

Graduate Certificate: Validation Sciences

SCHOOL OF PHARMACY

About the Certificate

The graduate certificate in Validation Sciences provides students with a strong foundation in validation science principles, whether the student is an experienced professional or someone seeking entry into the career field. Validation is a critical and all-encompassing tool in the pharmaceutical, medical device, biotechnology and related regulated industries. At the heart of quality assurance practices, validation includes every test and scientific methodology used to demonstrate that facilities, utilities, equipment, processes, computers and products meet agreed-upon standards. Validation relies on the measured precision of scientific methods.

Coursework explores validation sciences in a global environment, combining key regulatory, scientific and analytical concepts. Through completion of the certificate, students understand and can apply:

- the benefits, principles and concepts associated with validation science; and
- the domestic and international regulations that govern the discipline.

Time Limit for Certificate Completion: 4 years

Campus Location: Health Sciences and Online

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.

Coursework Required for Admission Consideration: Students pursuing the certificate in Validation Sciences are expected to have knowledge of current Good Manufacturing Practice regulations. Students without such knowledge should consider taking QARA 5477 Good Manufacturing Practices (3 s.h.) before starting the program.

Bachelor's Degree in Discipline/Related Discipline: Applicants must hold a bachelor's degree from an accredited institution. While no specific major is required, most applicants should have a background in biological sciences, engineering, healthcare, natural sciences or related disciplines.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 15

Required Courses:

| Code | Title | Credit Hours |
|----------------------------------|--|--------------|
| Core Courses | | |
| QARA 5468 | Validation of Facilities, Utilities and Equipment (FUE) | 3 |
| QARA 5474 | Process Validation ¹ | 3 |
| Electives | | 9 |
| Select three from the following: | | |
| QARA 5451 | Statistical Quality Control | |
| QARA 5478 | High Purity Water Systems | |
| QARA 5492 | Production of Sterile Parenterals | |
| QARA 5493 | Sterilization Processes | |
| QARA 5498 | Computerized System Validation | |
| QARA 5503 | Design Controls for Medical Devices and Combination Products | |
| QARA 5516 | Cleaning Validation | |
| QARA 5627 | Statistical Design of Experiments (DOE) | |

| | |
|-----------|---|
| QARA 5629 | Process Monitoring |
| QARA 5650 | Special Topics in Regulatory Affairs and Quality Assurance ² |

Total Credit Hours**15**

- ¹ Students are expected to take QARA 5474 as their first course. However, students with educational or professional experience in validation science may begin the certificate program with an elective, although all required courses must be completed to earn the certificate.
- ² QARA 5650 should focus on current development and regulatory practices in validation science.

GPA Required to be Awarded the Certificate: 3.0 minimum

Contacts

Certificate Program Web Address:

<https://pharmacy.temple.edu/raqa/certificate-programs/pre-masters-certificates/validation-science>

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:

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