

Graduate Certificate: Biopharmaceutical Regulatory Affairs

Quarter to Semester Program Comparison

| Degree Requirements | Current Quarter Hours | Semester Hours - Fall 2026 |
|---------------------|-----------------------|----------------------------|
| Required Courses | 14 | 12 |
| Electives | 4 | 0 |
| Total Cert Hours | 18 | 12 |

Quarter Format

Campus:
Boston / Virtual

Semester Format

Core Courses: 14 Quarter Hours (QH)

Complete all the required courses:

- 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)



Required Courses: 12 Semester Hours (SH)

Complete all the required courses:

- 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)

Elective Courses: 4 Quarter Hours (QH):

Complete 4 quarter hours from the following:

- RGA 6217 Biomedical Product Development: From Biotech to Boardroom to Market (4)
- RGA 6235 Emerging Product Categories in the Regulation of Drugs and Biologics (4)



Elective Courses: 0 Semester Hours (SH)

No elective options