

# REGULATORY SCIENCE, MASTER OF SCIENCE

## MS in Regulatory Science

regulatory.jhu.edu (<http://www.regulatory.jhu.edu>)

As the biomedical industry continues to grow, more companies are developing and commercializing new products. There are thousands of biomedical products in the development pipeline that require regulatory oversight. Many of the companies providing reagents and supplies to the industry must also provide stringent quality controls to ensure compliance with the Food and Drug Administration's Current Good Manufacturing Practices and Quality Systems Regulations. These companies will continue to require trained and educated staffing in regulatory science.

Students entering this program will have completed the prerequisite courses in biochemistry and cell biology, and must undertake six required core regulatory courses. Students then may specialize in an aspect of regulatory science of their choice through three elective courses, including advanced regulatory and science courses. Students receive practical, hands-on, real-life regulatory science experience through case study assignments and a unique practicum course at the end of the program, which distinguishes this program as a leader in graduate, regulatory science education. Students completing this regulatory science program are expected to become regulatory science leaders in government and industry.

This degree program is designed for full-time working adults and should take approximately two to three years to complete, although students may accelerate completion of the program if they wish. The entire 10-course curriculum may be completed entirely online. The faculty members teaching the program are all leaders in the field of regulatory sciences. They work in the industry for both private biomedical science organizations and the federal government, including the FDA.

**Admissions Criteria for all Advanced Academic Programs** (<http://e-catalog.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:

- 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

- Six core courses
- One practicum
- Three electives

The three electives can be chosen from any of the Advanced Biotechnology Studies program courses for which a student has met the prerequisites or have received permission from the program committee.

Code	Title	Credits
<b>Required Courses</b>		
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.410.679	Practicum in Regulatory Science	4
AS.410.683	Introduction to cGMP Compliance	4

See course requirements in the Center for Biotechnology Education (<http://e-catalog.jhu.edu/arts-sciences/advanced-academic-programs/programs/center-biotechnology-education/>).

Prerequisite for provisional students accepted in program who have not previously taken biochemistry or cell biology:

AS.410.303 Foundations in Bioscience(4 credits)