



**Penn**  
MASTER *of* REGULATORY AFFAIRS

2022-2023 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. 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 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. As such, the program educates trainees in the foundation and application of science-based regulation to maximize compliance and minimize risk.

## MRA Program Goals

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 part-time, two-year (5 semester) program is ideal for working professionals and allows students the option to choose a concentration in Clinical Research or Quality Assurance to further specialize their skills.

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, graduates 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 allows graduates 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. Students will become an expert in a chosen area for their Capstone project and will produce a deliverable to position them for the next step in their career.

The MRA program is an online degree program. MRA courses include both asynchronous and synchronous components. This allows students to take advantage of both the increased flexibility of asynchronous learning (to learn and work on their own schedule, from anywhere) and the interaction and relationship-building of synchronous course sessions.

## MRA Degree Requirements

The University of Pennsylvania operates on an academic semester system (fall, spring, and summer). The MRA degree program requires 10 course units for completion, with 5 core courses, 3 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 students 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 students in selecting a concentration.

### Standard Coursework

COURSES	COURSE UNITS
REG 6190 RESEARCH ETHICS	1.0
REG 5100 INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH	1.0
REG 6100 FUNDAMENTALS OF FDA REGULATION	1.0
REG 6120 INTRO TO DRUG DEVELOPMENT	1.0
REG 6150 POST-APPROVAL MAINTENANCE OF DRUGS, DEVICES, AND BIOLOGICS	1.0
REG 6400 CAPSTONE I	1.0
REG 6410 CAPSTONE II	1.0
ELECTIVES (3 CU)	3.0

### Sample Standard Concentration Study Plan

	SUMMER	FALL	SPRING
<b>YEAR 1</b>		REG 5100 Intro to Clinical Research REG 6120 Intro to Drug Development	REG 6400 Capstone I REG 6190 Research Ethics
<b>YEAR 2</b>	REG 6100 Fundamentals of FDA Regulations <i>Elective</i>	<i>Elective</i> <i>Elective</i>	REG 6150 Post-approval Maintenance REG 6410 Capstone II

Year 1: 4 CU

Year 2: 6 CU

**Total: 10 CU**

### Clinical Research Coursework

COURSES	COURSE UNITS
REG 6190 RESEARCH ETHICS	1.0
REG 5100 INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH	1.0
REG 6100 FUNDAMENTALS OF FDA REGULATION	1.0
REG 6110 CLINICAL TRIAL MANAGEMENT	1.0
REG 6120 INTRO TO DRUG DEVELOPMENT	1.0
REG 6400 CAPSTONE I	1.0
REG 6410 CAPSTONE II	1.0

ELECTIVES (3 CU)

3.0

### Sample Clinical Research Concentration Study Plan

	SUMMER	FALL	SPRING
<b>YEAR 1</b>		REG 5100 Intro Clinical Research REG 6120 Intro Drug Development	REG 6400 Capstone I <i>REG 6190 or Elective</i>
<b>YEAR 2</b>	REG 6100 Fundamentals of FDA Regulations REG 6110 Clinical Trial Management	<i>Elective</i> <i>Elective</i>	REG 6410 Capstone II <i>Elective or REG 6190</i>

Year 1: 4 CU

Year 2: 6 CU

**Total: 10 CU**

### Quality Assurance Coursework

COURSES	COURSE UNITS
REG 6190 RESEARCH ETHICS	1.0
REG 5100 INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH	1.0
REG 6100 FUNDAMENTALS OF FDA REGULATION	1.0
REG 6120 INTRO TO DRUG DEVELOPMENT	1.0
REG 6160 QUALITY ASSURANCE	1.0
REG 6400 CAPSTONE I	1.0
REG 6410 CAPSTONE II	1.0
ELECTIVES (3 CU)	3.0

### Sample Quality Assurance Concentration Study Plan

	SUMMER	FALL	SPRING
<b>YEAR 1</b>		REG 5100 Intro Clinical Research REG 6120 Intro Drug Development	REG 6400 Capstone I <i>REG 6190 or Elective</i>
<b>YEAR 2</b>	REG 6100 Fundamentals of FDA Regulations <i>Elective</i>	REG 6160 Quality Assurance <i>Elective</i>	REG 6410 Capstone II <i>Elective or REG 6190</i>

Year 1: 4 CU

Year 2: 6 CU

**Total: 10 CU**

### Course Descriptions

#### REG 5100 Introduction to Clinical and Translational Research

*\*Required for all concentrations*

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 6100 Fundamentals of FDA Regulation**

*\*Required for all concentrations*

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 6110 Clinical Trial Management**

*\*Required for Clinical Research concentration*

This course will focus on the practical aspects of executing clinical trials in an academic environment in a GCP compliant fashion. Upon course completion students will be able to effectively implement and manage both investigator-initiated and industry-sponsored clinical research studies. This course is divided into three segments. In the first segment, students will be guided through the operational aspects and regulatory processes of clinical trial management across the clinical trial life cycle from pre-study activities through study start-up and implementation, and ongoing compliance through study close out. Students will learn strategies for navigating the complex regulatory/operational clinical research environment and for successful protocol development and approval, subject recruitment, data management and IRB/FDA interactions. In the second segment of the course, students will learn about specific trial management challenges that may arise based on study type and will learn skills for navigating these challenges for investigator-initiated studies, federally-funded and commercially-sponsored research and research with unique trial management concerns such as conflicts of interest and the use of new technologies. Finally students will have the opportunity to apply the skills they have learned through a final course project which includes identification of a trial management challenge and a proposal for solutions to address that challenge. Protection of human research subjects and adherence to good clinical practices guiding research in humans is a critical concept that will be integrated throughout each of the lectures and course assignments.

### **REG 6120 Introduction to Drug Development**

*\*Required for all concentrations*

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 6150 Post-Approval Maintenance of Drugs, Devices, and Biologics**

*\*Required for Standard concentration*

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, including topics such as understanding pertinent US regulations, general requirements for license maintenance, key periodic reports submitted to regulatory agencies, types of post-approval changes, and reporting categories for post-approval changes and reporting procedures.

### **REG 6160 Quality Assurance**

*\*Required for Quality Assurance concentration*

Quality assurance (QA) plays a critical role in the reliability and reproducibility of product development and, manufacturing. As a component of the Quality Management System, quality assurance includes all activities performed by an organization for the prevention of errors and defects. This course intends to focus on QA principles, standards, and requirements, with regard to the FDA-regulated product development lifecycle. Further, the course aims to offer examples of QA and quality control measures through auditing monitoring and risk management. Application of quality assurance and the interfaces between GLP, GTP, GMP-and Pharmacovigilance regulatory regulated activities during product development and manufacturing will also be addressed.

### **REG 6180 Introduction to Vaccine Development**

This introductory course lays the foundation for conducting vaccine research in many ways. It begins with a brief review of the history of vaccine discovery and development and explains the phases of vaccine development in detail. Global health history and impact of vaccines is described as well as the various stakeholders (e.g., WHO and World Bank) involved, which distinguish vaccine from drug development. The decision-making process, vaccine 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 vaccine development process, understand the regulatory basis by which new vaccines are evaluated, ultimately approved, and distributed around the world.

### **REG 6190 Research Ethics**

*\*Required for all concentrations*

This course will focus on of the connection between research ethics and aspects of regulatory affairs. Students will review core methodological aspects of research, trace the history of research ethics, and describe systematic approaches to designing ethical research. Students will cultivate competency in the development, implementation, and limitation of US human subjects regulation. This course will prepare students to critically evaluate the ethics of specific research designs and apply ethics-informed decision-making in the regulatory affairs domain.

The course also includes analysis of regulatory bodies governing biomedical and behavioral research. Additional topics may include (but are not limited to) conflicts of interest, ethics codes and regulation, IRBs, informed consent, working with vulnerable populations, privacy/confidentiality.

### **REG 6210 Cell & Gene Therapy**

This course will provide students with a general overview of translational research in the area of gene and cell therapy. This would include technical considerations, translating preclinical investigation into therapeutics, the execution of gene and cell therapies clinical trials, and key regulatory issues. Entrepreneurial considerations will be discussed as well. By the end of this course, students will understand the basic technologies employed for gene and cell therapy along with approaches and pitfalls

to translating these therapies into clinical applications including regulatory and commercial aspects of this emerging area.

### **REG 6220 New Trends in Medicine and Vaccine Discovery**

The purpose of this course is to provide an overview of drug and vaccine discovery, with emphasis on

- Technologies that empower drug and vaccine discovery
- Newer treatment modalities beyond small molecule drugs
- Recent areas of progress: rare diseases, immuno-oncology, precision medicine, biomarkers and diagnostics
- The regulations governing medicine discovery and development
- Business aspects, building start-up biotechs from academic research
- Societal aspects, from affordability to healthcare company considerations to medicine pricing

### **REG 6250 Manufacturing Novel Therapies & Imaging Agents**

Novel therapeutic and diagnostic agents (e.g., CAR T cells, gene therapy for sickle cell disease, radionuclides etc.) have revolutionized modern clinical medicine. Historically, these agents were first developed in academia then transferred to industry for clinical scale manufacturing. Recently, however, some academic centers have developed clinical scale biomanufacturing facilities. Operation of these new facilities requires a unique blend of manufacturing, clinical, basic, regulatory and laboratory sciences. Examples of areas in which academic medical centers have developed in-house manufacturing include cell therapy, gene therapy and novel imaging agents. This course will cover manufacturing approaches, challenges, and controversies in each of these domains.

### **REG 6260 Patent Law for Drug Development**

This course will examine the role and impact of patent law on the behavior of major players in the biotechnology and pharmaceutical industries as they navigate the regulatory process. This course begins with an overview of the current patent laws in the U.S. and how policies and recent changes to those laws affect the research and development of new medicines. This course will also examine the dilemmas created by patents as patent holder's seek to bring their technology on to the market. The course will consist of synchronous and asynchronous materials and readings that will conclude with a paper and presentation analyzing a complex issue facing drug innovation and regulatory affairs.

### **REG 6400 Capstone I**

*\*Required for all concentrations*

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 6400, which focuses on the Capstone proposal, and REG 6410, 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 6410 Capstone II.

*Note: In between REG 6400: Capstone I and REG 6410: Capstone II, three progress reports are to be submitted and approved.*

### **REG 6410 Capstone II**

*\*Required for all concentrations*

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 6400, which focuses on the Capstone proposal, and REG 6410, 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 Director.

### MRA Approved Electives

In addition to the standard required courses, students must enroll in three electives that total three course units. These must be graduate level courses that complement the student’s future career plans. The following electives have been approved for the MRA degree program. The electives are categorized by concentration. All REG electives are offered in an online format. Courses taken as electives in other programs may be in-person and require students to come to campus unless otherwise noted.

#### MRA Standard Curriculum

<b>REG 6110</b> Clinical Trial Management	<b>LAW 5110</b> Intro to US Law and Legal Methods
<b>REG 6180</b> Introduction to Vaccine Development	<b>LAWM 5360</b> Fundamentals of US Legal Research <i>(online)</i>
<b>REG 6160</b> Quality Assurance	<b>LAW 5220</b> Compliance and Corporate Governance
<b>REG 6210</b> Cell & Gene Therapy	<b>LAW 5290</b> Navigating the Regulatory State
<b>REG 6220</b> New Trends in Medicine & Vaccine Discovery	<b>LAW 5300</b> Intro to Health Law & Policy
<b>REG 6240</b> Applied Regulatory Processes of Vaccines and Biologics	<b>LAW 9200</b> Pharmaceutical Regulation & Enforcement
<b>REG 6250</b> Manufacturing Novel Therapies & Imaging Agents	<b>BMIN 5010</b> Intro to Biomedical Informatics
<b>MTR 6200</b> Commercializing Translational Therapeutics	<b>BMIN 5020</b> Databases in Biomedical Research
<b>HCMG 8990</b> Management & Economics of the Pharma, Biotech & Medical Device Industries	<b>BIOE 5520</b> Bioethics & the Law
<b>PUBH 5020</b> Introduction to Epidemiology	<b>BIOE 5750</b> Health Policy

#### MRA Clinical Research Concentration

<b>REG 6150</b> Post-Approval Maintenance	<b>LAW 5110</b> Intro to US Law and Legal Methods
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<b>REG 6160</b> Quality Assurance	<b>LAW 5220</b> Compliance and Corporate Governance
<b>REG 6180</b> Introduction to Vaccine Development	<b>LAWM 5360</b> Fundamentals of US Legal Research <i>(online)</i>
<b>REG 6210</b> Cell & Gene Therapy	<b>LAW 5290</b> Navigating the Regulatory State
<b>REG 6220</b> New Trends in Medicine & Vaccine Discovery	<b>LAW 5300</b> Intro to Health Law & Policy
<b>EPID 6300</b> Clinical Trials	<b>LAW 9200</b> Pharmaceutical Regulation & Enforcement
<b>REG 6240</b> Applied Regulatory Processes of Vaccines and Biologics	<b>BMIN 5010</b> Intro to Biomedical Informatics
<b>REG 6250</b> Manufacturing Novel Therapies & Imaging Agents	<b>BMIN 5020</b> Databases in Biomedical Research
<b>MTR 6200</b> Commercializing Translational Therapeutics	<b>BIOE 5520</b> Bioethics & the Law
<b>HCMG 8990</b> Management & Economics of the Pharma, Biotech & Medical Device Industries	<b>BIOE 5750</b> Health Policy
<b>PUBH 5020</b> Introduction to Epidemiology	

**MRA Quality Assurance Concentration**

<b>REG 6110</b> Clinical Trial Management	<b>LAW 5110</b> Intro to US Law and Legal Methods
<b>REG 6150</b> Post-Approval Maintenance	<b>LAW 5220</b> Compliance and Corporate Governance
<b>REG 6160</b> Quality Assurance	<b>LAW 5290</b> Navigating the Regulatory State
<b>REG 6180</b> Introduction to Vaccine Development	<b>LAW 5300</b> Intro to Health Law & Policy
<b>REG 6210</b> Cell & Gene Therapy	<b>LAWM 5360</b> Fundamentals of US Legal Research <i>(online)</i>
<b>REG 6220</b> New Trends in Medicine & Vaccine Discovery	<b>LAW 9200</b> Pharmaceutical Regulation & Enforcement
<b>EPID 6300</b> Clinical Trials	<b>BMIN 5010</b> Intro to Biomedical Informatics

<b>REG 6240</b> Applied Regulatory Processes of Vaccines and Biologics	<b>BMIN 5020</b> Databases in Biomedical Research
<b>REG 6250</b> Manufacturing Novel Therapies & Imaging Agents	<b>BIOE 5520</b> Bioethics & the Law
<b>MTR 6200</b> Commercializing Translational Therapeutics	<b>BIOE 5750</b> Health Policy
<b>HCMG 8990</b> Management & Economics of the Pharma, Biotech & Medical Device Industries	<b>PUBH 5020</b> Introduction to Epidemiology

## 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 for 2022 Cohort



## Sample Capstone Projects

Find titles of recent capstone projects below.

### 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
- Review of the Proposed Model of Regulation for Plant Biostimulants and Guidance on Their Use

### 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
- Review of Direct-to-Consumer Advertisement Regulations in Direct Across Worldwide Regulatory Bodies

### 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
- Review and Recommendations Related Virtual Reality (VR) Design as it Relates to Chronic Pain
- Exploration of How Social Media Data is Used in Post-marketing Pregnancy Drug Safety Research

## 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.

LETTER GRADE	PERCENT SCORE
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## Master of Regulatory Affairs

<b>A</b>	93-100
<b>A-</b>	90-92
<b>B+</b>	87-89
<b>B</b>	83-86
<b>B-</b>	80-82
<b>C+</b>	77-79
<b>C</b>	73-76
<b>C-</b>	70-72
<b>D+</b>	67-69
<b>D</b>	63-66
<b>D-</b>	60-62
<b>F</b>	0-59

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 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

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 their instructor. Should the student and instructor 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 not 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 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

A student 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 students should contact their program staff. Audited courses are charged tuition, the same 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.

### 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. Program staff 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 [Path@Penn](mailto:Path@Penn).

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 [JTMAT Education courses page](#).

## Continuous Registration

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, at the discretion of the program, and may "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.

The MRA degree program is structured for completion in 2 years. Students may request an alternative plan of study to extend their planned time to degree. All students must complete the degree in five years. Failure to complete degree requirements will result in the student being dismissed from the program.

Students are required to register in each mandatory term of their degree these include the fall, spring, and summer term. Students who do not plan to register during a mandatory term should request a leave of absence.

## Leave of Absence

A student may request a leave of absence at any time. A leave of absence may be granted by the program director for up to one year with the possibility of renewal. Students may wish to take a leave for various reasons, including but not limited to, personal circumstances, military service, health issues, or family medical leave. Upon requesting a leave of absence, a student should provide a written request with an estimated date of return. Failing to register for coursework without permission from the University does not constitute a leave of absence. If the student requests leave after the start of the term, all normal drop and withdrawal policies apply.

When returning from a leave, students will contact their program at least thirty days before the start of the term in which they plan to return to confirm they are returning. If a student fails to return from leave within the set time limit or request a renewal, they will be dismissed from the program.

Leave of absence will affect any student loans—either those sought to pay for the degree or those from a previous academic career. This may include loans going into repayment before the end of the leave. Students are encouraged to talk to Student Registration and Financial Services prior to taking a leave of absence to ensure they have planned for shifting financial responsibility.

To request a leave of absence contact Bethany Sanghani, [bgermany@upenn.edu](mailto:bgermany@upenn.edu) or submit the form available [here \(link\)](#).

## Registration Timeline

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.

## Leave of Absence

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 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 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 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@penmedicine.upenn.edu](mailto:macregistrar@penmedicine.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.

### 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

A student may be dropped from their program for several reasons. Like a voluntary withdrawal, students will be responsible for any charges or financial obligations to the University incurred before the effective date of the drop.

1. **Time Limit:** Students are expected to complete their degree within five years of matriculation. Should a student fail to complete their degree within the time limit, the program will drop the student.
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.
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.
5. A student dropped from their program will receive a letter stating that they have been dropped along with the reason for their drop.

## 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.

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](#).

## 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.

## 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 Disability Services](#). Please contact a MRA program staff (the Associate Director and/or Instructional Designer) as soon as possible in order to discuss your accommodations and your needs. If you would like to request accommodations or ask questions, make an appointment by contacting the office of Student Disability Services at 215-573-9235 or [vpul-sds@mail@pobox.upenn.edu](mailto:vpul-sds@mail@pobox.upenn.edu). The office of Student Disability Services is located in Hamilton Village at 220 S. 40th Street, Suite 260. All services are confidential.

## 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. Please include the title of the holiday or religious observance in your message.

If an assignment is due during a holiday, program staff and faculty will work with the student to determine an alternative due date.

If a student observes a holiday that is not listed, please inform program staff of this holiday and staff will make sure to include this moving forward.

## Administrative Requirements

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:

1. **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 BLUE evaluation system during and/or at the end of each term. Grades will not be released until evaluations are complete.

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 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.

## 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 you may 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@penmedicine.upenn.edu](mailto:medhelp@penmedicine.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. <http://canvas.upenn.edu>. Support: [canvas@pobox.upenn.edu](mailto:canvas@pobox.upenn.edu).

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.

## Penn InTouch Course Registration Guide

### [Course Registration Site](#)

Path@Penn is the course registration system. The system is user friendly, though if you have any issues, please contact [Student Support Resources](#).

## University Resources

Many resources are available to students via the [Graduate Student Center](#) including:

- [New Graduate Student Orientation](#)
- [Wellness at Penn](#)
- [Family Center at Penn](#)
- [Weingarten Learning Resources Center](#)
- [Counseling and Psychological Services \(CAPS\)](#)
- [Penn Career Services](#)
- [Penn Libraries](#)

## University Required Disclosures

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

## Disclosure on Credential Recognition

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

## Financial Information

### Description of Tuition and Fees 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, and students should contact the individual department to verify tuition cost.

Tuition rates for 2022-2023 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

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 only removed when registration is below 3 CU. Clinical Fee will be removed through the Drop Deadline but not afterward.

### ***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](#).

**Generally, MRA students will not be full-time, as they take 2 CUs per semester and 3 CUs confers full-time status.**

### Tuition Benefits

University of Pennsylvania employees should refer to the [Human Resources Website](#) for specific details about tuition benefits, including tax implications.

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](#).

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 2022-2023 year.

Semester	System Opens to Requests	Deadline for Submitting Requests
Spring	November 1	March 15
Summer Session I and 12-week Summer Session	April 1	June 15
Summer Session II	April 1	August 15
Fall	June 1	November 15

### Billing Information

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

All students are billed per course unit (CU) up to 3 CU. At 3 CU, the Online Services Fee, and Technology Fee are billed at a flat rate and will not increase after 3 CU. Tuition will not be billed at a flat rate.

At 3 CU, a student is considered full-time and is eligible for access to campus recreation spaces. Full-time students will be billed a Clinical Fee each term, which provides access to Student Health Services. Students who are full-time employees—at Penn or elsewhere—and have health insurance through their employer should notify the program so that the Clinical Fee may be removed; Penn employees do not have access to Student Health Services.

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](#).

## 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 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 directs the Capstone process. The Associate Director also supports the director and committee in program development and implementation. The current Associate Director is Bethany Sanghani, MA.

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 Associate Director with student affairs matters when necessary. The current Instructional Designer is Nik Kroushl.

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.