

# REG 6120 Introduction to Drug Development

Spring 2023

Time: Tuesdays 5:15-8:15 PM

Location: Online

## Instructor Information

### Course Director

**Eileen Doyle, PharmD**  
Director, Clinical Pharmacology  
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### Course Coordinator

**Bethany Sanghani**  
Associate Director, ITMAT Education  
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## 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.

### Evaluation Methods:

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

Grading Scale	
Category	Percentage
Attendance & Participation	10%
Assignments	90%

### Course Policies:

#### Academic Integrity:

As a student at The University of Pennsylvania, you are required to uphold the Code of Academic Integrity. Specifically, this means that materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (i.e. do not cheat, fabricate, or plagiarize, amongst others). We encourage you to reach out to the course director or coordinator if you are not clear on what potential violations are.

#### Attendance & Participation

Students are expected to attend *and participate* in all classes. If for any reason a student will not be in class, they should contact the course coordinator prior to class to alert them of the absence and make arrangements to make up course content. Two absences are allowed during the course which will not affect the attendance grade.

If a class date conflicts with a holiday or religious observance, please contact the course coordinator. If an assignment is due during this time, please work with the course director and course coordinator to determine an alternative due date.

#### Canvas:

All course materials (ppts, announcements, lecture recordings) and assignments will be posted on Canvas. We recommend that you choose the “Notify me right away” option for your most frequently checked email address in the “Announcements” area of the “Notification Preferences” page: <https://canvas.upenn.edu/profile/communication>.

#### Course Evaluations:

Course evaluations are completed in the BLUE system. These are a required part of course participation. An email from the BLUE team will be sent to students with a link and directions on how to complete the course evaluation(s).

#### Student Disabilities 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 me as soon as possible in order to discuss your accommodations and your needs. If you have not yet contacted SDS, and would like to request accommodations or have questions, you can make an appointment by calling SDS at 215-573-9235. The office is located in the Weingarten Learning Resources Center at Stouffer Commons 3702 Spruce Street, Site 300. All services are confidential.

## Course Schedule

Week	Date	Topic	Modality & Topic	Discussion (in class)
1	Tue Jan 17	Class Introduction Personal Introductions Brief introduction to drug development	<b>Synchronous Online</b>	What do you think drug development is? A brief introduction to drug development
2	Tue Jan 24	Corporate and Team Structure Target Product Profile	<b>Lectures on Canvas</b> TPP assignment on Canvas <b>Synchronous Online</b> Questions about the TPP, Doyle to go through example of TPP	Questions about the TPP, Doyle to go through example of TPP
3	Tue Jan 31	FDA (CDER) Regulation of Drug Review and Approval General Introduction to the EU Regulatory System	FDA quiz on Canvas <sup>1</sup> EU quiz on Canvas <sup>1</sup> <b>Lecture on Canvas</b>	Asynchronous Class, No Live Class
4	Tue Feb 7	Preclinical	<b>Lecture on Canvas</b> Preclinical assignment on Canvas <sup>1</sup>	Asynchronous Class, No Live Class
5	Tue Feb 14	Phase 1 Clinical Pharmacology and model-informed drug development considerations	<b>Synchronous Online</b> Phase 1 Exercise assignment on Canvas <sup>1</sup>	
6	Tues Feb 21	Phase 2 Phase 3	<b>Lectures On Canvas</b> Phase 2 Exercise on Canvas <sup>1</sup> Phase 3 Exercise 3 on Canvas <sup>1</sup> <b>Lecture on Canvas</b>	Discussion of preclinical through Phase 3
7	Tue Feb 28	Competitive Intelligence	<b>Synchronous Online</b>	Asynchronous Class, No Live Class
	Tue Mar 7	SPRING BREAK		
8	Tue Mar 14	Competitive Intelligence	<b>Lecture On Canvas</b> Competitive Intelligence assignment on Canvas <sup>1</sup> <b>Synchronous Online</b> CI presentations	CI presentations
9	Tue Mar 21	Attrition Rates and Strategies	<b>Lecture On Canvas</b> Jeff Barrett pre-recorded lecture Attrition rates assignment posted on Canvas <sup>1</sup>	Asynchronous Class, No Live Class
10	Tue Mar 28	Make up day	<b>Synchronous Online</b>	Live lecture - catch up
11	Tue Apr 4	Regulatory Writing	<b>Lecture On Canvas</b> Sara Elliot pre-recorded lecture	Asynchronous Class, No Live Class
12	Tue Apr 11	Product & Portfolio Management	<b>Lecture On Canvas</b> Kevin Matchett pre-recorded lecture	Asynchronous Class, No Live Class
13	Tue Apr 18	Pricing, Access and Patient Outcomes	Max Vargas, PhD	Live Lecture
14	Tue Apr 24	Course Wrap Up	<b>Synchronous Online</b>	Live Lecture

15	Tue May 2	<i>Final Exam Week</i>		
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