Graduate Certificate: Biologics and Biosimilars Manufacturing

SCHOOL OF PHARMACY

About the Certificate

Given the rapidly expanded development of biopharmaceuticals in the past decade, an immediate need exists for professionals with knowledge of and credentials in key manufacturing quality issues governing biologics and biosimilar drugs. The graduate certificate in Biologics and Biosimilars Manufacturing requires the completion of coursework focusing on how biologics and biosimilars are manufactured, looking specifically at regulatory compliance elements, fundamentals of Quality by Design (QbD) and Statistical Process Control (SPC). Chemistry, Manufacturing and Controls (CMC) strategies, including materials sourcing and testing requirements, are also studied. Discussions include the technologies used in manufacturing and the unique considerations that arise when dealing with such technologies as cell and gene therapies, therapeutic monoclonal antibodies, vaccines, cytokines, antisense technology, interference RNA and growth factors.

Time Limit for Certificate Completion: 4 years, with courses meeting for a minimum of 36 class contact hours over 10 or 12 consecutive weeks

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 Biology, Chemistry, Engineering, Pharmacy, Physics or related fields.

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>PS 8005</td>
<td>Pharmaceutical Biotechnology</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5471</td>
<td>Biotechnology: Bioprocess Basics</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>
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Elective

Select one from the following:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
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<tbody>
<tr>
<td>PS 5501</td>
<td>Development of Sterile Products</td>
</tr>
<tr>
<td>QARA 5000</td>
<td>Special Topics in Regulatory Affairs and Quality Assurance</td>
</tr>
<tr>
<td>QARA 5451</td>
<td>Statistical Quality Control</td>
</tr>
<tr>
<td>QARA 5468</td>
<td>Validation of Facilities, Utilities and Equipment (FUE)</td>
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<tr>
<td>QARA 5474</td>
<td>Process Validation</td>
</tr>
<tr>
<td>QARA 5479</td>
<td>Advanced Good Manufacturing Practices - Defining &quot;c&quot;</td>
</tr>
<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 5512</td>
<td>Microbiological Concepts in Pharmaceutical Manufacturing</td>
</tr>
<tr>
<td>QARA 5516</td>
<td>Cleaning Validation</td>
</tr>
</tbody>
</table>

1. Required for QbD Credit
2. Required for SPC Credit
3. Required for Regulatory Compliance Credit
QARA 5572 Vaccines: Regulatory Affairs and Quality Assurance Issues
QARA 5627 Statistical Design of Experiments (DOE)
QARA 5629 Process Monitoring

Total Credit Hours 15

1 With prior written approval of the RAQA Office, students with demonstrated experience in biotechnology or biologics/biosimilar regulatory aspects may substitute an elective for QARA 5471 or QARA 5515.

2 Before taking QARA 5000 Special Topics in Regulatory Affairs and Quality Assurance as an elective, students must receive prior written approval from the RAQA Office to ensure that the course content focuses specifically on biologics and biosimilars.

GPA Required to be Awarded the Certificate: 3.0 minimum

Contacts
Certificate Program Web Address:

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
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