

Pharmaceutical Sciences/Regulatory Affairs and Quality Assurance, Ph.D.

SCHOOL OF PHARMACY

About the Program

The School of Pharmacy offers a graduate program leading to the Ph.D. in Pharmaceutical Sciences with a concentration in Regulatory Affairs and Quality Assurance (RAQA). Emphasis is placed on combining scientific principles and methodology with regulatory and quality practices to streamline the discovery, manufacturing, safety profiling, and post-approval processes. The program applies academic research methods to current industry regulatory issues, enabling candidates to pursue a dissertation that helps to define and resolve regulatory or quality problems with data research and scientific methodology. The goal of each dissertation is to present new and thoughtful answers to industry questions and problems that result in cost savings, safer and/or more effective products, better safety profiles, and other benefits for patients and manufacturers.

The RAQA concentration is designed for professionals who have a minimum of 15 years of relevant work experience, including supervisory responsibilities, in pharmaceutical and related sciences and/or regulation in such areas as analytical methods, clinical and pharmacovigilance supervision, corporate drug development or manufacturing science, quality practices, validation implementation, and other pertinent industry practices that draw heavily on regulatory policy and quality assurance. Work experience must be applicable to the topic candidates plan to investigate for their dissertation.

Selection is highly competitive as a very limited number of candidates is accepted each year. Successful candidates are expected to have:

- a master's degree or the equivalent in a pharmaceutical, science, medical, engineering, or related field;
- a minimum of 15 years of work experience in the field related to their Ph.D. dissertation;
- current work experience that can be applied to the regulatory/quality topic to be investigated for their Ph.D. dissertation;
- the ability to work both independently and as part of a team, displaying recognizable initiative;
- a willingness to pursue original, independent research, utilizing a multidisciplinary approach to problem solving;
- strong communication skills, both verbal and written, including the ability to write academic research papers containing original thought and cogent arguments;
- basic knowledge of data analysis, having completed at least one course in statistical methods; and
- the ability to accept constructive criticism and welcome feedback provided by the Dissertation Advisor and Dissertation Advisory Committee.

Time Limit for Degree Completion: 7 years

Campus Location: Health Sciences Center, Fort Washington

Courses may also be offered at Main campus. Research must be carried out, however, at the Health Sciences Center campus under the supervision of an advisor who is a member of the Graduate Faculty.

Full-Time/Part-Time Status: The degree is completed on a part-time basis in 2 to 5 years. Successful candidates are expected to pursue the Ph.D. program at least two terms every academic year (Fall, Spring, or Summer) until the dissertation is completed. Typically, students pursue the Ph.D. every Fall and Spring term, but a Summer term may be substituted. Note that a minimum of one credit each Fall and Spring term is required to maintain the candidate's active student status.

Job Prospects: Job opportunities include positions as postdoctoral researchers, scientists in the pharmaceutical industry, and faculty members.

Non-Matriculated Student Policy: Non-matriculated students are ineligible for participation in the program.

Admission Requirements and Deadlines

Application Deadline:

Fall: March 1

All applications are evaluated together after the deadline. Selection is highly competitive. A very limited number of candidates is accepted each year.

APPLY to this graduate program, submitting the application to RAQAPHD@temple.edu. For more information, visit https://www.temple.edu/pharmacy_qara/applyingtoMS.html.

Letters of Reference:

Number Required: 3

From Whom: Letters of recommendation should be obtained from college/university faculty members familiar with the applicant's academic competence and/or professionals in a supervisory position.

Master's Degree in Discipline/Related Discipline: A master's degree or equivalent is required in a pharmaceutical, science, medical, engineering, or related field. Course credits achieved in the master's degree may be applied toward the Ph.D. program's credit requirements.

Bachelor's Degree in Discipline/Related Discipline: A baccalaureate degree is required.

Preferably, official transcripts are forwarded electronically. Transcripts from all post-secondary institutions attended may be sent electronically to RAQAPHD@temple.edu. Alternately, unopened official transcripts bearing the school's seal must be sent directly from the Registrar at each institution to the Regulatory Affairs and Quality Assurance Graduate Program.

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: In approximately 500 to 1,000 words, state your specific interest in Temple's program, research goals, future career goals, and academic and research achievements.

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 required.

Other Requirement: It is recommended that applicants provide a commitment statement from their employer indicating that the employer supports the individual's involvement in the RAQA Ph.D. program.

Program Requirements

General Program Requirements:

Number of Credits Required Beyond the Baccalaureate: 40

Required Courses:

| Code | Title | Credit Hours |
|--|-------------------------------------|--------------|
| Graduate-level coursework completed while earning a pharmaceutical, science, medical, engineering, or related degree ¹ | | 30 |
| Coursework beyond the M.S. degree | | |
| PS 8051 | Seminar in Pharm Science | 1 |
| Graduate-level course in Data Science, Data Analytics, or Healthcare Analytics ² | | 3 |
| Additional coursework as required by the Dissertation Advisor and School of Pharmacy Graduate Committee ³ | | |
| Research Courses | | |
| PS 9998 | Pre-Dissertation Research (2 terms) | 4 |
| PS 9999 | Dissertation Research (2 terms) | 2 |
| Total Credit Hours | | 40 |

¹ The School of Pharmacy accepts up to 30 credits. The decision of the School on the number of credits accepted is final.

² A minimum of one 3-credit graduate-level course is to be completed. This coursework is related to decision analysis, quantitative methods, research design, scientific decision making, statistics and probability for data analysis, and the like.

³ The number of credits accepted toward the Ph.D. and the number required for completion of the Ph.D. are determined by the Dissertation Advisor and the Graduate Committee of the School of Pharmacy. It may be determined that additional coursework is required to prepare the student to write the dissertation. The course grid below lists approved course options.

Additional Approved Coursework Options¹

| Code | Title | Credit Hours |
|--------------|---|--------------|
| PS 5451 | Statistical Quality Control | 3 |
| or QARA 5627 | Statistical Design of Experiments (DOE) | |

| | | |
|--------------|--|---|
| PS 8005 | Pharmaceutical Biotechnology | 3 |
| QARA 5473 | Generic Drug Regulation (ANDAs) | 3 |
| QARA 5474 | Process Validation ² | 3 |
| or QARA 5498 | Computerized System Validation | |
| QARA 5492 | Production of Sterile Parenterals ³ | 3 |
| or QARA 5493 | Sterilization Processes | |
| QARA 5496 | Regulation of Medical Devices: Compliance ⁴ | 3 |
| or QARA 5502 | Regulation of Medical Devices: Submissions | |
| QARA 5503 | Design Controls for Medical Devices and Combination Products | 3 |
| or QARA 5548 | Risk Management of Pharmaceutical and Medical Devices | |
| QARA 5508 | Good Pharmacovigilance Operations | 3 |
| or QARA 5538 | Clinical Drug Safety and Pharmacovigilance | |
| QARA 5512 | Microbiological Concepts in Pharmaceutical Manufacturing | 3 |
| QARA 5513 | Active Pharmaceutical Ingredients (APIs) | 3 |
| or QARA 5546 | Global Pharmaceutical Excipient Regulation | |
| QARA 5515 | Biologics/Biosimilars: A Regulatory Overview | 3 |
| QARA 5532 | Global Labeling Regulation: Principles and Practices | 3 |
| QARA 5544 | Regulatory Intelligence | 3 |
| QARA 5572 | Vaccines: Regulatory Affairs and Quality Assurance Issues | 3 |
| QARA 5574 | Pharmaceutical Quality Management Systems | 3 |
| or QARA 5575 | Regulatory Sciences: Managing the Guidelines to Quality | |
| QARA 5576 | Global CMC Issues and Regulatory Dossier | 3 |
| or QARA 5577 | Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics | |
| QARA 5578 | Benefit Risk Management and Safety Signaling of Healthcare Products ⁵ | 3 |
| or QARA 5579 | Regulatory and Legal Basis of Pharmacovigilance | |
| QARA 5618 | Clinical Data Management (CDM) | 3 |
| QARA 5650 | Special Topics in Regulatory Affairs and Quality Assurance ⁶ | 3 |
| QARA 5655 | Analytical Chemistry in Pharmaceutical Laboratories | 3 |
| or QARA 8002 | Pharmaceutical Analysis | |
| QARA 8003 | Pharmaceutical Manufacturing I: Preformulation/Formulation | 3 |
| or QARA 8004 | Pharmaceutical Manufacturing II: Solid Dosage Forms | |

¹ Other coursework in Regulatory Affairs and Quality Assurance may also be assigned by the Dissertation Advisor.

² QARA 5478 High Purity Water Systems is a third choice.

³ PS 5501 Development of Sterile Products is another option.

⁴ QARA 5505 Global Regulation of Medical Devices is also approved.

⁵ QARA 5591 Global Regulatory Affairs can also be selected.

⁶ QARA 5650 may only be taken with departmental approval.

Other Requirement: Formal evaluation of each Ph.D. student's progress occurs at the end of the first year and each year thereafter to ensure that the quality of work will result in a fully approved dissertation project. Failure to conduct a reasonable amount of research or writing could result in suspension or dismissal from the program. The following is a typical dissertation schedule:

Year 1:

- Assess dissertation proposal topic, including candidate's knowledge span to determine strengths and deficiencies
- Determine additional coursework required, if any
- Review candidate's past work and publications as they pertain to the Ph.D. dissertation
- Select final dissertation topic and possible research protocol
- Outline dissertation proposal, research protocol, and introductory chapter by Year 1's end
- Meet with research advisor as required and recommended

Years 2-4:

- Pursue research activities to depict quantitative, qualitative, and policy analysis methods, including literature review and annotated bibliography
- Prepare dissertation introduction, discussion, and conclusion

Final Year:

- Prepare dissertation material for one or more publications
- Defend dissertation as required by the School of Pharmacy

Culminating Events:

Dissertation Proposal:

The dissertation proposal demonstrates the student's knowledge of and ability to conduct the proposed research. The proposal should consist of:

- the context and background surrounding a particular research problem;
- an exhaustive survey and review of literature related to the problem; and
- a detailed methodological plan for investigating the problem.

Upon approval of the dissertation proposal, the doctoral student is promoted to a Ph.D. candidate, and a timeline for completing the investigation and writing process are established.

Dissertation:

The doctoral dissertation is an original, theoretical, and/or empirical study that makes a significant contribution to the field. It should expand existing knowledge and demonstrate the student's knowledge of research methods and a mastery of her/his primary area of interest. The dissertation should be rigorously investigated; uphold the ethics and standards of the field; demonstrate an understanding of the relationship between the primary area of interest and the broader field; and be prepared for publication in a professional journal. It is expected that the dissertation will consist of an appropriate mix of quantitative and qualitative research methodology and be suitable for publication.

The Dissertation Examining Committee (DEC) is formed to oversee the student's doctoral research. It is charged with evaluating the student's dissertation and oral defense, including the student's ability to express verbally her/his research question, methodological approach, primary findings, and implications. The DEC, which includes the members of the DAC, is comprised of at least three Graduate Faculty members. Two members, including the Chair, must be from the School of Pharmacy. The Chair is responsible for overseeing and guiding the student's progress, coordinating the responses of the Committee members, and informing the student of her/his academic progress. At least one additional Graduate Faculty member from outside the School of Pharmacy must be included on the DEC. This outside examiner should be identified no later than the beginning of the academic term in which the student will defend the dissertation. The DEC members vote to pass or fail the dissertation and the defense at the conclusion of the public presentation.

Committee compositions must be approved by the departmental graduate committee. If a student needs to change a member of a committee, the new member must be approved by the departmental graduate committee and by the Graduate School. The changes must be documented with the Administrative Assistant and the Graduate School using the "Request for Change in Dissertation Committee" form, found in TUportal under the Tools tab within "University Forms."

Students who are preparing to defend their dissertation should confirm a time and date with their DEC and register with the Office of Graduate Studies at least 15 days before the defense is to be scheduled. The Office of Graduate Studies arranges the time, date, and room and forwards to the student the appropriate forms. After the Administrative Assistant has made the arrangements, the student must send the Graduate School a completed "Announcement of Dissertation Defense" form, found in TUportal under the Tools tab within "University Forms," at least 10 days before the defense date. The department posts announcements for the defense.

Contacts

Program Web Address:

https://www.temple.edu/pharmacy_qara/PhD_RAQA_Concentration.html

Department Information:

Dept. of Pharmaceutical Sciences Office of Graduate Studies
School of Pharmacy
3307 N. Broad Street, Suite 528
Philadelphia, PA 19140
tuspgrad@temple.edu
215-707-4972

Submission Address for Application:

RAQAPHD@temple.edu

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:

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