

Upper Division Courses

BIOT 401

Biomanufacturing Process Sciences and Engineering Principles (5 units)

This lecture/laboratory course 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

Design of Experiments for Biomanufacturing (4 units)

This course 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

Design of Biomanufacturing Facilities, Critical Utilities, Processes, and Equipment (4 units)

In this course 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 the 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 units)

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.

BIOT 405**Emerging Biomanufacturing Technologies (3 units)**

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

BIOT 406**Supply Chain and Enterprise Resource Planning in Biomanufacturing (3 units)**

In this course 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**Advanced Topics in Quality Assurance and Regulatory Affairs (4 units)**

This course builds upon previous knowledge of quality assurance and regulatory affairs to study the harmonized quality system approaches of ICH (the 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.

BIOT 408**Six Sigma and Lean Manufacturing (4 units)**

This course 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**Methods in Quality Improvements, Investigations, and Audits (4 units)**

This lecture/laboratory course 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**Emerging Trends in Biomanufacturing Quality (3 units)**

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 pharmaceutical manufacturing. In this course students evaluate the effectiveness of the laws and regulations governing pharmaceutical manufacturing.

Upper Division General Education Courses**ENGL 400****Advanced Technical Writing: Writing in the Scientific Professions (3 units)**

Advanced study in technical writing with a focus on writing for the sciences, including memos, forms, resumes, 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.

BUS 400**Project Management (3 units)**

In this course students 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.

PHIL 400**Bioethics (3 units)**

This course 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.