health Sciences ..... 5

This is a Gainful Employment Program. For additional information, please visit  
[http://www.solano.edu/gainful\\_employment/](http://www.solano.edu/gainful_employment/) and select "Stem Cells and Cell-Based Technologies."