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 Domestic 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**

<table>
<thead>
<tr>
<th>Course</th>
<th>Title</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>RGA 6000</td>
<td>Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation</td>
<td>2</td>
</tr>
<tr>
<td>RGA 6001</td>
<td>Introduction to Food and Drug Administration Medical Device Regulation</td>
<td>2</td>
</tr>
<tr>
<td>RGA 6101</td>
<td>Therapeutic Product Development: A Regulatory Overview</td>
<td>4</td>
</tr>
<tr>
<td>RGA 6202</td>
<td>Medical Device Development: A Regulatory Overview</td>
<td>4</td>
</tr>
</tbody>
</table>

Complete one of the following: 4-5

- RGA 6203 Food, Drug, and Medical Device Law: Topics and Cases
- RGA 6210 Strategic Planning and Project Management for Regulatory Affairs
- RGA 6211 Combination Products and Convergence
- RGA 6212 Introduction to Safety Sciences
- RGA 6214
- RGA 6216 The Medical, Social, and Financial Dimensions of Orphan Drugs
- RGA 6217 Biomedical Product Development: From Biotech to Boardroom to Market
- RGA 6370 Regulatory Writing: Medical Device Submissions
- RGA 6380 Regulatory Writing: New Drug Applications

**Program Credit/GPA Requirements**

16 total quarter hours required
Minimum 3.000 GPA required