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Program Contacts

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Introduction & MRA Program Goals
The Master of Regulatory Affairs (MRA) program was developed at Penn to broaden the spectrum of and enhance the quality of training by providing an educational curriculum to teach the skill set needed to implement Regulatory Affairs. To this end, the program aims to define the professionals who assume responsibility to implement and comply with stated regulations, and these professionals must be versed in both the foundation and application of science-based regulation to effectively maximize compliance and minimize risk. The MRA program is thus designed to create a culture of professionals who promote science-based regulation and drive knowledge and acceptance down the pipeline.

MRA Program Overview
The University of Pennsylvania’s Master of Regulatory Affairs (MRA) program is designed to prepare professionals to play key roles in bringing innovative products to market while also ensuring that products are safe and effective. Graduates will be trained in the skills necessary to maximize compliance and minimize risk in the development of FDA-regulated products and will learn both the foundation and application of science-based clinical investigation and corresponding regulations. This is accomplished through a 10-credit unit curriculum consisting of coursework and an experiential capstone project. The MRA Program is housed in the Perelman School of Medicine at the University of Pennsylvania. The Perelman School of Medicine is consistently ranked in the top five research-intensive universities according to US News & World Report. Being part of a world-class research institution gives you the opportunity to learn from leaders in the field and a seat at the table to see innovations being driven down the pipeline.

Our part-time, two-year (5 semester) program is ideal for working professionals and allows you the option to choose a concentration in clinical research or quality assurance to further specialize your skills. Our program is in person so you will build relationships with your instructors, who are Penn faculty and industry experts, and members of your 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. This will allow you to be competitive in securing positions that are integral to the navigation of new medical products and technologies through regulatory, clinical, and quality assurance channels.

The development of additional skills—including oral and written communication, problem-solving, and teaming—are considered integral to this training. You will also 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.

Institutional Commitment to the MRA Program
The University of Pennsylvania is committed to both maintaining the highest standards of excellence in education and providing a superior quality program to ensure that, when completed, the student can function independently as a professional in the field of research regulation. The Vice Provost for Education, Beth Winkelstein, PhD, oversees educational programs at the University and Jon Epstein, MD is the Executive Vice Dean and Chief Scientific Officer within the Perelman School of Medicine (PSOM). Dr. Epstein has designated the oversight for all PSOM masters programs to the PSOM Master’s and Certificate Programs (MaC), led by Emma Meagher, MD. The daily operations of the MRA program are the responsibility of the ITMAT education administrative support staff under the direction of the Program Director, Emma Meagher, MD.
Quality Training in the MRA Program
The goal of the MRA program is to train future regulatory professionals. Individuals in this program are provided with the expertise and methods required to attain this goal. Regulatory Affairs graduates will master key approaches required for the evaluation of novel devices, biologics, and therapeutics. The program will produce professionals who are:

i. Competitive in securing positions that are integral to the navigation of new medical products/technologies through regulatory, clinical and quality assurance channels
ii. Well-versed in the complex strategic process in academia, industry, and government sectors.
MRA Degree Requirements
The University of Pennsylvania operates on an academic semester system. The MRA degree program requires 10 course units for completion, with 6 core courses, 2 electives, and 2 capstone courses. The core courses are taught once per year in the semester designated in the study plans below. There are 3 concentrations within the MRA degree program you may select upon acceptance to the program. These 3 concentrations are the MRA Standard Curriculum, Clinical Research, and Quality Assurance. Each concentration is outlined below in a study plan. Course descriptions are also included to assist you in selecting a concentration.

Standard Coursework

<table>
<thead>
<tr>
<th>COURSES</th>
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<tr>
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<tr>
<td>REG 510 INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH</td>
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</tr>
<tr>
<td>REG 610 FUNDAMENTALS OF FDA REGULATION</td>
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<tr>
<td>REG 612 INTRO TO DRUG DEVELOPMENT</td>
<td>1.0</td>
</tr>
<tr>
<td>REG 614 BIOPHARMACEUTICAL DEVELOPMENT, MANUFACTURING AND REGULATORY AFFAIRS</td>
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<tr>
<td>REG 615 POST-APPROVAL MAINTENANCE OF DRUGS, DEVICES, AND BIOLOGICS</td>
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<td>REG 640 CAPSTONE I</td>
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</tr>
<tr>
<td>ELECTIVES (2 C.U)</td>
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Sample Standard Concentration Study Plan

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<tr>
<th>SUMMER</th>
<th>FALL</th>
<th>SPRING</th>
</tr>
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<tbody>
<tr>
<td>YEAR 1</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>REG 510 Intro Clinical Research</td>
<td>REG 640 Capstone I</td>
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<td>REG 612 Intro Drug Development</td>
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<tr>
<td>YEAR 2</td>
<td>REG 610 Fundamentals of FDA Regulations</td>
<td>REG 614 Biopharm Dev, Manufacturing, &amp; Reg Affairs</td>
</tr>
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<td>REG 615 Post-approval Maintenance</td>
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<td>REG 641 Capstone II</td>
</tr>
</tbody>
</table>

BIOE 580 Research Ethics to be taken in Spring Year 1 or 2

Year 1: 4 c.u.
Year 2: 6 c.u.
Total: 10 c.u.

Clinical Research Coursework

<table>
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<td>REG 510 INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH</td>
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Sample Clinical Research Concentration Study Plan

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<tr>
<td><strong>YEAR 1</strong></td>
<td></td>
<td>REG 510 Intro Clinical Research</td>
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<td>REG 640 Capstone I</td>
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<td>REG 641 Capstone II</td>
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<tr>
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*BioE 580 Research Ethics to be taken in Spring Year 1 or 2*

- Year 1: 4 c.u.
- Year 2: 6 c.u.
- Total: 10 c.u.

Quality Assurance Coursework

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<td>REG 616 QUALITY ASSURANCE</td>
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<td>ELECTIVES (2 C.U.)</td>
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Sample Quality Assurance Concentration Study Plan

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*BIOE 580 Research Ethics & REG 616 Quality Assurance to be taken in Spring Year 1 or 2*
Year 1: 4 c.u.
Year 2: 6 c.u.
Total: 10 c.u.

Course Descriptions

**BIOE 580 Research Ethics**
This class is intended to give students a broad overview of research ethics and regulation. The students will come out of the class with an understanding of the moral bases of scientific ethics and the historical evolution of biomedical research ethics. Students will be fully conversant with the development, implementation, and limitation of US human subjects regulation. The course will include reading assignments and lectures addressing the following topics: ethics and morality in science, science in society; scientific integrity; misconduct: from FFP to MIM; conflicts of interest; collegiality, publication, and authorship; ethics codes and regulation; research with human subjects; historical review of human experimentation; human subjects regulation (HHS, FDA), Institutional Review Boards; informed consent, waivers, vulnerable populations, privacy and the confidentiality of records; and research on animals.

**REG 510 Introduction to Clinical and Translational Research**
This introductory course lays the foundation for understanding practical aspects of conducting clinical research in an academic environment. The course is divided into two modules: Module 1: Research Methods & Protocol Development and Module 2: Regulatory Environment for Clinical Trials. The first module introduces clinical research, clinical protocols, study designs and biostatistics that underlie such studies. The second module covers ethical considerations in clinical research, study execution and oversight, and the regulatory environment for clinical research. Upon completion, students should have a strong foundation in the fundamentals of clinical research and should be able to apply contemporary research tools to clinically relevant areas of investigation.

**REG 610 Fundamentals of FDA Regulation**
This introductory course provides an overview of Regulatory Affairs in relation to three key areas of development: Drugs, Biologics, and Medical Devices. The course will look at the rules governing prescription and over-the-counter drugs as well as the changes introduced by the influence of genetic engineering and biological product development. The developmental and regulatory path for new devices, as well as the way products are governed once in the marketplace will be explained.
Throughout the course, practical issues facing regulatory specialists as they work with the FDA and other international regulatory bodies to secure and keep product approval will be addressed.

REG 612 Introduction to Drug Development
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. 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.

REG 614 Biopharmaceutical Development, Manufacturing and Regulatory Affairs
Biopharmaceutical protein products have been successfully used to treat a number of diseases and currently represent a large segment of the product pipeline in most major pharmaceutical companies. More than half of the current top 20 blockbuster drugs are biopharmaceuticals. Drugs like Activase®, Humira®, and Avastin® have revolutionized the drug industry in treating the unmet medical needs of many patients. With innovation at the heart of the biopharmaceutical industry, this course is aimed at developing the student’s understanding of the application of basic research in molecular biology and genetics to the development of novel drugs for treating diseases. The course is designed to provide an overview of biopharmaceutical protein drug development and manufacturing processes with an emphasis on regulatory affairs activities. The class has been developed and is taught by a former VP of biopharmaceutical product development with over 30 years of experience in biotechnology and the biopharmaceutical industry. The course director will provide insights into the unique challenges and opportunities facing the biopharmaceutical industry and how they relate to regulatory affairs. Subject area experts from industry will also participate as guest lecturers.

REG 615 Post-Approval Maintenance of Drugs, Devices, and Biologics
The FDA regulates prescription drugs, biologics and medical devices for utilization in the United States. The approval of a marketing application is a major accomplishment; however, it comes with significant responsibilities for a sponsor including numerous reporting requirements and activities to maintain a license as well as a need for lifecycle maintenance activities to stay competitive. The purpose of this course is to provide an overview of post-approval activities required for drugs, biologics and devices.

REG 640 Capstone I
The Capstone is an intensive project focused on your specific area of interest within Regulatory affairs. The Capstone project is broken up into two course units, REG 640, which is an in-person class and focuses on the Capstone proposal and REG 641 which provides credit for your final Capstone project. In this Capstone proposal course you will select a topic related to your area of interest within Regulatory Affairs and identify an appropriate advisor to oversee your project. During this course you will define objectives and formulate your Capstone around deliverables that will further your knowledge and career. Successful completion of the course is determined by a finalized proposal approved by your advisor which will propel your work on the Capstone project in REG 641 Capstone II.

Note: In between REG 640: Capstone I and REG 641: Capstone II three progress reports are to be submitted and approved.
Master of Regulatory Affairs Program

**REG 641 Capstone II**
The Capstone is an intensive project focused on your specific area of interest within Regulatory affairs. The Capstone project is broken up into two course units, REG 640, which is an in-person class and focuses on the Capstone proposal and REG 641 which provides credit for your final Capstone project. You will be required to submit three progress reports and your final capstone deliverable. Your advisor will continue to oversee your Capstone project providing feedback for improvement. Successful completion of the course is determined by a finalized deliverable with evaluation and approval from the Program Directors.

**MRA Approved Electives**
The following electives have been approved for the MRA degree program. The electives are categorized by concentration.

### MRA Standard Curriculum

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<td>REG 616 Quality Assurance</td>
<td>LAW 522 Compliance and Corporate Governance</td>
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<tr>
<td>REG 621 Cell &amp; Gene Therapy</td>
<td>LAW 529 Navigating the Regulatory State</td>
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<tr>
<td>REG 622 New Trends in Medicine &amp; Vaccine Discovery</td>
<td>LAW 530 Intro to Health Law &amp; Policy</td>
</tr>
<tr>
<td>REG 630 Clinical Trials</td>
<td>LAW 920 Pharmaceutical Regulation &amp; Enforcement</td>
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<tr>
<td>MTR 620 Commercializing Translational Therapeutics</td>
<td>BMIN 501 Intro to Biomedical Informatics</td>
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<tr>
<td>HCMG 899 Management &amp; Economics of the Pharma, Biotech &amp; Medical Device Industries</td>
<td>BMIN 502 Databases in Biomedical Research</td>
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<tr>
<td>PUBH 502 Introduction to Epidemiology</td>
<td>BIOE 552 Bioethics &amp; the Law</td>
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<td>BIOE 575 Health Policy</td>
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### MRA Clinical Research Concentration

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### MRA Quality Assurance Concentration

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<td>Quality Assurance</td>
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<td>Cell &amp; Gene Therapy</td>
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<td>New Trends in Medicine &amp; Vaccine Discovery</td>
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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. Students will develop a detailed project with a defined objective and deliverable. Students will work on the Capstone with advisement from a Capstone Advisor which will be selected no later than the end of their second term in the program. The advisor will be selected for their expertise in the topic being addressed. Projects may align with their current employment or may be in a new area of interest. Upon approval from the Program Director, the student will begin the project in their third term. Throughout their second year in the program, students will implement the work under the supervision of the Capstone Advisor. In the final term, students will submit a deliverable that provides independent and novel insight into their project.

Students will be evaluated in two ways. First, the Capstone Advisor will evaluate their performance throughout the project and second, the Program Director will evaluate the final deliverable(s).

Capstone Timeline

Sample Capstone Projects
Training Programs
- Creation, Implementation, and Evaluation via Compliance Parameters of a Continuing Drug Manufacturing Compliance Education Program within the Penn Cyclotron Facility
- Tackling Learning Gaps and Operational Deficiencies in the Field of Regulatory and Compliance Using Tailored Educational Workshops
- A Training System and Reference for High Throughput Xenograft Modeling in Immune Deficient Mice

Targeted Regulatory Guidance
- Regulatory Pathway Guide for New Medical Devices and Technology at the University of Pennsylvania
- Developing an Internal Regulatory Guidance Document for Filing a Companion Diagnostics Application
- Guidance Toward Implementing a GLP Compliance Program in an Academic Setting: Overcoming Challenges and Pitfalls
- Evaluation of Gaps & Challenges in Developing Rare Disease Registry Endpoints: A Case Study of PRO Endpoints in Registries for CDKL5 Deficiency Disorder and Spinal Muscular Atrophy
- Implications Affecting Regulatory Preparation and Workflow for Continuing Reviews: Site-level Differences when Using Local or National IRB (CIRB) in Oncology

Process Improvement
- Developing a New Master Manufacturing Batch Record
- Risk-based Monitoring of Gene Therapy Clinical Trials for Hereditary Retinal Degeneration
• Implementation of the CNT Imaging Core Data Collection and Analysis Pipeline
• Preclinical Data Collection for Successful IDE Submission
• Quality Management Systems at an Academic Research Institution: Development and Implementation of a Pilot Quality Management System at the University of Pennsylvania
• Evaluating Timelines, Processes and the Downstream Operational Activation Impacted by Differences in IRB Review Models

Topics of Interest
• Trends in Reporting to the FDA Adverse Events Reporting System (FAERS)
• Evaluating the Impact of the New Informed Consent Ruling from the Pennsylvania Supreme Court
• CAR-T Therapy Product Development and Approval in the US for the Treatment of Orphan Diseases
• Deception in Human Subjects Research and the Effect of Subject Payment: Subjects’ Views and Staff Views
• Longitudinal Study to Assess Long Term Comorbidities in Women with PCOS-Longitudinal PCOS
• Evaluating the Impact of Chinese Regulatory Reforms from 2015-2020
Academic Policies

Grading
The grading system is as follows: A, excellent; B, good; C, fair; D, poor; and F, failure. Letter grades may be modified by a plus (+) or minus (-) sign at the discretion of the course director. The typical grade scale is as follows but may vary based on the course director.

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<th>LETTER GRADE</th>
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</tr>
<tr>
<td>A-</td>
<td>90-92</td>
</tr>
<tr>
<td>B+</td>
<td>87-89</td>
</tr>
<tr>
<td>B</td>
<td>83-86</td>
</tr>
<tr>
<td>B-</td>
<td>80-82</td>
</tr>
<tr>
<td>C+</td>
<td>77-79</td>
</tr>
<tr>
<td>C</td>
<td>73-76</td>
</tr>
<tr>
<td>C-</td>
<td>70-72</td>
</tr>
<tr>
<td>D+</td>
<td>67-69</td>
</tr>
<tr>
<td>D</td>
<td>63-66</td>
</tr>
<tr>
<td>D-</td>
<td>60-62</td>
</tr>
<tr>
<td>F</td>
<td>0-59</td>
</tr>
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</table>

At the graduate level for the MRA program, the grade of C, while passing, does not constitute satisfactory performance. The minimum standard for satisfactory work in each course is a B-. The MRA program additionally requires that the quality of the student’s work and their conduct in the program is of an appropriate professional quality to ensure advancement. Failure to meet these requirements may result in a student being placed on probation and/or require a student to withdraw despite a satisfactory grade average.

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). It is expected, in general, that a student shall complete the work of a course during the term in which that course is taken. The instructor may permit an extension of time up to one year for the completion of the course, this includes both REG and non-REG electives. In such cases, 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 at minimum 2 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 MRA degree program has specific academic standards that are expected of all students. If a student fails to obtain a B- or better for a required course, they will be placed on academic probation. Students may continue to enroll in other courses while on probation with the permission of the MRA Program Director and input from the course director, as needed. The student 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.

A remediation may include one of the following: retake an end of course exam, submit a written assignment as designed by the course instructor, or take another course. This will be at the discretion of the instructor for that course. The grade as entered into the student record system (SRS) will not be changed. 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.

Academic Grievances
Students who have a concern about a matter related to the MRA program, whether it concerns a course, instructor, or other program issue are encouraged to come to the MRA program office and share any concerns with either Bethany Germany, Associate Director of Regulatory Education or Andrew Fesnak, Associate Director of ITMAT Education. Alternatively, the student may wish to speak directly with the MRA Program Director.

Transfer Credit Policy
Ten 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) 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 to the MRA Associate Director together with a course syllabus for the course under consideration. The Associate Director will then request a review of the course by an MRA faculty member in that content area for its appropriateness for MRA transfer credit. 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
Students who wish to audit a course are expected to designate the audit at the time of registration. Auditing course work is discouraged, as full tuition is charged but no credit is earned toward the MRA
degree. If a student wishes to change a course status from credit to audit, they must obtain permission from the course instructor before the add/drop period ends. The audited course will appear on the transcript with the grade of “AUD” and no credit will be earned toward graduation. Students are not permitted to change the course status from graded to audit after the course has ended.

Time Limitation
The MRA program may be taken on a part-time basis. The timing of course work is optimized to permit students to continue in their employment while working toward the completion of the degree. The maximum time permitted to complete the MRA degree is 5 years from the date of matriculation.

Registration
Students are responsible for registering themselves in MRA program courses and electives outside of the MRA program. The MRA Associate Director will provide specific MRA registration deadlines, billing schedule reminders, and assistance to students registering for courses. Prior to registering for courses students will meet individually with the Associate Director to develop their study plan. Students should use the study plan to guide them in registering for courses each semester. Students are required to verify course registration, tuition bills and grades through the student portal Penn InTouch.

Students 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.

Penn InTouch Course Registration Guide
Course Registration Site: www.upenn.edu/pennintouch

Selecting Courses
1. Select Course search and verify that appropriate term is selected

![Penn InTouch Course Registration Guide](image-url)
2. Search by Course ID / Subject

![Course search interface]

3. Add desired courses to cart

![Course search results]

4. Select **Register for courses**

![Course registration options]

5. Select course cart from right hand menu

![Course selection interface]

6. Select **Add request**
Master of Regulatory Affairs Program

Course Registration Complete
Claim Authorizations / Permits: Go directly to register for courses

a. Look below course cart for authorizations and permits

b. Select permit to claim and add request
You have now registered for your courses!

**Continuous Registration & Leave of Absence**

A leave of absence will be granted for military duty, medical reasons, and for family leave; this leave is typically for up to one year and “stops the clock” on time to completion. Personal leave for other reasons may include but are limited to pursuing career-related opportunities, working on a political campaign, completing coursework attempted from a previous term may be some reason. Personal leave reasons may be granted for up to one year with the approval of the Program Director, but it does not automatically change the time limit.

Continuous registration as a graduate student is required unless a formal leave of absence is requested and granted by the Program Director. If an approved academic leave of absence is granted, it may, at the discretion of the program, “stop the clock” on time to degree completion. The length of the leave is determined by the program based on program policies and individual circumstances. Students on leave should remain in contact with their program and provide updates about changes in plans. Students may not be required to complete any degree-related activities during a leave of absence. Exceptions may be made for repeating or completing coursework students have already attempted in previous terms. Such exceptions should be outlined in the leave of absence request and reflected in the approval letter. When preparing to return, students must consult with their program to develop a plan that includes the connection with appropriate resources and reactivation in the student record system.

**Student Conduct**

MRA 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.

Any student who exhibits unprofessional behavior as determined by program leadership will be evaluated for probation. Continued unprofessional behavior will be grounds for removal from the program.

**Code of Academic Integrity**

The most fundamental value of any academic community is intellectual honesty; accordingly, all academic communities rely upon the integrity of each and 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. The Code of Academic Integrity can be viewed in the PennBook or below. Violations of the Code include but are not limited to the following acts:

A. **Cheating:** using or attempting to use unauthorized assistance, material or study aids in examinations or any other academic work, or preventing, or attempting to prevent another from using authorized assistance, material, or study aids. Example: using a cheat sheet in a quiz or exam, altering a graded exam and resubmitting it for a better grade, etc.

B. **Plagiarism:** using the ideas, data or language of another without specific and proper acknowledgment. Example: copying another person’s paper, article, or computer work and submitting it for an assignment, cloning someone else’s ideas without attribution, failing to use quotation marks where appropriate, etc.

C. **Fabrication:** submitting contrived or altered information in any academic exercise. Example: making up data for an experiment, fudging data, citing nonexistent articles, contriving sources, etc.

D. **Multiple Submission:** submitting, without prior permission, any work submitted to fulfill another academic requirement.

E. **Misrepresentation of Academic Records:** misrepresenting or tampering with or attempting to tamper with any portion of one’s own or any other person’s transcripts or academic record, either before or after coming to the University of Pennsylvania. Example: forging a change of grade slip, tampering with computer records, falsifying academic information on one’s resume, etc.

F. **Facilitating Academic Dishonesty:** knowingly helping or attempting to help another violate provisions of this Code. Example: working together on a take-home exam, etc.

G. **Unfair Advantage:** attempting to gain unauthorized advantage over fellow students in an academic exercise. Example: gaining or providing unauthorized access to examination materials, obstructing or interfering with another student’s efforts in an academic exercise, lying about a need for an extension for an exam or paper, continuing to write even when time is up during an exam, destroying or keeping library materials for one’s own use, etc.

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, then it is that student’s responsibility to consult with the instructor to clarify any ambiguities.
**Administrative Requirements**

1. Throughout the program, students 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:
   a. **Course Evaluations** – students are required to complete an evaluation for every MRA course. Students will receive an email notification and website link to the online evaluation in the OASIS evaluation system at the end of each term. Grades will not be released until evaluations are complete. Students may directly access the [OASIS evaluation site](#).

2. **MRA Surveys** – students are required to complete an online evaluation of the MRA program each year. You will receive an email with a survey link from the MRA Associate Director. Graduating students are required to complete an exit survey evaluating the program.

3. **Graduation Application** – in order to be considered for conferral of the degree, students must complete an online graduation application approximately two months prior to the expected conferral date. The graduation application initiates an academic audit that, assuming all requirements are met, places the student with the next graduation cohort. The MRA degree is conferred by the University Of Pennsylvania Perelman School Of Medicine and is granted in May, August and December of each year.
University of Pennsylvania Systems

PennCard
PennCard is the official identification card of the University of Pennsylvania and is required for all students. The PennCard Center is located on the 1st floor of the Franklin Building at 3451 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 via e-mail at penncard@upenn.edu and online at http://www.upenn.edu/penncard.

PennKey
Your PennKey name and password gives you access to PennNet, a Penn e-mail account, and many other essential services managed through the MRA Program. All students are required to have a current, active PennKey and password. If you already have a PennKey, you do not need to set up a new one.

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.

Penn InTouch
Penn InTouch 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. https://portal.apps.upenn.edu/penn_portal/intouch/splash.html

The PennPortal
The PennPortal webpage bundles together links to important information for students. Access the PennPortal at https://portal.apps.upenn.edu/penn_portal/portal.php 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. http://canvas.upenn.edu
Financial Information

Tuition Rates
MRA tuition is calculated based on course unit tuition plus general and technical fees. Tuition for non-MRA courses vary by school/department in the summer, and students should contact the individual department to verify tuition cost.

Tuition rates for 2018-2019:

<table>
<thead>
<tr>
<th>CREDITS</th>
<th>TUITION</th>
<th>GENERAL FEE</th>
<th>TECHNICAL FEE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 C.U.</td>
<td>$4,453</td>
<td>$394</td>
<td>$181</td>
<td>$5,028</td>
</tr>
<tr>
<td>2 C.U.</td>
<td>$8,906</td>
<td>$788</td>
<td>$362</td>
<td>$10,056</td>
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</tbody>
</table>

General Fee
The amount of the general fee is based on the number of course units taken. The general fee enables the University to maintain essential facilities such as the library system, museums and institutes, special laboratories, the Student Health Service, Athletics, and Career Services, all of which provide benefits to students both before and after graduation.

Technical Fee
Students are charged a technical fee for computing services such as access to computer labs and use of email accounts.

Clinical Fee
The Clinical Fee is a mandatory fee charged to all full-time students each term where full-time is defined as taking 3 or more course units per term.

Tuition Benefits
University employees may use their employee tuition benefits to pay for a portion of the cost of their MRA degree. Please note the tuition benefits are taxable. To learn more about the tuition benefits for University employees visit the Human Resources Website.

University employees must request tuition benefits during each and every semester via the Online Tuition Management System. See benefit request deadlines.

1. Go to the Online Tuition Management System
2. Click Continue, then log in with your PennKey.
3. Click Tuition Benefits Management.
4. Click Tuition Benefits for Myself, on the top left.
5. Request Payment.

Tuition benefits are available for each semester during particular windows. Below are the dates which tuition benefits are available for the 2019-2020 year.
Billing Schedule
Once students are registered for courses an electronic bill for the course units will be sent, students are expected to complete payment by the dated noted on the bill. The billing schedule details the date bills will be sent and the date bills are due. For example, if you register for a summer 2019 course prior to July 9 then you will receive an e-bill on July 9 and are expected to pay this bill by July 31. Visit the Billing Schedule Website to view the due dates for upcoming semesters.

Health Insurance
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. Information on insurance compliance can be found here:
http://www.vpul.upenn.edu/shs/compliance.php
ITMAT Ed Administrative Structure

The institutional governance and oversight of the Master of Regulatory Affairs Program resides in the PSOM Master’s and Certificate Program Office (http://www.med.upenn.edu/masters.shtml) 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 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 Emma Meagher, MD.

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

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

The MRA Associate Director is responsible for student affairs including course registration and advising. The Associate Director periodically evaluates the program curriculum and directs the Capstone process. The Associate Director also supports the director and committee in program development and implementation. The current Associate Director is Bethany Germany, MA.