

# MASTER'S IN REGULATORY AFFAIRS FOR DRUGS, BIOLOGICS, & MEDICAL DEVICES

This degree is designed to deepen your understanding of current regulations and their practical applications in the development global and commercialization of drugs, biologics, and medical devices. Students are offered the opportunity to tailor their education to meet their professional goals by choosing one of six unique concentration offerings that span the entire global regulatory affairs sector.

## PROGRAM OBJECTIVES

- > Help regulatory professionals navigate an increasingly complex global regulatory environment
- > Acquire the foundation necessary to work within a variety of life science fields – regulatory affairs, quality assurance and clinical research of biomedical products
- > Examine every step of the drug development and regulation process
- > Understand and apply laws and regulations that govern the development, manufacturing, and commercial distribution of biomedical products

### Get Started

- > Available fully online
- > No application fee
- > No GRE or GMAT required
- > Meets international visa requirements (check website for specific campus availability)

## CURRICULUM OUTLINE

**Required Courses (21-29 Q.H.)** | Course requirements vary depending on which concentration a student selects. Required course topics include:

- > Therapeutic Product Development: A Regulatory Overview
- > Medical Device Development: A Regulatory Overview
- > Practical Applications in Biomedical Product Global Regulatory Affairs: XN Project
- > Core and Advanced eCTD: Electronic Common Technical Document submission process

**Concentrations\* (16-24 Q.H.)** | Students select one of the following concentrations:

- > Operational Regulatory Affairs
  - > Offers students the opportunity to gain practical knowledge in strategizing and compiling regulatory filings in the United States, as well as other major markets such as Europe and Canada.
- > Strategic Regulatory Affairs
  - > Provides philosophy and methodologies to support life science companies' business objectives with regulatory strategy, while supporting it with clinical strategy. Students will also study methodologies to align regulatory and clinical strategies to product approvals, health economics, and reimbursement.
- > Clinical Research Regulatory Affairs
  - > Provides students with a practical knowledge of regulatory requirements and methodologies for clinical human and animal research in order to support product development.
- > International Regulatory Affairs
  - > Allows students to gain practical knowledge on the processes of international registrations of life science products, as well as methods of international regulatory and clinical filings.
- > Regulatory Compliance
  - > Provides students with an in-depth practical knowledge of regulatory compliance of life science manufacturing (including CMC) and quality systems.
- > General Regulatory Affairs
  - > Provide students the opportunity to gain a broad, but comprehensive knowledge of regulatory professions and practices.

### Total Degree Requirements (45 Q.H.)

- > On average, students can complete this degree in less than two years.



## INDUSTRY INFORMATION

The average total compensation for all US-based regulatory professionals at all levels was \$150,422 in 2015, and has had an average increase of 3% per year since 1995.



Source: RAPS, 2016

Percent of Jobs Typically Requiring Master's Degree for Entry:



Source: U.S. Bureau of Labor Statistics, 2012

### Graduate Certificates Available\*:

- > Domestic Biopharmaceutical Regulatory Affairs
- > International Biopharmaceutical Regulatory Affairs
- > Medical Devices Regulatory Affairs

\*Check our website for program and concentration availability at specific campus locations.