

REG 6400 – Capstone I

Spring 2025

Instructor Information

Course Director

Andrew Fesnak, MD, MHCI

*syllabus is subject to change at professor's discretion

Class Location & Time

Online – Mondays

Synchronous sessions 4-5 pm

General Information

Prerequisite Requirements

Capstone courses are designed for MRA students only. Prior to enrolling in the Capstone courses students must successfully complete 2 MRA courses receiving the minimum grade of B- or higher.

Description

The Capstone is an intensive project focused on the student's specific area of interest within Regulatory Affairs. The Capstone is composed of two course units, REG 6400, which consists of scheduled in-person and asynchronous classes focused on the Capstone proposal development and REG 6410 which consists of student-driven completion of the Capstone project. During REG 6400 the student, with the guidance of their Capstone Advisor, the Course Director, and program staff will define objectives and formulate their Capstone proposal and delineate deliverables and milestones. Successful completion of REG 6400 is determined by a finalized proposal approved by the Course Director. The work proposed in the Capstone Project proposal will be the focus of the student's efforts in REG 6410 Capstone II. Prior to the start of this course students should have a topic idea(s) they are interested in pursuing for their capstone. This topic must be related to their area of interest within Regulatory Affairs.

Note: During completion of REG 6410: Capstone II, three progress report meetings will be conducted and documented.

Course Objectives

By the end of this course students will be able to:

- Identify a Capstone topic that relates to an area of interest within Regulatory Affairs.
- Develop a work plan and outcomes related to the Capstone topic.
- Assess relevant literature and studies to be applied to the Capstone proposal.
- Engage in the appropriate writing style and include accurate citations.
- Effectively engage with your Capstone Advisor and incorporate their feedback into the Capstone Proposal.
- Deliver a finalized Capstone proposal to be approved by the advisor and the Course Director.

Assignments & Writing Workshops

There will be 2 main deliverables, along with a few other deliverables that work alongside the proposal. Participation in peer groups is expected. At the end of the term students will give a presentation of their proposal to the class.

- 30% Participation (attendance, class participation, group work)
- 10% Annotated bibliography
- 10% Proposal Outline
- 40% Final Written Proposal
- 10% Final Proposal Presentation

Academic Policies

Communication Policy

Students, teaching assistants (TAs), and faculty for this course should communicate using the inbox feature in Canvas. This ensures an accessible communication record for all parties. Faculty will also use Canvas as the primary medium for course-related updates and feedback.

For matters requiring immediate attention, you may contact Dr. Fesnak directly via email or through phone/text communication, as needed. However, general course inquiries and assignments should remain within the Canvas platform.

Participation Expectations

Participation in class is crucial to students' education in this program. Students are expected to attend and actively participate in all courses. Examples of active participation in a synchronous session may include asking or answering questions, posting comments in the chat, or collaborating with other students during group work. Examples of active participation in an asynchronous session may include asking or answering questions via Canvas or email, commenting on discussion boards, or interacting with other students outside of class.

This program is committed to providing a supportive and productive learning environment for all. Active participation requires professionalism and demonstration of respect for peers, course instructors, and guest lecturers.

Attendance Expectations

Students are allowed 1 excused absence. If you anticipate the need to be absent, please contact the course coordinator prior to your absence. If you have other concerns about your ability to meet the attendance requirements, you must contact the course coordinator prior to your absence.

Students are expected to be on time to all classes and stay for the duration of the class. If you anticipate being late to class or may need to leave early, please email the course coordinator and instructor in a timely manner to let them know of may be late or need to leave early. Any student who is more than 15 minutes late will be considered absent from that class. Additionally, any student who leaves early may be marked absent. Attendance also includes keeping video feed on during synchronous sessions.

Prior to the Capstone Courses

Before enrolling in REG 6400: Capstone I ensure the following are met:

- Have a general idea of the topic(s) you want to approach for the Capstone project.
- Consider possible advisors who meet the Capstone Advisor Role & Expectations.
- Consider the methodology that might work best for your topic.
- Familiarize yourself with that [AMA citation style](#) and appropriate writing style.

Course Director Expectations

The course director will provide guidance and direction throughout the Capstone proposal process. The course director will be available for online, in person, or phone meetings to answer any question and address concerns. The Capstone Advisor will be the student's main source of contact and feedback throughout the Capstone process and the Course Director is able to provide additional guidance and direction as needed.

Advisor Meetings

At particular times during the course meeting with advisors will be helpful in further refining your work. In these instances, meeting with your advisor may occur at a time that is convenient for the both of you outside of scheduled class hours.

Reference Manager

To manage references for the Capstone, you will be required to use a citation manager. Please see the following link for a description of available options to Penn users: <http://guides.library.upenn.edu/citationmgmt>. Select which reference tool manager you intend to use.

For guidance on the AMA citation style visit this site: https://research.library.oakland.edu/sp/subjects/tutorial.php?faq_id=187

Library Services

The Penn library also provides a research tutorial that discusses how to locate, evaluate, and use sources of information: <http://gethelp.library.upenn.edu/PORT/>.

Canvas

All course materials (ppts, announcements, lecture recordings) and assignments will be posted on Canvas. Contact the course coordinator with questions. Log in with Pennkey: <https://canvas.upenn.edu>

Academic Integrity

As a student at The University of Pennsylvania, you are required to uphold the [Code of Academic Integrity](#). Please be sure to review this policy and be fully aware of the requirements. All material that you submit either online or in person must be independent works created by you that uphold all tenets of Penn academic integrity policies. Any concerns with respect to academic integrity (plagiarism and or fabrication amongst others) will be referred to the University of Pennsylvania Office Of Student Conduct for evaluation. We encourage you to reach out to the MRA administration if you are not clear on any aspect of Penn's expectations.

In this course, the use of generative AI is strongly **discouraged**. A main goal of this course is to train you on the **process** of developing a proposal. To best learn the process, you have to engage with the material conceptually and in practice. It is in your best interest to create your project deliverables without AI-assistance because developing your own skills at generating this content will better prepare you for future projects. Being able to capably use the concepts taught in this course will improve your ability to conduct future projects with or without AI-assistance. While use of generative AI is strongly discouraged, it is not absolutely disallowed. However, if you do choose to use AI, you must cite the source. Failing to do so constitutes plagiarism per our AI policy (see Student Handbook).

Student Support Services

The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the [Weingarten Center](#). Please make an appointment with the Weingarten Center online as soon as possible to discuss your accommodations and your needs.

Small Group Meetings

Small Group Meetings will happen periodically throughout the term. These meetings are meant to ensure you are on the path to complete your proposal. These meetings are for your benefit, to ensure your success in the course and your proposal. The small group aspect of the group

allows both program staff and peers to share and provide suggestions on your project to date. Below is a list of the weeks and expectations of each meeting.

- 2/10: You will discuss your topic and literature search. You should bring your annotated bibliography to this session.
- 2/24: You will bring your timeline exercise to this session for discussion.
- 3/03: You will bring your outline draft to this session for discussion.
- 3/24: You will bring your proposal draft to this session for discussion.
- 4/14: You will discuss your final preparations of your proposal at this session.

Schedule

	<u>Topic</u>	<u>Before the sync session</u>	<u>Sync session date</u>	<u>At the sync session</u>
<u>Week 1</u>	Introduction to Capstone and Proposal Development	Watch videos (due 1/27) -Formulating a research question -Study design -Capstone timeline and template Complete Introduction discussion board post and review peer posts (due 1/27)	Monday 1/13/25	Office hours: Be prepared to ask any questions about the capstone process.
MLK observed (1/20) - NO SYNC SESSION				
<u>Week 2</u>	Capstone expectations	Complete timeline exercise (due 1/27)	Monday 1/27/25	Will discuss introduction to capstone and capstone expectations. All students should be prepared to discuss challenges with timeline exercise.

<u>Week 3</u>	Literature search	None	Monday 2/3/25	PSOM librarian will introduce library databases.
<u>Week 4</u>	<i>Small group</i> - topic and literature	Complete annotated bibliography with 2-3 sources (due 2/10)	Monday 2/10/25	Meet in TA-led small group to present and discuss your topics and annotated bibliographies/literature searches.
<u>Week 5</u>	The writing process	Watch video (due 2/17) -Kachine Allen "The writing process"	NO SYNC SESSION THIS WEEK	N/A
<u>Week 6</u>	<i>Small group</i> - timeline	Watch video (due 2/24) -Writing an outline Complete capstone update post and response (due 2/24) Begin draft of outlines	Monday 2/24/25	Meet in TA-led small group to present and discussion timeline exercise.
<u>Week 7</u>	<i>Small group</i> - outline	Continue to work on your proposal outline	Monday 3/3/25	Meet in TA-led small group to present and discuss your outline.
Spring break - NO SYNC SESSION				
<u>Week 8</u>	Writing workshop	Finalize and submit outline (3/17)	NO SYNC SESSION THIS WEEK (optional office hours by appointment)	Office hours by appointment.
<u>Week 9</u>	<i>Small group</i> - proposal draft	Begin proposal draft	Monday 3/24/25	Meet in TA-led small group to discussion writing process.
<u>Week 10</u>	Writing week	Continue working on proposal draft Send draft for prelim review (optional)	NO SYNC SESSION THIS WEEK	N/A

<u>Week 11</u>	Presentation best practices	Continue to work on proposal draft Watch videos (due 4/7) -Presentation best practices Begin working on presentation	NO SYNC SESSION THIS WEEK	N/A
<u>Week 12</u>	<i>Small group</i> - finalize proposal	Continue to work on proposal and presentation	Monday 4/14/25	Meet in TA-led small group to discuss finalized proposals prior to submission.
<u>Week 13</u>	Final proposal due	Submit finalized proposal (due 4/21)	NO SYNC SESSION THIS WEEK	N/A
<u>Week 14</u>	Final presentation due	Submit finalized presentation (due 4/28)	NO SYNC SESSION THIS WEEK (watch peer presentations)	N/A