

REG 6120 INTRODUCTION TO DRUG DEVELOPMENT

Time: Tuesdays, 5:30PM - 8:30PM

Location: Virtual Class via Zoom

Course Director

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*all opinions expressed are those of Dr. Doyle individually, and are not a reflection or endorsement by GSK

*syllabus is subject to change at professor's discretion

Description

Drug development is the process by which new chemical entities are discovered, studied in laboratory and preclinical models and investigated clinically in patients to determine if they are safe and efficacious. Assuming the compound under investigation passes systematically defined milestones, submission of all documentation to regulatory authorities (e.g., US FDA) can ensue and, pending a favorable review, market access can be granted. The process is highly regulated and there is significant cost involved for pharmaceutical sponsors to research and develop drugs with the entire process averaging around 12 years once a product is discovered.

This introductory course lays the foundation for conducting pharmaceutical research in many ways. It begins with a brief review of the history of drug development and explains the phases of drug development in detail. The decision making process, drug development milestones and compound progression metrics are defined and explained with examples. At the conclusion of this

course, students should have a working knowledge of the drug development process, understand the regulatory basis by which new chemical entities are evaluated and ultimately approved, and appreciate the time and expense of drug development.

This course will be important to students who are working in the healthcare field, especially as regulatory partners in the drug development process. Students will gain an understanding of the environment where they will apply this knowledge, understand the connection between drug development and regulation, have greater awareness of perspectives and biases of stakeholders, and develop communication skills in this environment.

Evaluation Methods:

Students will be graded based on class attendance, participation, group assignments and a short paper.

Category	Percentage
Attendance & Participation	10%
Assignments	90%

Course Policies:

Online Community Standards and Program Expectations

All students taking ITMAT Education online and hybrid courses must ensure that their learning environment for synchronous course meetings is appropriate and free from distractions to themselves, other students, and instructors. Specifically, participate in the session in a physical space and surrounding environment that allows you to devote your full attention to the course meeting. Remain stationary in that location for the duration of class. You are expected to log on using a computer, with working microphone and video capabilities. During class, your video must be operational and be on at all times, with your background blurred and your microphone muted to minimize unexpected distractions to you and your fellow students. Please be appropriately attired (casual wear is fine). If you identify issues that compromise your ability to meet these expectations, contact the course director to seek ways to resolve the situation in a timely manner.

Two general rules are (i) if you wouldn't expect your instructor to facilitate a class under any condition or set of conditions, it is equally unacceptable for a student to attend class under those same conditions; (ii) if you would not do something in an in-person classroom environment, it should not be done in a synchronous online class. Some examples of unacceptable conduct during synchronous sessions include attending class while driving; attending class while walking; attending class while also working; attending class while being physically located in a busy environment or an environment likely to be disrupted by other

people or significant background noise; attending class using your cell phone; smoking or vaping during class; drinking alcoholic beverages during class.

ITMAT Ed is committed to creating a supportive, respectful, and productive learning environment for all students. Students will remain professional and respectful of their peers, course instructors, and guest lecturers. We expect students to approach debates and disagreements in a thoughtful and respectful manner.

Attendance

Students must make every effort to prioritize class. While the synchronous and asynchronous classes are denoted on Canvas in the Modules, the schedule is changed frequently to accommodate the pace of the class and the availability of guest lecturers. Therefore, you should not make plans during class time, regardless of the draft schedule.

Students are allowed 1 excused absence. Beyond the excused absence, you must contact the course director for a makeup assignment. Missing 2 or more synchronous classes will result in a maximum final grade of C+.

Students are required to attend the first and last class. The first class is an introduction to your classmates (your teams for the semester) and the last class is the wrap-up.

If you must miss class, please email the Course Director and Course Coordinator (prior to your absence when possible). If you miss a class in which you are presenting, you will not be able to obtain full points for the assignment.

Students will be on time, keep their video feed on, and remain presently engaged in class for the duration of the class. If you will be late to class or need to leave early, please email the course coordinator and instructor prior to class. Any student more than 15 minutes late or who does not keep video on will be considered absent from class. Additionally, any student who leaves early may be marked absent.

Students who are absent from any class are at a minimum always responsible for reviewing and other materials covered during a class. This may include recording, slides, assigned readings.

Participation and Active Participation

Participation in class is crucial to students' success. Students will attend and actively engage with the content and participate in discussion in all courses.

Examples of active participation in a synchronous session include:

- asking or answering questions during class
- collaborating with other students during group work
- sharing relevant expertise with other students and the instructor
- incorporating knowledge or information from out-of-class readings and videos to enrich the conversation
- You are expected to speak up in every class period to gain full participation points

Examples of active participation in an asynchronous session include:

- asking or answering questions after class via Canvas or email
- responding to threads on discussion boards
- interacting with other students outside of synchronous class

Student Disability Services

The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the office of Student Disabilities Services (SDS). Please make an appointment to meet with your instructor and the course coordinator as soon as possible to discuss your accommodations and your needs. To request accommodations or ask questions, you can make an appointment by calling SDS at 215-573-9235 or accessing the [MyWeingartenCenter](#) portal. The office is in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260. All services are confidential.

Learn more about the [types of services and accommodations offered by Weingarten](#).

Grading, Late Work, Extension, and Resubmission

Grading

The grading system is as follows: A, excellent; B, good; C, fair; D, poor; and F, failure.

LETTER GRADE	PERCENT SCORE
A	93-100
A-	90-92
B+	87-89

B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
D+	67-69
D	63-66
D-	60-62
F	0-59

At the graduate level for students enrolled in ITMAT Ed programs, **the minimum standard for satisfactory work in each course is a B-.**

Extensions

Students are required to request an extension in advance of due dates and preferably at least 48 hours in advance. Extensions will be approved at the discretion of the course director.

Late Work

Due to the collaborative nature of this class, late work is typically not accepted, as it would impact the overall presentation for your group.

If you have a conflict with the due date of any assignment, please request an extension. Note that if you are unable to participate in class discussions due to not having prepared an assignment, points may be deducted from your participation or overall grade.

Course Evaluations

Course evaluations are an opportunity to share feedback on the strengths of the course, and opportunities for improvement. We welcome constructive feedback in the BLUE system. Completing evaluations is a required part of course participation. An email from the BLUE system is sent to students with a link and directions on how to complete the course evaluation(s).

Course Management: Canvas

All course materials and assignments will be managed on [Canvas](#). Log in with Pennkey and password. Additional information on configuring and using Canvas will be provided in the Canvas site.

Student Conduct

ITMAT Ed students must comply with the University's Code of Student Conduct and other University policies that appear in [The PennBook: Resources, Policies and Procedures Handbook](#). An important principal of code of conduct is to behave in the virtual space in the same way you would during an in-person class and/or a work meeting. **If you wouldn't do it in a work meeting or in-person class, don't do it in the virtual space.**

Academic Integrity

The fundamental value of our academic community is intellectual honesty; accordingly, our academic community relies upon the integrity of every member. Students are responsible not only for adhering to the highest standards of truth and honesty but also for upholding the principles and spirit of the Academic Code. Violations of the Code include but are not limited to plagiarism, cheating, and fabrication, among others. Please review the [Code of Academic Integrity](#) in the PennBook.

Alleged violations of the Code of Academic Integrity are reviewed by the Program Director and as necessary referred to the Penn [Center for Community Standards and Accountability](#). If a student is unsure whether their action(s) constitute a violation of the Code of Academic Integrity, it is that student's responsibility to consult with the instructor to clarify any ambiguities.

Use of Generative AI

It is plagiarism to submit work produced by a generative artificial intelligence (AI) service as your own without citing the source. Any use of generative AI services must be in alignment with course requirements and restrictions. Course Directors have full discretion to allow or deny use of ChatGPT or similar AI tools in their courses. Ask the course director for permission before using these tools for course assignments.

Note that due to the nature of the assignments in this course, ChatGPT and other AI has routinely produced D- or F-level work. You are better off citing the lectures than resorting to AI in this class.

Religious and Cultural Holidays

Religious and cultural holidays are listed on the [University of Pennsylvania's Chaplain website](#). If a student observes any of the listed holidays and they conflict with a class date, please contact program staff with class date with which the holiday coincides. Other holidays are at the discretion of the Course Director. Please email early to let the instructor know of the conflict, and accommodations will be made when possible.

If an assignment is due during a holiday, program staff and faculty will work with the student to determine an alternative due date.

Course Schedule

Week	Date 5:30PM - 8:30PM EST	Topic	Modality & Assignments	Due-dates
1	Tues, Jan. 21 Synchronous Online Session	<ul style="list-style-type: none"> Class Introduction Personal Introductions 	<p>Attend: Online Session</p> <p>Class Discussion:</p> <ul style="list-style-type: none"> What, if any, is your experience in Drug Development? Questions about the TPP, work on TPP presentations <p>Complete: Group work (TPP)</p>	
2	Tues, Jan. 28 Asynchronous	<ul style="list-style-type: none"> Corporate and Team Structure Target Product Profile (TPP) 	<p>Watch:</p> <ul style="list-style-type: none"> Corporate Structure and Product Teams Target Product Profile <p>Review: Target Product Profile (TPP) (Due 2/10 by 11:59PM)</p>	

3	Tues, Feb. 4 Synchronous Online Session	<ul style="list-style-type: none"> FDA (CDER) Regulation of Drug Review and Approval General Introduction to the EU Regulatory System TPP presentations 	<p>Submit Before Class: Target Product Profile</p> <p>Watch Before Class:</p> <ul style="list-style-type: none"> FDA (CDER) Regulation of Drug Review and Approval Video General Intro to the EU Regulatory System <p>Attend: Online Session</p> <p>Present (all groups): Target Product Profile</p>	Due: Target Product Profile on 2/3 by 11:59PM
4	Tues, Feb. 11 Asynchronous	<ul style="list-style-type: none"> Preclinical/nonclinical 	<p>Watch Before Class: Compton Preclinical Lecture</p> <p>Review: Optional readings</p>	
5	Tues, Feb. 18 Synchronous Online Session	<ul style="list-style-type: none"> Preclinical/nonclinical Phase 1 	<p>Watch Before Class:</p> <ul style="list-style-type: none"> Clinical Studies Phase 1 Intro to Clinical Pharmacology <p>Attend: Online Session</p> <p>In-Class Exercise: Human Dose Prediction</p>	
6	Tues, Feb. 25 Asynchronous	<ul style="list-style-type: none"> Phase 2 and 3 	<p>Submit: Phase 1 Exercise</p> <p>Watch: Clinical Studies Phase 2 and 3</p> <p>Work on: Phase 2 & 3 Presentation (due by 3/3 at 11:59PM)</p>	Due: Phase 1 Exercise on 2/24 by 11:59PM
7	Tues, Mar. 4 Synchronous Online Session	<ul style="list-style-type: none"> Phase 2 and 3 Presentations 	<p>Submit: Phase 2 & 3 Presentation</p> <p>Attend: Online Session and present</p>	Due: Phase 2 & 3 Presentation on 3/3 by 11:59PM

8	Tues, Mar. 11	Spring Break – No Class		
9	Tues, Mar. 18 Synchronous Online Session	<ul style="list-style-type: none"> Competitive Intelligence 	Attend: Online Session Work on: Competitive Intelligence (CI) Presentations (due on 3/31 by 11:59PM)	
10	Tues, Mar. 25 Asynchronous	<ul style="list-style-type: none"> Attrition Rates and Strategies Competitive Intelligence Regulatory Writing 	Watch Before Class: <ul style="list-style-type: none"> Jeff Barrett Attrition Rates & Strategies Sara Elliot Regulatory Writing Work on: CI presentations (due on 3/31 by 11:59PM)	
11	Tues, Apr. 1 Synchronous Online Session	<ul style="list-style-type: none"> Competitive Intelligence Presentations 	Submit Before Class: CI presentations Attend: Online Session - CI presentations	Due: CI Presentation on 3/31 by 11:59PM
12	Tues, Apr. 8 Synchronous Online Session	<ul style="list-style-type: none"> Product and Portfolio Management 	Read Before Class: <ul style="list-style-type: none"> Chapter 2 - Project Management for Drug Developers (Dr. Stalder) Portfolio, Program, and Project Management in Biopharama PPT Attend: Online Session <ul style="list-style-type: none"> Class Lecture: Joe Stalder, Pharm.D. 	
13	Tues, Apr. 15 Asynchronous	<ul style="list-style-type: none"> Pricing, Access and Patient Outcomes 	Watch: How is a Drug Priced in the United States? (Vargas) Submit: <ul style="list-style-type: none"> Drug Pricing and Access Discussion Board Clarifying Question from a Lecture 	Due: <ul style="list-style-type: none"> Drug Pricing Discussion Board on 4/15 by 11:59PM Clarifying Question on 4/16 by 11:59PM
14	Tues, Apr. 22 Synchronous Online Session	<ul style="list-style-type: none"> Course Wrap Up 	Attend: Online Session <ul style="list-style-type: none"> Course review Complete Course & Lecturer Evaluation 	

			Submit: Discussion Board TBA	
15	Tues, Apr. 29 Asynchronous	<ul style="list-style-type: none"> Reading Day 	Review: Personal Perspective Assignment (due on 5/5 by 11:59PM)	
16	Tues, May 6 Asynchronous	<i>Final Exam Week</i>	Submit: Personal Perspectives Assignment	Due: Personal Perspective Assignment on 5/5 by 11:59PM