REGULATORY COMPLIANCE, MS QUALITY SYSTEMS SPECIALIZATION

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. The quality systems specialization 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.

Quality Systems specialization students will have the knowledge they need to sit for the ASQ Six Sigma Green Belt (https://asq.org/cert/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.

Curriculum

Core Courses (6 units)

Course	Title
MSRC 401-DL	Quality Systems
MSRC 405-DL	Applied Research and Writing
MSHA 409-DL	Statistical Analysis
MSRC 435-DL	Risk and Decision Management
MSRC 481-DL	Leadership in the Regulatory Environment
MSRC 498-DL	Capstone
or MSRC 590-0	Thesis Research

Specialization Courses (4 units)

Course	Title
QARS 420-DL	Practical Quality Management
QARS 421-DL	Applied Quality & Regulatory Practices
QARS 425-DL	Quality Assurance Project Management
QARS 450-DL	Medical Device Regulations
or QARS 460-DL	Drug and Biologics Regulations

Cross-Specialization Elective (1 unit)

Course	Title
Choose one	
CLIN_RES 400-DL	Essentials of Initiating Clinical Research
CLIN_RES 401-DL	Responsible Conduct of Research
CLIN_RES 403-DL	Clinical Research Design & Methodology
HC_COM 410-DL	Healthcare Regulatory Environment
HC_COM 411-DL	Healthcare Programs and Enforcement
HC_COM 413-DL	Healthcare Billing Models & Systems
HC_COM 415-DL	IT Systems Compliance

About the Final Project

Students pursue their capstone experience independently or as part of a team. As their final course, students take either the individual research project in an independent study format or the classroom final course in which students integrate the knowledge they have gained in the core curriculum in work assigned by the instructor. In both cases, students are guided by faculty in exploring the body of knowledge on regulatory compliance while contributing research of practical value to the field. The capstone independent project and capstone class project count as one unit of credit.

Course	Title
Choose one	
MSRC 498-DL	Capstone
MSRC 590-0	Thesis Research