

Penn
MASTER *of* REGULATORY AFFAIRS

2024 MRA Program Handbook

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MRA Program Overview

The Master of Regulatory Affairs (MRA) is housed within the Institute for Translational Medicine and Therapeutics (ITMAT) in the Perelman School of Medicine at the University of Pennsylvania. Being part of a world-class research institution gives you the opportunity to learn from leaders in the field and a view of innovations driving down the pipeline.

The MRA program aims to serve regulatory professionals who are responsible for implementing and complying with the relevant biomedical regulations. The program educates trainees in the foundations and application of science-based regulation to maximize compliance and minimize risk. Students will have the option of completing the MRA degree in either two or three years, with the first year consisting of two mandatory foundational classes per term. They will have the option to choose from three paths of study: Standard Curriculum, Clinical Research concentration or Quality Assurance concentration.

MRA Program Goals

The University of Pennsylvania's Master of Regulatory Affairs (MRA) program prepares professionals to play key roles in bringing innovative products (including drugs, biologics, vaccines, medical devices, and others) to market, while also ensuring that products are safe and effective. You'll train the skills necessary to move products through the lifecycle of FDA regulation. You'll gain familiarity with clinical research foundations and apply science-based clinical investigation techniques, complying with corresponding regulations. You will move through a 10-credit unit curriculum that includes coursework and an experiential capstone project.

The fully online program offers synchronous opportunities to build relationships with instructors, who are Penn faculty and industry experts, and members of the MRA cohort. At the conclusion of the program, you will be well-versed in the complete healthcare product lifecycle for drugs, devices, and biologics, including an understanding of how this field works inside academia, industry, and government sectors. MRA graduates are competitive candidates for positions integral to the navigation of new medical products and technologies through regulatory, clinical, and quality assurance channels.

Additional skills—including oral and written communication, problem-solving, and teaming—are integral to this training and the MRA program. You'll become an expert in a chosen area for your Capstone project and will produce a deliverable to position you for the next step in your career.

ITMAT Education Online Learners Guide

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.). As an ITMAT Ed student you may engage in both delivery methods. This guide aims to prepare you to engage meaningfully in ITMAT Ed courses.

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

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. 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; 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; make sure to log in to the virtual session a few minutes early to double check your audio and video.
- **Be Visible.** Have your video on during class. It is important to the instructor and other students to feel engaged and attentive. The expectation is that videos remain on. 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.
- **Be Respectful.** Be considerate and professional to the instructor and your peers. Avoid any behaviors that might be distracting to others.
- **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.
- **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.
- **Enable Live Transcription.** If captions would help you better understand or retain the conversation, [enable live transcription in Zoom. \(This is enabled on an individual basis\)](#)
- **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.

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 remote 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 let 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 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.)

MRA Degree Requirements

The University of Pennsylvania operates on a 3-semester system (fall, spring, and summer). The MRA degree program requires 10 course units for completion, with 4 core courses, 1 concentration course, 3 electives, and 2 capstone courses. All students are required to complete the 4 core courses and Capstone I in year 1. Sample study plans are found on the website. There are 3 concentrations within the MRA degree program students may select upon acceptance to the program: Standard Curriculum, Clinical Research, and Quality Assurance. Each concentration is designated by a specific concentration course.

Core Courses

All students take 4 core courses.

- **REG 5100** Introduction to Clinical and Translational Research (1 c.u.)
- **REG 6100** Fundamentals of FDA Regulation (1 c.u.)
- **REG 6120** Introduction to Drug Development (1 c.u.)
- **REG 6190** Research Ethics (1 c.u.)

Concentration Courses

You may choose to take the standard curriculum or elect a concentration to further specialize your training. Based on your choice, you enroll in 1 concentration course (1 c.u.).

- **Standard Concentration**
 - **REG 6150** Post-Approval Maintenance of Drugs, Devices, and Biologics
- **Quality Assurance Concentration:** Offers a particular focus on GLP and GMP-compliant management of product development and manufacturing.
 - **REG 6160** Quality Assurance
- **Clinical Research Concentration:** Offers a particular focus on GCP-compliant management of clinical trials.
 - **REG 6110** Clinical Trial Management

Electives

- 3 Approved Electives (3 c.u.)

Capstone

- **REG 6400** Capstone I (1 c.u.)
- **REG 6410** Capstone II (1 c.u.)

Sample study plans can be found on the [Regulatory Affairs website](#) and in the Canvas page.

Courses

Please refer to the [ITMAT Education Courses webpage](#) for the most up-to-date course descriptions, days, times, and recent syllabi.

MRA Approved Electives

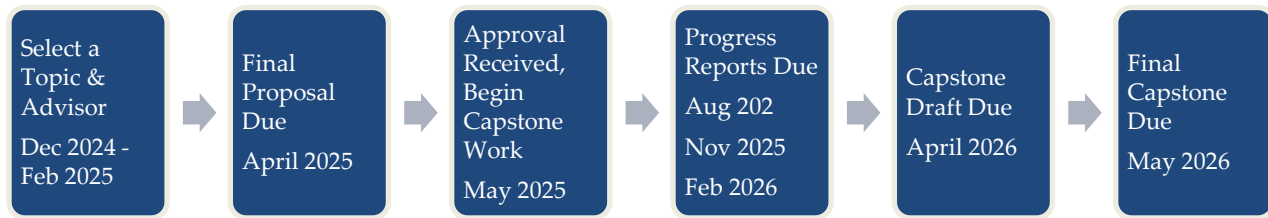
In addition to the standard required courses, students must enroll in electives that total three course units. Electives must be graduate-level, and can be taken within the program or from another program at Penn. Courses taken as electives in other programs may be in-person and require students to come to campus. These must be graduate level courses that complement the student's future career plans. Electives will be considered MRA electives on a case-by-base basis in consultation with a program advisor. The MRA program may consider additional courses not listed if provided with appropriate rationale and notice by the student.

An [up-to-date spreadsheet of elective options can be found in Box](#) and on the program Canvas page.

Capstone Project

The culmination of the Master of Regulatory Affairs program is the completion of a Capstone project. The Capstone is an intensive learning experience focused on the student's specific area of interest within Regulatory Affairs and their overall career aims.

1. In REG 6400, you will develop a detailed project proposal with a defined objective and deliverable. Projects may align with your current employment or may be in a new area of interest.
2. You will work with program leadership to find and select a Capstone Advisor by the end of your second term in the program. The advisor will be selected for their expertise in the topic being addressed.
3. Upon approval from the Program Director, you'll begin the project in your third term under the guidance of your Capstone Advisor.
4. Throughout your second year in the program, you will implement the work under the supervision of the Capstone Advisor.
5. In the final term, you will submit a deliverable that provides independent and novel insight into your project.



Sample Capstone Projects

Find recent [capstone project titles and topics on the MRA website](#).

Program Completion and Graduation

You will complete the MRA program once you have received grades for all ten (10) credit units of coursework, including the capstone courses. In some cases, students may receive a grade of Incomplete for the second capstone class, REG 6410: Capstone II, if completion of the capstone product requires additional time. You will graduate in the semester in which the final grade letter is assigned, pursuant to completion of other degree requirements (GPA requirements, administrative requirements, etc.).

Typically, each May, ITMAT Education hosts an informal reception in Philadelphia for the graduating MRA, MSTR, and MSRS cohorts. This is an optional, mostly social event that takes place within 1-2 weeks of Penn's formal commencement ceremonies.

University of Pennsylvania Graduation Ceremony/Commencement

The University of Pennsylvania holds one commencement ceremony each year in May. [Details are on Penn's Commencement Website](#). You can also check the [Frequently Asked Questions](#).

Regulatory Affairs graduates can plan to participate in Penn's commencement. The Penn commencement ceremony includes all May graduates **and** graduates from the prior fall and summer semesters; anyone who graduated within 1 prior calendar year of the May commencement may attend. Names are not read and students do not walk on stage due to the size of the event. Information about obtaining regalia is posted on the Commencement website in early spring each year.

Academic Policies

Attendance

Refer to each course syllabus to ensure you have a complete understanding of attendance requirements. If you will be absent, please contact the course coordinator and course director prior to your absence. If you have other concerns regarding your ability to meet course attendance requirements, contact the course coordinator at the time of registration. If an unexpected problem arises after the course begins please email the coordinator and course director to discuss as soon as your become aware of the conflict. Beyond allowable excused absence, the impact of absences on your course grade is at the discretion of the course director as described in the syllabus.

Students are expected to arrive on time, keep their video feed on, and remain engaged for the duration of the class. If you know you will arrive late to class or need to leave early, please email the course coordinator and course director prior to class. Any student who arrives more than 15 minutes late, leaves class before it is concluded and/or does not keep their video on will be considered absent from class.

Participation

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

Examples of active participation in a synchronous session include:

- asking or answering questions during class
- posting comments in the chat
- collaborating with other students during group work
- sharing relevant expertise with other students and the instructor

Examples of active participation in an asynchronous session include:

- asking or answering questions after class via Canvas or email
- interacting with other students outside of class
- commenting on discussion boards

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. 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.**

We expect you to:

- Refer to "[Community Standards and Program Expectations](#)" (heading above) for details on creating a quiet, distraction free environment
- Keep your video on
- Be appropriately attired (casual wear is fine)
- Approach debates and disagreements in a thoughtful and respectful manner

If you have questions regarding appropriate behavior in a synchronous class, contact the course coordinator.

Grading, Late Work, Extension, and Resubmission

Course Directors determine grading policies, late work policies, offering of assignment extensions or resubmissions.

Grading

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

LETTER GRADE	PERCENT SCORE	LETTER GRADE	PERCENT SCORE
A	93-100	C+	77-79
A-	90-92	C	73-76
B+	87-89	C-	70-72
B	83-86	D+	67-69
B-	80-82	D	63-66
		D-	60-62
		F	0-59

At the graduate level for Regulatory Affairs programs, the minimum standard for satisfactory work in each course is a B-.

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 which 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.

Academic Standing

The Regulatory Affairs degree programs have specific academic standards that are expected of all students.

If you fail to obtain a B- or better for a required course, you will be placed on academic probation. You may continue to enroll in other courses while on probation with the permission of the Program Director and input from the course director, as needed.

You must make arrangements with the course director to remediate any grades lower than a B-, and these arrangements must be approved by the Program Director with input from the Program Curriculum Committee as needed.

Examples of remediation include:

- retake an end of course exam,
- submit a written assignment as designed by the course instructor,
- other work as specified by the course director, or
- take the same course again or take another course.

This will be at the discretion of the course director for that course.

The grade as entered into the student record system will not be changed and will continue to impact your overall GPA.

Additional remediation may be required based on the judgment of the Program Director, the Program Curriculum Committee, and/or the course directors. A student who is or has previously been on probation and who receives an unacceptable grade for an additional course may be reviewed by the Program Director and the Program Curriculum Committee. The committee is authorized to dismiss the student or allow the student to remain in the program on a probationary status.

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 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](#). I

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 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 [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. This reflects the reality that although Regulatory Affairs programs are online, most students, staff, and instructors still reside in the Philadelphia area and would be impacted by severe weather or related events.

In the case that a student not located near Philadelphia is experiencing a severe weather event, students should communicate with the Course Director and Course Coordinator to determine accommodations.

Operational Processes and Policies

Student Conduct

Students must comply with the University's Code of Student Conduct and other University policies related to student conduct that appear in [The PennBook: Resources, Policies and Procedures Handbook](#). 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.

Additional codes of conducts and expectations students should be familiar with are the [nondiscrimination statement](#), the [sexual misconduct policy and resource offices](#), and [student grievance procedures](#).

Registering for Classes

You are responsible for registering yourself in MRA program courses and electives outside of the MRA program. Program staff will provide specific registration deadlines, billing schedule reminders, and assistance to students registering for courses. Prior to registering for courses, you will meet individually with program staff (or have an asynchronous discussion) to develop or update your study plan.

Your study plan should guide the courses for which you register each semester, and rather than deviating from the plan, you should contact program staff to discuss changes at any time. Students are required to verify course registration, tuition bills and grades through the student portal [Path@Penn](#).

You may refer to the Penn Three-Year Academic Calendar to find out registration dates and add/drop periods on the [Registrar's website](#). Information on course offerings (e.g., timetables, classrooms, and course descriptions) may vary from the Registrar's website. For the most up-to-date information on MRA courses, visit the [ITMAT Education courses page](#).

Continuous Enrollment & Time Limitation

The MRA is designed for continuous enrollment from program start to graduation, including fall, spring, and summer semesters (see study plans for examples). You are required to be continuously enrolled in coursework unless you request a leave of absence (see below).

The MRA degree program is structured for completion in two (2) years. Students may request an alternative plan of study to extend their planned time to degree to 3 years. Students may request an extension beyond 3 years for extenuating circumstances; a program fee may apply. Leaves of absence do count toward the total time “on the clock.” Failure to complete degree requirements will result in the student being dismissed from the program.

Leave of Absence

The following leave of absence policy is adapted from the policy applied across all of the Perelman School of Medicine's Masters and Certificate programs.

A student may request a leave of absence at any time during their program of study. Students may wish to take a leave of absence from their studies for various reasons, including but not limited to: health issues, family medical leave, military service, or other personal circumstances.

1. **Requesting a Leave of Absence:** A request for leave of absence, including the reason and anticipated date of return, must be submitted in writing to the Program Director. The program reserves the right to stipulate conditions that must be met for a student to return from a leave of absence. Any stipulations will be provided to the student in writing. A leave of absence may be granted for up to one (1) year. Students must be mindful to adhere to the established time to completion of their program when considering taking a leave of absence.
2. **Extending a Leave of Absence:** If a student wishes to request an extension of their leave of absence, they must submit a request, including the reason and new anticipated return date, to the Program Director no less than six (6) weeks prior to the start of the semester in which they were originally anticipated to return.
3. **Returning from Leave of Absence:** When returning from a leave, the student must formally declare their intent to return from leave by contacting their Program Director no less than six (6) weeks prior to the start of the semester in which they plan to return. If a student fails to initiate the process to return from leave of absence within the established time limit, the student may be administratively withdrawn from the program and will be required to re-apply in order to be considered for readmission into the program.

Student Grievance: Should the student be denied permission by the program to take, extend, or return from a leave of absence, the student may petition the Associate Dean for Perelman School of Medicine Master's & Certificate Programs by e-mail (macregistrar@pennmedicine.upenn.edu) for further consideration. The decision rendered by the Associate Dean is final.

Student Status and Systems Access: Students have access to various systems at the University while enrolled. Upon taking a leave of absence, certain systems access may be suspended. Because systems access is constantly evolving, it is incumbent upon the student to engage with [DART](#) to confirm how a leave of absence will impact access to University systems.

Billing and Loans: If the student requests leave after the start of the semester, all normal drop and withdrawal policies apply, including policies related to tuition and fees. A leave of absence may impact student loan eligibility and repayment. This includes loans sought to pay for the degree which the student is taking a leave of absence and those from a previous academic career. This may result in loans going into repayment before the end of the leave of absence. Students are encouraged to talk to Student Registration and Financial Services prior to taking a leave of absence to ensure they have planned for any impact related to student loan eligibility and repayment.

Students considering a leave of absence are advised to review the [Checklist for Withdrawal/Leave of Absence](#) provided by Student Registration and Financial Services.

Registration, Drops, and Billing

Student registration may be adjusted through Path@Penn through the end of the Course Selection Period for each term, as listed in the term Academic Calendar. After the Course Selection Period ends, registration adjustments must be requested through the program administrators. There will be a financial penalty assessed for dropping a course after the Course Selection Period, following the scheme below:

Drop on or before the Course Selection Period ends	100% reduction of tuition & fees*
Drop after the Course Selection Period ends and before the Drop Deadline	50% reduction of tuition & fees*
Drop after the Drop Deadline and before the Withdrawal Deadline	0% reduction in tuition & fees* Mark of 'W' added to the transcript
Drop after the Withdrawal Deadline	0% reduction in tuition & fees* Mark of 'WF' on the transcript, indicating Withdrawal with Failure

***Note to students with Penn Faculty / Staff Tuition Benefits:** Tuition benefits are calculated based on the number of registered CU and are adjusted in accordance with registration. Tuition benefits are always reduced 100%, regardless of the date of the drop, meaning they will **not** cover partial tuition & fees left on the bill as a result of dropping a course after the Course Selection Period ends. The portion of tuition and fees remaining on the bill after courses have been dropped are the student's responsibility. In practical terms, this means that if you withdraw from a course after the Course Selection Period ends, you are responsible for 50% of the **total** tuition & fees cost, not just 50% of the amount you may have paid in taxes. If you drop after the Withdrawal Deadline you will be responsible for the entirety of the listed tuition & fees with no subsidy from the Penn Tuition Benefit.

Withdrawal

Students may withdraw from their program at any time. Please contact your program for the appropriate form to commence official withdrawal proceedings. Students who are considering withdrawal are strongly encouraged to contact and meet with their Program Director to discuss their situation and options. Students are responsible for dropping all registered courses in the semester they wish to withdraw to effectively stop the billing process (in other words, withdrawal from the program does not automatically cancel course registration). Students are responsible for all tuition charges and other financial obligations to the University incurred prior to the effective date of withdrawal. Once students have withdrawn, they may reapply for admission under the program's application portal. Credit completed prior to readmission will be reviewed as transfer credit under the program's transfer credit policy.

Drop from Program or Courses

A student may be dropped from their program or courses for several reasons.

1. **Time Limit:** Students are expected to complete their degree within three years of matriculation. Should a student fail to complete their degree within the time limit, the program may drop the student. Students may request an extension for extenuating circumstances; a program fee may apply.
2. **Academic Progress:** Students are expected to maintain continuous registration, maintain a GPA of at least 3.0, carry incomplete marks for no more than a year, and achieve grades of B- or better in all coursework. If a student does not meet these criteria, they may be placed on probation—with an opportunity to remediate issues with their progress—or dropped from the program.
3. **Academic Integrity:** Students are expected to follow the [University Code of Academic Integrity](#). Violations of this code may result in the student being dropped from the program. They may also

have consequences in courses, e.g. failure of an assignment or a course. If an academic integrity violation is found to have significant negative impacts on classmates or the course environment, a student in violation may be dropped from the course.

4. **Student Conduct:** Students are expected to follow the [University Code of Student Conduct](#). Violations of this code may result in the student being dropped from the program and/or from any enrolled courses.
5. **Professionalism:** Students are expected to act in accordance with the [PSOM Standards of Professionalism and Student Conduct](#), specifically the [R.I.S.E. Code of Conduct](#) requiring Respect, Integrity, Self-Care and Etiquette. Violations of professionalism may result in the student being dropped from the program and/or from any enrolled courses.
6. **Community Standards:** Students are expected to adhere to the [ITMAT Ed Community Standards](#) outlined previously in this document. Students who repeatedly fail to meet these standards may be dropped from course(s) in which the violation occurs or, facing continuing failure to meet the standards, may be dropped from the program.

A student dropped from their program and/or courses will receive a letter stating that they have been dropped along with the reasoning. Regulatory Affairs program staff will make reasonable and good-faith efforts to work with students to address the issues listed above, but if no resolution can be achieved, the program reserves the right to initiate an involuntary drop. Students will be responsible for any charges or financial obligations to the University incurred before the effective date of the drop. In the case of a removal from course(s) before completion, students will receive a tuition refund.

Academic Grievances

Instructors and faculty members have the authority to make academic judgments in relation to their students. Therefore, if a graduate student wishes to have an evaluation, exam, or course grade reviewed, they must first discuss the matter with the course director. Should the student and course director not find a satisfactory resolution, or should a discussion prove impossible, the student may submit a request in writing to the Program Director.

Should the matter fail to be resolved with the aid of the Program Director, students may ask that their request be elevated to the Associate Dean for PSOM Master's and Certificate Programs for further review. The role of the Associate Dean is to ensure that the program has arranged for a proper review of the matter and that the evaluation was fair and impartial and in accordance with relevant University policies.

Transfer Credit Policy

Ten (10) course units are required for completion of the MRA degree. MRA students may request to transfer credit for graduate level courses completed at the University or from an accredited program outside of the University. All transfer credit requests will be considered on a case-by-case basis.

Courses taken on a pass/fail basis and courses taken more than three years ago will not be considered for transfer credit. Only courses in which the student received a grade of "B" (3.0), when converted to the Penn University scale, or higher will be considered for transfer credit. No course may be counted toward degree requirements if it has been used toward the requirements for another degree.

Requests for transfer credit should be submitted including:

1. The course description and syllabus,

2. A copy of the transcript that includes your grade in the course,
3. A short paragraph of rationale describing the relevance of the course to MRA curriculum and your career path as a regulatory affairs professional.

Approval is at discretion of the Program Director.

Students may request substitution of a core course with a more advanced course in that content area. The process for substitution is the same as that for transfer credit.

Audit Policy

You may opt to audit a course at the time of registration—by selecting Audit as the grade type—and may reverse this decision up until the Drop Deadline. The option to update registration is not available in Path@Penn after the Course Selection Period closes, so you should contact their program staff immediately if you have questions or need assistance.

Audited courses are charged tuition, at the same rate as regular courses, and do not count toward the degree. Students may not audit more than 49% of the coursework they are attempting in a term, in accordance with financial aid policies.

Administrative Requirements

Throughout the program, you will be required to keep track of and follow through on all administrative requirements for the MRA degree. Below is a summarized list of the requirements:

1. **Course Evaluations** – You must complete an evaluation for every MRA course. You will receive an email notification and website link to the online evaluation in the BLUE evaluation system during and/or at the end of each term. Grades will not be released until evaluations are complete.
2. **MRA Surveys** – You are required to complete an online evaluation of the MRA program each year. You will receive an email with a survey link from program staff. Graduating students are required to complete an exit survey evaluating the program.
3. **Graduation Application** – The MRA degree is conferred by the University of Pennsylvania Perelman School of Medicine and is granted in May, August, or December. To be considered for conferral of the degree, a student must complete a graduation application approximately three months prior to the expected conferral date. Prior to each graduation period, the program office will email details and deadlines to all eligible candidates.

Financial Information

Description of Tuition and Fees Tuition Rates

MRA tuition is calculated based on course unit tuition plus general and technical fees. Tuition rates can be viewed on the [Master's Program Costs website](#). Scroll down to "Regulatory Affairs" and select the plus sign icon to view the tuition costs. Financial information related to payment can be viewed on the [financial policies](#) page.

Online Services Fee

The online services fee is particular to online programs and enables the University to maintain essential facilities both in person and online such as the library system, career services, special laboratories, the Student Health Services, online portals and databases, and so on. The Online Services Fee is a reduced General Fee for online students.

Technical Fee

Students are charged a technical fee for computing services such as the course portals and use of email accounts.

Clinical Fee

As the MRA is a part-time program, in which students enroll in 2 CU or fewer per term, students are not typically subject to the clinical fee.

Full-time students (enrolled in more than 2 CU in a term) are required either to pay a separate Clinical Fee for access to the Student Health Service or to enroll in a health insurance plan that provides a capitated payment to the Student Health Service (i.e., the Penn Student Insurance Plan or a private plan that provides and equivalent capitated payment).

A review of the Penn Student Insurance Plan can be found on the [wellness website](#).

****Tuition & fees**** refers to Tuition, General Fee, and Technology Fee. Clinical Fee is separate and is removed when registration is below 3 CU. Clinical Fee will be removed through the Drop Deadline but not afterward.

Health Insurance

As the MRA is a part-time program, in which students enroll in 2 CU or fewer per term, students are not typically subject to the health insurance requirements.

All full-time students enrolled for a semester or more must carry adequate health insurance as a condition of student enrollment. Students who have their own insurance can waive enrollment in the Penn Student Insurance Plan (PSIP) only if their plan meets certain criteria found on the [Student Health Service website](#).

Immunization Policies

Please review the [Immunization Requirements webpage](#) at Wellness@Penn. Although the MRA is an online program, some electives are offered in-person. Students who believe they may take an in-person elective must comply with the Penn immunization requirements. (This would be under "Universal Immunization Requirements," not the Healthcare Professional Students requirements.)

University of Pennsylvania Tuition Benefits

University of Pennsylvania employees should refer to the [Human Resources Website](#) for specific details about tuition benefits, including tax implications. Please thoroughly review the websites [Tuition Benefits for Faculty and Staff](#) and [Tax Liability for Graduate Tuition Benefits](#) and contact the Tuition Administrator at tuition@hr.upenn.edu with any questions as soon as possible.

University employees who desire (and are eligible) to use tuition benefits must request tuition benefits during each and every semester via the [Online Tuition Management System](#). See benefit request [deadlines](#).

Billing Information

Once students are registered for courses, an electronic bill for the course units will be sent, and students are expected to complete payment by the date noted on the bill. Visit the [Billing Schedule Website](#) to view the due dates for upcoming semesters. You can access your bill, pay your bill, and view third-party payment plans on the [billing payment](#) website.

During the fall and spring terms, Penn offers a payment plan for students who wish to pay their bills in installments. The Penn Payment Plan is a voluntary, interest-free installment plan designed for students who prefer to spread all or a portion of their educational expenses across multiple payments each semester. To learn more and enroll in the plan, see the [Student Registration and Financial Services website](#). Students who have a balance and wish to go on a payment plan may not be able to register for classes.

A financial hold may be placed on your account if you have an overdue balance. If there is a hold on your account then you will be unable to register for courses. To remove the hold, you need to pay the balance. If you do not pay the balance, your account will be transitioned to the [fund recovery](#) process. Students who have a balance and wish to go on a payment plan may not be able to register for classes.

Financial Aid Requirements for Satisfactory Academic Progress

If you are using financial aid, then you must meet the following requirements.

- GPA of 3.0 or higher at the end of every term
- The student must be completing credit units at a rate which would enable them to complete the requirements for the degree in a maximum time frame of 150 percent of the published length of the academic program (2 years). 150% of 2 years would be 3 years.
- The student must successfully complete at least two thirds of courses attempted during their degree program. Marks, such as NR, GR, and I, do not count as completed coursework.

To learn more, visit the [financial aid website](#).

University Policies for Withdrawal, Refunds, and the Return of Financial Aid

Please review the university policies on:

- [Return of Funds](#)
- [Reduction of Tuition and Fees \(upon withdrawal\)](#)
- [Unofficial Withdrawals](#)

MRA Administrative Structure

The institutional governance and oversight of the Master of Regulatory Affairs program resides in the [PSOM Master's and Certificate \(MaC\) Program Office](#) within the Office of the Executive Vice Dean and Chief Scientific Officer. The academic home for the MRA program is the Institute for Translational Medicine and Therapeutics (ITMAT).

The **Program Director** is a faculty member responsible for administrative oversight and academic leadership of the program. The Director also serves as the chairperson of the Program Curriculum Committee. The current Program Director is Andrew Fesnak, MD, MHCI.

The **MRA Associate Director** is responsible for student affairs including course registration and advising. The Associate Director periodically evaluates the program curriculum and oversees new and cyclical curricular and operational initiatives. The Associate Director also supports the director and committee in program development and implementation. The current Associate Director is Erika Callaghan, MS, MA, CAPM.

The **Instructional Designer** is responsible for supporting the design, development, maintenance, and evaluation of Regulatory Affairs courses. The instructional designer also helps manage the Canvas LMS, website, and related domains, and assists the Assistant Director with student affairs matters when necessary. The current Instructional Designer is Esther Martin.

The **ITMAT Education Leadership Committee** serves as the Student Standards Committee for ITMAT Ed programs to review student academics and professionalism.

The **MRA Curriculum Committee** serves to advise the program leadership on all matters related to course development, curricular requirements, course implementation and modification, and program evaluation.

Additional Programs, Resources, and Information

MRA-ML Dual Degree

The Master of Regulatory Affairs and Penn Law have partnered together to offer the MRA-ML dual degree. The purpose of this dual degree is to expand your knowledge of both regulatory and legal affairs as well as highlight the connection between these two fields. Upon completion of the dual degree, you should have a deeper understanding of the intersections between these two fields.

Dual Degree Curriculum

Students who elect to pursue the MRA-ML dual degree will be required to complete a select number of courses from the MRA and LAW programs. The curriculum is designed to provide knowledge of both legal and regulatory affairs. Students may take 3 LAW courses to replace REG 6190 Research Ethics and 2 electives.

Students who are interested in pursuing the MRA-ML dual degree will be required to attend in-person law classes.

Sample study plans can be found on the [Regulatory Affairs website](#) and in the Canvas page. Students interested in pursuing the MRA-ML dual degree should contact program staff.

University of Pennsylvania Systems and Resources

PennCard

PennCard is the official identification card of the University of Pennsylvania. Students in fully online programs (such as the MRA) are **not** required to have a PennCard, but you may request one if you are local to Philadelphia or intend to visit campus. The PennCard Center is located on the 2nd floor of the Penn Bookstore at 3601 Walnut Street. A valid government issued photo I.D. will be required in order to pick up your new PennCard. The Office can be reached at <http://www.upenn.edu/penncard>.

PennKey

Your PennKey name and password gives you access to AirPennNet, Penn e-mail account and many other essential services. All students are required to have a current, active PennKey and password.

Once admitted into the MRA Program, if you are not already a Penn employee or alum, you will receive an email from PennKey with instructions to set up your PennKey. If you have not received this email, then please contact [PennKey Support](#).

Penn Email Address

If you are currently a Penn employee, you will not need to set up a Penn email address. If you are not a Penn employee or student, you will need to set up your PennKey before an email address can be requested for you.

For new students, we will email you with your Penn student email address. Please do not set one up through any Penn system. Once your Penn email address is sent to you, then you will be able to [activate your email address](#), you can use the temporary password sent to you to log into your email account. Then, you can change your password to something you will remember.

For technical email assistance, contact medhelp@pennmedicine.upenn.edu, or 215-573-4636.

Path@Penn

[Path@Penn](#) provides secure web access to view current billing information, course registration and schedules, academic records, student health insurance, etc. Access to this site requires login with PennKey and password.

The PennPortal

The PennPortal webpage bundles together links to important information for students. Access the [PennPortal](#) and log in with your PennKey and password.

Canvas

Canvas is the official learning management system at Penn. All MRA courses will host course content through Canvas along with course assignments and all communication regarding the course. Canvas can be accessed at <http://canvas.upenn.edu> with your Pennkey login. Support can be reached at canvas@pobox.upenn.edu.

Canvas requires certain technology specifications to work properly. Please review the [Canvas supported browsers](#), and ensure you are running the most recent version of your browser on your device.

Canvas also has a useful mobile app available on Android and iOS.

You can review the [Canvas LMS privacy policy](#).

Regulatory Affairs has [a joint Canvas page](#) for all students enrolled in REG programs. You will see this Canvas community in your Canvas dashboard. Find resources and opportunities there. You will also find information and tutorials on how to use program technology such as Canvas and Zoom.

Zoom

Zoom is the virtual meeting platform on which all Regulatory Affairs synchronous classes are held.

Zoom requires certain technology specifications to work properly. Please review the [Zoom system requirements](#), to ensure your devices are compatible with Zoom and ensure you are running the most recent version of your browser on your device.

You can review the [Zoom privacy policy](#).

General Technology Recommendations

As a fully online program, Regulatory Affairs recommends a certain baseline of technology tools:

- A laptop or desktop computer, Mac or PC. Notebook computers like Chromebooks and tablets are NOT recommended as they may not support all course technologies.
- Keep your computer up to date. Update your operating system, your preferred browser(s) and other software frequently. Generally, Penn online learning supports Windows 7, 8, or 10, Mac OS X 10.10 or higher, and ChromeOs latest version. Make sure your browser is updated to the latest version each semester. (We recommend Chrome or Firefox. Students have had issues with Safari in the past.)
- Check your internet connection. Students need a connection with at least 1Mbps upload and download. 3G/4G/LTE mobile networks can provide adequate speed (i.e., with a mobile hotspot) but performance will vary widely with location. So, we highly recommend a wired broadband connection.
- Students enrolled in Penn degree programs are eligible for [free Microsoft Office](#).
- Most classes include live online class sessions, and students are expected to participate via video and audio feeds. Thus, your device should be equipped with a webcam, microphone, and computer speakers (or headphones). The camera, mic and speakers built into most laptops work well. If you don't have a mic or speakers on your computer, you will be able to call into a telephone number to join the audio conference. For the best possible classroom experience in Zoom, we recommend using a headset with a microphone. Smartphone earbuds with a microphone will work in a pinch, but a headset with microphone is the best option.

Adapted from [Penn Arts & Sciences Online Learning](#)

University Resources

Graduate Student Center

The [Graduate Student Center](#) provides helpful information on acclimating to graduate programs. Below is a list of helpful resources from the Graduate Student Center.

- [Welcome to Penn Video](#)
- [New Student Resources: Student Orientation & Penn Accounts](#)
- [Thrive at Penn Resources & Support](#)
- [Graduate Student Programs](#)
- [Professional Development Opportunities](#)
- [New Student Checklist](#)

- [SRFS FAQ](#)
- [Maintaining your LinkedIn Profile](#)

CAPS & EAP

The Counseling & Psychological Services (CAPS) at Penn can provide helpful assistance with time management, stress, distress, and other concerns. CAPS can be contacted via [website](#) or phone, 215-898-7021

The [Employee Assistance Program](#) can provide Penn employees with services similar to CAPS. If you are a student and a Penn employee then you have access to the EAP.

Penn Resources

Below are a few resources for navigating the various Penn systems.

- The [billing schedule](#) marks when bills are sent and due. Remember, if you are using your Penn tuition benefits you will still be billed for taxes.
- The [academic calendar](#) details when terms begin, holidays, and school events. You can use this calendar to track the current and upcoming terms.
- [Student Financial Services](#) can offer guidance of billing, payments, and tuition costs
- The [AMA Manual of Style](#) can assist you in checking your citations as you work on class projects and your capstone. Read more about how the online guide can help you in the [about](#) section.
- [DART \[Digital Academic Resource Transformation\]](#) houses technical support.

Support Resources

Note that resources marked as *confidential* indicate that the information shared with these offices generally will be held in confidence, consistent with the University's obligation to address these complaints unless the person sharing the information gives their consent to the disclosure of that information.

[The LGBT Center](#) | 215-898-5044 – confidential | center@dolphin.upenn.edu

[The Penn Women's Center](#) | 215-898-8611 – confidential | vpul-pwc@pobox.upenn.edu

[The African American Resource Center](#) | 215-898-0104 – confidential | aarc@pobox.upenn.edu

[La Casa Latina](#) | 215-746-6043 | lacasa@upennlcl.com

[The Pan-Asian American Community House \(PAACH\)](#) | 215-746-6046 | paach@lists.upenn.edu

University Required Disclosures

Please review the PennBook's [Student-Related Required Disclosures](#).

Disclosure on Credential Recognition Abroad & Considerations for International Students

The Master of Regulatory Affairs program is offered by the University of Pennsylvania, an institution of higher education authorized to confer degrees and certificates conferring academic credit under applicable laws of the United States. Students who are interested in participating in the program from countries other than the United States are advised that each jurisdiction may have its own laws and regulations governing online educational programs, and some jurisdictions may not recognize course credit or an online degree awarded by the University as satisfying local requirements for professional licensure, employment qualification, or other purposes. Before enrolling in this program, prospective

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students should investigate their jurisdiction's treatment of foreign online programs to ensure that participation in this program will meet their objectives.

The Master of Regulatory Affairs and the Regulatory Affairs Certificate are both [STEM OPT extension](#) eligible programs for holders of F-1 visas. The programs cannot provide initial F-1 visa sponsorship.

If you have additional questions about the format of the program or its ability to fit your schedule, access, etc. please contact program staff.

Accreditation

The University of Pennsylvania is accredited, but there is no separate accreditation for regulatory affairs programs. The online degree programs in Regulatory Affairs meet the standards set by the Higher Education Opportunity Act for online for-credit programs.