PURDUE UNIVERSITY | Agricultural and Biological Engineering

Biotechnology Quality and Regulatory Compliance Graduate Certificate Curriculum Overview

The Biotechnology Quality and Regulatory Compliance Graduate Certificate requires 12 credit hours. The program will consist of 4 courses.

Required (Primary) – Biotechnology Quality and Regulatory Compliance (BQRC) core courses:

☐ ABE 51100 Drug Development

A review of drug discovery and drug development, with emphasis on the regulatory aspects of these activities. Animal preclinical research and human clinical research are discussed in detail. In addition, the process for the assembly of an IND and NDA is discussed along with the Phases (I, II, III) of human clinical trials. The CMC (chemistry manufacturing and control) aspects of drug development are presented along with ICH documents and manufacturing process analytical technologies. The course concludes with a brief review of international regulatory issues and patents.

- Credit Hours: 3
- Offered: primarily spring or fall semester

☐ ABE 51200 Good Regulatory Practices

Includes a review of the FDA and ICH regulations on good manufacturing, good laboratory, good clinical practices. The meaning of these regulations, the globalization of practices and the roles and responsibilities of various professionals implementing these regulations will be addressed. Special emphasis will be detailed coverage of the process for the assembly and submission of an IND or NDA, and the function of the regulatory affairs department in a pharmaceutical company.

- Credit Hours: 3
- Offered: primarily spring or fall semester

☐ ABE 51300 Quality Management, Audits & Inspections

This course provides advanced topics in quality management and business improvement methods that apply to the pharmaceutical industry. Emphasis will be placed on specific issues of industry, audits, and inspections, as well as the successful selection and presentation of business and quality improvement projects to produce compliance and competitive advantage.

- Credit Hours: 3
- Offered: primarily spring or fall semester

☐ ABE 51500 Molecular Basis in Manufacturing

This advanced course addresses important Chemistry Manufacturing and Control (CMC) issues related to manufacturing and quality by design. The course provides important information on strategies for quality by design, manufacturing strategies for early development, the best approaches to analyzing data, and strategies for reporting the information to the FDA. This course will also focus on product design and processing. Using product and process design helps achieve quality by design (QbD), strong development reports, excellent regulatory submissions and allows continuous improvement. The course includes laboratory exercises, laboratory tours, and/or workshops outlining how to interpret the data.

- Credit Hours: 3
- Offered: primarily offered summer semester

Tips:

- Purdue courses that are more than five years old may ***not*** be used.
- A Plan of Study is not required for the graduate certificate.