Advanced Biotherapeutics: Manufacturing and Regulatory Affairs MS

SCHOOL OF PHARMACY

Learn more about the Master of Science in Advanced Biotherapeutics: Manufacturing and Regulatory Affairs.

About the Program

The MS in Advanced Biotherapeutics: Manufacturing and Regulatory Affairs (ABMRA) is a program arising from a partnership between Temple University's School of Pharmacy and the Kanbar College of Design, Engineering & Commerce at Thomas Jefferson University. The program combines courses from Temple's Regulatory Affairs and Quality Assurance (RAQA) graduate program with courses from the Jefferson Institute for Bioprocessing (JIB). Students may earn the ABMRA degree from either Temple University or Thomas Jefferson University, depending on their area of interest: biopharmaceutical manufacturing (JIB) or regulatory affairs and quality assurance (Temple).

The ABMRA degree addresses the career needs of individuals involved in the discovery and manufacture of large-molecule therapeutic agents, including cell and gene therapies (GCT), vaccines and personalized medicines. The demand and discovery of these therapeutic agents rooted in monoclonal antibody-based therapies and messenger-RA technology continue to burgeon, creating a national shortage of skilled and knowledgeable professionals familiar with the manufacturing processes and regulatory/quality requirements of these agents.

Temple's ABMRA degree highlights the regulatory science practices and strategies as well as quality expectations involved in the development and manufacture of biopharmaceutical products. Jefferson's ABMRA degree focuses more on the development, manufacturing and analytical processes associated with the production of biopharmaceutical therapeutic agents on state-of-the-art equipment located at the JIB facility in Spring House, PA. Students have the ability to earn certificates from either school while also earning a degree from either Temple or Jefferson, depending on their preferred area of focus.

Graduates of the ABMRA degree from either university have a broad foundation in:

- U.S. and global regulatory landscapes for biologics and biosimilars;
- regulatory strategies for non-clinical and clinical studies for biologics and biosimilar products;
- Chemistry, Manufacturing and Control (CMC) strategies for biologics and biosimilars;
- phase-appropriate regulatory compliance elements applicable to biologics and biosimilars;
- fundamentals of Quality by Design (QbD) and Statistical Process Control (SPC) principles as relevant to biologics and biosimilars manufacturing;
- mastery of core engineering, scientific, regulatory and quality principles utilized in the development and manufacturing of biopharmaceuticals, biologics and advanced therapies;
- biopharmaceutical manufacturing operations, including bioreactor, chromatography, formulation and product concentration operations; and
- process development concepts, from early to late phase development and launch.

Time Limit for Degree Completion: 5 years

Campus Location: Online, in a hybrid format with some in-person instruction but largely learning online, or:

- at Fort Washington evenings and weekends for Temple courses
- at Spring House, PA for JIB courses

Full-Time/Part-Time Status: The degree program can be completed on a full- or part-time basis.

Interdisciplinary Study: The program fosters interdisciplinary study between biopharmaceutical sciences and technology as well as mandated regulatory and quality requirements.

Job Prospects: The program prepares graduates for positions in the global marketplace related to biosimilars and biologics.

Non-Matriculated Student Policy: Non-matriculated students are able to take up to 9 credits before formal application must be made to the program.

Financing Opportunities: Master's students are generally not considered for financial support.

Admission Requirements and Deadlines

Application Deadline:

Fall: March 1; December 15 international
Spring: November 1; September 1 international

Summer I: March 1; January 15 international

Applications are processed throughout the year. Late applications may be considered for admission. However, the entire application packet must be received by the Regulatory Affairs and Quality Assurance Office before it is reviewed by the Admissions Committee. Applicants are responsible for making sure that all materials have been received.

APPLY to this graduate program, submitting the application to QARA2@temple.edu.

Students who wish to apply to Jefferson's ABMRA MS should visit https://www.jefferson.edu/admissions/graduate/apply.html.

Letters of Reference:
Number Required: 2

From Whom: One letter of recommendation should be obtained from a college/university faculty member familiar with academic competence and one from a work supervisor.

Coursework Required for Admission Consideration: It is expected that applicants have a strong science or engineering background.

Bachelor's Degree in Discipline/Related Discipline: A BS in Bioengineering or Chemical Engineering, Biochemistry, Biology, Chemistry, Physics or a related discipline is required.

Applicants who earned a degree at a non-U.S. institution must submit an equivalency evaluation of their transcript(s) through a third-party provider, either World Education Services (WES) or Educational Credential Evaluators (ECE).

Statement of Goals: Describe your experience in the pharmaceutical, biopharmaceutical or related industries, indicating how the ABMRA MS program will help you achieve your career objectives.

Standardized Test Scores:
Applicants who earned their baccalaureate degree from an institution where the language of instruction was other than English, with the exception of those who subsequently earned a master's degree at a U.S. institution, must report scores for a standardized test of English that meet these minimums:

- TOEFL iBT: 85
- IELTS Academic: 6.5
- PTE Academic: 58

Resume: Current resume or CV, signed by the applicant, required.

Transfer Credit: Transfer credits are not accepted. Any student who has completed a similar RAQA course through an accredited graduate program may request to replace a required course with a listed elective course. Such requests are considered on a case-by-case basis.

Program Requirements

General Program Requirements:
Number of Credits Required Beyond the Baccalaureate: 36, of which 21 are completed at Temple University's School of Pharmacy and 15 at Thomas Jefferson University's Jefferson Institute for Bioprocessing (JIB)

Required Courses:

Code	Title	Credit Hours
Core Courses		
QARA 5459	Drug Development	3
QARA 5515	Biologics/Biosimilars: A Regulatory Overview	3
QARA 5572	Vaccines: Regulatory Affairs and Quality Assurance Issues	3
QARA 5577	Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics	3
Electives		
Select three from the following:		9
PS 5501	Development of Sterile Products	
PS 8005	Pharmaceutical Biotechnology	
QARA 5451	Statistical Quality Control	
QARA 5468	Validation of Facilities, Utilities and Equipment (FUE)	
QARA 5471	Biotechnology: Bioprocess Basics	
QARA 5474	Process Validation	

QARA 5479	Advanced Good Manufacturing Practices - Defining "c"	
QARA 5492	Production of Sterile Parenterals	
QARA 5493	Sterilization Processes	
QARA 5512	Microbiological Concepts in Pharmaceutical Manufacturing	
QARA 5514	Regulatory eSubmissions	
QARA 5516	Cleaning Validation	
QARA 5538	Clinical Drug Safety and Pharmacovigilance [1]	
QARA 5544	Regulatory Intelligence	
QARA 5571	Post-Marketing Safety Surveillance [1]	
QARA 5574	Pharmaceutical Quality Management Systems	
QARA 5575	Regulatory Sciences: Managing the Guidelines to Quality	
QARA 5625	Process Analytical Technology (PAT)	
QARA 5627	Statistical Design of Experiments (DOE)	
QARA 5629	Process Monitoring	
JIB Required Courses [2]		**12**
JIB Elective(s) [3]		**3**
Total Credit Hours		**36**

1

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

2

Four 3-credit courses required by JIB include ENGR 604 Biopharm Process Operations, ENGR 609 Bioprocess Engineering for Scientists, ENGR 611 Principles of Biopharmaceutical Process Engineering, and ENGR 621 Introduction to Biopharmaceutical and Biologics Production. Coursework is subject to change to reflect the most current trends and techniques in the production of biopharmaceutical therapeutic agents.

3

Electives approved by JIB include four 3-credit courses: ENGR 601 Intro Upstream Unit Operations, ENGR 602 Intro Downstream Unit Operations, ENGR 613 Vector and Cell Line Design, and ENGR 622 Biotherapeutic Formulation. Three 1.5-credit courses are also approved: ENGR 612 Emerging Therapeutics; ENGR 614 Vaccine Formulation; and ENGR 618 Technical and Regulatory Aspects of Analytical Method Validation. Coursework is subject to change to reflect the most current trends and techniques in the production of biopharmaceutical therapeutic agents.

Culminating Event: Successful completion of coursework is required to earn Temple's ABMRA MS.

Contacts

Program Web Address:

https://pharmacy.temple.edu/raqa/programs-degrees-certificates/advanced-biotherapeutics-manufacturing-and-ra-abmra-ms-degree

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

Submission Address for Application Materials:

QARA2@temple.edu

Mailing Address for Application Materials:

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