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 VALIDATION SCIENCE

BACKGROUND

Temple University's School of Pharmacy continues to be the leader in providing outstanding graduate-level courses in Regulatory Affairs and Quality Assurance. As the program launches new programs, it recognizes that many graduates with the MS in RAQA wish to continue taking courses to keep current with industry issues and meet regulatory requirements for training. The ***Post Master's Certificate in Validation Science*** allows RAQA graduates to pursue additional coursework and receive formal recognition for their work. The certificate is also open to professionals with other master's or doctoral degrees.

The U.S. Food and Drug Administration defines process validation as, "the collection and evaluation of data, from the…design stage through commercial production, which establishes scientific evidence that a process [product or system] is capable of consistently delivering quality products." (*Guidance for Industry Process Validation: General Principles and Practices, 2011.)*

Prior to the 1970s, quality was demonstrated by testing finished products, but in 1976, the FDA proposed a series of changes to the cGMP regulations. Initially these changes focused on sterilization processes, followed by other aspects of product and process validation.

Today Validation Science is a multidisciplinary activity that includes engineering, chemistry, microbiology, pharmacology, information technology, and statistics as applied to the development, production, distribution, and monitoring of products regulated under the U.S. Food, Drug and Cosmetic Act. It encompasses numerous activities that are done to demonstrate and document that products, processes, and systems are reliable, reproducible and perform as expected. Its concepts are applied to a broad spectrum of activities, such as systems, facilities, utilities, equipment, test methods, processes, data, and final products.

as well as understanding the domestic and international regulations which govern the discipline.

Validation Science is constantly evolving in a dynamic regulatory, economic, and scientific environment. The ***Post Master's Certificate in Validation Science*** provides a strong foundation in validation principles for both experienced professionals and those seeking entry into this career field. It explores Validation Science in a global environment, combining key regulatory, scientific, and analytical concepts that define the field. Students completing the ***Post Master's Certificate in Validation Science*** will understand and be able to apply the benefits, principles, and concepts associated with

Validation Science. They will also become familiar with the domestic and international regulations governing the discipline.

The ***Post Master's Certificate in Validation Science*** 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 needed to understand the multiple aspects of validation science, from both a philosophical and hands-on approach.

Temple University's RAQA Graduate Program

For 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 original institution of higher learning in the world 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 program specifically examines RA and QA issues facing the pharmaceutical, medical device, biotechnology, and related industries by integrating law and regulation, science and technology, and quality assurance practices. Faculty are FDA and industry experts with years of expertise, who share their extensive knowledge with students through discussions and hands-on workshops.

Candidates must formally apply for the ***Post Master's Certificate in Validation Science*** before registering for any courses. To receive the certificate, candidates must complete the required courses and application procedures. Students who completed master's or PhD degrees from accredited U.S. institutions of higher learning with extensive pharmaceutical industry experience may also petition the School to pursue the ***Post Master's Certificate in Validation Science***.

Temple's RAQA graduate program is based in Fort Washington, PA. Courses are conveniently scheduled on evenings and weekends for working professionals. The RAQA program may be completed on-campus or online in real time. Courses may also be transmitted through videoconferencing to corporate sites.

The *Post-Master's Certificate in Validation Science* may be pursued entirely online.

To receive the ***Post-Master's Certificate,*** candidates must complete the required courses and application procedures.

LEARNING OBJECTIVES

The ***Post Master's Certificate in Validation Science*** encompasses a critical analysis of the validation field. Upon successfully completing the required courses, students pursuing the Certificate will be able to understand and apply

- the purpose, benefits, basic concepts and terminology of Validation Science;

- the domestic and international regulations, guidance documents, and standards associated with Validation Science;
- validation principles and concepts associated with pharmaceutical, biotechnology, medical device and other regulated industries;
- validation principles and concepts associated with facilities, utilities, equipment, processes, test methods, cleaning, computerized systems, and products;
- documentation necessary to support validation life-cycle activities, including Validation Master Planning;
- how scientific and statistical principles in the development of verification and validation requirements are used.

ACADEMIC REQUIREMENTS

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

Two Required Courses

Process Validation (5474)
Validation of Facilities, Utilities, and Equipment Validation (5468)

Three Elective Courses from

Statistical Quality Control (5451)
High Purity Water Systems (5478)
Production of Sterile Products (5492)
Sterilization Processes (5493)
Computerized System Validation (5498)
Design Control for Medical Devices and Combination Products (5503)
Cleaning Validation (5516)
- Statistical Design of Experiments (5627)
- Process Monitoring (5629)
- Special Topics (5650) (focusing on current validation issues)

Students pursuing the ***Post Master's Certificate in Validation Science*** are expected to have a knowledge of cGMPs. Students without such knowledge should consider taking *Good Manufacturing Practices* (5477) before beginning the ***Post Master's Certificate in Validation Science***.

Students should start the ***Certificate*** with *Process Validation* (5474) or *Validation of FUE (Facilities, Utilities, and Equipment)* (5468); however, those with prior educational or professional experience in Validation Science may begin with an elective.

2. Participants must have a master's or PhD from an accredited institution of higher learning. While no specific major is required, most applicants should have a background in health care, natural science, biological sciences, engineering, or related disciplines.

3. All courses must be completed from Temple University's RAQA graduate program. Transfer credits from other institutions are not accepted.

4. GREs are not required for the ***Certificate***.

4. Candidates must formally apply before starting any courses in the ***Certificate***.

5. Students should complete the ***Certificate*** courses within four years. Students must apply for the ***Post Master's Certificate in Validation Science*** within one year of completing all coursework for the program.

APPLICATION PROCESS

Temple University Students

Once you receive your MS from Temple, the University closes your academic file. If you wish to pursue the ***Post Master's Certificate in Validation Science***, you must formally apply, so we can open your file to register you. The **Application** for the ***Post Master's Certificate in Validation Science*** is available on the **Certificates** link of the RAQA homepage.

You will be required to take five courses relating to Validation Science, including the two required courses to earn the Post Master's Certificate. If you took the two required courses as part of your MS in RAQA, you may substitute electives.

Please mail the application to:

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

Students with Advanced Science Degrees from Other Schools

To apply for the ***Post Master's Certificate in Validation Science***, you must have received an advanced degree (master's level or higher) from an accredited institution of higher learning and must have worked in the pharmaceutical industry for a minimum of three years.

Your application for the ***Post Master's Certificate in Validation Science*** must include

- A letter addressed to the Assistant Dean of RAQA, indicating which courses you wish to pursue and explaining your experience in regulated industry.

- The **Application** for the ***Post Master's Certificate in Validation Science***
- A signed copy of your current resume
- Photocopies of transcripts from all undergraduate and graduate programs you have attended.

Mail your Application to

Temple University – RAQA Graduate Program
Attention: Assistant Dean
425 Commerce Drive, Ste 175
Fort Washington, PA 19034

Formal permission to pursue the ***Post Master's Certificate in Validation Science*** must be received from the Assistant Dean before commencing any courses in the program.

If the candidate subsequently decides to apply for the MS in Regulatory Affairs and Quality Assurance within five years, all credits earned in the ***Post Master's Certificate in Validation Science*** will count towards the master's degree, provided a grade of B (3.0) or higher is earned in each course and the student is accepted into the MS program.

TO RECEIVE THE CERTIFICATE

After you have finished the required courses, fill out the **Notice of Completion** (available on the RAQA website) and forward it to the RAQA Office by fax (267.468.8565), email (qarareg@temple.edu), or hard copy.

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 semesters

If you miss the deadline, you will need to wait until the next processing period.

It takes the RAQA approximately six weeks to process certificates. If you have not received your certificate by Feb 28, June 30, or Sept 30, please contact the RAQA Office.

DESCRIPTIONS OF COURSES

We suggest you start the ***Certificate*** with the required courses. Electives are rotated each semester, so we urge you to take desired electives when they are scheduled. You may also write to the RAQA Office if you wish to see a course scheduled in a particular semester.

Required Courses

5474. Process Validation (3 credits) (Required)
Validation encompasses every step in product manufacturing from building the plant to methods used for testing and releasing products. All aspects of validation are discussed, including FDA Guides and Guidelines and current FDA validation concerns (as identified in 483 and Warning Letter observations). Traditional pharmaceutical and biologic manufacturing processes are discussed along with acceptable validation protocols. How recent FDA and European regulatory guidance documents view process as a life-cycle concept will be included, along with underlying regulatory guidance, process validation lifecycle stages, validation aims and deliverables, and industry practices.

5468. Validation of FUE (Facilities, Utilities and Equipment) (3 credits) (Required)
Prerequisite: Good Manufacturing Practices (5477) or appropriate industry experience in GMPs.
The production of FDA-regulated products (pharmaceutical, medical device, food, etc.) is highly dependent on both the initial qualification of facilities, utilities, and equipment (FUE) along with the ongoing efforts to maintain the qualified/validated state meeting current user and regulatory needs. This course focuses on the key validation elements specific to qualifying and validating facilities, utilities, and equipment. In practice, validation of these items is also a prerequisite for other validation efforts including process, cleaning and test method. The class will examine the key concepts of FUE qualification/validation as well as the life-cycle through retirement of the FUE.

Elective Courses

5451. Statistical Quality Control (3 credits)
This course provides an introduction to statistical quality control (SQC) concepts, methods and tools. Topics include control charts for variables, control charts for attributes, design of experiments and acceptance sampling systems. Emphasis is placed on how to use SQC concepts, methods and tools to monitor, adjust, and improve pharmaceutical and biotech manufacturing processes. This general methodology is useful in processes that support manufacturing, such as QC testing, change control, etc. Also addressed are the links between SQC approaches, Quality by Design, Lean Manufacturing and Six Sigma improvement.

5478. High Purity Water Systems (3 credits)
This course examines high purity water systems from a Quality Function perspective, covering basic aspects of system design and operation. Special attention is paid to unit operations, sanitization procedures, and routine monitoring programs. Topics include planning validations and establishing routine monitoring programs to assess ongoing quality. Comparisons between domestic requirements and international standards and regulatory expectations are included.

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. Topics include 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)
Sterilization processes used in the pharmaceutical, medical device, in-vitro diagnostic, and biotech industries are covered in this course. Current methods of sterilization are discussed, including thermal, gaseous, radiation, filtration, and aseptic processing. Basic aspects of sterilization science are included, as well as design, review, and audit of sterilization validations and processes according to industry practices.

5498. Computerized System Validation (3 credits)
This course studies the regulatory history and background for Computerized System Validation (CSV). The current FDA and global CSV relevant regulations including the predicate rules will be discussed. The course will also address compliance with 21 CFR Part 11, as well as introduce students to software development methods and deliverables as they relate to CSV. A wide range of computerized systems typically employed in regulated environments and their unique challenges will be examined. Students will have hands-on practice in the development of a key validation deliverable and will complete an assigned project. Software development experience is not needed, but a better than average understanding of technology and the systems used in Life Sciences is expected.

5503. Design Controls for Medical Devices and Combination Products (3 credits)
This course covers design control requirements and practices in the medical device and combination products industry. Class discussions include design control requirements as they apply to medical devices and combination products. Current regulations and practices are discussed and utilized, providing students with experience in executing design control activities for a range of products.

5516. Cleaning Validation (3 credits)
Aspects of a pharmaceutical cleaning validation program and the criteria for each are discussed. Topics include protocol to final report with emphasis on the regulatory risks and consequences. FDA and other regulatory agency observations are highlighted to reinforce class material.

5627. Statistical Design of Experiments (3 credits)
This course exposes students to modern methods for the design, collection, analysis and interpretation of experiments, including using statistical methods to design optimal processes by incorporating data sets and data charting. Discussions include experimental plans to optimize a process; creation of screening study to limit experiments; and use of surface methodology to set process specifications. Issues encountered by scientists and engineers as they develop and improve products and processes will be discussed. Some of those covered are sorting excipient and API components to develop/revise pharmaceutical formulations; selecting the right process variables in the right

combinations to optimize a process so products are consistently produced and meet specifications at minimal cost; and getting a process back on track after it has developed a habit of producing defective batches.)

5629. Process Monitoring (3 credits)
Process control is an integral part of using Quality by Design (QbD) to build quality into products. This course discusses state-of-the-art process monitoring and controls used in the pharmaceutical and biotechnology industries, along with process flowcharting and improvement, control charting, and process capability analysis to assess the stability and capability of processes. These concepts, methods and tools are integrated into a process performance and product quality monitoring and improvement system. Discussions include an introduction to process improvement using lean and Six Sigma methods. Minitab statistical software is used for statistical calculations. Students learn to collect process monitoring data; analyze process data for stability and capability; identify opportunities for improvement; conduct studies to solve problems and create process improvements; and use statistical software to analyze process data.

5650. Special Topics (in Validation Science) (1 – 3 credits)
This course will examine current topics in Validation Science, such as data integrity, rapid methods validation, and multi-use facilities.

QUESTIONS AND ANSWERS

Where is the RAQA program offered?
The RAQA program is based at Temple University Fort Washington in suburban Montgomery County, PA. We offer courses on-campus and online in real time. We also transmit our courses via videoconferencing to corporate sites.

You may pursue the ***Post Master's Certificate in Validation Science*** **entirely online**.

When can I start the program?
We offer courses three semesters a year (fall, spring and summer). You may start the ***Certificate*** at your convenience.

What course sequence is recommended?
If possible, you should start with *Process Validation* (5474) or *Validation of FUE (Facilities, Utilities, and Equipment)* (5468), but this is not mandatory, particularly if you have prior educational or professional experience in Validation Science.

We have over 80 different courses in our program. Every course is not offered every semester. Electives are rotated over a 2 to 3 year period. If you wish to take a particular elective, please register for it when it appears on the schedule or ask our Office when it will next be offered.

How do I obtain a current class schedule?
Please check our website: **www.temple.edu/pharmacy_QARA** Click: **Schedule**

How do I register for classes?
You must be formally admitted to the ***Post-Master's Certificate in Validation Science*** before registering for any courses.

- If you received your MS from Temple, download the registration form from the RAQA homepage**:** **http://www.temple.edu/pharmacy_QARA/forms.htm**
  You do not need to submit a state residency form, unless you have moved from one state to another.

- If you have not registered for Temple University RAQA courses before, 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 e-mail registrations do not guarantee your spot in a class, since sections fill quickly. You will receive an email confirmation once you are registered and an electronic tuition bill through your Temple email account.

Do I need to submit GRE scores to complete the *Post Master's Certificate in Validation Science*?
No. GRE or other advanced test scores are not required for this certificate or for the MS in RAQA.

When should I indicate that I plan to pursue the *Post Master's Certificate in Validation Science*?
You must formally apply for and be accepted to the ***Post Master's Certificate in Validation Science*** before starting any courses.

If I did not previously receive the MS in RAQA from Temple, can I earn that degree after finishing the *Post Master's Certificate in Validation Science?*
Yes. You may complete both programs, but the MS in RAQA has a different application process. For information, please request a **Program Guide** and the **Application for Graduate Study** by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *Post Master's Certificate in Validation Science*?
Transfer credits from other institutions are not accepted. All five courses must be from Temple University's RAQA program.

Will the *Post Master's Certificate in Validation Science* automatically be awarded when I complete the required courses?
No. You must notify the RAQA Office that you have finished the certificate by submitting the **Notice of Completion** by the stated deadlines. The form is available on the RAQA website, under Certificates

When you have finished your courses, submit the **Notice of Completion** by mail or fax (267.468.8565) by the stipulated deadline (Jan 15, May 15, or Aug 20). If you miss the deadline, you will have to wait until the next time they are processed.

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

Will new electives be added to the program?
Yes, the RAQA program continues to expand its curriculum. For a listing of new courses, please consult the RAQA website.

Can I complete two Post Master's Certificates in Temple's MS program?
Temple MS graduates are welcome to complete two or more Post-Master's Certificates. Students who did not receive their degree at Temple should contact the RAQA Office about pursuing a second Post Master's Certificate. Courses may count towards one certificate only. For details, see **www.temple.edu/pharmacy_QARA/certificates.htm.**

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