

REGULATORY SCIENCE, MASTER OF SCIENCE

MS in Regulatory Science (<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.

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

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

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 MS in Regulatory Science program requires an undergraduate degree in the natural sciences or engineering, with a grade point average of at least a 3.0 on a 4.0 scale. Meeting the minimum GPA requirement does not guarantee admission. Additional requirements:

- **Resume**
- **Statement of Purpose:** Discuss why you wish to pursue the MS in Regulatory Science degree. Focus on your long-term goals and how this academic program will complement these goals. Discuss the strengths of your academic and professional background, as well as any additional comments that will assist in evaluating your application materials.
- **Required Courses:**
 - One semester of biochemistry
 - One semester of cell biology

Program Requirements

Students take 10 courses to complete the degree—seven core required courses, and three electives. The three electives will be chosen from the Center for Biotechnology Education courses (https://e-catalogue.jhu.edu/course-descriptions/_biotechnology/).

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.410.675	International 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 (three required)		12
Total Credits		40

Learning Outcomes

Graduates of the MS in Regulatory Science program will be equipped to:

- 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 the ability to communicate scientifically, both orally and in writing
- Demonstrate the ability to collaborate in a diverse group to achieve an objective