The expanding field of biotechnology devotes itself to improving human health and well-being through the research, development, testing, manufacturing, and marketing of products related to the biomedical, food and beverage, cosmetics, and agricultural industries. The Biotechnology program provides both the theoretical background and practical experience necessary to gain employment in the biotechnology industry. Career paths include research, development, quality control and assurance, manufacturing, analytical testing, and lab technician work.

Bachelor's Degree Program

The bachelor's degree program in biomanufacturing builds upon lower-division coursework in biotechnology and general education, allowing students to enter as juniors and earn a baccalaureate. Information about the program, including eligibility requirements, the application process, and upper-division tuition, is available under Bachelor's Degree. For inquiries about the bachelor's program, please contact Wally Perez at waperez@miracosta.edu.

Academic and Career Pathway

Math and Sciences (https://www.miracosta.edu/academics/degree-and-certificate-programs/math-and-sciences/)

Contact Information

Chair: Wally Perez Medina
Dean: Michael Fino
https://www.miracosta.edu/
academics/degree-andcertificate-programs/
math-and-sciences/
biotechnology/index.html
(https://www.miracosta.edu/
academics/degree-andcertificate-programs/mathand-sciences/biotechnology/)

Department: Biotechnology **Office:** Building OC4800, 760.757.2121 x6924

Full-Time Faculty

Dominique Ingato Barbara Juncosa Wally Perez Medina

Bachelor's Degree

Bachelor of Science Degree Biomanufacturing

The biomanufacturing bachelor's degree program develops the skills, abilities, and knowledge students need to work in the unique environment of biological production. It emphasizes the applied, quantitative analysis of biomanufacturing process design and performance to prepare students for employment in technical or quality positions in the manufacturing sector of the biotechnology industry, which includes biotherapeutics, diagnostics, supplies and services, and industrial products.

The biomanufacturing bachelor's degree program requires the completion of 120 semester units, including 45 units of upper-

division coursework with a minimum of 12 units in residence at MiraCosta College. All upper-division coursework must be completed with a minimum grade of "C" (or "P").

The program builds upon the college's associate degree program in biomanufacturing, allowing students who complete the associate degree or equivalent coursework from other colleges to enter as juniors and earn a baccalaureate. Students earning the college's associate degree in biomanufacturing must complete the Cal-GETC general education pattern, or have been awarded a bachelor's degree from an institution accredited by an agency recognized by the U.S. Secretary of Education, to graduate with a bachelor's degree in biomanufacturing.

Lower-Division Major Preparation

- Overall GPA of 2.0 for all coursework
- Completion of the following lower-division course requirements with no grade less than "C" or "P":
 - General biology (BIO 105 or equivalent)
 - ▶ CHEM 150
 - ▶ CHEM 151
 - ▶ BTFC 107
 - ▶ BTEC 110
 - ▶ BTFC 120
 - ▶ BTEC 210
 - ▶ BTEC 211
 - ▶ BTEC 221▶ BTEC 222
 - ► ENGL C1000
 - Statistics (BTEC 180 or equivalent).

Application for Admission

Students complete the standard online application to the college as well as the Application for the Bachelor of Science in Biomanufacturing, which is available in SURF (see miracosta.edu/bachelors (https://www.miracosta.edu/academics/degree-and-certificate-programs/math-and-sciences/biotechnology/biomanufacturing-bachelors-degree/)). Applications for the fall 2026 cohort become available on August 1. Applications are due in mid-November for priority consideration and are accepted on a rolling basis after this priority deadline until the cohort is full.

Certain lower-division courses must be completed or in progress in order to submit an application for admission to the program. Please see the Biomanufacturing Bachelor's Degree Program webpage for details.

Admission/Selection Criteria

Qualified applicants are selected for admission based on a comprehensive review process that gives additional weight to the following:

- Percentage of lower-division major preparation completed at the time of applying.
- Completion of an associate degree in biomanufacturing, research and development, or equivalent.
- Completion before entry date of BTEC 221 and BTEC 222 (or equivalent).
- Completion of additional 200-level biotechnology, biology, or chemistry courses or 100-level physics courses not listed in the program requirements.

- Completion, before entry date, of lower-division general education requirements.
- ▶ GPA in lower-division major preparation courses.
- Employment in the biotechnology/biomedical industry, including internships.
- Relevant life experiences or special circumstances, such as disabilities, low family income, first generation college student, DACA, former foster youth, veteran status, and other criteria.

For more specific information about the comprehensive review process, please see miracosta.edu/bachelors (https://www.miracosta.edu/academics/degree-and-certificate-programs/math-and-sciences/biotechnology/biomanufacturing-bachelors-degree/).

Upper-Division Tuition

Upper-division coursework costs \$130 per unit, which is an additional \$84 per unit currently charged for lower-division coursework.

Program Student Learning Outcomes

Upon completion of this program, students will be able to do the following:

- Design and execute a project that identifies possible options of new biomanufacturing technologies that serve as process improvements, including technical and financial benefits, and write a report evaluating those options with a final recommendation.
- Perform an investigation that requires them to analyze an Out of Specification (OOS) occurrence during a production step in the manufacture of a biological substance, perform the analysis to justify the batch disposition, and incorporate this into a CAPA (Corrective Action Preventative Action) report.

Course Requirements

Required lower-division courses:

BIO 105	Introductory Biology: Biotechnology in Society *	3
BTEC 107	Exploring Biotechnology: Emerging Trends, Careers, and the Local Industry	3
BTEC 110	Basic Techniques in Biotechnology	5
BTEC 120	Business and Regulatory Practices in Biotechnology	3
BTEC 180	Biostatistics *	4
BTEC 210	Data Analysis with Excel	1
BTEC 211	Technical Writing for Regulated Environments	1
BTEC 221	Bioprocessing: Cell Culture and Scale-up	1.5
BTEC 222	Bioprocessing: Large Scale Purification	1.5
CHEM 150	General Chemistry I: For Science Majors *	5
CHEM 151	General Chemistry II: For Science Majors *	5
ENGL C1000	Academic Reading and Writing *	4

Required upper-division courses:		
BTEC 300	Supply Chain and Enterprise Resource Planning in Biomanufacturing	3
BTEC 310	Biomanufacturing Process Sciences	5
BTEC 320	Design of Experiments for Biomanufacturing	4
BTEC 330	Advanced Topics in Quality Assurance and Regulatory Affairs	4
BTEC 340	Six Sigma and Lean Manufacturing	3
BTEC 360	Design of Biomanufacturing Facilities, Critical Utilities, Processes, and Equipment	3
BTEC 400	Bioprocess Monitoring and Control	4
BTEC 410	Methods in Quality, Improvements, Investigations, and Audits	4
BTEC 460	Capstone Seminar in Biomanufacturing Technologies	3
BTEC 470	Capstone Seminar in Biomanufacturing Quality	3
BIO 340	Molecular Mechanisms of Disease	3
BUS 302	Leadership and Personal Development	3
PHIL 302	Bioethics	3
Remaining require and elective cours	d lower-division general education ework:	
General education	n requirements remaining	24
Electives		14
Total Units		120

 $^{^{\}ast}$ Course satisfies a general education requirement on the Cal-GETC general education pattern.

Associate Degrees

Associate in Science Degree Biomanufacturing

Students may earn the associate degree by completing the Certificate of Achievement in Biomanufacturing as well as a general education (GE) pattern of courses. To be eligible for admission to the bachelor's degree program (see miracosta.edu/bachelors (https://www.miracosta.edu/academics/degree-and-certificate-programs/math-and-sciences/biotechnology/biomanufacturing-bachelors-degree/)), students must complete the Cal-GETC pattern or a bachelor's degree from an institution accredited by an agency recognized by the U.S. Secretary of Education. Students should meet with a MiraCosta counselor to develop a written educational plan for the specific degree they wish to earn.

Research and Development

Students may earn the associate degree by completing the Certificate of Achievement in Research and Development as well as the general education courses required for MiraCosta College's Associate in Science degree (see Associate Degrees (http://catalog.miracosta.edu/degreecertificatetransferinfo/requirements/)). Students should meet with a MiraCosta counselor to identify required courses and to develop a written educational plan for the specific degree or certificate they wish to earn.

Certificates

Certificate of Achievement Biomanufacturing

The biomanufacturing degree expands on the skills and theoretical foundation presented in the bioprocess technology certificate to further prepare entry-level technicians for employment in the regulated environment of biomanufacturing. Technicians in this field must learn and implement laboratory procedures and use specialized laboratory equipment in the production of a cell-based product. Competency in organizational, computational, and communication skills is required. This program is designed to give

students the theoretical background and practical experience necessary to work effectively in biomanufacturing at the entry level as well as to prepare them for advancement to the baccalaureate degree in biomanufacturing at MiraCosta College. Graduates of this program can expect to be employed in various capacities, including quality control, quality assurance, production, process development, and analytical testing.

Program Student Learning Outcome

Upon completion of this program, students will be able to successfully perform a technical laboratory task common to the biomanufacturing environment by employing the appropriate equipment and tools, safely and effectively.

Course Requirements

Required courses:		
BIO 105	Introductory Biology: Biotechnology in Society	3
BTEC 107	Exploring Biotechnology: Emerging Trends, Careers, and the Local Industry	3
BTEC 110	Basic Techniques in Biotechnology	5
BTEC 120	Business and Regulatory Practices in Biotechnology	3
BTEC 180	Biostatistics	4
BTEC 210	Data Analysis with Excel	1
BTEC 211	Technical Writing for Regulated Environments	1
BTEC 221	Bioprocessing: Cell Culture and Scale-up	1.5
BTEC 222	Bioprocessing: Large Scale Purification	1.5
CHEM 150	General Chemistry I: For Science Majors	5

	BTEC 231 BTEC 232	Gene Editing Techniques: CRISPR- Cas9 Principles of Flow Cytometry	
		Cas9	
		Cas9	
	BTEC 207 BTEC 231	Techniques in Immunochemistry and ELISA Gene Editing Techniques: CRISPR-	
	BTEC 206	Principles of Separation and HPLC	
	BTEC 204	Recombinant DNA	
	BTEC 203	Techniques in DNA Amplification	
	BTEC 201	Advanced Cell Culture	
	Select two course	es from the following:	2
	ENGL C1000	Majors Academic Reading and Writing	4
	CHEM 151	General Chemistry II: For Science	5

Certificate of Achievement Bioprocess Technology

This certificate provides a foundation in, and practical application of, the technologies employed by biotechnology companies engaged in the production of cell-derived products from small to large scales. Through a combination of applied lecture and hands-on laboratory instruction, students acquire the confidence, competence, and compliance for technical work in a regulated environment.

Bioprocess technologies encompass the operation of specialized equipment and instrumentation used to produce biopharmaceuticals or reagents utilized by biotechnology, pharmaceutical, and academic research labs. Students learn to grow a variety of cells, express a biomolecule of interest, and recover the desired biomolecule through a series of purification steps. They learn to follow good manufacturing practices by maintaining records in order to comply with quality system requirements and government regulations. This certificate is designed for bioprocess-technician skill development as well as professional development for those already employed in the industry.

Program Student Learning Outcome

Upon completion of the program, students will be able to successfully perform a technical laboratory task by employing the appropriate equipment and tools, safely and effectively.

Course Requirements

Required courses:		
BTEC 110	Basic Techniques in Biotechnology	5
BTEC 120	Business and Regulatory Practices in Biotechnology	3
BTEC 211	Technical Writing for Regulated Environments	1
BTEC 221	Bioprocessing: Cell Culture and Scale-up	1.5
BTEC 222	Bioprocessing: Large Scale Purification	1.5
Select at least one course from the following:		

BTEC 107	Exploring Biotechnology: Emerging Trends, Careers, and the Local Industry
BTEC 210	Data Analysis with Excel
BTEC 232	Principles of Flow Cytometry
BTEC 292	Internship Studies
BTEC 299	Occupational Work Experience Education

Total Units 13-15

Certificate of Achievement Laboratory Skills

This certificate is designed to meet the increasing need for trained and competent associates in laboratory environments. The required courses provide students with fundamental laboratory skills to start or enhance a career in the biosciences.

Students completing this certificate can expect employment utilizing their technical skills in the performance of tests and routine tasks inherent to a wide range of laboratory environments. This certificate is intended for the development of general laboratory skills as well as professional growth for those already employed in the industry.

Program Student Learning Outcome

Upon completion of the program, students will be able to successfully perform a technical laboratory task by employing the appropriate equipment and tools, safely and effectively.

Course Requirements

Certificate of Achievement Research and Development

This certificate is designed to meet the increasing need for entry-level laboratory technicians, especially in the field of research and development. Technicians in this field must be proficient in the application of scientific methodology to solve problems. They must learn and implement laboratory procedures and use specialized laboratory equipment. Competency in organizational, computational, and communication skills is required.

This program is designed to give students the theoretical background and practical experience necessary to be a bench-level scientist in both academic and industrial settings. Completion of this program prepares students to gain entry-level employment, or with additional coursework students can transfer to four-year institutions in the biosciences. Graduates

of this biotechnology program can expect to be employed in various capacities, including quality control, applied research, product development, analytical testing, and academic (basic) research.

Program Student Learning Outcome

Upon completion of the program, students will report that they were sufficiently developed to meet employer expectations for entry-level performance in a technical laboratory.

Course Requirements

Required courses:		
BIO 105	Introductory Biology: Biotechnology in Society	3-4
or BIO 204	Foundations of Biology: Biochemistry, O Biology, Genetics, and Molecular Biology	
BTEC 107	Exploring Biotechnology: Emerging Trends, Careers, and the Local Industry	3
BTEC 110	Basic Techniques in Biotechnology	5
BTEC 120	Business and Regulatory Practices in Biotechnology	3
BTEC 180	Biostatistics	4-7
or MATH 150	Calculus and Analytic Geometry I	
or MATH 150H	Calculus and Analytic Geometry I (Ho	nors)
or MATH 150S	Calculus and Analytical Geometry I wi Integrated Support	th
BTEC 210	Data Analysis with Excel	1
CHEM 150	General Chemistry I: For Science Majors	5
CHEM 151	General Chemistry II: For Science Majors	5
ENGL C1000	Academic Reading and Writing	4
Select at least two	electives from the following:	2
BTEC 201	Advanced Cell Culture	
BTEC 203	Techniques in DNA Amplification	
BTEC 204	Recombinant DNA	
BTEC 206	Principles of Separation and HPLC	
BTEC 207	Techniques in Immunochemistry and ELISA	
BTEC 231	Gene Editing Techniques: CRISPR- Cas9	
BTEC 232	Principles of Flow Cytometry	
BTEC 292	Internship Studies	
BTEC 299	Occupational Work Experience Education	
Total Units	;	35-39

Courses

BTEC 107: Exploring Biotechnology: Emerging Trends, Careers, and the Local Industry

Units: 3

Prerequisites: None Acceptable for Credit: CSU

Lecture 3 hours.

Course Typically Offered: Fall, Spring, and Summer

This course introduces students to the emerging role of biotechnology in modern society. It examines the origins and impact of the biotechnology industry from physiological and socio-cultural aspects, including how biotechnology advances have transformed individual lives and communities. Topics include new technologies in development and the role of biotechnology in addressing societal challenges, such as the COVID-19 pandemic and climate change. Students are oriented to biotechnology careers, employment trends, and the required high-tech, high-touch workforce skills necessary for success in a globally and locally robust professional environment.

BTEC 110: Basic Techniques in Biotechnology

Units: 5

Prerequisites: BIO 105 or BIO 204.

Enrollment Limitation: Concurrent enrollment in BIO 105 or BIO 204 if prerequisite not met and not open to students with prior credit in BTEC 110H.

Acceptable for Credit: CSU, UC Lecture 3 hours, laboratory 6 hours. Course Typically Offered: Fall, Spring

This course focuses on the basic laboratory skills needed for employment in the biotechnology/biomanufacturing industry. Students learn laboratory safety and documentation while acquiring skills in the maintenance and calibration of basic lab equipment, calculation and preparation of lab solutions and media, and routine handling of cell cultures. Students also develop fundamental skills in spectroscopy, centrifugation, performance of assays, gel electrophoresis, and the purification and handling of biological molecules, such as proteins. (Materials Fee: \$30.00)

BTEC 120: Business and Regulatory Practices in Biotechnology

Units: 3

Prerequisites: None Acceptable for Credit: CSU

Lecture 3 hours.

Course Typically Offered: Fall, Spring, and Summer

This course examines basic business principles and practices utilized in the discovery, development, and production phases of new product development. It explores the role of governmental oversight and regulation in assuring the safety, efficacy, and quality of a biotechnology product.

BTEC 180: Biostatistics

Prerequisites: Prealgebra or eligibility determined by the math

placement process.

Advisory: BIO 105, BIO 110, BIO 111, BIO 202, or BIO 204. Enrollment Limitation: Not open to students with prior credit in

BTEC 180H.

Acceptable for Credit: CSU, UC Lecture 3 hours, laboratory 3 hours. Course Typically Offered: Fall, Spring

This introductory statistics course covers the principles and practice of statistical design and analysis for scientific experimentation. Topics include hypothesis formation, experimental design and execution, data analysis, and communication with application to scientific fields, such as the biological and health sciences. The course includes laboratory application with extensive use of computer software for statistical analysis and simulation. UC CREDIT LIMITATION: Credit for BTEC 180, BUS 204, PSYC 104/PSYC 104H, SOC 125, or STAT C1000/STAT C1000E/STAT C1000H. Some CSU campuses may also impose this credit limitation.

BTEC 201: Advanced Cell Culture

Units: 1

Prerequisites: BTEC 110. Acceptable for Credit: CSU, UC Lecture 0.50 hour, laboratory 1.50 hours.

Course Typically Offered: Spring

This advanced course teaches skills in the proper handling of cells from higher organisms, such as plants, mammals, and insects, that are routinely maintained in culture in the biotechnology laboratory. Instruction focuses on growth and manipulation techniques and long-term maintenance of various laboratory cell cultures that may include anchoragedependent and suspension cell lines as well as stem cell cultures.

BTEC 203: Techniques in DNA Amplification

Units: 1

Prerequisites: BTEC 110. Acceptable for Credit: CSU

Lecture 0.50 hour, laboratory 1.50 hours.

Course Typically Offered: Fall or Spring every 3rd sem

This advanced course provides skills in the performance of the polymerase chain reaction (PCR), a technique commonly used to amplify DNA in forensics and the biotechnology laboratory. Instruction focuses on understanding the process; potential applications of DNA amplification; and the skills related to the setup, performance, and evaluation of the technique's outcome. The course assumes some prior knowledge of solution preparation and gel electrophoresis.

BTEC 204: Recombinant DNA

Units: 1

Prerequisites: BTEC 110. Acceptable for Credit: CSU

Lecture 0.50 hour, laboratory 1.50 hours.

Course Typically Offered: Fall or Spring every 3rd sem

This advanced course provides skills in recombinant DNA technology used to analyze and manipulate DNA in the biotechnology laboratory. Students learn about the process of cloning and analyzing DNA and acquire the skills necessary to cut, piece together, and introduce new DNA molecules into prepared host bacterial cells.

BTEC 206: Principles of Separation and HPLC

Units: 1

Prerequisites: BTEC 110. Acceptable for Credit: CSU

Lecture 0.50 hour, laboratory 1.50 hours.

Course Typically Offered: Fall or Spring every 3rd sem

This advanced course provides skills in the separation of biomolecules from complex mixtures using high performance liquid chromatography (HPLC). Instruction focuses on understanding the principles of separation, acquiring skills in the separation of various biomolecules, and analyzing the outcome for the purpose of determining system performance and biomolecular purification. The course assumes some prior knowledge of solution preparation, assays, and spectroscopy.

BTEC 207: Techniques in Immunochemistry and ELISA

Units: 1

Prerequisites: BTEC 110. Acceptable for Credit: CSU

Lecture 0.50 hour, laboratory 1.50 hours.

Course Typically Offered: Fall or Spring every 3rd sem

This advanced course provides skills in the use of antibody reagents as a tool in the biotechnology laboratory. It focuses on the nature and specificity of antibody reagents for the identification and quantification of biological molecules. Students learn how to set up, perform, and analyze techniques utilizing antibodies, such as Westerns and ELISAs.

BTEC 210: Data Analysis with Excel

Units: 1

Prerequisites: None Advisory: CSIT 101 Acceptable for Credit: CSU

Acceptable for Cledit. C30

Lecture 0.75 hour, laboratory 0.75 hour. Course Typically Offered: Fall, Spring

This course teaches students how modern spreadsheet programs can be used to collect and organize data for subsequent tabulation, summarization, and graphical display. It utilizes various forms of scientific data to teach the techniques and skill that facilitate the capture, analysis, and management of data. Topics include importing and organizing data, filtering and sorting, graphing, and statistical analysis functions.

BTEC 211: Technical Writing for Regulated Environments

Units: 1

Prerequisites: None

Advisory: BTEC 110 and ESL 150 or eligibility determined by the

English placement process. Acceptable for Credit: CSU

Lecture 1 hour.

Course Typically Offered: Fall, Spring

This course provides the requisite tools to understand why technical writing exists and how that writing works in conjunction with the many types of documents found in regulated environments. It also develops the techniques needed to deliver clear and complete passages with precise language. Students apply best practices for technical writing to a variety of documents, including reports, standard operating procedures (SOP), and investigations.

BTEC 221: Bioprocessing: Cell Culture and Scale-up

Units: 1.5

Prerequisites: BTEC 110. Advisory: BTEC 120 Acceptable for Credit: CSU

Lecture 0.75 hour, laboratory 2.25 hours. Course Typically Offered: Fall, Spring

This laboratory course develops the skills and knowledge related to the culture of cells in increasingly larger scales for the production of biological molecules. Students grow and monitor a variety of cells (bacterial, yeast, and/or mammalian) on a laboratory scale that emulates the large-scale production used in industry. They become familiar with the cleaning, sterilization, aseptic inoculation, operation, and monitoring of fermenters and bioreactors. The course emphasizes the use of current Good Manufacturing Practices (cGMPs) and process control strategies, and students gain experience following Standard Operating Procedures (SOPs).

BTEC 222: Bioprocessing: Large Scale Purification

Units: 1.5

Prerequisites: BTEC 110. Advisory: BTEC 120 Acceptable for Credit: CSU

Lecture 0.75 hour, laboratory 2.25 hours. Course Typically Offered: Fall, Spring

This laboratory course develops the skills and knowledge related to purification of biological molecules produced on a large scale. Students utilize the most common types of separation equipment, including tangential flow filtration, centrifugation, and column chromatography. They become familiar with the cleaning, sanitization, calibration, operation, and monitoring of large-scale purification equipment. The course emphasizes the use of current Good Manufacturing Practices (cGMPs) and process control strategies, and students gain experience following Standard Operating Procedures (SOPs).

BTEC 231: Gene Editing Techniques: CRISPR-Cas9

Units: 1

Prerequisites: BTEC 110. Acceptable for Credit: CSU

Lecture 0.50 hour, laboratory 1.50 hours.

Course Typically Offered: Fall or Spring every 3rd sem

This advanced course provides skills in the performance of the revolutionary genome editing technique CRISPR-Cas9. Instruction focuses on a deep understanding of this powerful and popular gene-editing technique to better appreciate the promise, risks, and ethics behind its many applications. Laboratory activities develop skills related to the setup, performance, and evaluation of the technique's outcome. The course assumes some prior knowledge of solution preparation and aseptic streak-plating of bacterial cultures.

BTEC 232: Principles of Flow Cytometry

Units: 1

Prerequisites: BTEC 110. Acceptable for Credit: CSU

Lecture 0.50 hour, laboratory 1.50 hours.

Course Typically Offered: Fall or Spring every 3rd sem

This advanced course addresses the basic theory and practice of flow cytometry. Instruction focuses on understanding the principles of flow cytometry, acquiring skills in the detection and measurement of physical and chemical characteristics of a population of cells, and analyzing the outcome for the purpose of determining system performance and cell characteristics. The course assumes some prior knowledge of solution preparation, assays, and cell culture.

BTEC 292: Internship Studies

Units: 0.5-14 Prerequisites: None

Corequisite: Complete 54 hours of work per unit, paid or

unpaid.

Enrollment Limitation: Instructor, dept chair, and Career Center approval. Fourteen unit maximum in any combination of work experience education and/or internship studies per semester.

Acceptable for Credit: CSU

Course Typically Offered: To be arranged

This course provides students the opportunity to apply the theories and techniques of their discipline in an internship position in a professional setting under the instruction of a faculty-mentor and site supervisor. It introduces students to aspects of the roles and responsibilities of professionals employed in the field of study. Topics include goal-setting, employability skills development, and examination of the world of work as it relates to the student's career plans. Students must develop new learning objectives and/or work/intern at a new site upon each enrollment.

BTEC 296: Topics in Biotechnology

Units: 1-4

Prerequisites: None Acceptable for Credit: CSU

Lecture 1 hour. Lecture 2 hours. Lecture 3 hours. Lecture 4 hours.

Course Typically Offered: To be arranged

This course gives students an opportunity to study topics in Biotechnology that are not included in regular course offerings. Each Topics course is announced, described, and given its own title and 296 number designation in the class schedule.

BTEC 299: Occupational Work Experience Education

Units: 0.5-14 Prerequisites: None

Corequisite: Complete 54 hours of work per unit, paid or

unpaid.

Enrollment Limitation: Career Center approval. Fourteen unit maximum in any combination of work experience education and/or internship studies per semester.

Acceptable for Credit: CSU

Course Typically Offered: Fall, Spring, and Summer

This course is intended for students who are employed in a job directly related to their major or career area of interest. It allows such students the opportunity to apply the theories and skills of their discipline to their position and to undertake new responsibilities and learn new skills at work. Topics include goal-setting, employability skills development, and examination of the world of work as it relates to the student's career plans. Students must develop new learning objectives and/or work/intern at a new site upon each enrollment.

BTEC 300: Supply Chain and Enterprise Resource Planning in Biomanufacturing

Units: 3

Prerequisites: BTEC 120.

Enrollment Limitation: Only open to students enrolled in the bachelor's degree program in biomanufacturing at MiraCosta

Lecture 3 hours.

Course Typically Offered: Fall

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). This course is open only to students enrolled in the biomanufacturing bachelor's degree program.

BTEC 310: Biomanufacturing Process Sciences

Units: 5

Prerequisites: BTEC 221 and BTEC 222.

Enrollment Limitation: Only open to students enrolled in the bachelor's degree program in biomanufacturing at MiraCosta College.

Lecture 3 hours, laboratory 6 hours. Course Typically Offered: Fall

This lecture/laboratory course examines the biological, physical, and chemical scientific principles that support the design, development, and optimization of key parameters in a biomanufacturing process. Process sciences covers the essential theories that underpin the biomanufacturing operations from product formation through product purification and how those operations scale up and scale down. The topics include fermenter and bioreactor design and the design of downstream processes that maximize the yield, safety, and efficacy of a protein pharmaceutical. This course is open only to students enrolled in the biomanufacturing bachelor's degree program.

BTEC 320: Design of Experiments for Biomanufacturing

Units: 4

Prerequisites: BTEC 110 and BTEC 180.

Enrollment Limitation: Only open to students enrolled in the bachelor's degree program in biomanufacturing at MiraCosta

Lecture 3 hours, laboratory 3 hours. Course Typically Offered: Spring

This course teaches formalized design of experiments (DOE), a system that optimizes a process through the methodical varying of key parameters and a formalized approach to analyzing, interpreting, and applying the results. DOE is designed to make any process more robust and 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 process to improve its operation. This course is open only to students enrolled in the biomanufacturing bachelor's degree program.

BTEC 330: Advanced Topics in Quality Assurance and Regulatory Affairs

Units: 4

Prerequisites: BTEC 120.

Enrollment Limitation: Only open to students enrolled in the bachelor's degree program in biomanufacturing at MiraCosta College.

Lecture 4 hours.

Course Typically Offered: Spring

This course builds upon previous knowledge of quality assurance and regulatory affairs to study the harmonized quality system approaches of the International Council for Harmonisation Q8 through Q11. The course pays special attention to the topics of quality risk management, qualification, and validation. This course is open only to students enrolled in the biomanufacturing bachelor's degree program.

BTEC 340: Six Sigma and Lean Manufacturing

Units: 3

Prerequisites: BTEC 120 and BTEC 180.

Enrollment Limitation: Only open to students enrolled in the bachelor's degree program in biomanufacturing at MiraCosta College.

Lecture 3 hours.

Course Typically Offered: Fall

This course covers the Six Sigma approach to the maintenance and improvement of biomanufacturing processes. It incorporates the DMAIC phases: define, 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 for qualification with a yellow belt in Six Sigma. This course is open only to students enrolled in the biomanufacturing bachelor's degree program.

BTEC 360: Design of Biomanufacturing Facilities, Critical Utilities, Processes, and Equipment

Units: 3

Prerequisites: BTEC 120, BTEC 221, and BTEC 222. Enrollment Limitation: Concurrent enrollment in BTEC 221 and BTEC 222 if prerequisites not met.

Lecture 3 hours.

Course Typically Offered: Fall

Students evaluate how the design of a biomanufacturing facility maintains appropriate levels of cleanliness and sterility and promotes 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. This course is open only to students enrolled in the biomanufacturing bachelor's degree program.

BTEC 400: Bioprocess Monitoring and Control

Units: 4

Prerequisites: BTEC 310.

Enrollment Limitation: Open only to students enrolled in the bachelor's degree program in biomanufacturing at MiraCosta College.

Lecture 3 hours, laboratory 3 hours. Course Typically Offered: Spring

This course 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. This course is open only to students enrolled in the biomanufacturing bachelor's degree program.

BTEC 410: Methods in Quality, Improvements, Investigations, and Audits

Units: 4

Prerequisites: BTEC 330 and BTEC 340.

Enrollment Limitation: Only open to students enrolled in the bachelor's degree program in biomanufacturing at MiraCosta

College.

Lecture 4 hours.

Course Typically Offered: Spring

This course examines investigational methods used by quality assurance departments to analyze process deviations and make decisions about severity of deviation. Students learn to write industry-standard corrective and preventive action (CAPA) reports to conclude what corrective and preventive actions result from the investigation. The course also covers how a company would perform an audit in anticipation of an inspection by the Food and Drug Administration or for the supplier of a key raw material. Course content is aligned with the American Society for Quality's Body of Knowledge for a Certified Quality Technician examination. This course is open only to students enrolled in the biomanufacturing bachelor's degree program.

BTEC 460: Capstone Seminar in Biomanufacturing Technologies

Units: 3

Prerequisites: BTEC 310.

Enrollment Limitation: Only open to students enrolled in the bachelor's degree program in biomanufacturing at MiraCosta

College. Lecture 3 hours.

Course Typically Offered: Spring

This course examines the breadth of products that are produced through biological processes. The course will focus on the advances and emerging technologies in biological production and purification operations. This course is open only to students enrolled in the biomanufacturing bachelor's degree program.

BTEC 470: Capstone Seminar in Biomanufacturing Quality

Units: 3

Prerequisites: BTEC 330.

Enrollment Limitation: Only open to students enrolled in the bachelor's degree program in biomanufacturing at MiraCosta College.

Lecture 3 hours.

Course Typically Offered: Fall

This course examines the process by which the quality systems of biomanufacturing evolve by examining a selected current trend in the laws and regulations governing biopharmaceutical manufacturing. Students evaluate the effectiveness of the laws and regulations governing biopharmaceutical manufacturing. This course serves as a capstone experience for students in biomanufacturing quality. This course is open only to students enrolled in the biomanufacturing bachelor's degree program.