

REGULATORY COMPLIANCE

Department website: <https://www.sps.northwestern.edu/masters/regulatory-compliance/>

Regulatory compliance is increasingly visible in healthcare, life science and clinical research arenas. As a result, career opportunities in regulatory compliance are multiplying for those with the kind of training students receive in the Master of Science in Regulatory Compliance (MSRC) program. An interdisciplinary professional program, Northwestern University's part-time MSRC program addresses core areas of compliance, including risk management, quality and regulatory science, practices and enforcement, leadership and communication skills. The MSRC curriculum focuses on core competencies while also stressing practical applications within the program's three tracks:

- Healthcare Compliance (<https://catalogs.northwestern.edu/spgs/graduate/regulatory-compliance/regulatory-compliance-ms-healthcare-specialization/>)
- Clinical Research (<https://catalogs.northwestern.edu/spgs/graduate/regulatory-compliance/regulatory-compliance-ms-clinical-research-specialization/>)
- Quality Systems (<https://catalogs.northwestern.edu/spgs/graduate/regulatory-compliance/regulatory-compliance-ms-quality-systems-specialization/>)

MSRC graduates are prepared to assume leadership positions in healthcare compliance, clinical compliance, and in quality and regulatory industries, including pharmaceutical, life sciences, food, and medical device industries. Even PhDs can significantly enhance their skill sets and find new professional opportunities in this increasingly important and sensitive field.

The program offers a thorough grounding in the interdisciplinary core competencies of regulatory compliance, including risk management, quality and regulatory science, leadership and communication skills. MSRC places a strong emphasis on practical application: courses are taught by industry experts – leading minds with extensive experience in navigating regulatory compliance challenges. MSRC's partnership with Northwestern's Feinberg School of Medicine and the university's Clinical and Translational Science Institute is another benefit, providing the program with the latest insights on healthcare, translational research, and regulation.

Degrees Offered

- Regulatory Compliance, MS (<https://catalogs.northwestern.edu/spgs/graduate/regulatory-compliance/regulatory-compliance-ms/>)
- Regulatory Compliance, MS Clinical Research Specialization (<https://catalogs.northwestern.edu/spgs/graduate/regulatory-compliance/regulatory-compliance-ms-clinical-research-specialization/>)
- Regulatory Compliance, MS Healthcare Compliance Specialization (<https://catalogs.northwestern.edu/spgs/graduate/regulatory-compliance/regulatory-compliance-ms-healthcare-specialization/>)
- Regulatory Compliance, MS Quality Systems Specialization (<https://catalogs.northwestern.edu/spgs/graduate/regulatory-compliance/regulatory-compliance-ms-quality-systems-specialization/>)

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.

MSRC 401-DL Quality Systems (1 Unit)

Introduction to essential quality systems and the domestic and global regulatory landscape governing regulated industries. Includes a review of the historical context for the creation of the organizations that protect public health, including the Department of Health and Human Services and the Food and Drug Administration. Discusses the pivotal role of quality in determining value chains and innovation; compliance with quality systems contained within the Code of Federal Regulations (GxP and DHHS regulations), Malcolm Baldrige National Quality Award, International Organization for Standards, Total Quality Management, and International Conference on Harmonization, FDA Quality System Inspection Technique, National Committee for Quality Assurance and The Joint Commission for Accreditation of Healthcare Systems.

MSRC 405-DL Applied Research and Writing (1 Unit)

This course provides a foundation for writing academic and technical papers, affording students the opportunity to recognize and address the strengths and weaknesses in their own critical thinking and writing skills. The course emphasizes logical argument development, structure, clarity of thinking, and effective use of documentation. Students learn to evaluate the strengths and limitations of various research methods and how to select the best method for a given task.

MSRC 435-DL Risk and Decision Management (1 Unit)

This course explores theories and practical applications of risk management, risk communication, decision management, and crisis management in life science industries. Topics include failure modes and effects analysis; fault-tree analysis; human factors analysis, and hazard analysis and critical control points. Students learn to anticipate and avoid risk and hazards and manage those that arise in a holistic manner.

MSRC 481-DL Leadership in the Regulatory Environment (1 Unit)

Topics include leading teams, communication strategies, and navigating the particular challenges of the regulatory environment.

MSRC 498-DL Capstone (1 Unit)

he capstone project course is the culmination of the MSRC program and demonstrates to faculty a student's mastery of the curriculum and core competencies in the regulatory field. Assignments are chosen by the instructor. Students are individually assessed and graded throughout duration of the ten week class. Students should retain all course material from previous classes in the program, including textbooks, to successfully complete assignments.

Prerequisite: 9 courses and a 3.0 GPA.

MSRC 499-0 Independent Study (1 Unit)

Independent study.

MSRC 590-0 Thesis Research (1 Unit)

Independent thesis research.

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.