Penn

MASTER of REGULATORY AFFAIRS

2021-2022 HANDBOOK

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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.

The MRA program is an in-person degree program with online components. This means that some courses are fully in-person, some courses are hybrid, and some courses are fully online. In the coming years, we may transition more courses to an online format. Students will be informed of these transitions along with further instructions and expectations for online course engagement.

Religious and cultural holidays are listed on the University of Pennsylvania's Chaplin 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.

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, Andrew Fesank, MD, MHCI.

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

COURSES	COURSE UNITS
BIOE 580 RESEARCH ETHICS	1.0
REG 510 INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH	1.0
REG 610 FUNDAMENTALS OF FDA REGULATION	1.0
REG 612 INTRO TO DRUG DEVELOPMENT	1.0
REG 614 BIOPHARMACEUTICAL DEVELOPMENT, MANUFACTURING, AND REGULATORY AFFAIRS	1.0
REG 615 POST-APPROVAL MAINTENANCE OF DRUGS, DEVICES, AND BIOLOGICS	1.0
REG 640 CAPSTONE I	1.0
REG 641 CAPSTONE II	1.0
ELECTIVES (2 C.U)	2.0

Sample Standard Concentration Study Plan

	SUMMER	FALL	SPRING
YEAR 1		REG 510 Intro Clinical Research REG 612 Intro Drug Development	REG 640 Capstone I *BIOE 580 or Elective 1*
YEAR 2	REG 610 Fundamentals of FDA Regulations *BIOE 580 or Elective 1*	REG 614 Biopharm Dev, Manufacturing, & Reg Affairs *Elective 2*	REG 615 Post-approval Maintenance REG 641 Capstone II

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

Year 1: 4 c.u.

Year 2: 6 c.u.

Total: 10 c.u.

Clinical Research Coursework

COURSES	COURSE UNITS
BIOE 580 RESEARCH ETHICS	1.0
REG 510 INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH	1.0

REG 610 FUNDAMENTALS OF FDA REGULATION	1.0
REG 611 CLINCAL STUDY MANAGEMENT	1.0
REG 612 INTRO TO DRUG DEVELOPMENT	1.0
REG 614 BIOPHARMACEUTICAL DEVELOPMENT, MANUFACTURING AND REGULATORY AFFAIRS	1.0
REG 640 CAPSTONE I	1.0
REG CAPSTONE 641 II	1.0
ELECTIVES (2 C.U)	2.0

Sample Clinical Research Concentration Study Plan

	SUMMER	FALL	SPRING
YEAR 1		REG 510 Intro Clinical Research REG 612 Intro Drug Development	REG 640 Capstone I *BIOE 580 or Elective 1*
YEAR 2	REG 610 Fundamentals of FDA Regulations REG 611 Clinical Study Management	REG 614 Biopharm Dev, Manufacturing, & Reg Affairs *Elective 1 or 2*	REG 641 Capstone II *BIOE 580 or Elective 2*

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

COURSES	COURSE UNITS
BIOE 580 RESEARCH ETHICS	1.0
REG 510 INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH	1.0
REG 610 FUNDAMENTALS OF FDA REGULATION	1.0
REG 612 INTRO TO DRUG DEVELOPMENT	1.0
REG 614 BIOPHARMACEUTICAL DEVELOPMENT, MANUFACTURING AND REGULATORY AFFAIRS	1.0
REG 616 QUALITY ASSURANCE	1.0
REG 640 CAPSTONE I	1.0
REG 641 CAPSTONE II	1.0
ELECTIVES (2 C.U.)	2.0

Sample Quality Assurance Concentration Study Plan

	SUMMER	FALL	SPRING
YEAR 1		REG 510 Intro Clinical Research REG 612 Intro Drug Development	REG 640 Capstone I *BIOE 580 or Elective 1*
YEAR 2	REG 610 Fundamentals of FDA Regulations *BIOE 580 or Elective 1*	REG 614 Biopharm Dev, Manufacturing, & Reg Affairs REG 616 Quality Assurance	REG 641 Capstone II *Elective 2*

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

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 611 Clinical Study Management

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. Students will be guided through the operational aspects and regulatory processes for the three stages of study management: pre study, study start-up and implementation, ongoing compliance and 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. 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.

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 616 Quality Assurance
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 618 Introduction to Vaccine Development
Vaccine development is the process by which new vaccines are discovered, studied in laboratory and preclinical models and investigated clinically in patients to determine if they are safe and efficacious. Assuming the vaccine under investigation passes systematically defined milestones, submission of all documentation to regulatory authorities (e.g., US FDA and equivalent global regulatory authorities) can ensue and, pending a favorable review, market access can be granted. The process is highly regulated and there is significant cost involved for pharmaceutical sponsors to research and develop vaccines with the entire process averaging around 12 years once a product is discovered.

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 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.

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

REG 611 Clinical Study Management	**LAW 511** Intro to US Law and Legal Methods
REG 618 Introduction to Vaccine Development	**LAWM 536** Fundamentals of US Legal Research
REG 616 Quality Assurance	**LAW 522** Compliance and Corporate Governance
REG 621 Cell & Gene Therapy	**LAW 529** Navigating the Regulatory State
REG 622 New Trends in Medicine & Vaccine Discovery	**LAW 530** Intro to Health Law & Policy
REG 630 Clinical Trials	**LAW 920** Pharmaceutical Regulation & Enforcement
MTR 620 Commercializing Translational Therapeutics	**BMIN 501** Intro to Biomedical Informatics
HCMG 899 Management & Economics of the Pharma, Biotech & Medical Device Industries	**BMIN 502** Databases in Biomedical Research
PUBH 502 Introduction to Epidemiology	**BIOE 552** Bioethics & the Law
	BIOE 575 Health Policy

MRA Clinical Research Concentration

REG 615 Post-Approval Maintenance	**LAW 511** Intro to US Law and Legal Methods
REG 616 Quality Assurance	**LAW 522** Compliance and Corporate Governance
REG 618 Introduction to Vaccine Development	**LAWM 536** Fundamentals of US Legal Research
REG 621 Cell & Gene Therapy	**LAW 529** Navigating the Regulatory State
REG 622 New Trends in Medicine & Vaccine Discovery	**LAW 530** Intro to Health Law & Policy
REG 630 Clinical Trials	**LAW 920** Pharmaceutical Regulation & Enforcement

MTR 620 Commercializing Translational Therapeutics	**BMIN 501** Intro to Biomedical Informatics
HCMG 899 Management & Economics of the Pharma, Biotech & Medical Device Industries	**BMIN 502** Databases in Biomedical Research
PUBH 502 Introduction to Epidemiology	**BIOE 552** Bioethics & the Law
	BIOE 575 Health Policy

MRA Quality Assurance Concentration

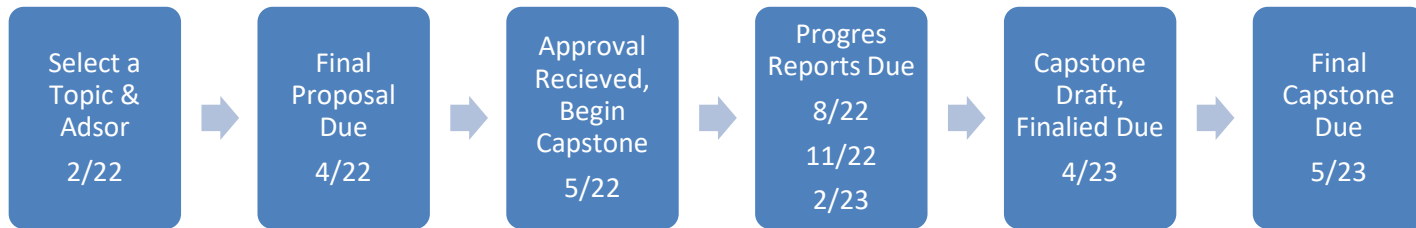|	
REG 615 Post-Approval Maintenance	**LAW 511** Intro to US Law and Legal Methods
REG 616 Quality Assurance	**LAW 522** Compliance and Corporate Governance
REG 618 Introduction to Vaccine Development	**LAWM 536** Fundamentals of US Legal Research
REG 621 Cell & Gene Therapy	**LAW 529** Navigating the Regulatory State
REG 622 New Trends in Medicine & Vaccine Discovery	**LAW 530** Intro to Health Law & Policy
REG 630 Clinical Trials	**LAW 920** Pharmaceutical Regulation & Enforcement
MTR 620 Commercializing Translational Therapeutics	**BMIN 501** Intro to Biomedical Informatics
HCMG 899 Management & Economics of the Pharma, Biotech & Medical Device Industries	**BMIN 502** Databases in Biomedical Research
PUBH 502 Introduction to Epidemiology	**BIOE 552** Bioethics & the Law
REG 611 Clinical Study Management	**BIOE 575** Health Policy

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

Select a Topic & Adsor 2/22	→	Final Proposal Due 4/22	→	Approval Recieved, Begin Capstone 5/22	→	Progres Reports Due 8/22 11/22 2/23	→	Capstone Draft, Finalied Due 4/23	→	Final Capstone Due 5/23

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

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 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 Penn InTouch 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. 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

2. Search by Course ID / Subject

3. Add desired courses to cart

4. Select *Register for courses*

5. Select course cart from right hand menu

6.   Select **Add request**

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, & Withdraw

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.

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. While on leave, students may access the library and other Penn resources upon paying a special fee each semester of the absence. 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 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 the MRA program associate director.

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, [achieve passing grades on comprehensive examinations], 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.

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 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 the MRA Associate Director. 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. In order 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

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 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@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. http://pennintouch.apps.upenn.edu

The PennPortal

The PennPortal webpage bundles together links to important information for students. Access the PennPortal at www.upenn.edu/penn_portal/ 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.

University Resources

Many resources are available to students via the Graduate Student Center (http://www.gsc.upenn.edu/) including:
New Student Orientation: https://gsc.upenn.edu/resources/new-students

Wellness at Penn: https://gsc.upenn.edu/resources/wellness
Family Center at Penn: https://familycenter.upenn.edu/
Weingarten Learning Resources Center: https://www.vpul.upenn.edu/lrc/
Counseling and Psychological Services (CAPS): https://caps.wellness.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 2021-2022 can be viewed on the Master's Program Costs Website. Scroll down to the Masters of 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.

General Fee

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

Full-time students (enrolled in more than 2 c.u. 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 3CU. Clinical Fee will be removed through the Drop Deadline but not afterward.

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 2021-2022 year.

The tuition benefit system opens and closes the following terms on these dates:

- Fall term: June 1 until November 15
- Spring term: November 1 until March 15
- Summer 1, 6-week term: April 1 until June 15
- Summer 1, 12-week term: April 1 until June 15
- Summer 2, 6-week term: April 1 until August 15

*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.

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 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 2021 course prior to July 8 then you will receive an e-bill on July 8 and are expected to pay this bill by July 30. 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 3CU. At 3CU, the General Fee *[substitute Online Services Fee for fully online programs]* and Technology Fee are billed at a flat rate and will not increase after 3CU. Tuition will not be billed at a flat rate.

At 3CU, 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.

Registration Timeline
Student registration may be adjusted through Penn InTouch 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

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.
- 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.

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 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 **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.