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/sps/graduate/regulatory-compliance/regulatory-compliance-ms-healthcare-specialization/)
- Clinical Research (https://catalogs.northwestern.edu/sps/graduate/regulatory-compliance/regulatory-compliance-ms-clinical-research-specialization/)
- Quality Systems (https://catalogs.northwestern.edu/sps/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/sps/graduate/regulatory-compliance/regulatory-compliance-ms/)
- Regulatory Compliance, MS Clinical Research Specialization (https://catalogs.northwestern.edu/sps/graduate/regulatory-compliance/regulatory-compliance-ms-clinical-research-specialization/)
- Regulatory Compliance, MS Healthcare Compliance Specialization (https://catalogs.northwestern.edu/sps/graduate/regulatory-compliance/regulatory-compliance-ms-healthcare-specialization/)
- Regulatory Compliance, MS Quality Systems Specialization (https://catalogs.northwestern.edu/sps/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 have a knowledge of statistics before taking this course.

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)**
The 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 the course. 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.