

# Bio manufacturing

## Bio manufacturing Bachelor of Science (Baccalaureate) Degree

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 Bio manufacturing. In bio manufacturing 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 Bio manufacturing 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 Bachelor of Science in Bio manufacturing program builds upon the Associate in Science in Industrial Biotechnology degree. In the baccalaureate program students gain knowledge in biology, chemistry, engineering, statistics, quality, regulatory affairs, and business. Students use bio manufacturing 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.

### Bachelor of Science Degree

The Bachelor of Science degree 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 bio manufacturing 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 bio manufacturing 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.

### 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
BIOT 401 Bio manufacturing Process Sciences .....	5
BIOT 407 Advanced Topics in Quality Assurance and Regulatory Affairs.....	4
ENGL 400 Advanced Technical Writing: Writing in the Scientific Professions .....	3

Second Semester.....	Units
BIOT 402 Design of Experiments for Bio manufacturing .....	4
BIOT 403 Design of Bio manufacturing Facilities, Critical Utilities, Processes, and Equipment .....	4
BIOT 404 Bioprocess Monitoring and Control.....	5

Third Semester .....	Units
BIOT 405 Emerging Bio manufacturing Technologies.....	3
BIOT 406 Supply Chain and Enterprise Resource Planning.....	3
BIOT 408 Six Sigma and Lean Manufacturing.....	4
PHIL 400 Bioethics .....	3

Fourth Semester.....	Units
BIOT 409 Methods in Quality Improvements, Investigations and Audits.....	4
BIOT 410 Emerging Trends in Bio manufacturing Quality .....	3
BUS 400 Project Management.....	3
<b>Total Units .....</b>	<b>48 Units</b>

# *Bio*manufacturing

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## **BIOMANUFACTURING BACCALAUREATE DEGREE PROGRAM APPLICATION/ACCEPTANCE REQUIREMENTS**

Currently the Bio*manufacturing* Bachelor of Science program admits students once per year in the fall. Applications are available online at [http://www.solano.edu/bio\*manufacturing\*](http://www.solano.edu/bio<i>manufacturing</i>).

### **Prerequisite:**

ALL of the following requirements must be met in order to APPLY to the Bio*manufacturing* Bachelor of Science degree program. If you are unsure about any of these items, please 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, the following prerequisites with a combined GPA of 2.5 and with no grade less than a C for each of the lower division courses: BIOT 001 (formerly BIOT 051), BIOT 052, BIOT 062, BIOT 063, CHEM 001, BIO 002.
3. Completion of lower division general education CSU/IGETC Option B or Option C program prerequisites (see SCC college catalog).
4. Students 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 above 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 Bio*manufacturing*. 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.

### **Transcripts:**

During the application process, unofficial transcripts may be submitted with the application. Upon admission to the Bio*manufacturing* Bachelor of Science degree program, you are required to submit one original official transcript in a sealed envelope to the Admissions and Records office from each college and university attended, including Solano Community College, prior to being granted permission to enroll and register for classes in the program.

Please send transcripts to:

**Solano Community College**  
**Admissions and Records**  
**Attn: Bio*manufacturing* 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 the Prerequisite requirements (1, 2, & 3) listed above. A list of approved agencies can be found in the Admissions and Records Office.

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## **Steps for Completing the Application Process**

- 1. New or Returning Solano Community College Students (Students currently enrolled in classes go to Step 2)**
  - a. Apply: 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 Application.
  - b. SCC ID number: After submitting your SCC application for admission, allow 30 minutes for processing. An email will be sent to the email address you provided in the application and will include your SCC ID number, username and password for your MySolano account. When completing a new application to Solano, if you previously had an ID number, the system will re-activate that same ID number. You will need your SCC ID number to complete the application.
- 2. Complete the Biomanufacturing Application**
  - a. Have your SCC ID number, unofficial transcripts, and your 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 Application is Submitted**
  - a. Email Account: All correspondence regarding the application status will be sent to the email address you provided on the application. Applicants will not receive any paper or phone verification regarding their status. Please notify the Admissions and Records office if you have 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.

## **Accepted Applicant Requirements**

1. If you received notification that you have been accepted into the program, a Biomanufacturing Admitted Student Information Session must be completed before your program begins. A schedule will be made available through the School of Math and Science, Fairfield Campus.
2. 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.

Eligibility requirements, application process, and related information is available on the web at <http://www.solano.edu/biomanufacturing>.

## **Cost for Biomanufacturing Bachelor of Science Degree**

Lower division courses (numbered 001-399/500+) cost \$46 per unit.

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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## **BIOT 401**

**5.0 Units**

### **Biomanufacturing Process Sciences and Engineering Principles**

*Prerequisite: Admission into the Biomanufacturing Baccalaureate program. MATH 011 with a minimum grade of C*  
*Transferable to CSU*

*Hours: 48-54 lecture, 96-108 lab*

Builds upon the scientific knowledge underlying chemical engineering principles (for example fluid flow, mass transfer, heat transfer, and the energy relationship of fluid systems) to design, develop, and optimize key parameters in a biomanufacturing process. Process development includes the optimization of media composition, fermenter and bioreactor design, the design of downstream processes, instrumentation, engineering systems, and process control systems to maximize the yield and integrity of a protein pharmaceutical.

## **BIOT 402**

**4.0 Units**

### **Design of Experiments for Biomanufacturing**

*Prerequisite: Admission into the Biomanufacturing Baccalaureate program. A minimum grade of C in MATH 011*  
*Transferable to CSU*

*Hours: 48-54 lecture, 48-54 lab*

Teaches the formal approach called Design of Experiments (DoE), a system that optimizes a process through the methodical varying of key parameters and a formalized approach to the analysis, interpretation, and application of the results. DoE is designed to make any process more robust and to minimize variability from external sources. The course builds upon the statistical concepts required for DoE including hypothesis testing, confidence intervals, statistical models, and analysis of variance (ANOVA). The DoE approach systematically varies the parameters of a biomanufacturing project to improve its operation.

## **BIOT 403**

**4.0 Units**

### **Design of Biomanufacturing Facilities, Critical Utilities, Processes, and Equipment**

*Prerequisite: Admission into the Biomanufacturing Baccalaureate program. Permission of faculty*  
*Transferable to CSU*  
*Hours: 64-72 lecture*

Students analyze and evaluate how the design of a biomanufacturing facility uses one-way personnel flow and one-way material flow to maintain appropriate levels of cleanliness and sterility to promote the production of safe and effective products. Students analyze the design of the processes, equipment, and instrumentation used in biological production to generate critical utilities, aseptic systems, environmental control and monitoring, upstream production, and downstream (recovery and purification) production within a regulated environment.

## **BIOT 404 Bioprocess Monitoring and Control 5.0 Units**

*Prerequisite: BIOT 401*

*Transferable to CSU*

*Hours: 48-54 lecture, 96-108 lab*

Covers the measurement, monitoring, modeling, and control of biomanufacturing processes and the statistical methodology used for measuring, analyzing, and controlling quality during the manufacturing process including control charts and the analysis of process capabilities.

## **BIOT 405**

**3.0 Units**

### **Emerging Biomanufacturing Technologies**

*Prerequisite: BIOT 401*

*Transferable to CSU*

*Hours: 48-54 lecture*

Focuses on biomanufacturing advances and emerging technologies in biological production and protein purification operations. In the course students compare the advantages and disadvantages of the new technology to the traditional technologies and approaches.

## **BIOT 406**

**3.0 Units**

### **Supply Chain and Enterprise Resource Planning in Biomanufacturing**

*Prerequisite: Permission of faculty*

*Transferable to CSU*

*Hours: 48-54 lecture*

Students gain knowledge of how companies manage the complete flow of materials in a supply chain from suppliers to customers. This course covers the design, planning, execution, monitoring, and control of raw materials, personnel resources, inventory management, and distribution. At the end students will have the knowledge required to take the CPIM (Certified in Production and Inventory Management) certification test administered by APICS (the American Production and Inventory Control Society).

## **BIOT 407**

**4.0 Units**

### **Advanced Topics in Quality Assurance and Regulatory Affairs**

*Prerequisite: Permission of faculty*

*Transferable to CSU*

*Hours: 64-72 lecture*

Builds upon previous knowledge of quality assurance and regulatory affairs to study the harmonized quality system approaches of ICH (International Committee on Harmonisation) Q8, Q9, Q10, and Q11. The course pays special attention to the topics of quality risk management, qualification, and validation. This course content has been aligned with the American Society for Quality's Body of Knowledge for a Certified Pharmaceutical Good Manufacturing Practice Professional examination.

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## **BIOT 408 Six Sigma and Lean Manufacturing 4.0 Units**

*Prerequisite: Permission of faculty*

*Transferable to CSU*

*Hours: 64-72 lecture*

Covers the Six Sigma approach to the maintenance and improvement of biomanufacturing processes. It incorporates the DMAIC phases: design, measure, analyze, improve, and control. The course covers the use and implementation of lean manufacturing tools that biomanufacturing companies use to reduce waste. At the end of the course students will be prepared to take the certification test administered by the American Society for Quality for qualification with a white belt in Six Sigma.

## **BIOT 409 4.0 Units Methods in Quality Improvements, Investigations, and Audits**

*Prerequisite: Admission into the Biomanufacturing Baccalaureate program;  
Permission of faculty; BIOT 407*

*Transferable to CSU*

*Hours: 48-54 lecture, 48-54 lab*

Examines the investigational methods used by quality assurance departments to analyze process deviations and make the decision about the severity of the deviation. In this course students learn to write industry-standard CAPA (Corrective Action Preventative Action) report to conclude what corrective and preventative actions result from the investigation. The course also covers how a company would perform an internal audit in anticipation of an inspection by the Food and Drug Administration or an external audit for the supplier of a key raw material. This course content has been aligned with the American Society for Quality's Body of Knowledge for a Certified Quality Technician examination.

## **BIOT 410 3.0 Units Emerging Trends in Biomanufacturing Quality**

*Prerequisite: Admission into the Biomanufacturing Baccalaureate program;  
Permission of faculty; BIOT 407*

*Transferable to CSU*

*Hours: 48-54 lecture*

Examines the process by which the quality systems of biomanufacturing evolve by examining a selected current trend in the laws and regulations governing pharmaceutical manufacturing. In this course students evaluate the effectiveness of the laws and regulations governing pharmaceutical manufacturing.

## **BUS 400 Project Management 3.0 Units**

*Prerequisite: Admission into the Biomanufacturing Baccalaureate program*

*Transferable to CSU*

*Hours: 48-54 lecture*

Learn the core characteristics of project management including project selection, initiation, planning, execution, monitoring and control, and closing. Students learn how the management of the project's scope, time, cost, quality, human resources, communication, procurement, stakeholders, and risk lead to the ability to deliver the project on-time and on-budget, while meeting performance specifications. This course is designed to fulfill the classroom component of a Project Management Professional credential.

## **ENGL 400 3.0 Units Advanced Technical Writing: Writing in the Scientific Professions**

*Prerequisite: Admission into the Biomanufacturing Baccalaureate program.  
A minimum grade of C in ENGL 001*

*Transferable to CSU*

*Hours: 48-54 lecture*

Advanced study in technical writing with a focus on writing for the sciences, including memos, forms, resumés, proposals, formal and informal reports, and peer review strategies. Emphasis is on understanding the differences between academic and technical writing, including techniques for organizing, evaluating, and presenting information in the objective style required in modern technical communications, as well as current trends in technology and scientific discourse. Instruction includes writing as a process, from researching a problem to organizing and drafting a document, to testing, revising and editing that document. Students will learn to employ rhetorical strategies for effective visual and document design as well as how to address ethical, cultural, and political issues related to writing in the sciences. Currency in scientific writing and electronic publishing, including peer review, will also be emphasized. This course trains scientists to become more effective, efficient, and confident writers.

## **PHIL 400 Bioethics 3.0 Units**

*Prerequisite: Admission into Biomanufacturing Baccalaureate program.*

*Transferable to CSU*

*Hours: 48-54 lecture.*

Builds upon a philosophical and critical thinking foundation to train students to be able to model sound ethical decision making in the life science and medical fields. The course requires application of moral theory to a variety of problems in the life science and medical fields such as: genetic engineering, stem cells, allocation of resources, medically assisted dying, genetic screening, genetic alteration, abortion and reproductive rights, and experiments on human or animal subjects. Enrollment in this upper division General Education course is limited to students enrolled in the Bachelors of Science in Biomanufacturing program.