

# REG 640 – Capstone I

Spring 2023

## Instructor Information

### Course Director

Andrew Fesnak, MD, MHCI

### Email

fesnak@penndmedicine.upenn.edu

### Class Location & Time

Online – Mondays

Synchronous sessions 4-5 pm

### Course Coordinator

Bethany Sanghani

### Email

bgermany@upenn.edu

215-898-5849

## 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 640, which is an in-person class focused on the Capstone proposal development and REG 641 which provides credit for successful completion of the Capstone project. During REG 640 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 640 is determined by a finalized proposal approved by the Capstone Advisor and the Course Director. The work proposed in the Capstone Project proposal will be the focus of the student's efforts in REG 641 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 and identify an appropriate Capstone Advisor to oversee the project

*Note: In between REG 640: Capstone I and REG 641: Capstone II three progress reports are to be submitted and approved.*

### 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 a committee with MRA program representatives.

- 50% participation (attendance, class participation, group work, outline)
- 25% final proposal
- 25% final presentation

### Participation

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.

### Academic Policies

#### Participation Expectations

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### **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 640: Capstone I ensure the following are met:

- Have a general idea of the topic 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

### **Progress Report Meetings**

Three progress report meetings are to be completed and approved in between REG 640 and REG 641. Progress report meetings should provide a brief overview of the goals and key deliverables reached thus far. Report meetings should primarily provide an update on the project, stating what you have accomplished, note the challenges and any adjustments, and next steps. Due dates for reports are established each semester by the course director.

### **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 you will not be required to attend class but will meet with your advisor at a time that is convenient for the both of you.

## 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](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.

## 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.

## Group Work Sessions

Certain classes will include group work using the breakout rooms. In the group work portion of a class you will share the item they are working on such as the outline or proposal draft. Each of you will share your draft using the screenshare function and walk your peers through your draft as well as any challenges you may be experiencing. Your peers will then offer feedback on the draft as well as any possible solutions to your challenges. A 2<sup>nd</sup> year MRA student or program alumnus will also be in the breakout room to offer their experience, support, and feedback.

## 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. Meeting options will be offered through canvas. Dates and times for each small group meeting will be offered and you may select the date and time, meetings will be between 45 minutes – 1 hour in length. 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.

- **Week of 2.6 Small Group Meeting:** You will share a brief status update on your project thus far including narrowing down your topic, your advisor search, literature search, challenges you are facing or anticipate facing, and we will brainstorm with you. If you completed the annotated bibliography, we will also discuss this with you.
- **Week of 2.27 Small Group Meeting:** This meeting will focus on the development of your outline. Please plan to bring your outline to the meeting; your outline should be in an early to mid-draft stage for this meeting. Feedback and suggestions on the outline and direction of the proposal will be provided.
- **Week of 4.10 Small Group Meeting:** We will discuss the pace of your proposal and its current state. Bring your proposal to this meeting, no matter what stage it is in this meeting. If you plan to share your proposal with us for a cursory review ahead of your meeting please share this at least 1 day before your meeting.

## Schedule

Week	Topic	Modality & Lecturer	Explanation
Week 1 Mon. 1/16	<b>Recorded Lectures</b> Introduction to the Capstone & Proposal Develop Formulating a Research Question Study design Proposal Template & Timeline Walk Through	<b>Asynchronous</b> Andrew Fesnak Bethany Sanghani	<b>Pre-work:</b> Review the videos and complete the discussion before coming to class.  Office hours by appointment
Week 2 Mon. 1/23	Capstone Expectations	<b>Synchronous</b> Andrew Fesnak Bethany Sanghani	1 hour class focused on an introduction to the course and capstone process along with any questions about the course and/or capstone process.  <b>Assignment:</b> Submit timeline exercise by 11:59 pm.
Week 3 Mon. 1/30	Literature Search	<b>Synchronous</b> Carlos Rodriguez	A literature search based class with the PSOM librarian  30-60 minute introduction to the library databases. Then you will search for your own literature and bring back 1-2 searches to discuss, we'll also discuss any complications in your literature search  After this class, you may choose to work on an annotated bibliography with 2-3 sources. This will help you in drafting your outline and proposal though this is not required. If you select to complete an annotated bibliography

			then please bring this your 2.6 small group meeting
Week 4 Mon. 2/6	<b>Small Group Meetings</b> Annotated Bibliography, Topic Selection, General Capstone Questions	<b>No Formal Class – Online Meetings</b>	Bethany will share details to schedule small group meetings. The focus of this meeting will be to crystalize your topic and focus.
Week 5 Mon. 2/13	The Writing Process & your Proposal	<b>Videos:</b> Kachina Allen, PhD  <b>Synchronous</b> Andrew Fesnak Bethany Sanghani	<b>Pre-work:</b> Review the writing videos before coming to class. 1 hour class. After viewing the videos start to think of how best to organize your proposal and begin to draft an outline  You will work on your outline in groups in the next class
Week 6 Mon. 2/20	<b>Recorded Lecture</b> Basics of Writing an Outline  Group Work	<b>Synchronous</b> Andrew Fesnak Bethany Sanghani	<b>Pre-work:</b> View the Basics of Writing an Outline video before coming to class this week.  We will use breakout rooms for you to work in groups on your individual outlines. 2 <sup>nd</sup> year students and program alumni will be in the breakout rooms to offer assistance and provide their experiences  You will need a working outline for your small meeting next week.
Week 7 Mon. 2/27	<b>Small Group Meetings</b> Working Outline, General Capstone Questions	<b>No Formal Class – Online Meetings</b>	Bethany will share details to schedule small group meetings. The focus of this meeting will continue to hone in on your topic and discuss the current stage of your outline.  Work on finalizing your outline.
Week 8 Mon. 3/6	<i>Spring Break</i>	<b>No Class</b>	

Week 9 Mon. 3/13	Writing Workshop	<b>No Class</b>	Your outline or proposal draft should be completed and sent to your small groups ahead of 3.20 class.  No formal class but we will be available to assist with questions or concerns
Week 10 Mon. 3/20	Outline & Proposal Draft Discussion, Plans Moving Forward  Group Work	<b>Synchronous</b> Andrew Fesnak Bethany Sanghani	30 – 60 minute class. Discussion of your outline and proposal draft thus far  We will use breakout rooms for you to work in groups to discuss your proposals and provide feedback to one another on what you have so far. 2 <sup>nd</sup> year students and program alumni will attend to provide support and feedback on your proposals.
Week 11 Mon. 3/27	Writing Workshop	<b>No Class</b>	No formal class but we will be available to assist with questions or concerns.  At this point you should be drafting the proposal. You may send your draft to Bethany & Andrew for a cursory review prior to your small group meeting, please give an appropriate amount of time to review.
Week 12 Mon. 4/3	<b>Recorded Lecture</b> Presentation Best Practices	<b>Asynchronous</b> Andrew Fesnak Bethany Sanghani	
Week 13 Mon. 4/10	<b>Small Group Meetings</b>	<b>No Formal Class – Online Meetings</b>	Bethany will share details to schedule small group meetings. The focus of this meeting will be the pace of your proposal, meeting with the writing center, general capstone questions.
Week 14 Mon. 4/17	Proposals due <i>Office hours</i>	<b>No Class</b>	Proposal draft is due for feedback



			No formal class but we will be available to assist with questions or concerns
Week 15 Mon. 4/24	Presentations Due <i>Office hours</i>	<b>No Class</b>	Review the presentation directions. Then, record and submit your 10 minute presentation.