BACHELOR OF SCIENCE IN BIOMANUFACTURING

Description of the New Program

The proposed baccalaureate program in biomanufacturing will prepare students for employment in the manufacturing sector of the biotechnology industry, which includes biotherapeutics, diagnostics, supplies and services, and industrial products. The degree will prepare graduates for technical and quality assurance/control-related positions.

Biomanufacturing leverages the understanding of biology to manufacture products or perform services that impact health, agriculture, the environment, and industrial needs. As a product or service progresses from discovery research through development and into production, the science becomes increasingly less isolated. Through a transformation of scale, process control, and compliance, the science of biomanufacturing lives across the product and process lifecycle within a quality management system. The applied biomanufacturing baccalaureate will prepare students for work within the biotechnology industry in the unique environment of biological production where the science thrives in partnership with quality and compliance.

This degree program explicitly emphasizes the applied, quantitative analysis of biomanufacturing-process design and performance. In addition, students completing the program may choose to sit for certification exams from the American Society for Quality. Certification provides valuable, third-party recognition of industry-relevant skills, abilities, and knowledge.

Appropriateness of Upper-Division Courses

The major upper-division course work will be comprised of two primary areas of concentration: *Biomanufacturing Science and Technology* and *Biomanufacturing Quality,* as illustrated in Table 1.

Table 1. Biomanufacturing Baccalaureate Upper-Division Course Work

Upper-Division Major Course Work		
Biomanufacturing Science and Technology Concentration Course	**Course Description**	**Units**
Process Sciences (Lecture/Lab)	Fundamental physical and chemical principles and technologies enabling large scale biomanufacturing. Thermodynamics and the properties of fluids; mass and heat transfer, fluid flow, and the energy relationships in fluid systems	4 units
Design of Experiments for Biomanufacturing (Lecture/Lab)	Formal methods in connecting process parameters and quality attributes towards improved process understanding. Full and fractional factorial experimentation.	4 units
Design of Biomanufacturing Processes and Equipment (Lecture/Lab)	Advanced course work in the design of processes and equipment in biological production, recovery, and purification within a quality framework. Aseptic process design, fitness for use, critical utilities, modes of operation.	4 units
Bioprocess Monitoring and Control (Lecture/Lab)	The measurement, monitoring, modeling, and control of biomanufacturing processes.	3 units
Seminar in Biomanufacturing Technologies	Advances and current technology in biological production and purification operations.	2 units
Biomanufacturing Science and Technology concentration subtotal:		**17 units**
Biomanufacturing Quality Concentration Course	**Course Description**	**Units**
Statistical Process Control (Lecture/Lab)	Concepts and methodology for measuring and controlling quality during the manufacturing process; control charts, process capability.	3 units

Global Quality System Regulations (Lecture)	Study of the harmonized quality system approaches of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Q8, 9, 10, and 11, including quality risk management, qualification, and validation.	4 units
Six Sigma and Lean Manufacturing (Lecture/Lab)	Study of key six sigma concepts and tools; the DMAIC phases: design, measure, analyze, improve, and control. Use and implementation of lean tools to reduce waste.	4 units
Methods in Quality Improvements and Investigations (Lecture/Lab)	The study of continuous quality improvement techniques, including the investigational methods into process deviations.	4 units
Seminar in Biomanufacturing Quality (Lecture)	Advances and current practices in biomanufacturing quality.	2 units
Biomanufacturing Quality concentration subtotal:		**17 units**
Upper-Division General Education Course Work		
Course	**Course Description**	**Units**
Advanced Technical Writing for Regulated Environments (Lecture)	Advanced technical writing applied to a variety of documents including reports, standard operating procedures (SOP), batch production records, and investigations	3 units
Public Health/Principles of Epidemiology (Lecture/Lab)	Application of epidemiologic procedures to the understanding of the occurrence and control of infectious and chronic diseases, mental illness, environmental health hazards, accidents, and geriatric problems.	3 units
Leadership Skills and Team Dynamics (Lecture)	Leadership concepts and skills, including the psychological process, conflict resolution, counseling, and human service skills. The course further addresses awareness and development of personal leadership styles.	3 units
Upper-Division General Education Subtotal:		**9 units**
Upper-Division Course Work Total:		**43 units**

The first concentration focuses on the science and technology of a biological production process, developing connections between process understanding, process scale, and process control in biomanufacturing. The *Biomanufacturing Quality* concentration focuses on the impact of quality and compliance on regulated biological products and the business practices employed by biotechnology companies to assure product safety, efficacy, and quality.

The upper-division course work integrates foundational knowledge and skills developed in the lower-division programming. It includes advanced application of critical thinking and increases

currency in the field as evidenced in lecture, laboratory activities, assignments, and readings. Students will demonstrate this integration of knowledge and skill though writing, oral communication, and/or computation.

Program Length

The new Bachelor of Science in Biomanufacturing will follow a format that builds on the existing associate in arts program within the Biotechnology Department.

Prior to enrolling in the program, students will be given the baccalaureate course requirements as well as a two-year education plan of specific major course offerings. Table 2 illustrates how a full-time student's educational plan will be structured.

Table 2. Baccalaureate Education Plan

Lower Division	Biotechnology associate degree or equivalent preparation	
Upper Division, Year One	**Fall Term**	**Spring Term**
	● Process Sciences ● Design of Experiments for Biomanufacturing ● Global Quality System Regulations ● Elective courses	● Design of Biomanufacturing Processes and Equipment ● Statistical Process Control ● Advanced Technical Writing for Regulated Environments ● Elective courses
Upper Division, Year Two	**Fall Term**	**Spring Term**
	● Bioprocess Monitoring and Control ● Six Sigma and Lean Manufacturing ● Seminar in Biomanufacturing Technologies ● Public Health/Principles of Epidemiology ● Elective courses	● Methods in Quality Improvements and Investigations ● Seminar in Biomanufacturing Quality ● Leadership Skills and Team Dynamics ● Elective courses

Course sequencing will permit a full-time student to complete the requisite 120 units for the baccalaureate in four years.

Instructional Delivery

Upper-division biomanufacturing and general education course work will be offered in lecture through traditional face-to-face as well as distance education formats as appropriate. Laboratory courses will be delivered face-to-face with hands-on instruction and practice. Assignments will include research papers with technical writing components, individual and group projects, and other authentic assessments of student learning. All hybrid and completely online instruction will utilize the selected existing online learning platform (e.g., Blackboard), and students will have access to the library and supplemental instruction as well as counseling services and other student support services.