Graduate Certificate: Biopharmaceutical Manufacturing and Regulatory Affairs

SCHOOL OF PHARMACY

About the Certificate

The graduate certificate in Biopharmaceutical Manufacturing and Regulatory Affairs is intended to enable Regulatory Affairs and Quality Assurance (RAQA) students to receive formal recognition for studying the highly specialized, rapidly growing field of pharmaceutical biotechnology, which includes the manufacturing techniques and applicable regulations used in the development and production of biotechnology products. The first biopharmaceutical product, namely, recombinant human insulin, was approved in 1982. Since then, products derived through biotechnology have provided advances in medicine that include therapeutic monoclonal antibodies, cancer vaccines, cytokines, antisense technology, interference RNA, and growth factors. The regulatory framework required for the approval of biotechnology-derived products (or biologics) is lengthy, rigorous, and highly complicated. This certificate delves into the complex regulations governing the development, manufacturing, and distribution of such products.

Through completion of the certificate, students understand the following:

• the pharmaceutical science behind the discovery of biotechnology products, including biologics, biosimilars, and biopharmaceuticals;
• the requirements for sourcing and testing materials used in the production of biotechnology products;
• the technologies and unique considerations associated with the manufacturing and distribution of biotechnology products;
• the applicable regulations involved with biotechnology products; and
• the processes used to sterilize biotechnology products, including regulatory requirements for thermal, gaseous, radiation, filtration, and aseptic processing.

Time Limit for Certificate Completion: 3 years

Campus Location: Online and Fort Washington

Full-Time/Part-Time Status: The certificate may be completed on a part-time basis. NOTE: International students may not be eligible to apply for a student visa based on admission to the certificate program. Please contact the School of Pharmacy’s program coordinator for more information.

Non-Matriculated Student Policy: Non-matriculated students may take up to 9 credits of coursework before applying to the certificate program.

Admission Requirements and Deadlines

Application Deadline:
Fall and Spring admissions are on a rolling basis. Interested students should contact the School of Pharmacy for permission to enroll in coursework.

APPLY HERE to the post-baccalaureate certificate program.

Bachelor’s Degree in Discipline/Related Discipline: Applicants must hold a BS degree in Biochemistry, Biology, Chemistry, Physics or a health-related discipline.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 15

Required Courses:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Courses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QARA 5471</td>
<td>Biotechnology: Bioprocess Basics</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5475</td>
<td>Pharmaceutical Biotechnology</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5515</td>
<td>Biologics/Biosimilars: A Regulatory Overview</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5577</td>
<td>Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics</td>
<td>3</td>
</tr>
<tr>
<td>Elective</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

Select one from the following:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>QARA 5492</td>
<td>Production of Sterile Parenterals</td>
</tr>
<tr>
<td>QARA 5493</td>
<td>Sterilization Processes</td>
</tr>
<tr>
<td>QARA 5501</td>
<td>Development of Sterile Products</td>
</tr>
</tbody>
</table>
Graduate Certificate: Biopharmaceutical Manufacturing and Regulatory Affairs

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>QARA 5512</td>
<td>Microbiological Concepts in Pharmaceutical Manufacturing</td>
</tr>
<tr>
<td>QARA 5572</td>
<td>Vaccines: Regulatory Affairs and Quality Assurance Issues</td>
</tr>
</tbody>
</table>

**Total Credit Hours**: 15

**GPA Required to be Awarded the Certificate**: 3.0 minimum

**Contacts**

**Certificate Program Web Address:**
https://pharmacy.temple.edu/raqa/certificate-programs/pre-masters-certificates/biopharmaceutical-manufacturing-and-ra

**Department Information:**

Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728
qara@temple.edu
267-468-8560

**Mailing Address for Application Materials:**
Temple University
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728

**Department Contacts:**

Admissions:
Wendy Lebing, MALD, MS
Assistant Dean
qara@temple.edu
267-468-8560