Biopharmaceutical Regulatory Affairs, Graduate Certificate (Online)

The biotechnology and pharmaceutical industries continue to experience rapid growth in the U.S. market. As companies in these industries seek approval to market their products in the United States, demand for qualified regulatory affairs professionals continues to increase. Product development scientists, marketers, quality personnel, and legal experts who guide companies through the Food and Drug Administration approval process will benefit from regulatory affairs training.

The Graduate Certificate in Biopharmaceutical Regulatory Affairs is designed to provide students with a greater understanding of U.S. biologic and pharmaceutical products and regulation—their unique development, marketing, manufacturing, postmarket approval-related issues, regulatory compliance, proper validation, and utilization of appropriate quantitative measurement techniques.

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Required Courses

Code	Title	Hours
RGA 6600	Introduction to Food and Drug Administration Pharmaceutical Regulation	3
RGA 6660	Therapeutic Product Development: A Regulatory Overview	3
RGA 6670	Global Impact of Electronic Common Technical Document (eCTD) Submissions	3
RGA 6680	Project Management in Early Drug Discovery and Development	3

Program Credit/GPA Requirements

12 total semester hours required
Minimum 3.000 GPA required