

# REG 6120 INTRODUCTION TO DRUG DEVELOPMENT

## FALL 2025

Course Director	Class Time & Format
Eileen Doyle, PharmD Director, Clinical Pharmacology Modeling and Simulation GlaxoSmithKline (GSK)	Online; Tuesdays, 5:30PM – 8:30PM ET

Course Coordinator
Layah Bogen

\*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

### General Course Information:

#### 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.

#### Learning Objectives:

1. Broadly describe the drug development process and distinguish between Phases 1-3.
2. Explain the regulatory basis by which new chemical entities are evaluated and approved, including FDA and EU regulations.
3. Conduct competitive intelligence at a basic level.

4. Analyze and interpret FDA documents (e.g., labels/package inserts, Summary Basis of Approval) related to drug products.
5. Recognize the perspectives and biases of stakeholders in the drug development process.
6. Utilize communication and presentation skills in the drug development 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%

## ITMAT Education Learners Guide

This guide aims to prepare you to engage meaningfully in ITMAT Ed courses. As an ITMAT Ed student, you may engage in both in-person and remote delivery methods. Remote course delivery can add flexibility for instructors and students by allowing for both synchronous interactions (live remote sessions) and asynchronous learning (out-of-class learning time used for studying resources, completing assignments, etc.).

If you have questions, feel free to reach out to your course coordinator, course director, and/or program director. If you have a circumstance or disability for which particular accommodations might be helpful, please check the [Weingarten Center Resources for Students in Online Programs](#) and contact program staff.

## Community Standards and Program Expectations

Students must comply with the University's [Code of Student Conduct](#), [Code of Academic Integrity](#), and other University policies related to student conduct that appear in the [PennBook](#). These include, but are not limited to, policies on sexual harassment, acquaintance rape and sexual violence, appropriate use of electronic resources, open expression, and drug and alcohol usage. Students must comply with all [PSOM research policies](#), including but not limited to, policies on authorship. Additional codes of conduct and expectations students should be familiar with are the [equal opportunity and nondiscrimination statement](#), the [sexual misconduct policy and resource offices](#), and [student grievance procedures](#).

## Online and Hybrid Courses

All students engaging in a virtual classroom must ensure that their learning environment 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 a 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. 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 of thumb 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, and attending class using your cell phone. Course directors will, at their discretion, include course-specific policies articulated in the course syllabus.

If you have concerns about your learning environment, contact the course director and coordinator at the time of registration to get clarity on what is acceptable.

## Synchronous Session Guidelines

- **Arrive Early.** Be on time; if online, make sure to log in to the virtual session a few minutes early to double-check your audio and video.
- **Be Respectful.** Be considerate and professional to the instructor and your peers. Avoid any behaviors that might be distracting to others.
- **Be an Active Participant.** Bring questions for instructors and classmates. During student presentations, actively engage with the content being presented by other students in the same way you would with an instructor.
- **Review Resources Ahead of Time.** Ensure you have a firm grasp on any content provided in advance of class and that you have followed instructions related to that content.
- **If online: Limit Noise.** Be in a quiet place, free of distractions or background noise. Keep yourself muted to reduce background noise, and then un-mute to ask questions or engage in discussion.
- **If online: Be Visible.** Have your video on during class. Be appropriately attired (casual wear is fine). It is important to the instructor and other students to feel engaged and attentive. If you need to step away to deal with a time-sensitive issue, you should turn off your video, send a message in the Zoom chat about needing to step away, and return as promptly as possible.
- **If online: Enable Live Transcription.** If captions would help you better understand or retain the conversation, [enable live transcription in Zoom. \(This is enabled on an individual basis\)](#)

## Asynchronous Learning

- **Complete Assignments on Time.** Identify an effective method to keep track of assignments and due dates.
- **Engage with Peers.** Participate actively in discussion boards, group work, and other forums for peer communication.
- **Ask for Insight on Feedback.** If you have questions about feedback you received on an assignment, reach out to your course director.
- **Ask Questions as You Have Them.** Stay connected. Email your course director or program staff, ask for a phone call or meeting. Both program staff and course directors are happy to assist.

## Canvas Best Practices

- **Turn on Notifications.** You can find your notification settings under "Account" on the top left menu. Please also ensure you've included your preferred email indicated through Account Settings and updated under "Ways to Contact" on the far right. Settings that will be most helpful to you are:
  - Announcement – Notify immediately (bell icon)
  - Grading – Notify immediately (bell icon)
- **Fill in Your Canvas Profile.** Adding a profile photo and your pronouns to your Canvas page lets your instructor and classmates get to know you better.
- **Use the course calendar and To-Dos.** The "Calendar" can help you keep track of due dates. Review the syllabus for important dates and transfer them into your personal calendar.
- **Check your browser compatibility.** Refer to the "**Policies, Procedures, and Technology**" page in your Canvas course to learn more about the browser and other technical information you need for Canvas. We recommend Chrome and Firefox's most up-to-date versions. (Safari has caused problems in the past.)

## Academic Policies

### 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 (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 director. 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.

### 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

This program 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. For online classrooms, an important principle of the 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.**

## Grading, Late Work, Extension, and Resubmission

### Grading

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

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

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

## 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.

## Incompletes

The mark of I is used to designate “incomplete”. A student who fails to complete a course and does not withdraw or change their status to auditor within the prescribed period shall receive, at the instructor’s discretion, either a grade of I (incomplete) or F (failure). When assigning an incomplete, the instructor may permit an extension of time up to one year for the completion of the course. Any course that is still incomplete after one calendar year from its official ending must remain as “incomplete” on the student’s record and shall not be credited toward a degree. If a student has 2 or more incompletes on their academic transcript, the student is ineligible to register for future courses and must meet with program leadership to develop a plan for how the incompletes will be resolved.

## Code of 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.

If you have questions regarding what is considered a violation of academic integrity, 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 Office of Student Conduct. 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 the use of ChatGPT or similar AI tools in their courses. Ask the course director for permission before using these tools for course assignments.

## Students with Disabilities

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](#).

## Religious & 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 the class date with which the holiday coincides. If an assignment is due during a holiday, program staff and faculty will work with the student to determine an alternative due date.

## Suspension of Normal Operations Policy

In line with the university's [Suspension of Normal Operations Policy](#), when the University of Pennsylvania closes, synchronous classes will not be held. Assignments due on days impacted by a "suspension of normal operations" will be extended. In the case that a student is not located near Philadelphia and is experiencing a severe weather event, students should communicate with the Course Director and Course Coordinator to determine accommodations.

## 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.

## Course Schedule

Week	Date 5:30PM - 8:30PM ET	Topic	Modality & Assignments
1	Synchronous Online Session	<ul style="list-style-type: none"> <li>• Class Introduction</li> <li>• Personal Introductions</li> </ul>	<p><b>Attend:</b> Online Session</p> <p><b>Class Discussion:</b></p> <ul style="list-style-type: none"> <li>• What, if any, is your experience in Drug Development?</li> <li>• Questions about the TPP, work on TPP presentations</li> </ul> <p><b>Complete:</b> Group work (TPP)</p>
2	Synchronous Online Session	<ul style="list-style-type: none"> <li>• Corporate and Team Structure</li> <li>• Target Product Profile (TPP)</li> </ul>	<p><b>Watch Before Class:</b> Corporate Structure and Product Teams</p> <p><b>Attend:</b> Online Session</p> <ul style="list-style-type: none"> <li>• <b>Review:</b> Target Product Profile (TPP)</li> </ul>
3	Synchronous Online Session	<ul style="list-style-type: none"> <li>• FDA (CDER) Regulation of Drug Review and Approval</li> <li>• General Introduction to the EU Regulatory System</li> <li>• TPP presentations</li> </ul>	<p><b>Submit Before Class:</b> Target Product Profile</p> <p><b>Attend:</b> Online Session</p> <p><b>Present (all groups):</b> Target Product Profile</p>
4	Asynchronous	<ul style="list-style-type: none"> <li>• Preclinical/nonclinical</li> </ul>	<p><b>Watch:</b> Compton Preclinical Lecture</p> <p><b>Review:</b> Optional readings</p>
5	Synchronous Online Session	<ul style="list-style-type: none"> <li>• Human Dose Prediction</li> <li>• Phase 1</li> </ul>	<p><b>Watch Before Class:</b></p> <ul style="list-style-type: none"> <li>• Clinical Studies Phase 1</li> <li>• Intro to Clinical Pharmacology</li> </ul> <p><b>Attend:</b> Online Session</p> <p><b>In-Class Exercise:</b> Human Dose Prediction</p>
6	Asynchronous	<ul style="list-style-type: none"> <li>• Phase 2 and 3</li> </ul>	<p><b>Submit:</b> Phase 1 Exercise</p> <p><b>Watch:</b> Clinical Studies Phase 2 and 3</p> <p><b>Work on:</b> Phase 2 &amp; 3 Presentation</p>
7	Synchronous Online Session	<ul style="list-style-type: none"> <li>• Phase 2 and 3 Presentations</li> </ul>	<p><b>Submit:</b> Phase 2 &amp; 3 Presentation</p> <p><b>Attend:</b> Online Session and present</p>

8	Synchronous Online Session	<ul style="list-style-type: none"> <li>Competitive Intelligence</li> </ul>	<p><b>Attend:</b> Online Session</p> <p><b>Work on:</b> Competitive Intelligence (CI) Presentations</p>
9	Asynchronous	<ul style="list-style-type: none"> <li>Attrition Rates and Strategies</li> <li>Competitive Intelligence</li> <li>Regulatory Writing</li> </ul>	<p><b>Watch:</b></p> <ul style="list-style-type: none"> <li>Jeff Barrett Attrition Rates &amp; Strategies</li> <li>Sara Elliot Regulatory Writing</li> </ul> <p><b>Work on:</b> CI presentations</p>
10	Synchronous Online Session	<ul style="list-style-type: none"> <li>Competitive Intelligence Presentations</li> </ul>	<p><b>Submit Before Class:</b> CI presentations</p> <p><b>Attend:</b> Online Session - CI presentations</p>
11	Synchronous Online Session	<ul style="list-style-type: none"> <li>Product and Portfolio Management</li> </ul>	<p><b>Read Before Class:</b></p> <ul style="list-style-type: none"> <li>Chapter 2 - Project Management for Drug Developers (Dr. Stalder)</li> <li>Portfolio, Program, and Project Management in Biopharma PPT</li> </ul> <p><b>Attend:</b> Online Session</p> <ul style="list-style-type: none"> <li><b>Class Lecture:</b> Joe Stalder, Pharm.D.</li> </ul>
12	Asynchronous	<ul style="list-style-type: none"> <li>Pricing, Access and Patient Outcomes</li> </ul>	<p><b>Watch:</b> How is a Drug Priced in the United States? (Vargas)</p> <p><b>Submit:</b></p> <ul style="list-style-type: none"> <li>Drug Pricing and Access Discussion Board</li> <li>Submit Clarifying Question from a Lecture</li> </ul>
13	Asynchronous	<ul style="list-style-type: none"> <li>Drug Review &amp; Approval</li> </ul>	<p><b>Watch:</b></p> <ul style="list-style-type: none"> <li>General Intro to the EU Regulatory System (Berglund)</li> <li>FDA (CDER) Regulation of Drug Review and Approval (Bullock)</li> </ul> <p><b>Submit:</b> Answer Clarifying Question from a Lecture</p>
14		Thanksgiving Break – No Class	
15	Synchronous Online Session	<ul style="list-style-type: none"> <li>Course Wrap Up</li> </ul>	<p><b>Attend:</b> Online Session</p> <ul style="list-style-type: none"> <li>Course review</li> <li>Complete Course &amp; Lecturer Evaluation</li> </ul>
16	Asynchronous	Final Exam Week	<p><b>Submit:</b> Personal Perspectives Assignment</p>