# New Course EFD Template

PURDUE UNIVERSITY | College of Engineering

Engineering Faculty Document
No.: 50-25
September 26, 2024

**TO**: The Engineering Faculty

**FROM**: The Faculty of the Agricultural and Biological Engineering Department

**RE**: New graduate course–ABE 61900– Biotechnology Innovation in Regulatory Science

The Faculty of the department has approved the following new graduate course. This action is now submitted to the Engineering Faculty with a recommendation for approval.

**FROM** (IF ALREADY OFFERED WITH TEMPORARY NUMBER)**:**

ABE 59100 – Biotechnology Innovation in Regulatory Science

Fall, Spring, Summer

3 total credits; **LEC/50/2/16 and LAB/50/1/16**

Prerequisites: None

This course has been taught 2-3 times since transferring the program to the Agricultural and Biological Engineering Department in fall 2019 with approximately 30 domestic students enrolled. There is also an increased global demand for this course with 100+ enrollments in recent course offerings.

**TO:**

ABE 61900 – Biotechnology Innovation in Regulatory Science

Fall, Spring, Summer

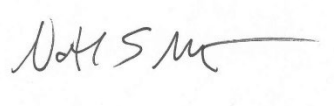
3 total credits; **LEC/50/2/16 and LAB/50/1/16**

Prerequisites: No

**This course is an introduction to biotechnology innovation and strategy. The framework for innovation and how this translates to regulatory science and drug development will be the focus. Students will learn key pharmaceutical strategy concepts including differences between large and small molecules, clinical and manufacturing statistics, and current pharmaceutical trends. Guest lecturers from both industry and regulatory organizations will provide applications of the topics above within the biotechnology manufacturing and regulatory industry. This course is an elective for the M.S. degree in Biotechnology Innovation and Regulatory Science.**

**RATIONALE:**

Today, pharmaceutical 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 quality management principles and practices is a critical part of getting things "right the first time." This course is an important part component of the M.S. concentration in Biotechnology Innovation and Regulatory Science. The purpose of the M.S. degree is to provide graduate students with an education in the important aspects of regulatory affairs, quality control and quality assurance. 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 program also provides an enrichment in quality control and quality assurance to people who are already working in the field and seeking ways to improve their skills or differentiate themselves from their counterparts. The rationale of the course ties to the program's purpose. 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, the pharmaceutical industry staff for QC and QA are most often recruited from operations areas; few have any formal education on the policy and regulations and core principles of their new professions...and most all have no detailed knowledge on specific skills for the job. In fact, only a few formal QA/QC education programs exist in America. The initial target audience for the Biotechnology Innovation and Regulatory Science M.S. program includes regulatory affairs, quality control, or quality assurance professionals who are already in the field and seeking a continuing education experience in order to grow their knowledge or a way to differentiate themselves from their counterparts in an organization. This course builds on our core technical strengths, integrates professional competencies, and capitalizes on biotechnology and innovation to equip the next generation of leaders in regulatory science.



Head/Director of the Department

Link to Curriculog entry: [Paste link to Curriculog entry.]

# ABE 59100-031 DIS: Biotechnology Innovation – Fall 2023 Syllabus

## 1. Course Information

ABE 59100-031 DIS: Biotechnology Innovation (3 credit hours)

- Virtual Only
  - Video Sessions
  - Class Sessions (Synchronous Learning Sessions with global Purdue BIRS alumni and student cohort):
    - Select Fridays throughout the semester beginning in October: Zoom details will be provided. All of the topics and speakers are relevant for our students because they are aligned with our overall program outcomes.
  - An experiential Saturday session will be held December 2, 2023 from 8:00 a.m. – 5:00 p.m..
- Course credit hours: 3
- Course will be managed in the Brightspace learning system

## 2. Instructional Team

**Faculty Instructor:**


- Dr. Kari Clase
  - Professor, Department of Agricultural & Biological Engineering
  - Phone: 765-494-4649
  - Email: kclase@purdue.edu
- Stephen Byrn, Ph.D.
  - Charles B. Jordan Professor of Medicinal Chemistry, Dept of Industrial and Physical Pharmacy
  - Phone: 765-714-2808
  - Email: sbyrn@purdue.edu


*Office hours available by appointment. Please don't hesitate to reach out to the course leadership team with questions or concerns. We are happy to schedule a time to meet with you.*

## 3. Course Description

- This course is an introduction to biotechnology innovation and strategy. The framework for innovation and how this translates to regulatory science and drug development will be the focus.
- Students will learn key pharmaceutical strategy concepts including differences between large and small molecules, clinical and manufacturing statistics, and current pharmaceutical trends.
- Guest lecturers from both industry and regulatory organizations will provide applications of the topics above within the biotechnology manufacturing and regulatory industry.

This course is an elective for the M.S. degree in Biotechnology Innovation and Regulatory Science.

## 4. Course Materials

- Readings from the primary literature will be used in addition to online databases. Purdue students can access primary literature and databases online through the Purdue Libraries: https://www.lib.purdue.edu/.
- Additional Readings: Readings and resources may be recommended based upon project interests. Access to additional readings and online chapters will be through the Brightspace course readings folder and through the Library Resources Link.
- Software/web resources.
    - Word Processor (i.e. MS Word), remember that MS Office is free for all students.
- Brightspace page
    - You can access the course via Brightspace. It is strongly suggested that you explore and become familiar not only with the site navigation, but with content and resources available for this course. See the Help tab for resources.

## 5. Assignments and Points

Your learning will be assessed through a combination of participation, case studies, discussions, reflections, quizzes, and a final project spread throughout the semester. Details on these assignments, including rubrics to guide evaluation, and guidelines for the assignments will be posted on the course website.

| ASSIGNMENTS | PERCENTAGE OF FINAL GRADE |
|---|---|
| Business Canvas Strategy Semester Project | 40% |
| Reflections | 20% |
| Research Paper | 30% |
| Professionalism & Participation | 10% |

This course is online, you are responsible for your own progress. You should check Brightspace on a regular basis and the course schedule to make sure you are doing everything required. There will be videos to watch as well as supplemental information exploring a variety of topics.

**Reflections (20% of your grade):**

Reflections will be assigned throughout the semester based upon the course materials, including the weekly online BIRS Learning Sessions. You are encouraged to attend the BIRS learning sessions each Friday (please see the weekly schedule posted in Brightspace for additional topics and information). You will have periodic reflections assigned from the BIRS weekly learning sessions. If you are not able to attend during the synchronous session, you may review the recording asynchronously so you can still complete the reflection assignments.

Please note that each reflection and discussion is an INDIVIDUAL submission---this is not a group assignment. You may discuss the reflection and discussion questions with classmates, but your final submission must be written in your own words. *Sharing word-for-word answers on assignments constitutes academic dishonesty*.

When submitting work to Brightspace, you are affirming that it is your individual work per Purdue University's academic dishonesty policy. *If your answers match with another student's, you will both receive a 0 and you could be reported to the Dean of Students, per Purdue University guidelines (please see below for more details regarding university policies).*

**Final Project-- Business Canvas Strategy Semester Project (40%):**

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 biotechnology innovation. The deliverables for the final project will be scaffolded with the case study assignments throughout the semester to ensure progress is being made and to offer constructive guidance and feedback. The due dates for each deliverable are provided in the course schedule and the details and information for each deliverable will be posted weeks in advance. You will have the opportunity to incorporate feedback, and revise for improvement towards your final semester project submission.

If you have questions at any time, reach out to the course leadership team.

**Research Paper (30%)—please see Brightspace for more details**

If you have questions at any time, reach out to the course leadership team.

**Participation and Professionalism: (20% of grade)**

A portion of your grade will depend on your professionalism and participation. This includes watching the recorded videos, engaging with the content in Brightspace, and how you conduct yourself in discussions, emails, and assignments.

- Following the Protect Purdue Pledge: As the Protect Purdue guidelines continue to evolve, students are expected to adhere to any and all guidelines put forth by the university to protect its faculty, staff, and students.
- Be Professional: when writing emails, answering reflection and discussion questions, or communicating with peers or instructors, remember to be professional. You should conduct yourself in a respectable manner.

*We will schedule individual meetings throughout the semester to discuss and help guide students to develop a plan that best aligns with their goals and needs for the semester, depending upon where they are in their plan of study.*

## 6. Missed or Late Work

Assignments must be turned in by the due date and time noted on the assignment document.

Late assignments will be accepted up to one week past the due date with a 10% penalty. Late assignments beyond one week and up to one month will be accepted with a 50% penalty.

**Grade Complaints**

Grade complaints must be emailed to the instructors within a week of receiving the grade.

## 7. Grading Scale

| GRADE | PERCENTAGE |
|---|---|
| A | 93 – 100% |
| A- | 90 – 92.9% |
| B+ | 87 – 89.9% |
| B | 83 – 86.9% |
| B- | 80 – 82.9% |
| C+ | 77 – 79.9% |
| C | 73 – 76.9% |
| C- | 70 – 72.9% |
| D+ | 67 – 69.9% |
| D | 63 – 66.9% |
| D- | 60.0 – 62.9% |
| F | <60.0% |

*The final date to withdraw from a course with a W or WF for Fall 2022 is Tuesday, Oct. 25.

## 8. Attendance Policy

This course is asynchronous with optional synchronous learning sessions. Recordings for synchronous learning sessions will be posted in Brightspace.

The most recent updates related to attendance includes the addition of a Medically Excused Absence Policy for Students (MEAPS) among reasons to be granted an excused absence from class – in addition to Grief/Bereavement, Military Service, Jury Duty, Parenting Leave. MEAPS guidelines are covered in the Attendance section of Academic Regulations, and some clarification is offered on the ODOS website, since students must work with ODOS for any of these excused absences. Generally, MEAPS may be an option for students who must miss class for emergent or urgent care.

## 9. Learning Outcomes

*By the end of this course, you will be able to:*

- Describe how the framework for innovation translates to a biotechnology organization by developing a topic of interest into a research paper
- Explain the major steps in large molecule development by applying to an mRNA vaccine business case study:
    - Select a mRNA vaccine to manufacture and provide rationale
    - Describe the manufacturing methodology to be utilized
    - Describe how you will set up a GMP system within your manufacturing facility

    - Provide rationale for manufacturing facility to be utilized (pod versus bricks and mortar)
    - Describe analytical testing to be employed
    - Depict the strategy canvas for your project
- Understand the role of novel delivery systems in drug development
- Understand how data and computer systems enhance innovation
- Explain the risk of innovation and identify risk mitigation strategies

## 10. Academic Guidance for Quarantined/Isolated Students

If you have to quarantine for due to exposure to an infectious disease, the Office of the Dean of Students can provide you with an absence letter. You DO NOT have to inform us if you tested positive for COVID-19 or your vaccination status, that is your personal medical information and it is not necessary to share. However for an excused absence, it is required that we receive a notice from the Office of the Dean of Students that you will be absent from class. Your Academic Case Manager can be reached at acmq@purdue.edu and will provide you with general guidelines/resources around communicating with your instructors, be available for academic support, and offer suggestions for how to be successful when learning remotely.

Importantly, if you find yourself too sick to progress in the course, notify your academic case manager and notify Dr. Clase via email. We will make arrangements based on your particular situation.

Please see guidelines for students and instructors/staff in the Fall 2022: What you need to know **guidance published July 27**.

## 11. Academic Integrity

Academic integrity is one of the highest values that Purdue University holds. Individuals are encouraged to alert university officials to potential breaches of this value by either emailing or by calling 765-494-8778. While information may be submitted anonymously, the more information that is submitted provides the greatest opportunity for the university to investigate the concern.

The Honor Pledge Task Force, a student organization responsible for stewarding the mission of the Honor Pledge and encouraging a culture of academic integrity, asks all instructors to prominently include the student-initiated Purdue Honor Pledge on their syllabus, as well as exams and key assignments:

The Purdue Honor Pledge "As a boilermaker pursuing academic excellence, I pledge to be honest and true in all that I do. Accountable together - we are Purdue"

### AI Policy

In this course, the use of artificial intelligence (AI) language models, such as ChatGPT, is acceptable in some cases. Examples of acceptable and unacceptable uses of AI language models, such as ChatGPT, are included in the table below. If a student is unsure whether a particular use case of AI is acceptable for this course, they should ask the instructor for clarification prior to use of AI.

| Acceptable Uses of AI | Non-Acceptable Uses of AI |
|---|---|
| --Conducting background/supporting research on an assignment (case study, homework) -- Identifying sources for further examination<br>--Refining/checking grammar and writing style<br>--Refine design/visuals for assignments | --Completing course quizzes and exams<br>--Writing entire sections of text (e.g., full paragraphs) --Completing your portion of a group assignment without the group's knowledge and consent |

AI can be a powerful learning tool, but it must be used ethically and responsibly. In any cases where students use AI, it is critical that they cite their work; students are also required to submit: 1) any prompts they used and 2) the output generated by AI. Students are responsible for fact checking information provided by AI language models.

Students who use AI in an unacceptable way or do not disclose the use of AI in an assignment will be in violation of the academic integrity expectations for this course. Violations can include a failing grade on the assignment. All suspected incidents of academic dishonesty will also be referred to the Office of Student Rights and Responsibilities for further review of the student's status with the University.

## 12. Nondiscrimination Statement

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. Link to Purdue's nondiscrimination policy statement.

## 13. Students with Disabilities

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.

## 14. Emergency Preparation

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.

*Guidelines regarding ensuring access to emergency information:*

- *Keep your cell phone on to receive a Purdue ALERT text message.*
- *Log into a Purdue computer connected to the network to receive any Desktop Popup Alerts.*
- *If you have a "no cell phone" in class policy allow one or two students who have signed up for Purdue ALERT to keep their phones on to receive any alerts*

## 15. Mental Health Statement

- **If you find yourself beginning to feel some stress, anxiety and/or feeling slightly overwhelmed, try WellTrack.** Sign in and find information and tools at your fingertips, available to you at any time.
- **If you need support and information about options and resources**, please see the Office of the Dean of Students for drop-in hours (M-F, 8 am- 5 pm).
- **If you're struggling and need mental health services**: Purdue University is committed to advancing the mental health and well-being of its students. If you or someone you know is feeling overwhelmed, depressed, and/or in need of mental health support, services are available. For help, such individuals should contact Counseling and Psychological Services (CAPS) at 765-494-6995 during and after hours, on weekends and holidays, or by going to the CAPS office of the second floor of the Purdue University Student Health Center (PUSH) during business hours.

## 16. 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 full violent behavior policy for more detail.

## 17. Diversity and Inclusion Statement

In our discussions, structured and unstructured, we will explore a variety of challenging issues, which can help us enhance our understanding of different experiences and perspectives. This can be challenging, but in overcoming these challenges we find the greatest rewards. While we will design guidelines as a group, everyone should remember the following points:

- We are all in the process of learning about others and their experiences. Please speak with the GTAs or Dr. Clase, anonymously if needed, if something has made you uncomfortable.
- Intention and impact are not always aligned, and we should respect the impact something may have on someone even if it was not the speaker's intention.
- We all come to the class with a variety of experiences and a range of expertise, we should respect these in others while critically examining them in ourselves.

## 18. Course Evaluation

During the last two weeks of the course, you will be provided with an opportunity to evaluate this course and your instructor. Purdue uses an online course evaluation system. You will receive an official email from evaluation administrators with a link to the online evaluation site. You will have up to two weeks to complete this evaluation. Your participation is an integral part of this course, and your feedback is vital to improving education at Purdue University. I strongly urge you to participate in the evaluation system.

## 19. Disclaimer

This syllabus is subject to change. Any changes made to the syllabus will be announced via email and Brightspace.