



EXPERTISE. INFLUENCE. IMPACT.

ONLINE

MASTER OF SCIENCE AND GRADUATE CERTIFICATE IN REGULATORY SCIENCE

The MS and Graduate Certificate in Regulatory Science is a part-time science-driven program focused on drug and biologics product development and regulation, including aspects of diagnostics, devices, nutritional products, and worldwide regulatory principles.

Courses utilize asynchronous, pre-recorded lectures, web conferencing, and online active-learning instruction. In addition to virtual learning, students will interact with faculty, peers, and their personal industrial regulatory scientist mentor.

BUILD YOUR REGULATORY SCIENCE PORTFOLIO

A graduate of the MS in Regulatory Science program will be able to:

- Devise and implement global strategies for drug, biologic, and device development and evaluation
- Differentiate United States and other regional requirements for drug and biologics product development and registration
- Apply principles of basic and applied pharmaceutical sciences in drug and biologics discovery and development
- Formulate critical elements of chemistry, manufacturing, and controls (CMC) to drug and biologics development
- Relate principles of clinical research design to practices in clinical trial management
- Apply critical elements of risk and utilization to post-marketing surveillance and pharmacoepidemiology, and evaluate economic and human factors that impact drug and biologics use

WHO SHOULD APPLY?

This online program is primarily designed for individuals with bachelor's degrees who work in or would like to work in regulatory science at government agencies or in industry.

Potential students include:

- Regulatory affairs associates
- Scientists in research or development
- Clinical associates in clinical affairs or marketed-product support
- Associates in pharmacovigilance and Phase IV research
- Recent bachelor's degree graduates

MS - FIVE COURSES, TWO YEARS

The MS in Regulatory Science degree is earned through successful completion of five online courses in as little as two years. In each course, students are assessed via projects, online presentations, and mini-reviews.

COURSE OF STUDY

Drug, Biologics, and Device Regulation (6 credits)
Year 1 Fall

Drug and Biologics Discovery (6 credits)
Year 1 Spring

Drug and Biologics Development (6 credits)
Year 1 Summer

Clinical Research (6 credits)
Year 2 Fall

Regulated Products in the Marketplace (6 credits)
Year 2 Spring

GRADUATE CERTIFICATE - TWO COURSES, ONE YEAR

The Graduate Certificate in Regulatory Science is also completely online, and only consists of the first two courses (12 credits total) of the MS program, for students who seek a more limited course of study or commitment than the MS degree (30 credits). Certificate students can later apply for the MS program and use completed courses towards the MS degree.

CENTER OF EXCELLENCE IN REGULATORY SCIENCE AND INNOVATION

These two academic credentials are complemented by the University of Maryland's Center of Excellence in Regulatory Science and Innovation (M-CERSI), which is funded by the U.S. Food and Drug Administration (FDA). University researchers work with FDA staff to support the development of new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA regulated products.

For information about the University of Maryland's collaboration with FDA and M-CERSI regulatory science research, training, and exchange, visit www.cersi.umd.edu.

CONTACT

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