School of Pharmacy
TEMPLE UNIVERSITY
Regulatory Affairs and Quality Assurance Graduate Program

Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
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Post-Master's Certificate in Biologics and Biosimilars: Regulatory Aspects

The RAQA program offers two certificates related to biologics and biosimilars. The ***Post-Master's Certificate in Biologics and Biosimilars: Regulatory Aspects*** *provides a broad overview of general regulatory aspects related to biologics and biosimilars. However, if you are seeking a program with a greater emphasis on the technical regulatory aspects of biologics manufacturing we suggest you review the brochure for the* ***Post-Master's Certificate in Biologics Manufacturing****.*

BACKGROUND

There is a need for pharmaceutical professionals with knowledge of and credentials in the U.S and global regulations governing biologics and biosimilar drugs. Temple University's Regulatory Affairs and Quality Assurance graduate program is pleased to offer a certificate that focuses specifically on this topic.

What Regulatory issues are unique to biologics and biosimilar drug manufacturers? What are the clinical, manufacturing, regulatory, and strategic issues that challenge the path to global commercialization of a biological product? What are the current regulatory and technical/scientific issues involved in developing biological products in major ICH regions? What principles guide the development of biosimilar drugs, and how does biosimilar development differ from innovator drug development? How do biologics and biosimilars differ from chemically synthesized drugs? What analytical methods are used to characterize biologics and how does analytical testing differ from small molecule testing? What Quality by Design principles relate to development, manufacturing, and testing of biologics? Explore these issues as you pursue the ***Post Master's Certificate in Biologics and Biosimilars: Regulatory Aspects (Certificate)***.

This specialized curriculum delves into the requirements of major ICH markets for biologics and biosimilar products. The certificate builds a strong foundation in the biologics and biosimilar regulatory landscape. The courses also expose students to key trends and controversies facing the biologics and biosimilar industry.

The ***Post Master's Certificate in Biologics and Biosimilars: Regulatory Aspects*** enables students to sharpen their knowledge of this industry niche without committing to the entire master's degree. This certificate provides the tools and information to understand how biologics and biosimilars are regulated nationally, regionally, and globally.

Executive recruiters often call the RA and QA Office seeking candidates with demonstrated knowledge of the regulations governing this discipline. The ***Post Master's Certificate in Biologics and Biosimilars: Regulatory Aspects*** will provide students with credentials from Temple's well-respected Regulatory Affairs and Quality Assurance graduate program, giving them a solid grounding in the key U.S. and global regulations that affect biologic and biosimilar products.

The ***Post Master's Certificate*** is open to both MS applicants and also MS graduates, who can expand their career opportunities with this new credential.

LEARNING OBJECTIVES

Upon completion of the ***Post Master's Certificate in Biologics and Biosimilars: Regulatory Aspects*** students will better understand:

- U.S. and Global regulatory landscape for biologics and biosimilars;
- Differences between biologics and small molecules;
- The complexities and challenges in drug development across disciplines, e.g., toxicology, clinical, and CMC;
- The strategy for preclinical and clinical studies as applied to biologics and biosimilar products;
- The basics of biologics and biosimilar CMC strategies.

ACADEMIC REQUIREMENTS

1. It is strongly suggested that students have a Bachelor's degree in Biology, Chemistry, Engineering, Pharmacy, Physics or related fields, from an accredited institution of higher learning. to earn the ***Post Master's Certificate.***

2. The ***Post Master's Certificate*** may be earned on its own or on the way to the MS in RA and QA. To earn the ***Certificate***, five of the following courses must be completed within a four-year period with an overall B (3.0) average:

Students must complete three required courses:

- Drug Development (RAQA 5459)
- Biologics/Biosimilars: A Regulatory Overview (RAQA 5515)
- Global CMCs - Biologics (RAQA 5577)

PLUS, students must complete two electives from the following:

- Production of Sterile Products (RAQA 5492)
- Regulatory eSubmissions (RAQA 5514)
- Clinical Drug Safety and Pharmacovigilance (RAQA 5538) or 5571*
- Special Topics in RAQA – Current Trends In Clinical Trials (RAQA 5560)
- Post-Marketing Safety Surveillance (RAQA 5571) or 5538*
- Vaccines: RA and QA Issues (RAQA 5572)

*Students may take 5571 or 5538, but not both.

3. All courses must be completed from Temple University's RAQA graduate program. No transfer credits from other institutions are accepted. If a student has completed an identical course at an accredited U.S. graduate school, the student may petition the RAQA program to waive that course and take another approved elective in its place. This request must be made in writing and approved before the student pursues the certificate.

4. Candidates must formally apply and follow the application procedures stated below (**Application Form**, photocopies of transcripts, and **Notice of Completion**).

5. Only one certificate program may be completed before students receive the M.S.

6. The certificate must be completed within four years. Students must apply for the certificate no more than one year after completing the course requirements.

7. Students interested in pursuing the RAQA MS degree may apply all credits earned in the ***Certificate*** towards their graduate degree, provided they formally apply for admission to the MS program and are accepted by Temple University's Graduate School.

APPLICATON PROCESS

The ***Post Master's Certificate in Biologics and Biosimilars: Regulatory Aspects*** is part of Temple University's graduate program in Regulatory Affairs and Quality Assurance. It does not require the GRE. To earn the ***Certificate*** students must successfully complete all courses with an overall B average and formally apply for the certificate. To receive the certificate and letter of completion, the following must be submitted:

- **Application Form**
- Photocopies of all undergraduate and graduate transcripts from any schools previously attended, including Temple's RAQA program (copies of transcripts are acceptable; official transcripts are not required).
- **Notice of Completion**

These items must be mailed to:

Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034

TO RECEIVE THE CERTIFICATE

Certificates are not automatically conferred when students complete all courses. Students must formally apply and must also forward the **Notice of Completion** either by mail or email to the RAQA Office (267.468.8565) indicating that they have finished all courses. Photocopies of all undergraduate and graduate transcripts must be included.

The RAQA Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must submit your **Application Form,** transcripts, and **Notice of Completion** by these deadlines:

Jan 15 for certificates earned in the previous fall semester
May 15 for certificates earned in the previous spring semester
Aug 20 for certificates earned during the summer semesters

If you miss the deadline, you will need to wait until the next processing period.
It takes the RAQA Office approximately 6 weeks to process certificates. If you have not received your certificate by Feb 28, June 30, or Sept 30, please contact the RAQA Office.

DESCRIPTION OF COURSES

Required Courses

Students must complete the following three required courses:

5459. Drug Development (3 credits)
This course studies the drug development process from discovery through FDA marketing approval. It reviews the process of development and the interrelationships linking the various disciplines, introducing students to regulations governing the process, including the interactions with FDA, ICH, and other regulatory agencies.

5515. Biologics/Biosimilars: A Regulatory Overview (3 credits)
Prerequisites: Drug Development (5459). Science background required.
Since the first biopharmaceutical product approval in 1982 (recombinant human insulin), the biotechnology derived product market has been rapidly growing with introduction of a number of promising advances in medicine such as therapeutic monoclonal antibodies, cancer vaccines, cytokines, antisense technology, interference RNA, and growth factors. As with traditional drugs (small molecules), the regulatory framework for approval of a biotechnology derived product (biologics) is complicated. In addition, there has been much debate about the introduction of biosimilars using an abbreviated approval process. An overall biologics-based process map beginning with pre-clinical through the post-marketing stage will be discussed. Topics such as therapeutic proteins/peptides, gene therapy, stem cells, vaccines, interference RNAs, PK-PD, world-wide regulatory filings, pre-clinical IND-enabling studies, BLA/CTD filing, biosimilars/follow-on-biologics, selected case studies, immunogenicity, comparability studies, manufacturing challenges, clinical trials, market exclusivity, and related regulatory guidelines will be discussed.

5577. Global CMCs - Biologics (3 credits)
This course provides students with an introduction to the chemistry, manufacturing and controls (CMC) topics involved in the development and licensure of biologic products (biopharmaceuticals, vaccines) in the US, Europe and other highly regulated regions. Topics will be discussed from the perspective of Regulatory and QA requirements and expectations. Basic microbiology, cell biology and chemistry concepts will be reviewed with an emphasis on their practical application to product development and RA/QA. The class is designed to orient RA/QA professionals, managers and scientists responsible for biopharmaceutical CMC development and preparation of dossiers to the CMC content matter and technical issues that must be addressed in biologic product development and registration. Topics will include adventitious agents testing, cell and seed bank testing methods and requirements, drug substance production via cell culture, protein and virus purification methods, control and analysis of process impurities, analytical methods and potency testing for characterization and release, strategy for specification setting for release and stability, comparability studies for biologics.

Elective Courses

In addition, students must complete two of the following elective courses

5492. Production of Sterile Products (3 credits)
This course reviews the theory and practice involved in the preparation of sterile, injectable products, covering formulation, manufacturing, facility requirements, validation and regulatory issues. Upon completion of the course, students will develop an understanding of the routes of administration of injectable drugs and the types of injections, current formulation methods, aseptic manufacturing processes, requirements for sterile manufacturing facilities, and validation, compliance and regulatory issues.

5514. Regulatory eSubmissions (3 credits)
Prerequisite: Drug Development (5459) and IND/NDA Submissions (5495) are suggested. Students who have not taken these courses should submit a resume which indicates industry experience.
This course will explore the evolution of global regulatory submissions from the original paper format to the current electronic common technical document (eCTD) and non-eCTD electronic submissions (NeeS). This course will primarily focus on current regulations, tools, and specifications associated with electronic submissions and electronic requirements of included documentation.

5538. Clinical Drug Safety and Pharmacovigilance (3 credits) **OR 5571**
Prerequisite: Good Clinical Practices (5536) or appropriate experience in industry GCPs.
This course provides students with an in-depth understanding of what pre-marketing Clinical Safety and Risk Management (CSRM) means in the context of both American (FDA) and international (ICH-E2C) regulatory requirements. Beginning with an historical overview of IND and international safety requirements, it examines the processes and systems in place to support compliance and the strategic documentation required for applications. It also looks at the role of risk management and epidemiological methods used to identify the signals used to quantify, assess, and communicate adverse drug reactions (ADR). Topics include clinical trial policy, the roles of the investigator, patient, and IRBs, privacy issues, informed consent, DSMB, and other related matters.

5560. Special Topics in RAQA - Current Issues in Clinical Trials (3 credits)
Through seminars, discussion, and presentations, this course provides and exciting opportunity to pursue an in-depth look at current issues in clinical trials as well as innovative solutions to the contemporary challenges in conducting clinical trials. Sponsors and clinical study sites are experiencing unprecedented challenges as well as exciting opportunities to change the ways that clinical trials are conducted. The course will identify, explore, analyze, discuss and evaluate current and emerging issues affecting the design, conduct and reporting of clinical trials. Issues affecting the way clinical trials are conducted will be discussed. Case studies of recent trials that successfully resulted in marketing approvals by regulatory authorities will be examined, including those that failed to meet their primary endpoints and other studies that were delayed by slow recruitment. Topics include changes in the ways that clinical trials are designed,

conducted, managed and reported, opportunities to accelerate the use of technology for subject recruitment, data collection, site management, monitoring, quality management and the informed consent process, Challenges associated with conducting global studies during the COVID-19 pandemic, enhancing diversity of clinical trial participants, meeting regulatory requirements for study transparency and public disclosure, protecting studies from sources of bias, the assessment of placebo response that is contributing to the increase in negative and failed studies, and maintaining GCP standards to ensure the safety of clinical trial participants and preserving data integrity. Topics include collecting digital data from wearable and mobile devices, new study paradigms such as virtual, site-less and hybrid clinical studies, the use of social media and artificial intelligence for subject recruitment and the use of real-world data and real-world evidence.

5571. Post-Marketing Safety Surveillance (3 credits) **OR 5538**
This course provides an in-depth understanding of post-marketing safety surveillance (PMSS) in the context of both American (FDA) and international (ICH-E2C) regulatory requirements. It begins with a historical overview of PMSS and then reviews the role of epidemiological methods in identifying signals and quantifying, assessing, and preventing adverse drug reactions (ADR). Medical/legal issues, benefits and limitations of safety surveillance systems, labeling changes, the ability to refute false signals, and social and ethical obligations inherent in the conduct of PMSS are discussed.

5572. Vaccines: RA and QA Issues (3 credits)
Suggested prerequisite: Drug Development (5459).
This course addresses the history, research and development, manufacture, marketing, and medical impact of vaccines. Various public policy, regulatory, ethical, and legal issues in this area are discussed as they pertain to the U.S. and, to some extent, international markets. Beginning with the eradication of smallpox, this course covers the development of widely used vaccines against once common diseases (e.g., polio, mumps, varicella, etc.), to the development of vaccines against HIV, anthrax, and certain types of cancer.

QUESTIONS AND ANSWERS

Where is Temple's RAQA program offered?
Temple University's RAQA program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions, visit our website:
http://www.temple.edu/pharmacy_QARA/map.htm
Courses can also be videoconferenced to corporate sites.
Over 60 courses are available online in real-time.

When can I start the program?
Courses in the RAQA program are offered during the fall, spring and summer semesters every year. You may start the certificate program at your convenience.

What course sequence is recommended?

We recommend you start by taking *Drug Development (5459)* and *Biologics/Biosimilars: A Regulatory Overview (5515)*, since these courses serve as the foundation of knowledge for the program. You may then take the other courses in any sequence.

The RAQA program offers over 80 different courses, which are rotated over a 2 to 3-year period. Courses are not necessarily offered every semester. We urge students to take courses when they are scheduled or to write to the RAQA Office if they wish to see a course scheduled in a particular semester.

How do I obtain a current class schedule?
Please check the RAQA homepage: **pharmacy.temple/edu/raqa**

How do I register for classes?
Please download the Registration and State Residency Forms from the RAQA homepage: **pharmacy.temple/edu/raqa**

Both are required the first time you register. Fax, mail, and electronic registrations do not guarantee your spot in a class, since sections fill quickly. We will contact you immediately if there are problems with your registration. The RAQA Office will send a confirmation when you are officially registered. You will also receive a notice via your TUmail account when your tuition statement is available, including the payment due date. Please make sure that you pay your bill by the due date, so you do not incur a late fee.

Do I need to submit GRE scores to complete the certificate?
No. GRE scores are not required for this certificate or for the MS in RAQA.

When should I indicate that I plan to pursue the certificate?
You do not need to submit an application form to start taking courses. In fact, you may simply complete the courses and then submit your application. If you intend to pursue the MS, however, it is important that you complete your application to the MS as soon as possible, so all of your coursework applies to your degree.

Can I complete both the *Certificate* and the MS in RAQA?
Yes! You're welcome to complete both programs, but please be aware that the MS in RAQA has an entirely different application process. For additional information on the Master of Science in Regulatory Affairs and Quality Assurance, please request a Program Guide and an application form by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *Certificate*?
Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University's RAQA graduate program. It is possible to have a requirement waived; however, another *approved* Temple University RAQA elective from the ***Certificate*** will have to be taken in its place. To waive a course, please submit a letter to the Assistant Dean for approval.

Will the certificate automatically be awarded when I complete the required courses?
No. You must formally apply to receive the certificate. This consists of submitting: 1) the **Application Form**, 2) copies of all undergraduate and graduate transcripts from any schools previously attended (photocopies are acceptable; original transcripts are not required), and 3) the **Notice of Completion** form.

When you have finished your courses, you must submit the **Notice of Completion** to the RAQA Office via fax (267.468.8565) by the stipulated deadlines (Jan 15, May 15, or Aug 20). Otherwise you will have to wait until the next time they are processed.

Is there a deadline for completing the courses?
You should complete the ***Certificate*** within four years. If you need an extension, please email qara@temple.edu.

Can I complete two certificates in Temple's MS program?
Temple's RAQA program now offers certificates in multiple specialties. Students may complete only one certificate before pursuing the MS in RAQA; however, you are welcome to earn additional certificates after earning the MS in RAQA. Thus, if you prefer to earn the ***Drug Development Certificate*** before completing the MS, you may subsequently earn this ***Certificate*** (or another post-master's certificate) after earning the MS. Courses may only be counted towards one certificate. Refer to our homepage for more details: **pharmacy.temple/edu/raqa**

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