Course Requisite Change EFD Template

PURDUE UNIVERSITY | College of Engineering

Engineering Faculty Document
No.: 76-25
December 20, 2024

TO: The Engineering Faculty

FROM: The Faculty of the Agricultural and Biological Engineering Department

RE: Requisite Changes to ABE 51500 - Molecular Basis of Manufacturing

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

Requisite Change for ABE 51500 – Molecular Basis of Manufacturing

Underline the changes to be made.

FROM:

Lecture only

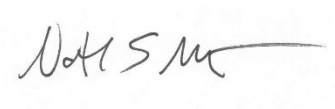
TO:

Lecture and Lab

1. LEC 90/1/16
2. DIS 90/1/16
3. LAB 360/1/1

RATIONALE:

For historical context, this course has been offered as part of the hybrid Biotechnology Innovation and Regulatory Science (BIRS) graduate program since the program's 20+ year existence. It is a lecture/lab, 3-credit hour course. When the BIRS program and its curriculum and courses moved to ABE from TLI, the course was categorized incorrectly as Lecture only. Due to the timing of the approval of the courses, and then the effects of COVID moving everything to an online delivery, this error was just realized.



Head of the Department

Link to Curriculog entry:

https://purdue.curriculog.com/proposal:30546/form

ABE 51500 Syllabus

Course Co-Instructors:

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Course Description

This hybrid 3-credit hour lecture with an advanced hands-on lab 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, and excellent regulatory submissions and allows continuous improvement. This course includes lectures, laboratory exercises, lab tours, and/or workshops outlining how to interpret data relevant to the field of biotechnology and regulatory science.

Modern pharmaceutical companies must conduct drug discovery, development, manufacturing and marketing in a highly regulated environment with increasing competition and pricing pressures. Systems for quality manufacturing, quality by design of manufacturing processes, process analytical technology, and on-line measurement are critical elements for success in this complex and evolving environment. The cost of poor quality and the penalties for noncompliance are unacceptable in today's drug development business. Knowledge of effective quality manufacturing principles and practices is critical to getting things right the first time. This course will provide information on best-in-class methods for quality manufacturing, quality by design and formulation.

The rationale of the course ties to the ABE 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.

Learning Outcomes

For example:

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

1. Identify
    - GMP manufacturing procedures operations including blending, granulation, drying, compression, coating, etc.
    - Specifications in manufacturing
    - Statistical principles important in manufacturing
2. Characterize
    - GMP manufacturing procedures
3. Evaluate
    - How drug products (solids, liquids, injectables) are characterized especially related to:
        - Dissolution
        - Weight variation
        - Content uniformity
        - Instrumental methods including X-ray diffraction
    - Approaches to determining critical quality attributes
    - Factors that influence the quality of the final product
    - DOE approaches to product optimization
4. Construct
    - QOS and Critical quality attributes diagram

5. Outline
    - How technology and innovation impact the manufacturing process
        - Strategies for continuous manufacturing
        - Process analytical technology methods
        - Innovations in manufacturing methods
    - How the global manufacturing environment impacts pharmaceutical manufacturing

Teaching Philosophy

As instructors, we try to maximize opportunities for every student to learn, grow, and succeed in reaching the course outcomes and reach their personal goals and desires related to the class. We draw on theory, frameworks, and practices rooted in principles of collaborative learning and student-faculty partnership. We focus on student learning, which we define as a process of individual change. This means developing skills to view the world in new ways, and engaging in different types of debates, discussions, and dialogues.

How to Succeed in this Course

If you want to be a successful student:

- Be self-motivated and self-disciplined.
- Be willing to “speak up” if problems arise.

- Be willing and able to commit to 4 to 15 hours per week to this course.
- Be able to communicate through writing.
- Be able to meet the minimum requirements for the course.
- Accept critical thinking and decision making as part of the learning process.

Learning Resources, Technology, & Texts

Chapters from a textbook (Theory and Practice of Industrial Pharmacy by Leon Lachman, Herbert A. Lieberman, and

Joseph L. Kanig, Stipes Publishing, LLC) is provided. These will be used to provide a foundational background.

Online lectures, quizzes, case studies, and other assignments as well as other current reading material and resources will be provided through the course management system or on box.

Course Logistics

During the 8 weerks of the active part of the course we will hold weekly 1 hour sessions by Zoom or WebEx. In addition, assignments will be provided on the course management system or by email. Due dates will be provided.

Instructor's Email Availability and Policies

This is an online course but feel free to contact the instructors with questions or problems. We will respond within 12-24 hours.

Assignments and Points

	Assignment	Points
1.	Select a product of your choice – identify type of dosage form, excipients used and potential role of excipient in the formulation, and packaging materials used in the product	25
2.	Statistics Quiz	25
3.	Suggest attributes that should be included in a specification for the product of your choice	25
4.	Identify potential in process controls for these unit ops	25
5.	Disintegration test	25
6.	Case study – content uniformity	50
7.	Design a multi factor DoE for optimization of a unit operation	50
8.	Final Project: Generate data from DOE in laboratory, analysis of data collected from laboratory experiments using JMP or Excel, Identify CQA/CPP and propose control strategy.	100
9.	Case study – X ray diffraction	25
10.	Quiz 1	25
11.	Quiz 2	25
	TOTAL	400

Missed or Late Work

Missed assignments may only be made up when you notify the instructors ahead of time with an explanation and plan for completion.

Grading Scale

In this class grades reflect the sum of your achievement throughout the semester. You will accumulate points as described in the assignments portion above, with each assignment graded according to a rubric. At the end of the semester, final grades will be calculated by adding the total points earned and translating those numbers (out of 200) into the following letters (there will be no partial points or rounding).

A: 90-100%
B: 80-90%
C: 70-80%
D: 60-70%
F:<60%

Attendance Policy

Students should attend all classes. If a student feels sick in any way, they must email the GTAs BEFORE the class period so they can provide the student with another assignment to make up for the missed in person activity. Students MUST tell GTAs in advance, otherwise they will be marked absent and points will be deducted from their Professionalism Grade. Students are allowed to miss three classes during the semester as long as students communicate with their lab partner, GTAs and Dr. Clase.

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 Office of the Dean of Students (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.

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"

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.

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.

Purdue has assistance available to help you make learning materials accessible. Some examples include:

- Information on Universal Design for Learning
- Guidance on creating accessible documents

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.

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.

Netiquette

Your instructor and fellow students wish to foster a safe online learning environment. All opinions and experiences, no matter how different or controversial they may be perceived, must be respected in the tolerant spirit of academic discourse. You are encouraged to comment, question, or critique an idea, but you are not to attack an individual. Our differences, some of which are outlined in the University's nondiscrimination statement below, will add richness to this learning experience. Please consider that sarcasm and humor can be misconstrued in online interactions and generate unintended disruptions. Working as a community of learners, we can build a polite and respectful course ambience.

Please read the Netiquette rules for this course:

• Do not dominate any discussion. Give other students the opportunity to join in the discussion.
• Do not use offensive language. Present ideas appropriately.
• Be cautious in using Internet language. For example, do not capitalize all letters since this suggests shouting.
• Avoid using vernacular and/or slang language. This could possibly lead to misinterpretation.
• Keep an "open-mind" and be willing to express even your minority opinion.
• Think and edit before you push the "Send" button.
• Do not hesitate to ask for feedback.

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.

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 me, 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.

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.

Disclaimer

This syllabus is subject to change. Any modifications will be communicated and shared through Brightspace.