MASTER OF REGULATORY AFFAIRS

2017-2018 Student Handbook
# Table of Contents

**Program Contacts** .................................................................................................................................................................................. 3

**Introduction & MRA Program Goals** ..................................................................................................................................................... 4
  - Institutional Commitment to the MRA Program ................................................................................................................................. 4
  - Quality Training in the MRA Program ................................................................................................................................................. 4

**MRA Degree Requirements** ....................................................................................................................................................................... 5
  - Required Coursework .................................................................................................................................................................................. 5
  - Sample Plan of Study ................................................................................................................................................................................ 5

**Capstone Project** ........................................................................................................................................................................................... 6
  - Sample Capstone Projects ........................................................................................................................................................................... 6

**Academic Policies** .......................................................................................................................................................................................... 7
  - Grading ........................................................................................................................................................................................................ 7
  - Academic Standing ................................................................................................................................................................................... 8
  - Academic Grievances ............................................................................................................................................................................... 8
  - Transfer Credit Policy ............................................................................................................................................................................. 8
  - Audit Policy .................................................................................................................................................................................................. 8
  - Time Limitation ................................................................................................................................................................................................ 9
  - Registration .................................................................................................................................................................................................. 9
  - Continuous Registration & Leave of Absence .................................................................................................................................... 9
  - HIPAA Compliance .................................................................................................................................................................................................. 9
  - Student Conduct .................................................................................................................................................................................................. 9
  - Code of Academic Integrity .................................................................................................................................................................... 10

**Administrative Requirements** ........................................................................................................................................................................ 12

**University of Pennsylvania Systems** .......................................................................................................................................................... 13
  - PennCard .................................................................................................................................................................................................. 13
  - PennKey ................................................................................................................................................................................................ 13
  - Penn InTouch .......................................................................................................................................................................................... 13
  - The PennPortal ......................................................................................................................................................................................... 13

**Financial Information** ...................................................................................................................................................................................... 14
  - Tuition Rates ................................................................................................................................................................................................ 14
  - General Fee ................................................................................................................................................................................................ 14
  - Technical Fee ................................................................................................................................................................................................ 14
  - Clinical Fee .................................................................................................................................................................................................. 14
  - Health Insurance ..................................................................................................................................................................................... 14

**ITMAT Ed Administrative Structure** .............................................................................................................................................................. 15
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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.

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 Office of Masters Programs (OMP), led by Donna George, PhD. The daily operations of the MRA program are the responsibility of the ITMAT education administrative support staff under the direction of the Program Director, Emma Meagher, MD.

Quality Training in the MRA Program

The goal of the MRA program is to train future regulatory professionals. Individuals in this program are provided with the expertise and methods required to attain this goal. Regulatory Affairs graduates will master key approaches required for the evaluation of novel devices, biologics, and therapeutics. The program will produce professionals who are:

i. competitive in securing positions that are integral to the navigation of new medical products/technologies through regulatory, clinical and quality assurance channels

ii. well-versed in the complex strategic process in academia, industry, and government sectors.
MRA Degree Requirements
The University of Pennsylvania operates on an academic semester system. The MRA degree program requires 10 course units for completion, with 7 core courses and 3 electives as outlined below. The core courses are taught once per year in the semester designated in the study plan below.

Required Coursework

<table>
<thead>
<tr>
<th>COURSES</th>
<th>COURSE UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIOE 601 INTRO TO BIOETHICS</td>
<td>1.0</td>
</tr>
<tr>
<td>REG 510 INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH</td>
<td>1.0</td>
</tr>
<tr>
<td>REG 610 FUNDAMENTALS OF FDA REGULATION</td>
<td>1.0</td>
</tr>
<tr>
<td>REG 611 CLINICAL STUDY MANAGEMENT</td>
<td>1.0</td>
</tr>
<tr>
<td>REG 612 INTRO TO DRUG DEVELOPMENT</td>
<td>1.0</td>
</tr>
<tr>
<td>REG 613 DRUG DEVELOPMENT DECISION CRITERIA</td>
<td>1.0</td>
</tr>
<tr>
<td>REG 640 CAPSTONE</td>
<td>1.0</td>
</tr>
<tr>
<td>ELECTIVES (3 C.U.)</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Sample Plan of Study

<table>
<thead>
<tr>
<th>SUMMER</th>
<th>FALL</th>
<th>SPRING</th>
</tr>
</thead>
<tbody>
<tr>
<td>YEAR 1</td>
<td>■ BIOE 601 Intro to Bioethics</td>
<td>■ REG 612 Intro to Drug Development</td>
</tr>
<tr>
<td></td>
<td>■ REG 510 Intro Clinical Research</td>
<td>■ Elective</td>
</tr>
<tr>
<td></td>
<td>■ REG 610 Fundamentals of FDA Regulation</td>
<td></td>
</tr>
<tr>
<td>■ REG 611 Clinical Study Management</td>
<td>■ REG 613 Drug Development Decision Criteria</td>
<td>■ REG 640 Capstone</td>
</tr>
<tr>
<td>■ Elective</td>
<td>■ Elective</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>YEAR 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>■ REG 610 Fundamentals of FDA Regulation</td>
<td>■ REG 613 Drug Development Decision Criteria</td>
<td>■ REG 640 Capstone</td>
</tr>
<tr>
<td>■ REG 611 Clinical Study Management</td>
<td>■ Elective</td>
<td>■ Elective</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Year 1: 4 c.u.  
Year 2: 6 c.u.  
Total: 10 c.u.
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 defined goals and objectives and choose a Capstone Advisor no later than the end of their second term. The advisor will be selected for expertise in the topic being addressed. Projects may align with their current employer 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).

Sample Capstone Projects
- Perform post-marketing surveillance of drug adverse effects
- Prepare a premarket approval application for a medical device
- Prepare a policy statement on an ethical consideration in human subject research
- Design a practice/process change implemented and the outcome
- Develop a regulatory guidance document
- Design and implement a regulatory education training program
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 instructor.

<table>
<thead>
<tr>
<th>LETTER GRADE</th>
<th>PERCENT SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>93-100</td>
</tr>
<tr>
<td>A-</td>
<td>90-92</td>
</tr>
<tr>
<td>B+</td>
<td>87-89</td>
</tr>
<tr>
<td>B</td>
<td>83-86</td>
</tr>
<tr>
<td>B-</td>
<td>80-82</td>
</tr>
<tr>
<td>C+</td>
<td>77-79</td>
</tr>
<tr>
<td>C</td>
<td>73-76</td>
</tr>
<tr>
<td>C-</td>
<td>70-72</td>
</tr>
<tr>
<td>D+</td>
<td>67-69</td>
</tr>
<tr>
<td>D</td>
<td>63-66</td>
</tr>
<tr>
<td>D-</td>
<td>60-62</td>
</tr>
<tr>
<td>F</td>
<td>0-59</td>
</tr>
</tbody>
</table>

At the graduate level, 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 degree 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. 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.
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 will be reviewed by the Program Director and the Program Curriculum Committee. The committee is authorized to dismiss the student or allow the student to remain in the program on a probationary status.

Academic Grievances
Students who have a concern about a matter related to the MRA program, whether it concerns a course, instructor, or other program issue are encouraged to come to the MRA program office (8035 Maloney Bldg/ HUP) to discuss their concern. Alternatively, the student may wish to speak directly with the MRA Program Director.

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

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

Requests for transfer credit should be submitted to the MRA Program Coordinator together with a course syllabus for the course under consideration. The Program Director will then request a review of the course by an MRA faculty member in that content area for its appropriateness for MRA transfer credit. Students may request substitution of a core course with a more advanced course in that content area. The process for substitution is the same as that for transfer credit.

Audit Policy
Students who wish to audit a course are expected to designate the audit at the time of registration. Auditing coursework is discouraged, as full tuition is charged but no credit is earned toward the MRA degree. If a student wishes to change a course status from credit to audit, they must obtain permission from the course instructor before the add/drop period ends. The audited course will appear on the
transcript with the grade of "AUD" and no credit will be earned toward graduation. Students are not permitted to change the course status from graded to audit after the course has ended.

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

**Registration**
The MRA Program Coordinator is responsible for registering all students for MRA courses and will provide specific MRA registration deadlines. Students are strongly encouraged to verify course registration, tuition bills and grades through the student portal Penn InTouch: [https://portal.apps.upenn.edu/penn_portal/intouch/splash.html](https://portal.apps.upenn.edu/penn_portal/intouch/splash.html)

Students may refer to the Penn Three-Year Academic Calendar to find out registration dates and add/drop periods on the Registrar's website [http://www.upenn.edu/registrar/](http://www.upenn.edu/registrar/). 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: [http://www.itmat.upenn.edu/ITMATEdCourses.html](http://www.itmat.upenn.edu/ITMATEdCourses.html).

**Continuous Registration & Leave of Absence**
Continuous registration as a graduate student is required unless a formal leave of absence is granted by the Program Director. A leave of absence will be granted for military duty, medical reasons, and for family leave; this leave is typically for up to one year and “stops the clock” on time to completion. Personal leave for other reasons may be granted for up to one year with the approval of the Program Director, but it does not automatically change the time limit.

A student who wishes to take a leave of absence must submit a written request to the MRA program office for initial approval and then it will be forwarded to the Associate Dean of OMP for final approval. The granting of a leave of absence does not automatically change the time limit for the degree.

**HIPAA Compliance**
All students in the Perelman School of Medicine must be HIPAA compliant, and training is required to be updated every two years. Students should complete HIPAA training in KnowledgeLink by the end of their first semester in the program if it has not already been completed in the past two years. The certificate received at the completion of the training should be submitted to the MRA Program Coordinator by the end of the first term in the program.

You can access HIPAA training through KnowledgeLink at: [http://knowledgelink.upenn.edu/](http://knowledgelink.upenn.edu/)

**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. Students are also expected to abide by the Biomedical Graduate Studies (BGS) policies adopted
by OMP including the Authorship Policy when publishing their research and BGS Student Expectations including the Code of Academic Integrity. The PennBook, BGS Policies, and a directory of other important University Policies relevant to graduate education are available here: http://www.med.upenn.edu/bgs/staff.shtml

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

**Code of Academic Integrity**

The most fundamental value of any academic community is intellectual honesty; accordingly, all academic communities rely upon the integrity of each and every member. Students are responsible not only for adhering to the highest standards of truth and honesty but also for upholding the principles and spirit of the Academic Code. 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 adjudicated in accordance with the Charter of Biomedical Graduate Studies Student Judicial System. Alleged research ethics violations are
handled in accordance with the University’s Procedures Regarding Misconduct in Research for Non-Faculty Members of the Research Community. If a student is unsure whether his 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
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) Graduation application – in order to be considered for conferral of the degree, students must complete an online graduation application approximately two months prior to the expected conferral date. The graduation application initiates an academic audit that, assuming all requirements are met, places the student with the next graduation cohort. The MRA degree is conferred by the University of Pennsylvania Perelman School of Medicine and is granted in May, August and December of each year.

2) Course evaluations – students are required to complete an evaluation for every MRA course. Students will receive an email notification and website link to the online evaluation in the OASIS evaluation system at the end of each term. Grades will not be released until evaluations are complete. To directly access the OASIS evaluation site, follow this link: http://gme-evals.med.upenn.edu/

3) 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 Program Coordinator. Graduating students are required to complete an exit survey evaluating the program and their capstone advisor. Capstone grades will not be released until the evaluations are complete.
University of Pennsylvania Systems

**PennCard**
PennCard is the official identification card of the University of Pennsylvania and is required for all students. The PennCard Center is located on the 1st floor of the Franklin Building at 3451 Walnut Street. A valid government issued photo I.D. will be required in order to pick up your new PennCard. The office can be reached via e-mail at penncard@pobox.upenn.edu and online at http://www.upenn.edu/penncard.

**PennKey**
Your PennKey name and password gives you access to PennNet, a Penn e-mail account, and many other essential services managed through the MRA Program. All students are required to have a current, active PennKey and password.

**Penn InTouch**
Penn InTouch provides secure web access to view current billing information, course registration and schedules, academic records, student health insurance, etc. Access to this site requires login with PennKey and password. https://portal.apps.upenn.edu/penn_portal/intouch/splash.html

**The PennPortal**
The PennPortal webpage bundles together links to important information for students. Access the PennPortal at https://portal.apps.upenn.edu/penn_portal/portal.php and log in with your PennKey and password.
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 department in the summer, and students should contact the individual department to verify tuition cost.

Tuition rates for 2017-2018:

<table>
<thead>
<tr>
<th>CREDITS</th>
<th>TUITION</th>
<th>GENERAL FEE</th>
<th>TECHNICAL FEE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 C.U.</td>
<td>$4,453</td>
<td>$372</td>
<td>$181</td>
<td>$5,006</td>
</tr>
<tr>
<td>2 C.U.</td>
<td>$8,906</td>
<td>$744</td>
<td>$362</td>
<td>$10,012</td>
</tr>
</tbody>
</table>

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

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

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

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 Perelman School of Medicine Office of Masters Programs within the Office of the Executive Vice Dean and Chief Scientific Officer. The academic home for the MRA program is the Institute for Translational Medicine and Therapeutics (ITMAT).

The Program Director is responsible for administrative oversight and academic leadership of the program. The Director also serves as the chairperson of the Program Curriculum Committee. The current Program Director is Emma Meagher, MD.

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

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

The Administrative Director is responsible for developing, implementing, and managing ITMAT Ed programs. The current Administrative Director is Rachel Bastian, MSEd.

The MRA Program Coordinator is responsible for student affairs including course registration and capstone support. The coordinator also supports the director and committee in program development and implementation. The current Program Coordinator is Anna Greene, PhD.