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

Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175 • Fort Washington, PA 19034
Phone: 267.468.8560 • Fax: 267.468.8565
Email: qara@temple.edu • Web: www.temple.edu/pharmacy_QARA

BIOPHARMACEUTICAL MANUFACTURING AND REGULATORY AFFAIRS CERTIFICATE

Pharmaceutical biotechnology development, manufacture, and distribution

BACKGROUND

Ever since the first biopharmaceutical product (recombinant human insulin) was approved in 1982, products derived through biotechnology have provided medical advances 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. Temple's certificate in ***Biopharmaceutical Manufacturing and Regulatory Affairs*** focuses on the complex regulations governing the development, manufacture, and distribution of these products, preparing students for positions in biotechnology and sharpening the skills and knowledge of those already working in this field.

This five-course certificate presents a strong regulatory focus, enabling students to become fluent in the most current regulations and trends affecting the industry. Current pharmaceutical science methods used in the discovery of biotechnology products are studied, including materials sourcing and testing requirements. Technologies and unique considerations associated with the manufacturing and distribution of biotechnology products are discussed, along including the regulatory requirements for sterilization processes.

Faculty are drawn from the FDA and the biotechnology industry, assuring that the latest developments and practices are taught. They are industry and regulatory veterans with years of expertise in their specialties, who share their considerable knowledge with students through classroom discussions and hands-on workshops.

The biotechnology industry continues to offer new job opportunities in the U.S. and abroad. The two largest U.S. hubs for biotechnology are Boston and San Francisco, accounting for over 50,000 jobs in pharmaceutical biotechnology discovery and development. Hundreds of small, start-up biotechnology companies exist throughout the U.S. All courses in the ***Biopharmaceutical Manufacturing and Regulatory Affairs Certificate*** are offered online, allowing remote students to participate in this highly relevant program.

For nearly five decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Regulatory Affairs and Quality Assurance. The School was the first institution of higher learning in the U.S. to create a master's program in the Quality Assurance (QA) and Regulatory Affairs (RA) disciplines and continues to offer the most comprehensive curriculum of its kind.

Temple's renowned program specifically examines RA and QA issues facing the medical device, biotechnology, pharmaceutical and related industries. Courses discuss current

practices and issues in device, biotechnology, and pharmaceutical law and regulation, technology, and quality assurance practices.

The RAQA master's program is based in Fort Washington, PA. Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals. More than 60 courses are offered online.

To receive the certificate, candidates must hold a bachelor's degree in the sciences and complete the required courses and application procedures.

ACADEMIC REQUIREMENTS

1. The ***Biopharmaceutical Manufacturing and Regulatory Affairs Certificate*** may be earned on its own or on the way to the MS in RA and QA. To earn the certificate, the following five courses must be completed within a four-year period with an overall B (3.0) average.

Required (may be taken in any order):

Pharmaceutical Biotechnology (8005)
Biotechnology: Bioprocess Basics (5471)
CMCs - Biologics (5577)
Biologics/Biosimilars: A Regulatory Overview (5515)

One elective course from:

Production of Sterile Products (5492)
Sterilization Processes (5493)
Development of Sterile Products (5501)
Microbiological Concepts in Pharmaceutical Manufacturing (5512)
Vaccines: RA and QA Issues (5572)
Regulatory Bioanalysis (5621)

2. 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.

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

4. Matriculated students may earn the ***Biopharmaceutical Manufacturing and Regulatory Affairs Certificate*** as they complete the MS in RAQA.

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

6. Students interested in pursuing the RAQA MS degree may apply all credits earned in the ***Biopharmaceutical Manufacturing and Regulatory Affairs 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 ***Biopharmaceutical Manufacturing and Regulatory Affairs Certificate*** is part of Temple University's graduate program in Regulatory Affairs and Quality Assurance. It does not require the GRE. To earn the ***Biopharmaceutical Manufacturing and Regulatory Affairs Certificate*** students must successfully complete the five required 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:

- The **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.

Certificates are not automatically conferred when students complete the required courses. Students must formally apply and must also forward the **Notice of Completion** either by mail or fax to the RAQA Office (267.468.8565) indicating that they have finished the required 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 the **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 semester.

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.

REQUIRED COURSES

These four courses are required:

8005. Pharmaceutical Biotechnology (3 credits)
This course introduces students to pharmaceutical biotechnology, biophysical and chemical aspects of biotech products, and their pharmaceutical formulations and clinical applications. Amino acids, proteins, peptides and nucleotides are of particular interest. The principles of pharmaceutical formulations and physiochemical evaluation of formulations will be extensively discussed. Pharmacokinetics of biologics and current analytical methods used in pharmaceutical biotechnology are included.

5471. Biotechnology: Bioprocess Basics (3 credits)
This course covers the major steps of the biotechnology process: preparation of media, fermentation, recovery, chromatography, and related purification processes. Emphasis is placed on Quality by Design (QbD) principles as well as regulatory and control aspects of bioprocessing. Included is an introduction to basic biosciences (e.g., microbiology, biochemistry, and genetic engineering).

5515. Biologics/Biosimilars: A Regulatory Overview (3 credits)
Prerequisites: Drug Development (5459) and Food and Drug Law (5592). Students are expected to have a strong science background, including familiarity with undergraduate chemistry and biology. An undergraduate course in general biochemistry is also recommended.
Since the first biopharmaceutical product approval in 1982 (recombinant human insulin), the biotechnology derived product market has been rapidly growing with the 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 and the 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/peptide, vaccines, 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, post-approval changes and related regulatory guidelines will be discussed.

5577. CMCs - Biologics (3 credits)
This course provides an introduction to RA and QA requirements of CMC topics (chemistry, manufacturing and controls) in the development and licensure of biologic products (biopharmaceuticals, vaccines) in the U.S., Europe and other highly regulated regions. Basic microbiology, cell biology and chemistry concepts are reviewed, emphasizing their practical application to product development and RAQA. The class orients RAQA professionals, managers, and scientists responsible for biopharmaceutical

CMC development and dossier preparation to CMC content matter and technical issues that must be addressed in biologic product development and registration. Topics 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.

One course from the following electives:

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.

5493. Sterilization Processes (3 credits)
This course surveys sterilization processes used in the pharmaceutical, medical device, in-vitro diagnostic, and biotech industries. Current methods of sterilization are discussed, including thermal, gaseous, radiation, filtration, and aseptic processing. Students learn basic aspects of sterilization science as well as design, review, and audit sterilization validations and processes according to industry practices.

5501. Development of Sterile Products (3 credits)
This course provides a study of the theory and practice in the development of parenteral products. Areas covered include dosage form design, formulation, solubility/physical pharmacy, excipients, assays, stability, physiochemical properties of biomolecules, and delivery systems for controlled/sustained release and manufacturing methods.

5512. Microbiological Concepts in Pharmaceutical Manufacturing (3 credits)
This course addresses essential microbiology concepts of manufacturing and quality control that form the basis of Good Manufacturing Practices for both sterile and non-sterile pharmaceuticals. Emphasis is placed on a review of the following from a microbiological perspective: manufacturing technologies and techniques, building quality into processes, influence of raw material quality on finished product, the meaning of the qualification and validation studies conducted by drug firms, and key microbiological tests performed at in-process and finished product stages. The course stresses practical matters and includes case studies to prepare students for daily issues arising in industry.

5572. Vaccines: RA and QA Issues (3 credits)

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 vaccines used in 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.

5621. Regulatory Bioanalysis (3 credits)
This course covers several broad topics: (1) high-level quantitative analysis of biological samples that provide data to support pharmaceutical drug/biological product approval, (2) detailed instruction of FDA and EMA regulations and guidances that govern bio-analytical method development, validation and application in routine sample analysis, (3) "best practices" recommended for implementing quality management systems in a bioanalytical laboratory, and (4) discussion of approaches to address common problems that may arise during method validation and sample analysis. This course benefits pharmaceutical quality professionals and scientists working in the laboratory, addressing subjects not routinely covered in the other RAQA courses, including the quantitative analysis of biological samples (e.g. plasma, serum, urine) from nonclinical animal and human clinical studies. A large part of the course will be devoted to exploring and understanding quality principles in the bioanalytical laboratory required to withstand regulatory inspection.

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, refer to 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. The ***Biopharmaceutical Manufacturing and Regulatory Affairs Certificate*** is offered entirely online.

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?
Required courses may be taken in any order, followed by the one elective.
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: **www.temple.edu/pharmacy_QARA**

How do I register for classes?
Please download the Registration and State Residency Forms from the RAQA homepage: **http://www.temple.edu/pharmacy_QARA/forms.htm**

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 complete the five 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 by the end of your fourth course, so all of your coursework applies to your degree.

Can I complete the *Biopharmaceutical Manufacturing and Regulatory Affairs Certificate* and apply the credits towards the MS in RAQA?
Matriculated students are welcome to pursue the ***Biopharmaceutical Manufacturing and Regulatory Affairs Certificate*** before receiving the MS in RAQA. 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 *Biopharmaceutical Manufacturing and Regulatory Affairs 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 ***Pharmaceutical Manufacturing and Regulatory Affairs Certificate*** will have to be taken in its place. To waive a course, please submit a letter to the Assistant Dean for approval, **before** registering for any courses.

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 ***Biopharmaceutical Manufacturing and Regulatory Affairs 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 eleven specialties. Students may complete only one certificate before pursuing the MS in RAQA; however, you are welcome to earn additional post-master's 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 the ***Post-Master's Certificate in Biopharmaceutical Manufacturing and Regulatory Affairs*** (or another post-master's certificate) after earning the MS. Courses may only be counted towards one certificate. Please refer to our homepage for more details: **www.temple.edu/pharmacy_QARA/certificates.htm**

For additional information:
RAQA Graduate Program
Temple University School of Pharmacy
425 Commerce Drive, Suite 175
Fort Washington, PA 19034

Voice: 267.468.8560
Fax: 267.468.8565
E-mail: QARA@temple.edu
www.temple.edu/pharmacy_QARA