

REGULATORY SCIENCE, MASTER OF SCIENCE

MS in Regulatory Science

regulatory.jhu.edu (<https://advanced.jhu.edu/academics/graduate/ms-regulatory-science/>)

There are thousands of potential medical products (drugs, biologics, devices) currently in the development pipelines of pharmaceutical and biotechnology companies - not to mention those that have already been granted marketing authorization across the globe. All of these require regulatory professionals to ensure compliance with U.S. Food and Drug Administration rules and regulations and/or their equivalents in other countries. This program prepares students to become leaders in the regulatory field by helping them to become fluent in the regulation of medical products both in the U.S and overseas.

The program is designed for full-time working adults, primarily delivered in an online format, and taught by faculty that work in the industry (both private enterprise and government).

The curriculum is designed to prepare the next generation of interdisciplinary professionals to address current and future challenges in the industry.

Admissions Criteria for all Advanced Academic Programs (<https://e-catalogue.jhu.edu/arts-sciences/advanced-academic-programs/enrollment-services/admission/>)

PROGRAM SPECIFIC REQUIREMENTS

In addition to the materials and credentials required for all programs, the Master of Science in Regulatory Sciences requires:

- Bachelor's degree from an accredited US college or university in the life sciences or in engineering.
- One semester of biochemistry and one semester of cell biology at the undergraduate or graduate level

The Admissions Committee reserves the right to request additional information from applicants, if needed, to assess their candidacy for admission.

PROGRAM REQUIREMENTS

- Seven core courses
- Three electives

The three electives can be chosen from any of the Center for Biotechnology Education courses (https://e-catalogue.jhu.edu/course-descriptions/_biotechnology/) for which a student has met the prerequisites.

Code	Title	Credits
Core Course - Required:		
AS.410.627	Translational Biotechnology: From Intellectual Property to Licensing	4
AS.410.649	Introduction to Regulatory Affairs	4
AS.410.651	Clinical Development of Drugs and Biologics	4
AS.410.673	Biological Processes in Regulatory Affairs	4

AS.410.676	Food And Drug Law	4
AS.410.683	Introduction to cGMP Compliance	4
AS.410.679	Practicum in Regulatory Science	4

Electives:

Select three electives	12
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Total Credits 40

- Justify recommendations to pursue a particular regulatory/clinical path from a legal and scientific point of view
- Identify the relationships between clinical trials, the approval process for medical products, and the impact of labeling
- Demonstrate ability to apply guidances and evaluate all aspects of clinical trials.
- Develop a regulatory strategy document for a medical product
- Analyze the requirements of Good Manufacturing Practices regulations for medical products
- Examine the relationships between medical product development and underlying scientific principles
- Identify the legal and regulatory requirements for all stages of medical products
- Demonstrate ability to communicate scientifically both orally and in writing.
- Demonstrate the ability to collaborate in a diverse group to achieve an objective