Regulatory Compliance

Choose from program tracks in healthcare compliance, clinical research or quality and regulatory science.
Expand your professional opportunities in this increasingly important and sensitive field

MASTER OF SCIENCE IN 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 these core competencies while also stressing practical applications within the program’s three tracks: healthcare compliance*, clinical research and quality and regulatory science.

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 Memorial Hospital, the Northwestern University Feinberg School of Medicine and the Northwestern University Clinical and Translational Science Institute supplies the curriculum with the latest insights on healthcare, translational research and regulation.

* MSRC is a CCB (Compliance Certification Board) accredited program for students in the healthcare compliances specialization. HC specialization students who complete the degree are exempt from the work-experience eligibility requirement and can sit for all seven of the healthcare compliance and general industry compliance and ethics exams.
The Master’s in Regulatory Compliance requires the completion of 11 courses. This covers four core courses, four courses corresponding to a declared program track, one cross-elective track course, one leadership course and a capstone (498) or thesis (590) project. Program tracks allow students to tailor their studies to specific career goals. Current students should refer to curriculum requirements in place at time of entry into the program.

**CORE COURSES (4 COURSES)**
- MSRC 401 Quality Systems
- MSRC 405 Research & Writing
- MSRC 409 Biostatistics
- MSRC 435 Risk and Decision Management
- LEADERS 481 Leadership
- MSRC 590 Thesis Research

**TRACK COURSES (4 COURSES)**
Students choose, at time of admission, one of the following tracks in healthcare compliance, clinical research or quality systems, designed to help students develop their industry expertise effectively.

**LEADERSHIP COURSE (1 COURSE)**
SPS strives to equip its students with fundamental skills in effective leadership, communication, innovation and change management. To gain exposure to theories and best practices in these administrative areas, MSRC students join other SPS graduate students in a 10-week leadership class. With these skills complementing the core curriculum, graduates are better prepared to face the challenges of the modern workplace.

**CLINICAL RESEARCH TRACK**
Students specializing in clinical research are given a solid framework from which to understand clinical research. A graduate’s understanding of clinical study 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.
- CLIN RES 400 Essentials of Initiating Clinical Research
- CLIN RES 401 Responsible Conduct of Research
- CLIN RES 402 Drug and Device Development, QARS 450 Medical Device Regulations or QARS 460 Drug and Biologics Regulations
- CLIN RES 403 Clinical Research Design and Methodology

**HEALTHCARE COMPLIANCE TRACK**
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 specialization 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.
- HC COM 410 Healthcare Regulatory Environment
- HC COM 411 Healthcare Compliance Programs
- HC COM 412 Healthcare Regulatory Enforcement
- HC COM 413 Healthcare Billing Models and Systems

**QUALITY SYSTEMS TRACK**
Rapid technological advances and increased globalization have spurred government and industry regulations. The changing environment has transformed job and performance expectations for chemists, scientists, technicians and managers. Students in the quality systems specialization 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.
- QARS 420 Practical Quality Management
- QARS 421 Applied Quality and Regulatory Practices
- QARS 425 Quality Assurance Project Management
- QARS 450 Medical Device Regulations or QARS 460 Drug and Biologics Regulations

Visit [sps.northwestern.edu/msrc](sps.northwestern.edu/msrc) for course descriptions, schedule information and faculty bios.
MENTORING PROGRAM
MSRC provides students with access to industry and healthcare system mentors who support and guide their professional development. Mentors can help students by guiding their professional growth — including enhancement of professional network connections — clarifying career goals and addressing career challenges. Students have the opportunity to work with mentors with roles that include medical writer, clinical research director, clinical research education director, clinical research compliance director, VP of development and regulatory affairs, documentation and reimbursement specialist.

INTERNSHIPS
MSRC offers its students unique access to professional internships in regulatory compliance, healthcare compliance, quality systems, and clinical research that enhance both their career and academic goals. Students choose among MSRC-affiliated internships at organizations and companies at the forefront of industry, such as GE Healthcare and Northwestern Memorial HealthCare. Students may consult with an MSRC mentor or academic adviser to choose an internship right for them in areas such as quality, regulatory compliance, clinical research, finance and product development.

CAREERS
MCRC graduates work in the entire spectrum of research — from clinical trials to management and compliance. They also work across the employer spectrum — from research clinics and academic medical centers to clinical research organizations, other research service providers to pharmaceutical companies. Their education skills often qualify them for careers in overlapping research and regulatory fields.

ACCREDITATION
MSRC is a CCB (Compliance Certification Board) accredited program for students in the healthcare compliance specialization. HC specialization students who complete the degree are exempt from the work-experience eligibility requirement and can sit for all seven of the healthcare compliance and general industry compliance and ethics exams:
• Certified in Healthcare Compliance (CHC)
• Certified in Healthcare Research Compliance (CHRC)
• Certified in Healthcare Privacy Compliance (CHPC)
• Certified in Healthcare Compliance Fellowship (CHC-F)
• Certified Compliance and Ethics Professional (CCEP)
• Certified Compliance and Ethics Professional-International (CCEP-I)
• Certified Compliance and Ethics Professional Fellowship (CCEP-F)

Quality Systems specialization students will have the knowledge they need to sit for the ASQ Six Sigma Green Belt certification exam after completing the degree. ASQ certification increases the potential for a higher salary and demonstrates proficiency in the quality and regulatory science fields.

The MSRC program was presented at the Clinical and Translational Science Award (CTSA) Consortium Steering Committee in December, 2013. The MSRC degree program abstract, Training the Clinical and Translational Workforce of Tomorrow, was selected from abstracts submitted by all sixty CTSA nationally as one of eleven to be orally presented at the 2013 national meeting held in Washington, DC. The MSRC program successfully meeting one of the primary goals of the CTSA, to increase the skills of the clinical and translational research workforce and provide them with career pathways to retain them in industry and academia.
Applicants must hold a bachelor’s degree from a regionally accredited institution or its foreign equivalent. A competitive undergraduate record that indicates strong academic ability is required. Work or research experience in a related field is highly desirable but not a requirement for admission. The Graduate Record Examination (GRE) is not required, but strong scores bolster chances for admission.

APPLICATION CHECKLIST

• Online application — access from sps.northwestern.edu/msrc and then click “Start Application Process”

• $75 nonrefundable application fee

• One sealed copy of official transcripts from ALL attended colleges and universities

• Official transcripts must arrive in our office in the original sealed envelope issued by the institution. Northwestern University School of Professional Studies accepts electronic transcripts from U.S. institutions via secure electronic transcript providers. Consult with your institution to see if they are part of a secure e-delivery network. All electronic transcripts should be sent to spsadmissions@northwestern.edu. Please note transcripts are not accepted by fax or personal email.

• Applicants with international transcripts must request an official course-by-course evaluation of transcripts from a NACES member such as WES or ECE. A course-by-course evaluation will translate courses, degrees and grades to U.S. equivalency.

• Two letters of recommendation focusing on academic achievement and ability

• Statement of purpose (see following)

• Current resume or curriculum vitae

STATEMENT OF PURPOSE

Applicants must submit a 300-word statement of purpose explaining how the program will help them meet their academic and professional goals. Those without previous education or training in a related field should explain how other academic and nonacademic experiences have equipped them to undertake graduate study in the program.

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<th>Application Deadlines</th>
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<td>Applications are accepted every quarter.</td>
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<td>FALL: July 15</td>
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<td>WINTER: October 15</td>
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<td>SPRING: January 15</td>
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<td>SUMMER: April 15</td>
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For detailed admission information visit sps.northwestern.edu/msrc
For application assistance call 312-503-2579.
“The understanding I gained of how clinical research works has given me a leg up over my classmates in medical school, and it will give me a major advantage when I enter my medical residency.”

Alex Dew, MD (MSRC ’11); resident, U.S. Army

“The program helped me to hit the ground running when I accepted my current position. There’s almost no responsibility I have now that I didn’t first encounter in the MSRC program”

Brynnan Foster (MSRC ’11), clinical research specialist
About

The MS in Regulatory Compliance is offered by Northwestern University School of Professional Studies in partnership with the Northwestern University Feinberg School of Medicine, Northwestern Memorial Hospital and the Northwestern University Clinical and Translational Science Institute.

NORTHWESTERN UNIVERSITY SCHOOL OF PROFESSIONAL STUDIES
Northwestern University School of Professional Studies (SPS) students are part of a unique and distinguished university community. They learn in a supportive, collaborative environment in evening and online courses that enable them to balance their personal and professional lives with the pursuit of learning. Classes are taught by some of the university’s most respected and talented teachers — scholars and professionals who value the diversity, energy and creativity of our students.

One of the 12 colleges and schools of Northwestern University, SPS and adult learning have been a core part of Northwestern’s mission for more than 80 years. SPS is enmeshed in many parts of the University — sharing faculty members, creating innovative programs and setting the standard for higher education for adults.

NORTHWESTERN UNIVERSITY CLINICAL AND TRANSLATIONAL SCIENCES INSTITUTE
The NUCATS Institute is an integral link in Northwestern University’s clinical and translational research enterprise, accelerating translational innovation by providing research teams with consultative resources and expertise. The Institute is a member of the Clinical and Translational Science Award (CTSA) consortium, an initiative led by the National Institutes of Health.

NUCATS functions as an integrated hub supporting and accelerating clinical and translational science across Northwestern University, our three nationally-renowned clinical partners, our Chicago community and stakeholders, and the broad consortium of CTSA-funded institutions.

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE
Northwestern University Feinberg School of Medicine, founded in 1859, attracts talented individuals to its faculty, staff, and student body through its cutting-edge research initiatives, superb clinical affiliates, global outlook, and innovative curriculum.

Feinberg has built a national reputation for excellence through a strong history of collaborative, interdisciplinary medical education and research, and along with Northwestern Memorial Hospital and Northwestern Medical Group is part of the premier academic medical center known as Northwestern Medicine.

Feinberg stands out among the nation’s research-intensive medical schools and consistently receives high marks in U.S. News & World Report surveys. Through its affiliates, it provides patient care to thousands of individuals every year, and plays an integral part in the communities it serves.
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