

BIOTECHNOLOGY

Program Purpose: Students who complete a biotechnology course will be able to understand and explain the operations that take place in an industrial biotechnology setting, perform many of these operations, and assess and critique the extent to which they are meeting or exceeding the standards appropriate to these activities.

Biotechnology is a rapidly growing industry with projections for continued growth and exciting opportunities for employment. The Biotechnology program is one of several in the State with a comprehensive curriculum in biomanufacturing. This program is designed in consultation with members of local industry (Baxter Healthcare Corporation, AMGEN Corporation, and others) to provide the essential technical experiences and training needed for this thriving field. The curriculum balances basic science courses with practical laboratory applications.

BIOT M02A Environmental Control and Process Support 2 Units

Same-As: BIOL M12A

In-Class Hours: 17.5 lecture, 52.5 laboratory

Provides skills training in manufacturing of biopharmaceuticals and medical devices. Presents an overview of the manufacturing process and introduces environmental control and process support with a focus on Good Laboratory Practices (GLP)/Good Manufacturing Practices (GMP), clean room procedure, monitoring techniques, and required documentation.

Grade Modes: Letter Graded, Student Option- Letter/Credit, Pass/No Pass Grading

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M02B Manufacturing: Quality Control and Validation 2 Units

Same-As: BIOL M12B

In-Class Hours: 17.5 lecture, 52.5 laboratory

C-ID: BIOT 210X

Provides skills training in industrial biotechnology with emphasis on manufacturing of pharmaceuticals and medical devices. Introduces validation and quality control. Reviews manufacturing process, including formulation, lyophilization, packaging and filling. Focuses on validation, systems evaluations, testing and reporting.

Grade Modes: Letter Graded, Student Option- Letter/Credit, Pass/No Pass Grading

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M02C Manufacturing: Cell Culture and Microbial Fermentation 3 Units

Same-As: BIOL M12C

In-Class Hours: 17.5 lecture, 105 laboratory

C-ID: BIOT 230X

Provides skills training in industrial biotechnology with emphasis on manufacturing pharmaceuticals. Introduces cell culture and microbial fermentation. Focuses on bacterial techniques, microbial assessment, mammalian cell culture, bioreactor fermentation, and media preparation. Compares small and large industrial scale cell culture.

Grade Modes: Letter Graded, Student Option- Letter/Credit, Pass/No Pass Grading

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M02D Bioprocessing: Recovery and Purification 2 Units

Same-As: BIOL M12D

In-Class Hours: 17.5 lecture, 52.5 laboratory

C-ID: BIOT 220BX

Provides skills training in industrial biotechnology with emphasis on manufacturing pharmaceuticals. Introduces bioprocessing, recovery, and purification techniques. Focuses on protein separation and purification, chromatography, large-scale recovery, and identification of assays. Reviews skills necessary for a successful job search in the field of biotechnology.

Grade Modes: Letter Graded, Student Option- Letter/Credit, Pass/No Pass Grading

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M02E Business & Government Regulation 2 Units

Same-As: BIOL M12E

In-Class Hours: 35 lecture

Provides skills training in industrial biotechnology with emphasis on manufacturing pharmaceuticals. Examines manufacturing from the perspective of company operations involved with the drug or medical device development process. Focuses on business practices and governmental regulations.

Grade Modes: Letter Graded, Student Option- Letter/Credit, Pass/No Pass Grading

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M10 Introduction to Biotechnology and Molecular Biology 4 Units*Same-As:* BIOL M13*In-Class Hours:* 52.5 lecture, 52.5 laboratory*C-ID:* BIOT 150BX

Examines the role of molecular biology in the manufacturing of commercial pharmaceutical and agricultural products. Introduces basic biotechnology laboratory skills, including documentation, safety, and solution and buffer preparation. Develops student proficiency in aseptic techniques, spectrophotometry, molecular biology techniques, and electrophoresis.

Grade Modes: Letter Graded, Student Option- Letter/Credit, Pass/No Pass Grading

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU, UC

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M301 Biomanufacturing Process Sciences and Engineering Principles 5 Units*In-Class Hours:* 52.5 lecture, 105 laboratory

Prerequisites: Introductory Statistics (MATH M15 or MATH M15H) or equivalent or placement as determined by the college's multiple measures assessment process, BIOL M02A or BIOL M02AH, BIOT M10 or BIOL M13, BIOT M02C or BIOL M12C, and BIOT M02D or BIOL M12D

Builds upon the scientific knowledge underlying chemical engineering principles to design, develop, and optimize key parameters in a biomanufacturing process. Includes the optimization of media composition, fermenter and bioreactor design, the design of downstream processes, instrumentation, engineering systems, and process control systems in process development to maximize the yield and integrity of a protein pharmaceutical.

Enrollment Limitations: Admitted to the program. Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program. .

Grade Modes: Letter Graded

Field Trips: May be required

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M302 Design of Experiments for Biomanufacturing 4 Units*In-Class Hours:* 52.5 lecture, 52.5 laboratory

Prerequisites: Introductory Statistics (MATH M15 or MATH M15H) or equivalent or placement as determined by the college's multiple measures assessment process, BIOL M02A or BIOL M02AH, BIOT M10 or BIOL M13, BIOT M02C or BIOL M12C, and BIOT M02D or BIOL M12D

Teaches the formal approach called "Design of Experiments" (DoE), a system that optimizes a process, makes it more robust, and minimizes variability from external sources through the methodical varying of key parameters and a formalized approach to the analysis, interpretation, and application of the results. Builds upon the statistical concepts required for DoE including hypothesis testing, confidence intervals, statistical models, and analysis of variance (ANOVA), and elucidates the approach to systematically vary the parameters of a biomanufacturing project to improve its operation.

Enrollment Limitations: Admitted to the program. Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program. .

Grade Modes: Letter Graded

Field Trips: May be required

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M303 Design of Biomanufacturing Facilities, Critical Utilities, Processes, and Equipment 4 Units*In-Class Hours:* 70 lecture

Prerequisites: Introductory Statistics (MATH M15 or MATH M15H) or equivalent or placement as determined by the college's multiple measures assessment process, BIOL M02A or BIOL M02H, BIOT M10 or BIOL M13, BIOT M02C or BIOL M12C, BIOT M02D or BIOL M12D, and BIOT M02E or BIOL M12E

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 that promote the production of safe and effective products. 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.

Enrollment Limitations: Admitted to the program. Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program.

Grade Modes: Letter Graded

Field Trips: May be required

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M304 Bioprocess Monitoring and Control 5 Units

In-Class Hours: 52.5 lecture, 105 laboratory

Prerequisites: Introductory Statistics (MATH M15 or MATH M15H) or equivalent or placement as determined by the college's multiple measures assessment process, BIOL M02A or BIOL M02AH, BIOT M10 or BIOL M13, BIOT M02C or BIOL M12C, and BIOT M02D or BIOL M12D
Covers the measurement, monitoring, modeling, and control of biomanufacturing processes. Utilizes statistical methodology for measuring, analyzing, and controlling quality during the manufacturing process including control charts and the analysis of process capabilities.
Enrollment Limitations: Admitted to the program. Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program.

Grade Modes: Letter Graded

Field Trips: May be required

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M307 Advanced Topics in Quality Assurance and Regulatory Affairs 4 Units

In-Class Hours: 70 lecture

Prerequisites: Introductory Statistics (MATH M15 or MATH M15H) or equivalent or placement as determined by the college's multiple measures assessment process, BIOL M02A or BIOL M02AH, BIOT M10 or BIOL M13, BIOT M02C or BIOL M12C, BIOT M02D or BIOL M12D, and BIOT M02E or BIOL M12E

Builds upon previous knowledge of quality assurance and regulatory affairs to study the harmonized quality system approaches of the International Committee on Harmonisation (ICH). Pays special attention to the topics of quality risk management, qualification, and validation. Covers topics in the American Society for Quality's Body of Knowledge for a Certified Pharmaceutical Good Manufacturing Practice Professional examination.

Enrollment Limitations: Admitted to the program. Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program.

Grade Modes: Letter Graded

Field Trips: May be required

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M405 Cell and Gene Therapy Manufacturing Technologies 3 Units

In-Class Hours: 52.5 lecture

Prerequisites: BIOT M301

Examines the emerging field of cell and gene therapy manufacturing for cancer and other therapies. Examines the differences between the new technologies and traditional Biotechnology processes.

Enrollment Limitations: Admitted to the program. Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program.

Grade Modes: Letter Graded

Field Trips: May be required

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M406 Supply Chain and Enterprise Resource Planning 3 Units

In-Class Hours: 52.5 lecture

Prerequisites: BIOT M302, BIOT M303, and BIOT M304

Examines how companies manage the complete flow of materials in a supply chain from suppliers to customers. Covers the design, planning, execution, monitoring, and control of raw materials, personnel resources, inventory management, and distribution. Prepares students to take the Certified in Production and Inventory Management (CPIM) certification test administered by the American Production and Inventory Control Society (APICS).

Enrollment Limitations: Admitted to the program. Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program.

Grade Modes: Letter Graded

Field Trips: May be required

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M408 Six Sigma and Lean Manufacturing 4 Units

In-Class Hours: 70 lecture

Prerequisites: BIOT M302, BIOT M303, and BIOT M304

Covers the Six Sigma approach to the maintenance and improvement of biomanufacturing processes. Incorporates the DMAIC phases: design, measure, analyze, improve, and control. Includes the use and implementation of lean manufacturing tools that biomanufacturing companies use to reduce waste. Prepares students to take the certification test administered by the American Society for Quality for qualification with a white belt in Six Sigma.

Enrollment Limitations: Admitted to the program. Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program.

Grade Modes: Letter Graded

Field Trips: May be required

Degree Applicability: Applies to Associate Degree

AA/AS GE: None

Transfer Credit: CSU

UC Credit Limitations: None

CSU GE-Breadth: None

IGETC: None

BIOT M409 Methods in Quality Improvements, Investigations, and Audits 4 Units*In-Class Hours:* 70 lecture*Prerequisites:* BIOT M307

Examines the investigational methods used by quality assurance departments to analyze process deviations and make the decision about the severity of the deviation. Prepares students to write industry-standard Corrective Action Preventative Action (CAPA) report to conclude what corrective and preventative actions result from the investigation. Explains 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. Provides students the body of knowledge required for American Society for Quality's Certified Quality Technician examination.

Enrollment Limitations: Admitted to the program. Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program. .

Grade Modes: Letter Graded**Field Trips:** May be required**Degree Applicability:** Applies to Associate Degree**AA/AS GE:** None**Transfer Credit:** CSU**UC Credit Limitations:** None**CSU GE-Breadth:** None**IGETC:** None**BIOT M410 Emerging Trends in Biomanufacturing Quality 3 Units***In-Class Hours:* 52.5 lecture*Prerequisites:* BIOT M307

Introduces the process by which the quality systems of biomanufacturing evolve by examining a selected current trend in the laws and regulations governing pharmaceutical manufacturing. Evaluates the effectiveness of the laws and regulations governing pharmaceutical manufacturing.

Enrollment Limitations: Enrollment in this course requires admission into the Biomanufacturing Baccalaureate degree program. .

Grade Modes: Letter Graded**Field Trips:** May be required**Degree Applicability:** Applies to Associate Degree**AA/AS GE:** None**Transfer Credit:** CSU**UC Credit Limitations:** None**CSU GE-Breadth:** None**IGETC:** None**BIOT M50A Bridge to Biotechnology 0.5 Units***Same-As:* BIOL M50A*In-Class Hours:* 26.25 laboratory

Develops practical, hands-on experience with laboratory techniques used in the field of biotechnology. Applies specific techniques that vary depending on the current state of technology. Provides a bridge for entry-level and high school students who are interested in exploring the field of biotechnology.

Grade Modes: Letter Graded, Student Option- Letter/Credit, Pass/No Pass Grading

Degree Applicability: Applies to Associate Degree**AA/AS GE:** None**Transfer Credit:** None**BIOT M80 Internship in Biotechnology 1-4 Units***In-Class Hours:* 75-300 paid cooperative

Prerequisites: Completion of or concurrent enrollment in one course in the discipline and instructor approval. Course Credit Limitation: To take this course, contact the Career Transfer Center. Requires orientation session. Students receive one unit of credit for each 60 hours unpaid or 75 hours paid work. May enroll in up to 4 units a semester with a maximum of 16 total units of any type of work experience

Provides on-the-job learning to develop effective work habits, attitudes, and career awareness in paid or unpaid internships that are related to the discipline. Involves the development and documentation of learning objectives and the completion of an internship paper, presentation, or project. Includes both workplace supervisor and faculty adviser feedback and/or written evaluations.

Grade Modes: Letter Graded, Student Option- Letter/Credit, Pass/No Pass Grading

Repeatable for Credit: Course may be taken up to 3 times for credit.**Field Trips:** May be required**Degree Applicability:** Applies to Associate Degree**AA/AS GE:** None**Transfer Credit:** CSU**UC Credit Limitations:** None**CSU GE-Breadth:** None**IGETC:** None

- Biotechnology, Associate in Science (<http://catalog.vcccd.edu/moorpark/programs-courses/biotechnology/biotechnology-as/>)
- Biomedical Device Manufacturing, Certificate of Achievement (<http://catalog.vcccd.edu/moorpark/programs-courses/biotechnology/biomedical-device-manufacturing-coa/>)
- Biotechnology Manufacturing Operator, Certificate of Achievement (<http://catalog.vcccd.edu/moorpark/programs-courses/biotechnology/biotechnology-manufacturing-operator-coa/>)
- Biotechnology, Certificate of Achievement (<http://catalog.vcccd.edu/moorpark/programs-courses/biotechnology/biotechnology-coa/>)

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