

## **BIOE 4000: Bioprocess Validation and Quality Engineering**

This course, or ICEE 4000 Quality Systems Engineering, is required for all Engineering majors.

Course Coordinator:

Stephanie T. Sullivan

Catalog Description:

Overview of bioprocess validation and quality control systems that ensure safe products, reduce the risk of adverse reactions, and avoid recalls. Emphasizes cost effectiveness and level of validation required for different phases of development, license application, and process improvements. Also covers design of experiments in bioprocess applications.

Course Structure:

Four 50-minute lectures (four credits)

Prerequisites:

MATH 3307, consent of instructor

Required Materials:

1. *Probability and Statistics for Engineers and Scientists, 8th Edition*, Ronald E. Walpole, et al. Pearson Education, 2006. (ISBN 0131877119)

Course Objectives:

Upon completion of this course, students shall be able to:

- Estimate one- and two-sample parameters
- Perform one- and two-sample statistical hypothesis testing
- Apply simple and multiple linear regression models
- Design and implement factorial experiments
- Analyze results of control charts
- Explain inspection and auditing techniques
- Compare qualified person and training factors for bioprocessing personnel
- Review calibration and maintenance of bioprocess equipment
- Understand and demonstrate knowledge of cleaning & cleaning validation principles
- Familiar with Installational /Operational Qualification
- Proficient in general GMP documentation techniques & Batch Record Review
- Development of process validation protocol
- Understand Quality investigation & Corrective Action development

Lecture Topics:

- Review of Probability Distributions and Sampling Distributions (2 classes)
- One-Sample Statistical Inference (3 classes)
- Two-Sample Statistical Inference (3 classes)
- One-Sample Statistical Hypothesis Testing (2 classes)
- Two-Sample Statistical Hypothesis Testing (2 classes)
- Simple Linear Regression Model (3 classes)
- Analysis-of-Variance Approach and Correlation (3 classes)
- Multiple Linear Regression Model (2 classes)
- One-Way Analysis of Variance (3 classes)
- Two-Factor Analysis of Variance (3 classes)
- Factorial Experiments (2 classes)
- Fractional Factorial Experiments (2 classes)
- Statistical Process Control (3 classes)
- Control Charts for Variables (2 classes)
- Control Charts for Attributes (2 classes)

- Process Capability Analysis and Acceptance Sampling (2 classes)
- Good Manufacturing Practices (GMP)
- Design of Experiments and Qualification
- Calibration
- Auditing/Inspections
- Validation

Relevant Program Outcomes:

Graduates of the BS in Engineering Program will demonstrate:

- a) an ability to apply knowledge of mathematics, science, and engineering.
- b) an ability to design and conduct experiments, as well as to analyze and interpret data.
- c) an ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability.
- e) an ability to identify, formulate, and solve engineering problems.
- g) an ability to communicate effectively.
- h) an understanding of the impact of engineering solutions in a global, economic, environmental, and societal context.
- i) a recognition of the need for, and an ability to engage in life-long learning.
- j) a knowledge of contemporary issues.

Professional Component Content:

Math/Science: 0;      Engineering: 4 cr;      General Education: 0

Assessment Requirements:

Student Work Samples:

- Homework report (Outcomes b and g)
- Assignment on contemporary issues (Outcome j)
- Course project and presentation (Outcomes a, b, c, e, g, i, and j)

Targeted Exam Questions

- Application of statistics (Outcome a)
- Solution of engineering problems (Outcome e)

Student Course Survey

Last Review:

October, 2008 by Stephanie T. Sullivan