

REGULATORY AFFAIRS, CERTIFICATE

The Institute for Translational Medicine and Therapeutics (ITMAT) Education program offers an online Regulatory Affairs Certificate. The certificate provides educational content, specific to the management of FDA products, for professionals who are interested in pursuing knowledge in this area.

The Regulatory Affairs Certificate is designed to develop learners' knowledge and skill necessary to bring medical products to market that are safe and effective. Graduates will be able to describe ways to maximize compliance and minimize risk in the development of FDA-regulated products and learn the foundation of science-based clinical investigation and corresponding regulations. This will be accomplished through a 4-credit unit online curriculum. The online format will allow students to seamlessly transition from work to evening classes and to engage with peers, faculty, and content in meaningful ways.

The certificate can be taken as a standalone program or in collaboration with another degree program. Interested students are welcome to complete the certificate and then apply to the MRA program with a waived fee at the time of the MRA application and transfer the credits into the MRA degree.

For more information: <https://www.itmat.upenn.edu/itmat-ed/regulatory-affairs-certificate.html>

Curriculum

Students must complete 4 course units and achieve a B- or higher for all course work counted toward the certificate.

Code	Title	Course Units
Core Requirements		
REG 5100	Introduction to Clinical and Translational Research	1
REG 6100	Fundamentals of FDA Regulation	1
Electives		
Advisor-approved Electives		2
Total Course Units		4

The degree and major requirements displayed are intended as a guide for students entering in the Fall of 2025 and later. Students should consult with their academic program regarding final certifications and requirements for graduation.
