

REGULATORY COMPLIANCE

SPS Certificate website: <https://sps.northwestern.edu/advanced-graduate-certificate/>

Clinical Research, Advanced Graduate Certificate

Students in this certificate program are given a solid framework from which to understand clinical research. A graduate's understanding of clinical trial design, drug development and regulatory requirements allows them to manage many facets of the clinical research endeavor, whether developing and implementing clinical research protocols or overseeing GCP, compliance and financial matters at an individual or multi-site level.

Healthcare Compliance, Advanced Graduate Certificate

Gain a strong grounding in healthcare laws and regulations and learn the basics of healthcare billing and payment and corporate compliance. Graduates of the Healthcare Compliance certificate program are able to employ their compliance knowledge at both a systems and discrete level. For example, they will be able to assess and manage compliance programs, develop compliance dashboards, and conduct and respond to audits, and screen and evaluate vendors.

Quality Systems Management, Advanced Graduate Certificate

The quality systems 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. A work force, including chemists, scientists, technicians, and managers, proficient in the principles and practices of quality, is a central concern of companies. Certification is a mark of excellence which demonstrates that the certified individual has the knowledge to assure the quality of products and services. Quality Systems course work supports preparation for the ASQ (American Society for Quality) certifications in the areas of:

- Quality Improvement Associate,
- Quality Process Analysts,
- Quality Auditor,
- Quality Engineer,
- Pharmaceutical GMP professional,
- Six Sigma Green Belt and Lean Certifications as well as
- Manager of Quality/Organization Excellence certification.

Certificates Offered

- Clinical Research, Advanced Graduate Certificate (<https://catalogs.northwestern.edu/sps/certificates/graduate/regulatory-compliance/clinical-research-advance-graduate-certificate/>)
- Healthcare Compliance, Advanced Graduate Certificate (<https://catalogs.northwestern.edu/sps/certificates/graduate/regulatory-compliance/healthcare-advance-graduate-certificate/>)
- Quality Systems Management, Advanced Graduate Certificate (<https://catalogs.northwestern.edu/sps/certificates/graduate/>)

[regulatory-compliance/quality-systems-management-advance-graduate-certificate/](https://catalogs.northwestern.edu/sps/certificates/graduate/regulatory-compliance/quality-systems-management-advance-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 take MHI 409-DL Biostatistics before this course.

CLIN_RES 499-0 Independent Study (1 Unit)

Independent Study.

CLIN_RES 590-0 Research (1 Unit)

CRRA Thesis Research.

HC_COM 410-DL Healthcare Regulatory Environment (1 Unit)

This course facilitates an in-depth exploration of the healthcare laws, regulations, statutes, policy guidance and enforcement initiatives that serve as a framework for healthcare compliance. Topics include but are not limited to legal and ethical issues, patient safety, patient privacy and security, coding and billing, conflict of interest, anti-kickback, and False Claims.

HC_COM 411-DL Healthcare Programs and Enforcement (1 Unit)

This course provides a comprehensive overview of health care compliance programs, including each of the seven core elements and strategies for developing, implementing and managing effective compliance programs in a heavily regulated environment. The course describes compliance healthcare enforcement authorities, such as Medicare and Medicaid auditors (e.g., Recovery Auditors, UPIC's) and current key healthcare fraud initiatives. Topics also include the basics of conducting risk assessments, audits and investigations. Previous title: Healthcare Compliance Programs.

HC_COM 413-DL Healthcare Billing Models & Systems (1 Unit)

This course provides a basic understanding of billing and payment structure for healthcare services in the U.S. and systems that promote compliance with federal and state laws, audits, and communications with government and other parties. See the MSRC website for more details.

HC_COM 415-DL IT Systems Compliance (1 Unit)

Provides a working knowledge of the compliance oversight of healthcare IT systems. Focus is on systems used in healthcare service provider settings. Topics include identification of legal and regulatory computer system requirements used in the industry; ensuring system specifications and configurations meet regulatory requirements; setting criteria of system documentation to ensure compliance to inspectors; ensuring cyber security risks are mitigated; addressing European Union Privacy Laws for international systems; and identifying special considerations for mobile devices. Students will have the ability to manage the compliance aspects of IT systems throughout the system lifecycle (acquisition, upgrades and retirement). Students learn how to build procedures to address any system violations.

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.