Biopharmaceutical Regulatory Affairs, Graduate Certificate

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, as well as legal experts that guide companies through the Food and Drug Administration (FDA) 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 product regulation and their unique development, marketing, manufacturing, and postmarket approval-related issues. The program also seeks to prepare students to ensure regulatory compliance, proper validation, and utilization of proper quantitative measurement techniques. Courses from this certificate may be applied toward the Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical Devices.

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Required Courses

Code	Title	Hours
RGA 6000	Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation	2
RGA 6101	Therapeutic Product Development: A Regulatory Overview	4
RGA 6207	Global Impact of Electronic Common Technical Document (eCTD) Submissions	4
RGA 6380	Advanced Regulatory Writing: New Drug Applications	4
Complete one of the following:		4
RGA 6217	Biomedical Product Development: From Biotech to Boardroom to Market	
RGA 6235	Emerging Product Categories in the Regulation of Drugs and Biologics	

Program Credit/GPA Requirements

18 total quarter hours required
Minimum 3.000 GPA required