

# REGULATORY COMPLIANCE

SPS Certificate website: <https://sps.northwestern.edu/program-search/certificates.php>

## Interdisciplinary Studies in Regulatory Compliance, Advanced Graduate Certificate

Students in this advanced graduate certificate program have the flexibility in their course selection to explore different aspects of the regulatory environment, in different industries. They may take a range of courses offered in the master's program (MSRC) curriculum in the areas of clinical research and quality systems. The certificate is designed for students to explore concepts and problems in quality assurance and regulatory affairs that span life science industries, thus encouraging a cross-pollination of best practices and systems. Students can concentrate on course work that supports preparation for the ASQ (American Society for Quality) certifications, for example, refresh their knowledge of the regulatory requirements of clinical research studies, or explore courses that will help them lead teams comprised of diverse industries. Students choose any four courses in the Master of Science in Regulatory Compliance program. It is suggested that students tailor their course selection to specific career goals.

## Regulatory Compliance, Graduate Certificate

Students enrolled in the Regulatory Compliance certificate have the flexibility in their course selection to explore different aspects of regulations, leading to a more informed choice of specialization when transferring to the master's program (MSRC). They may select four courses offered in the master's program curriculum in the areas of clinical research and quality systems. Students can concentrate on course work that supports preparation for the ASQ (American Society for Quality) certifications, for example, refresh their knowledge of the regulatory requirements of clinical research studies, and acquire foundational knowledge needed in all aspects of the health regulatory industry.

## Certificates Offered

- Interdisciplinary Studies in Regulatory Compliance, Advanced Graduate Certificate (<https://catalogs.northwestern.edu/sps/certificates/graduate/regulatory-compliance/regulatory-compliance-advance-graduate-certificate/>)
- Regulatory Compliance Graduate Certificate (<https://catalogs.northwestern.edu/sps/certificates/graduate/regulatory-compliance/regulatory-compliance-graduate-certificate/>)

## Regulatory Compliance Courses

### CLIN\_RES 400-DL Essentials of Initiating Clinical Research (1 Unit)

This course is designed to provide an overview of the drug development process with an emphasis on the conduct of clinical trials. This course will view trial conduct from both the sponsor and site perspectives and students will gain a basic understanding of the complexities of clinical research and critically think about how to navigate them. Upon completion, students will have the knowledge and basic skills to pursue a position coordinating clinical trials at an investigative site or an operational position within a pharmaceutical company.

### CLIN\_RES 401-DL Responsible Conduct of Research (1 Unit)

This course examines the primary regulatory and ethical requirements for researchers, research staff members, and institutions engaged in human, animal, and laboratory research. It encourages students to apply regulatory requirements to real-world settings. It includes various legal and ethical issues, and emphasizes the responsibilities of investigators and research staff within the research enterprise. The course challenges students to become critical thinkers and approach cases from a leadership perspective, considering how to integrate responsibility into organizational culture. It requires students to problem solve and draft remediation plans if needed.

### CLIN\_RES 403-DL Clinical Research Design & Methodology (1 Unit)

This course explores the application of research design and methodology theories and concepts to the practical conduct of a clinical trial. Topics include commonly used research designs, methods for randomization and blinding, data collection methods (including electronic data capture) and implications of design and methodology for clinical trial operations from study initiation to data lock. It is recommended that students have a knowledge of statistics before taking this course.

### QARS 420-DL Practical Quality Management (1 Unit)

Covers key quality management principles with much of the content based on the ASQ Six Sigma Body of Knowledge, which includes topics such as Lean concepts, Design for Six Sigma (DFSS), and the Define, Measure, Analyze, Improve, Control (DMAIC) technique for process improvement. Upon completion of this course, you will be able to apply the quality management principles to lead quality departments, participate in or lead continuous improvement projects, and advance these concepts as part of any quality professional role in pursuit of compliance and business success. Prepares students to pass ASQ's Six Sigma Green Belt Certification Exam. Recommended prior to course: MSRC 401-DL and Biostatistics.

### QARS 421-DL Applied Quality & Regulatory Practices (1 Unit)

Explores quality standards and compliance regulations governing the manufacture and quality control testing of products with a focus on the laboratory setting. Emphasis on the laboratory function, course covers how controls are identified and implemented, including quality control testing in accordance with Good Manufacturing Practices (GMP). Topics include design control, risk management, equipment qualification and validation, out-of-specification results, the CAPA (corrective action and preventive action) system, supplier controls, change control, and document control. By the end of the course, students will have demonstrated the ability to synthesize knowledge to create a comprehensive plan to control and test product quality.

### QARS 425-DL Quality Assurance Project Management (1 Unit)

Students will gain and apply skills in developing and leading projects that create value in any area, but with specific focus on improving quality, service, and regulatory compliance. Apply critical thinking to projects and determine which tools to use from a broad array of proven methodologies. Review current research in effective project management. Review of Total Quality Management (TQM), Malcolm Baldrige Criteria, and ISO Quality Management Systems will be performed to ensure that projects can deliver results that create the highest value by supporting the overall objectives of a quality/regulatory organization. Key concepts of leadership, talent management, and risk management will be integrated for successful project management.

### QARS 450-DL Medical Device Regulations (1 Unit)

Provides an analysis of global medical device development and approval requirements, concentrating on the preparation of global medical device strategies. Covers the medical device classification and regulation by ministries of health around the world. FDA regulation of medical

devices including Investigational Device Exemption (IDE), 510(k), and PMA will be taught as a foundation for looking at global regulatory submission pathways. In addition to FDA regulations, covers medical device regulations for the European Union, Canada, and other major markets. Students will be exposed to common post-market challenges such as change control and import/export issues.

**QARS 460-DL Drug and Biologics Regulations (1 Unit)**

Students in this quality systems course discuss current policies and guidelines under which pharmaceutical, biological and medical device products are developed for human use and regulated while in commerce. Topics include regulatory requirements for patented and generic pharmaceuticals, over-the-counter drugs, legal and ethical issues, and biological products. Students examine the newly implemented steps to harmonize international regulations. Students who complete this course will be prepared to research, identify and track the status of the regulations and guidance documents that impact the drug and/or biologics life cycle, as well as serving as valuable cross-functional team members representing regulatory affairs in a clinical operations setting.