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: http://www.itmat.upenn.edu/mra.html

Curriculum

Students must complete 10 course units and achieve a B- or higher for all course work counted toward the degree.

Code	Title	Course Units
Core Requirements		
BIOE 580	Research Ethics	1
REG 510	Introduction to Clinical and Translational Research	1
REG 610	Fundamentals of FDA Regulation	1
REG 612	Introduction to Drug Development	1
REG 614	Biopharmaceutical Product Development, Manufacturing and Regulatory Affairs	1
Capstone		
REG 640	Capstone	1
REG 641	Capstone II	1
Electives		
Advisor-approved electives		2
Concentration Courses		
Concentration requirements		1
Total Course Units		10

Concentrations

General

Code	Title	Course Units
General Concentration		
REG 615	Post-Approval Maintenance of Drugs, Biologics, and Devices.	1
Total Course Units		1

Clinical Research

Code	Title	Course Units
Clinical Research Concentration		
REG 611	Clinical Study Management	1
Total Course Units		1

Quality Assurance

Code	Title	Course Units
Quality Assurance Concentration		
REG 616	Quality Assurance	1
Total Course Units		1

The degree and major requirements displayed are intended as a guide for students entering in the Fall of 2020 and later. Students should consult with their academic program regarding final certifications and requirements for graduation.