

# REGULATORY AFFAIRS, MRA

The objective of the Master of Regulatory Affairs (MRA) degree program is to produce a cadre of highly trained and sophisticated practice professionals adept in the skills necessary to maximize compliance and minimize risk in the development of FDA regulated products. Students will learn both the foundation and application of science-based clinical investigation and the corresponding regulation. The program is designed to meet these objectives through didactic course work and an experiential capstone project.

**For more information:** <https://www.itmat.upenn.edu/education-and-training/mra-overview/>

## Curriculum

Students must complete 10 course units and achieve a B- or higher for all course work counted toward the degree. The MRA program is a fully online program.

Code	Title	Course Units
<b>Core Requirements</b>		
REG 5100	Introduction to Clinical and Translational Research	1
REG 6100	Fundamentals of FDA Regulation	1
REG 6120	Introduction to Drug Development	1
REG 6190	Research Ethics in Regulatory Affairs	1
<b>Capstone</b>		
REG 6400	Capstone I	1
REG 6410	Capstone II	1
<b>Electives</b>		
Advisor-approved electives		3
<b>Concentration Courses</b>		
Concentration requirements		1
<b>Total Course Units</b>		<b>10</b>

## Concentrations

### General

Code	Title	Course Units
<b>General Concentration</b>		
REG 6150	Post-Approval Maintenance of Drugs, Biologics, and Devices	1
<b>Total Course Units</b>		<b>1</b>

### Clinical Research

Code	Title	Course Units
<b>Clinical Research Concentration</b>		
REG 6110	Clinical Trial Management	1
<b>Total Course Units</b>		<b>1</b>

## Quality Assurance

Code	Title	Course Units
<b>Quality Assurance Concentration</b>		
REG 6160	Quality Assurance	1
<b>Total Course Units</b>		<b>1</b>

The degree and major requirements displayed are intended as a guide for students entering in the Fall of 2024 and later. Students should consult with their academic program regarding final certifications and requirements for graduation.