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

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Regulatory Affairs and Quality Assurance Graduate Program
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VALIDATION SCIENCE CERTIFICATE

BACKGROUND

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.

Validation Science is constantly evolving in a dynamic regulatory, economic, and scientific environment. The ***Validation Science Certificate*** 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 ***Validation Science Certificate*** 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.

Temple University's School of Pharmacy was the first institution of higher learning to create a master's program in Regulatory Affairs (RA) and Quality Assurance (QA) in 1968. For the last five decades, the program has provided the most comprehensive curriculum of its kind with more than 80 graduate-level courses.

Temple's graduate 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.

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.

The *Validation Science Certificate* may be pursued entirely online.

To receive the certificate, candidates must complete the required courses and application procedures.

LEARNING OBJECTIVES

The ***Validation Science Certificate*** 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;
- scientific and statistical principles in the development of verification and validation requirements.

ACADEMIC REQUIREMENTS

1. The ***Validation Science Certificate*** may be earned on its own or on the way to the MS in RAQA. To earn the ***Validation Science Certificate***, 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 ***Validation Science Certificate*** are expected to have a knowledge of cGMPs. Students without such knowledge should consider taking *Good Manufacturing Practices* (5477) before beginning the ***Validation Science Certificate***.

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 bachelor's level degree 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 and follow the application procedures stated below (**Application Form**, photocopies of transcripts and **Notice of Completion**).

5. Only one certificate may be completed before students receive the MS.

6. Students should complete the ***Certificate*** courses within four years. Students must apply for the ***Validation Science Certificate*** within one year of completing the five courses in the program

7. Students interested in pursuing the RAQA MS program may apply all credits earned from the ***Validation Science Certificate*** towards their graduate degree, provided they formally apply for admission to the MS program and are accepted by Temple University's Graduate School.

APPLICATION PROCESS

The ***Validation Science Certificate*** is part of Temple University's RAQA graduate program. To earn this ***Certificate***, students must successfully complete the five courses with an overall B average and formally apply for the certificate. To receive the certificate and letter of completion, students must submit

- The **Application Form** for the ***Validation Science Certificate***
- Photocopies of all undergraduate and graduate transcripts, including Temple transcripts for RAQA courses completed. (Copies of transcripts are acceptable. Official transcripts are not required.)
- **Notice of Completion** (when courses are completed)

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

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 all required materials (listed above) 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 both on-campus and online in real time. We also transmit our courses via videoconferencing to corporate sites.

You may pursue the ***Validation Science Certificate*** **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?
Please download the **Registration** and **State Residency Forms** from the RAQA website: **www.temple.edu/pharmacy_QARA/forms.htm**
You must send both forms the first time you register. Our courses fill quickly, so please register early. We will contact you if there are problems with your registration. We will also send you a confirmation via email when we receive your materials and officially register you. You will also receive a notice via your TUmail account when your tuition statement is available, including the payment due date. Please 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 *Validation Science 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 *Validation Science Certificate*?
You do not need to submit a formal application to start the ***Validation Science Certificate***. You may complete the five courses and then submit the **Application**, copies of your transcript, and the **Notice of Completion**.

Can I complete both the *Certificate* and the MS in RAQA?
Yes. You may complete both programs, but the MS in RAQA has a separate application process. For more 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 *Validation Science Certificate*?
Transfer credits from other institutions are not accepted. All five courses must be from Temple University's RAQA program.

Will the *Validation Science 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 undergraduate and graduate transcripts from any schools previously attended, and 3) the **Notice of Completion**.

When you have finished your courses, submit the **Notice of Completion** by mail 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 ***Validation Science 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 offers certificates in multiple specialties. You may complete one certificate before pursuing the MS in RAQA; however, you are welcome to earn additional certificates after earning the MS in RAQA. Courses may count towards one certificate only. For details, see **www.temple.edu/pharmacy_QARA/certificates.htm.**

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