TO: The Faculty of the College of Engineering

FROM: Bernard A. Engel, Department Head Agricultural & Biological Engineering

DATE: November 21, 2018

RE: New Graduate Course, ABE 51400, EFD – 68-19

The faculty of the School of Agricultural & Biological Engineering has approved the following new course. This submission is recommended to the Engineering Faculty for approval.

ABE 51400 Documents and Dialogues of Drug Development and Registration
Lecture, Cr. 3

Course Description

This course will integrate learning relating to laws and regulations, quality principles and practices, and the preparation and submission of documents for new and generic drug approvals within the biotechnology industry. Time will be devoted to preparing regulatory documents and conducting "mock" dialogues and negotiations with "pretend" agency officials.

Justification

A blended pedagogical approach for course delivery will be used. Class time will focus on interactive and engaging sessions, to learn and practice the application of course material. Guest lectures will be provided from professional experts from industry, focused on current topic lectures and discussions. Additional resources and fundamental core content is provided online using the Blackboard Learn course management system.

Student evaluation is based upon case studies, quizzes, reflections and a final project with application to drug development. Students also work in groups and practice professional communication through presentations and discussions surrounding the course topics, case studies and final project.

Students will have lectures from academic, industry and regulatory representatives. There will be detailed lectures on process, and many hands-on group activities to enable the student to "appreciate the course material by doing". Sample activities include undergoing the deposition

process by a patent attorney; defending a research proposal in an IACUC (Institutional Animal Care and Use Committee) meeting; experiencing an informed consent process; participating in a clinical research investigators' meeting; and understanding the sections and the assembly of an IND and an NDA. Case studies will be part of the learning, along with some role-play activities.

This course is a core course for both the Biotechnology Quality and Regulatory Compliance graduate certificate and the Area of Specialization in Biotechnology Innovation and Regulatory Science.

TLI 52300: Quality Management, Audits, Inspections

COURSE DESCRIPTION:

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

Course Rationale:

Modern biotechnology companies must conduct drug discovery, development, and sales in a highly regulated environment with competition and pricing pressures increasing. Integrated management systems for quality control, quality assurance, compliance, and business improvement are critical elements for success in this complex and evolving environment. The cost of poor quality and the penalties for non-compliance are unacceptable in today's drug development business. Knowledge of effective documentation, manufacturing principles and practices is a critical part of getting things "right the first time".

High quality and appropriate compliance (QA/QC) are essential for the viability of American industry, and academia as well. Almost daily, examples come to light showing the downside of poor quality or compliance: operations or organization closed, fines levied, careers affected, public images besmirched, credibility lost.

Interestingly, in the biotechnology industry staff for QC and QA are most often recruited from operations areas and few have any formal education on the policy and regulations and core principles of this profession. This course provides fundamental core principles for those interested in professional paths within regulatory affairs, quality control, or quality assurance specifically within the biotechnology industry. Individuals completing this program will be qualified for employment in regulatory affairs, quality control, and quality assurance departments in corporations or in analogous departments in academic institutions.

This course is a core course for both the Biotechnology Quality and Regulatory Compliance graduate certificate and the Area of Specialization in Biotechnology Innovation and Regulatory Science.

LEARNING OUTCOMES

The overall learning outcomes for the program include:

Comprehension: The student shall comprehend strategies used for biotechnology innovation: regulatory and quality documents and materials in the areas of drug development and discovery.

Integrative competence: The student shall be able to meld theory and practice

Critical thinking and decision making abilities: The student shall examine issues rationally, logically, and coherently; and shall acquire, evaluate, and synthesize information and knowledge relevant to an identified problem; and shall make sound decisions in both familiar and unfamiliar contexts.

Communication abilities: The student shall read, write, speak, listen, and use data, media and computers to send and respond effectively to communications for varied audiences and purposes.

Responsible use of values and ethical principles: The student shall demonstrate sensitivity to and facility with personal values and ethical principles in professional and social contexts.

COURSE LEARNING OUTCOMES

The following course learning objectives will focus on applications within the biotechnology industry.

After completing this course, the student will be able to:

- Understand quality management definitions, concepts, and guidelines
- Defining quality and how to establish a quality management system
- Define quality plan, describe its purpose for the organization as a whole and identify various functional areas and people that have responsibility for contributing to its development
- Understand the audit process and quality control, including the various approaches to audits, inspections and reviews.
- Understand basic skills required to manage audits, inspections and reviews. Learn how to set up effective self audit systems
- Understand the impact of changing technologies, such as electronic systems, on supporting a quality management system
- Understand how quality management functions support global business decisions for asset acquisitions and growth of a company.
- Understand the key elements of supply chain management, assessing risk, and managing outcomes from supplier and vendor audits.
- Understand regulatory compliance aspects and implementation of ICH and global quality principles in supply chain management, including good distribution practices.

- Define a continuous quality improvement or business improvement project within an organization. Select and define continuous quality improvement tools and techniques in order to achieve operational excellence.
- Independently develop in-depth knowledge of how to implement and obtain operational excellence and present the findings in a coherent and informative manner.

Textbooks and Resource Materials:

Westcott, R. and Duffy, G. (2014). The Certified Quality Improvement Associate Handbook: *Basic Quality Principles and Practices*. ASQ. (http://asq.org/quality-press/display-item/?item=H1470)

Purdue students can access primary literature and databases online through the Purdue Libraries: https://www.lib.purdue.edu/

Extensive use is made of the documents on the FDA website (www.fda.gov), including ICH Q8, ICH Q9, ICH Q10, ICH Q12

Pedagogy

A blended pedagogical approach for course delivery will be used. Class time will focus on interactive and engaging sessions, to learn and practice the application of course material. Guest lectures will be provided from professional experts from industry, focused on current topic lectures and discussions. Additional resources and fundamental core content is provided online using the Blackboard Learn course management system.

Student evaluation is based upon case studies, quizzes, reflections and a final project with application to drug development. Students also work in groups and practice professional communication through presentations and discussions surrounding the course topics, case studies and final project.

Assessment:

Assigned Readings.

Readings will be assigned to provide more information and background on the course concepts. There will be oral discussions in class over the readings, quizzes and case studies.

Quizzes

Quizzes may be given to evaluate your course progress. They will cover lecture material and course readings. Quiz items may be short answer, true-false, multiple choices, a short problem, or a combination of these.

Case Studies:

Case studies will be used extensively in this class. Case studies will be assigned to give you practice using the concepts learned in class. Therefore, it is particularly important that you personally do the work. Working with other individuals is fine as long as you actively participate; learning is virtually eliminated when simply copying another person's work. Due dates for case studies will be posted on Blackboard Learn.

Final Class Project:
A final project will be used to evaluate your understanding of course material and provide you with an additional opportunity to apply knowledge from the lectures and case studies to a project that is relevant to the current field of drug development. Students will work on the project in class during iterative, interactive sessions and will be required to submit a synopsis of their work for grading.

Grading:
The final grades for the course will be determined by a total accumulation of points from all activities and assignments. Individual progress toward course learning outcomes and final grades will be computed based on the following weights:

Assignments	**Percentage**
Case Studies	50
Final Class project	25
Attendance, Class Participation, and Reflection	25
Total	100

Grading Scale:

Grade	**GPA Value**	**% Range**
A	4.0	93-100
A-	3.7	90.0-92.9
B+	3.3	87.0-89.9
B	3.0	83.0-86.9

B-	2.7	80.0-82.9
C+	2.3	77.0-79.9
C	2.0	73.0-76.9
C-	1.7	70.0-72.9
D+	1.3	67.0-69.9
D	1.0	63.0-66.9
D-	0.7	60.0-62.9
F	0.0	<60.0

Academic Dishonesty

Purdue prohibits "dishonesty in connection with any University activity. Cheating, plagiarism, or knowingly furnishing false information to the University are examples of dishonesty." [Part 5, Section III-B-2-a, Student Regulations] Furthermore, the University Senate has stipulated that "the commitment of acts of cheating, lying, and deceit in any of their diverse forms (such as the use of substitutes for taking examinations, the use of illegal cribs, plagiarism, and copying during examinations) is dishonest and must not be tolerated. Moreover, knowingly to aid and abet, directly or indirectly, other parties in committing dishonest acts is in itself dishonest." [University Senate Document 72-18, December 15, 1972]

Please refer to Purdue's student guide for academic integrity for additional information: https://www.purdue.edu/odos/academic-integrity/

Use of Copyrighted Materials

Students are expected, within the context of the Regulations Governing Student Conduct and other applicable University policies, to act responsibly and ethically by applying the appropriate exception under the Copyright Act to the use of copyrighted works in their activities and studies. The University does not assume legal responsibility for violations of copyright law by students who are not employees of the University.

A Copyrightable Work created by any person subject to this policy primarily to express and preserve scholarship as evidence of academic advancement or academic accomplishment. Such works may include, but are not limited to, scholarly publications, journal articles, research bulletins, monographs, books, plays, poems, musical compositions and other works of artistic

imagination, and works of students created in the course of their education, such as exams, projects, theses or dissertations, papers and articles.

Please refer to the University Regulations on policies:
http://www.purdue.edu/policies/academic-research-affairs/ia3.html

Attendance
Purdue University policy states that all students are expected to be present for every meeting of the classes in which they are enrolled. Only the instructor can excuse a student from a course requirement or responsibility. When conflicts or absences can be anticipated, such as for many University sponsored activities and religious observations, the student should inform the instructor of the situation as far in advance as possible…For unanticipated or emergency absences when advance notification to an instructor is not possible, the student should contact the instructor as soon as possible by email, or by contacting the main office that offers the course. When the student is unable to make direct contact with the instructor and is unable to leave word with the instructor's department because of circumstances beyond the student's control, and in cases of bereavement, the student or the student's representative should contact the Office of the Dean of Students.

The link to the complete policy and implications can be found at:
http://www.purdue.edu/studentregulations/regulations_procedures/classes.html

Missed or Late Work
Assignments must be turned in at the beginning of class or submitted via Blackboard Learn. Assignments will not be accepted via email unless special arrangements have been made in advance.

Late assignments will not be accepted unless special arrangements have been made with the instructor, preferably in advance. If prior arrangements have not been made, missed or late assignments will not receive credit. See policy above regarding arriving late/leaving early. Assignments can be accepted early.

Grief Absence Policy for Students
Purdue University recognizes that a time of bereavement is very difficult for a student. The University therefore provides the following rights to students facing the loss of a family member through the Grief Absence Policy for Students (GAPS). GAPS Policy: Students will be excused for funeral leave and given the opportunity to earn equivalent credit and to demonstrate evidence of meeting the learning outcomes for misses assignments or assessments in the event of the death of a member of the student's family.

See the University's website for additional information:
http://www.purdue.edu/studentregulations/regulations_procedures/classes.html

Violent Behavior Policy

Purdue University is committed to providing a safe and secure campus environment for members of the university community. Purdue strives to create an educational environment for students and a work environment for employees that promote educational and career goals. Violent Behavior impedes such goals. Therefore, Violent Behavior is prohibited in or on any University Facility or while participating in any university activity.

See the University's website for additional information:
http://www.purdue.edu/policies/facilities-safety/iva3.html

Emergencies
In the event of a major campus emergency, course requirements, deadlines and grading percentages are subject to changes that may be necessitated by a revised semester calendar or other circumstances beyond the instructor's control. Relevant changes to this course will be posted onto the course website or can be obtained by contacting the instructors or TAs via email or phone. You are expected to read your @purdue.edu email on a frequent basis.

See the University's website for additional information:
https://www.purdue.edu/ehps/emergency_preparedness/

Accessibility and Accommodations
Purdue University strives to make learning experiences as accessible as possible. If you anticipate or experience physical or academic barriers based on disability, you are welcome to let me know so that we can discuss options. You are also encouraged to contact the Disability Resource Center at: drc@purdue.edu or by phone: 765-494-1247.

Nondiscrimination
Purdue University is committed to maintaining a community which recognizes and values the inherent worth and dignity of every person; fosters tolerance, sensitivity, understanding, and mutual respect among its members; and encourages each individual to strive to reach his or her own potential. In pursuit of its goal of academic excellence, the University seeks to develop and nurture diversity. The University believes that diversity among its many members strengthens the institution, stimulates creativity, promotes the exchange of ideas, and enriches campus life.

Purdue University prohibits discrimination against any member of the University community on the basis of race, religion, color, sex, age, national origin or ancestry, genetic information, marital status, parental status, sexual orientation, gender identity and expression, disability, or status as a veteran. The University will conduct its programs, services and activities consistent with applicable federal, state and local laws, regulations and orders and in conformance with the procedures and limitations as set forth in Executive Memorandum No. D-1, which provides specific contractual rights and remedies. Any student who believes they have been discriminated against may visit www.purdue.edu/report-hate to submit a complaint to the Office of Institutional Equity. Information may be reported anonymously.

Please refer students to Purdue's nondiscrimination statement:
http://www.purdue.edu/purdue/ea_eou_statement.html

Course Schedule and Lecture Topics

Lecture Topics:

- Quality Basics, Terms, Concepts, and Principles: Quality Management as Good Business
- ISO 9000-2000 and Related Quality Standards: Setting Performance Standards for Operations
- Six Sigma and Lean Enterprise: Introducing the Tolls of Business Improvement and Change
- Quality Benefits, Philosophies, and Models: Overview of the Different Approaches to Quality Management
- Introduction to Teams: Types of Teams, Roles and Responsibilities, Team Formation and Group Dynamics
- Improving Customer - Supplier Relationships: Internal and External Customers and Suppliers, Customer and Supplier Feedback
- Continuous Improvement Concepts: Incremental and Breakthrough Improvement Cycles
- Continuous Improvement Tools: Quality Improvement Tools for all Situations
- Business Process Modeling and Simulation
- Information Issues
- Data Exploration, Innovation and Creativity
- The Philosophy and Principles of Inspections and Audits
- The Management of a Quality Assurance Auditing Division
- Good Audits and Bad Audits...Good Auditors and Bad Auditors
- Detecting and Dealing with Fraud
- Auditing Pre-clinical (Discovery and Toxicology) Research
- Auditing Clinical Research
- Auditing Computers and IT Systems
- Auditing Manufacturing Facilities and Operations
- Auditing Financial Operations
- Auditing Sales and Marketing Operations
- Nuclear Regulatory Commission
- Drug Enforcement Agency (DEA) Inspections
- United States Department of Agriculture (USDA) Inspections
- Occupational Safety and Hazards Administration (OSHA) Inspections

- Effective Follow-up After Audits: Principles and Practices
- Instruction for Project Team Reviews and Coaching
- Effective Coaching and Constructive Criticism: Coaching Techniques
- Finding Appropriate Project Metrics and Measuring Performance
- Project Management and Effective Follow-up