

New Course EFD Template



College of Engineering

Engineering Faculty Document

No.: 49-25

September 26, 2024

TO: The Engineering Faculty
FROM: The Faculty of the Agricultural and Biological Engineering Department
RE: New graduate course – ABE 61800 – Project Management in BIRS

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 – Project Management in BIRS

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 25 domestic students enrolled. There is also an increased global demand for this course with 100+ enrollments in recent course offerings.

TO:
ABE 61800 - Project Management in BIRS
Fall, Spring, Summer
3 total credits; LEC/50/2/16 and LAB/50/1/16
Prerequisites: None

The factors influencing decisions during the initiation, implementation, and termination of industrial and manufacturing projects are examined. Students work as project teams, using project management tools to develop implementation strategies.

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: [\[Paste link to Curriculog entry.\]](#)

Spring 2024: Project Management in BIRS

- Meeting time: Please hold Fridays from 10:00 am to 1:00 pm---we will schedule weekly learning sessions for the course during this time; Zoom meeting information and details for each week will be shared via Brightspace. All of the topics and speakers are relevant for our students because they are aligned with our overall program outcomes.
- Course credit hours: 3
- Course will be managed in the Brightspace learning system
- An experiential Saturday session will be held on April 27, from 8:00 a.m. – 5:00 p.m. (ET).

1. Instructor(s) Contact Information

- **Faculty Instructors**

- Dr. Martin D. Hynes III
- Dr. Kari Clase
 - Professor, Department of Agricultural & Biological Engineering
 - Phone: 765-494-4649
 - Email: kclase@purdue.edu
- Dr. Stephen Byrn
 - 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.

2. Course Description

The factors influencing decisions during the initiation, implementation, and termination of industrial and manufacturing projects are examined. Students work as project teams, using project management tools to develop implementation strategies.

3. Course Rationale

Today, pharmaceutical companies must conduct drug discovery, development, manufacturing and sales in a highly regulated environment with competition and pricing pressures increasing. Integrated management systems for biotechnology

innovation, discovery, development, 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 and manufacturing business. Knowledge of effective manufacturing principles and practices is a critical part of getting things "right the first time".

4. Program Learning Goals

The overall learning goals for the program include:

Comprehension: The student shall comprehend strategies used for biotechnology innovation: regulatory and quality documents, statistics, 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.

5. Course Learning Goals

Students will:

- Understand and learn the latest tools and techniques used in projects
- Develop a systems perspective for understanding projects
- Align projects with strategic objectives
- Develop and think analytically in order to successfully apply knowledge and technical expertise to the solution of real business problems.

6. Learning Resources, Technology & Texts

- Learning resources, online lectures, quizzes, case studies, and the major project as well as other current reading material will be provided through the Purdue course management system, Brightspace.

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

7. Assignments

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

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

Reflections (10% of your grade):

Reflection questions will be assigned throughout the semester based upon the course materials. Please note that each reflection is an INDIVIDUAL submission---this is not a group assignment. You may have conversation about the reflection 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 and Gradescope, 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).*

Individual Project: (40% of grade)

You will be assigned an individual project 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 if you actively participate; learning is virtually eliminated when simply copying another person's work.

Final Semester Group Project (40 % grade)

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 and drug regulatory processes.

Participation and Professionalism: (10% of grade)

A portion of your grade will depend on your professionalism and participation within the course. You are expected to participate and attend the online learning sessions weekly, participate in the breakout group meetings during the semester, and present your project with your team at the end of the semester. You will also have an individual mid-term presentation as noted above.

Professionalism includes how you conduct yourself in online discussion posts and emails, and in learning session meetings (through WebEx or Zoom). This includes:

- *Attendance and punctuality:* You should plan to show up to the video meetings on time, and you must attend them. If you cannot make it to class or a meeting, you must reach out to the course leadership team so that we can work with you per the attendance policies detailed above.
- *Be Prepared:* You should have read the assigned readings, reviewed the recorded lectures, and come to the class learning sessions ready to participate in conversation.
- *Following Purdue University Policies and Procedures:* Purdue has clear guidance and policies as noted in the syllabus and online links within the Brightspace system
- *Be Professional:* Remember to use professional communication as you write emails, answer reflection questions, or reach out and speak with your course leadership team. You should conduct yourself in a respectable manner.

If you become ill and as a result, you will miss any class learning sessions or assignment due dates, you must contact the course leadership team as soon as possible. Arrangements for alternative activities to make up work as needed will be made based upon your unique situation and circumstances.

8. Grading

Our course will be meeting for synchronous learning sessions weekly with additional resources and materials provided online. You are responsible for your own progress.

Updates will be posted on Brightspace with upcoming due dates and information. You should check these updates and the course schedule to make sure you are doing everything required. There may be recorded lectures to review as well as supplemental information exploring a variety of topics. *You should make sure you are checking Brightspace weekly.*

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
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Reflections	10
Individual Project	40
Final Semester Group Project	40
Participation and Professionalism	10
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

Course Policies

DISCLAIMER: *This syllabus and the course schedule are subject to change. We may adapt the course based on the situation with COVID19 and may need to make changes as we go. You will be notified of any changes via Brightspace announcements.*

See policy under professionalism and participation regarding arriving late/leaving early. Assignments can be submitted early.

Grade Concerns: Grade concerns must be emailed to the course leadership team within a week of receiving the grade.

Class Participation: You should attend all live learning classe sessions and participate actively and professionally on the course discussion boards within Brightspace, but we will have a relaxed attendance policy. If you feel sick in any way, email the course BEFORE the class period and we may provide you with another assignment to make up for any missed in person activity. **You MUST tell us in advance, otherwise we will mark you as absent.**

Missed or Late Work: Assignments must be turned in by the due date and time noted on the assignment link, generally by 11:59 pm EST on the date it is due. *Late assignments will be evaluated on a case by case basis, please contact the course leadership team if you have any issues submitting assignments BEFORE the due date.*

Late assignments will be accepted up to one week past the due date with a 5% penalty. Late assignments beyond one week and up to one month will be accepted with a 10% penalty. Late assignments that are over one month will not be accepted unless special arrangements have been made with the instructor, preferably in advance.

Course Schedule

Please note details in Brightspace.

* Schedule and assignments subject to change. Any changes will be posted in the Brightspace learning management system.

9. Academic Integrity

Please note the link in Brightspace to Purdue's Student Guide for Academic Integrity under University Policies.

[Purdue's 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."

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 integrity@purdue.edu or by calling 765-494-8778. While information may be submitted anonymously, the more information is submitted the greater the opportunity for

the university to investigate the concern. More details are available on our course Brightspace table of contents, under University Policies.

Please note that notes from the course are “considered to be ‘derivative works’ of the instructor's presentations and materials, and they are thus subject to the instructor's copyright in such presentations and materials.” As such, they cannot be sold or bartered without the express written permission of the course instructors and guest faculty. See the policy below which can also be accessed at the following link ([see part J of the Purdue student miscellaneous conduct regulations](#)).

J. Commercial Note Taking in Classes (University Senate Document 03-9, April 19, 2004.)

As used in this paragraph, the term “instructor” is defined as the individual who authored the material being presented as part of the course.

Among the materials that may be protected by copyright law are the lectures, notes, and other material presented in class or as part of the course. Always assume the materials presented by an instructor are protected by copyright unless the instructor has stated otherwise. Students enrolled in, and authorized visitors to, Purdue University courses are permitted to take notes, which they may use for individual/group study or for other non-commercial purposes reasonably arising from enrollment in the course or the University generally.

Notes taken in class are, however, generally considered to be “derivative works” of the instructor's presentations and materials, and they are thus subject to the instructor's copyright in such presentations and materials. No individual is permitted to sell or otherwise barter notes, either to other students or to any commercial concern, for a course without the express written permission of the course instructor. To obtain permission to sell or barter notes, the individual wishing to sell or barter the notes must be registered in the course or must be an approved visitor to the class. Course instructors may choose to grant or not grant such permission at their own discretion, and may require a review of the notes prior to their being sold or bartered. If they do grant such permission, they may revoke it at any time, if they so choose.

10. Nondiscrimination Statement

A link to Purdue's nondiscrimination policy is included in the Brightspace template and can also be found [here](#). Here is the first paragraph of the policy.

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. More details are available on our course Brightspace table of contents, under University Policies.

11. Accessibility

The Brightspace template includes detailed information from the Office of Institutional Equity, and links to the Disability Resource Center website, Purdue's Web Accessibility Policy, and Brightspace's Accessibility Compliance statement.

The Disability Resource Center (DRC) is a resource for students. Students may present a "Letter of Accommodation" to us at any point in the semester. Should you have questions about accommodations, please contact the DRC at 765-494-1247 or [email](#).

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. More details are available on our course Brightspace under Accessibility Information.

12. Mental Health Statement

A link to CAPS (listed as Purdue Counseling and Psychological Services) is on the Brightspace template, under the Student Services and Resources section.

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 contact or see the [Office of the Dean of Students](#). Call 765-494-1747. Hours of operation are M-F, 8 am- 5 pm.

If you find yourself struggling to find a healthy balance between academics, social life, stress, etc. sign up for free one-on-one virtual or in-person sessions with a [Purdue Wellness Coach at RecWell](#). Student coaches can help you navigate through barriers and challenges toward your goals throughout the semester. Sign up is completely free and can be done on BoilerConnect. If you have any questions, please contact Purdue Wellness at evans240@purdue.edu.

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.

13. Emergency Preparation

A link to Purdue's Emergency Preparedness resources is located on the Brightspace shell under University Policies; this webpage includes a link to resources on COVID-19

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.

14. References

Heer, R. (n.d.). A Model of Learning Objectives–based on *A Taxonomy for Learning, Teaching, and Assessing: A Revision of Bloom's Taxonomy of Educational Objectives*. Center for Excellence in Learning and Teaching, Iowa State University. <https://www.celt.iastate.edu/wp-content/uploads/2015/09/RevisedBloomsHandout-1.pdf>

Stanny, C.J. (2016). [Reevaluating Bloom's Taxonomy](https://doi.org/10.3390/educsci6040037): What Measurable Verbs Can and Cannot Say about Student Learning. *Educ. Science*, 6(4), 37. <https://doi.org/10.3390/educsci6040037>.