REGULATORY SCIENCE, MASTER OF SCIENCE

MS in Regulatory Science (https://advanced.jhu.edu/academics/graduate/ms-regulatory-science/)

There are thousands of food drugs, biologics, devices, and other medical products currently in the global biotechnology marketplace and many in the development pipeline. These products and devices require regulatory professionals to ensure compliance with the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the Environmental Protection Agency, the Alcohol and Tobacco Tax and Trade Bureau 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 versed subject-matter collaborators in the U.S. and globally. The curriculum is designed to prepare the next generation of interdisciplinary professionals to address current and future challenges. Students will have the opportunity to tailor their studies either in the food or medical products and processes domain with curated core and elective courses.

The program is designed with a student-centered approach to ensure that its students' educational experience is as enriching and supportive as possible. As a 100% online program, it is designed to fit seamlessly into busy schedules and gives students the opportunity to learn from exemplary biotech professionals and advance their education without disrupting their career.

Admissions Criteria for All Advanced Academic Programs (https://e-catalogue.jhu.edu/arts-sciences/advanced-academic-programs/Admission/#admissionrequirementstext)

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:** Please provide a statement, up to one page in length, describing your personal background and/or a part of your life experience that has shaped you or your goals. Feel free to elaborate on personal challenges and opportunities that have influenced your decision to pursue a graduate degree at Johns Hopkins.
- **Required Courses:**
  - One semester of biochemistry
  - One semester of any of the following: cell biology, molecular biology, physiology, pharmacology, genetics, microbiology, food science, immunology, biomedical engineering, pharmacovigilance.

Program Requirements

Students in the MS in Regulatory Science program complete 10 courses:

- Seven required core courses
- Three electives courses

Code	Title	Credits
Core Course - Required:		**28**
AS.410.694	FDA Premarket Applications	
AS.410.701	Introduction to Regulatory Affairs-Food, Cosmetics, Drugs, Tobacco	
AS.410.649	Introduction to Regulatory Affairs - Medical Products	
AS.410.651	Clinical Development of Drugs and Biologics	
AS.410.676	Food And Drug Law	
AS.410.683	Introduction to cGMP Compliance	
AS.410.679	Practicum in Regulatory Science	
Electives (three required)		**12**
AS.410.648	Clinical Trial Design and Conduct	
AS.410.715	Medical Device Regulation	
AS.410.702	AI and Software Regulation in Biomedical Science	
AS.410.675	International Regulatory Affairs	
AS.410.673	Biological Processes in Regulatory Affairs	
AS.410.680	Finance for Biotechnology	
AS.410.684	Technology Transfer & Commercialization	
AS.410.686	Regulation of Good Food Production Practices	
AS.410.687	Ethical,Legal & Regulatory Aspects of the Biotechnology Enterprise	
AS.410.689	Leading Change in Biotechnology	
AS.410.700	Food Labeling and Packaging Regulations	
AS.410.703	Strategic Planning for the Biotechnology Enterprise	
AS.410.716	Food Toxicology	
AS.410.718	Food Safety Audits and Surveillance	
AS.410.717	Risk Assessment and Management	
AS.410.688	Project Management in Biotechnology	
AS.410.674	Food Microbiology	
AS.410.646	Creating a Biotechnology Enterprise	
AS.410.644	Marketing Aspects of Biotechnology	
AS.410.643	Managing and Leading Biotechnology Professionals	
AS.410.637	Bioethics	
AS.410.627	Translational Biotechnology: From Intellectual Property to Licensing	
AS.410.721	Cannabis Food Safety Regulations	
AS.410.719	Regulation of Dietary Supplements	
AS.410.727	Regulatory Strategies in Biopharmaceuticals	
AS.410.739	Traceability Outbreaks and Recalls	
Total Credits		**40**

Learning Outcomes

Graduates of the MS in Regulatory Science program will be equipped to engage with the following areas detailed below.

Medical Products and Processes

- 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
- Develop and apply AI/ML based technologies, and computational modeling solutions to advance medical product development
- Demonstrate the ability to communicate scientifically, both orally and in writing
- Demonstrate the ability to collaborate in a diverse group to achieve an objective

Food

- Interpret existing food, cosmetics, alcohol and tobacco regulations from the FDA and USDA
- Apply existing regulation guidances to real-world scenarios
- Assess risk based on known/anticipated assumptions
- Distinguish the methods to detect, quantify, and control microbial growth
- Analyze the requirements of Good Manufacturing Practices regulations in the United States
- Demonstrate ability to communicate scientifically, both orally and in writing
- Demonstrate the ability to collaborate in a diverse group to achieve an objective