

# REGULATORY COMPLIANCE, MS CLINICAL RESEARCH SPECIALIZATION

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.

## 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 or MSRC 590-0	Capstone Thesis Research

### Specialization Courses (4 units)

Course	Title
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
QARS 450-DL or QARS 460-DL	Medical Device Regulations Drug and Biologics Regulations

### Cross Specialization Elective (1 unit)

Course	Title
<b>Choose one</b>	
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
QARS 420-DL	Practical Quality Management
QARS 421-DL	Applied Quality & Regulatory Practices
QARS 425-DL	Quality Assurance Project Management
QARS 450-DL or QARS 460-DL	Medical Device Regulations <sup>1</sup> Drug and Biologics Regulations

<sup>1</sup> Whichever of the two courses (450 or 460) that was not taken as part of the specialization

## 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
<b>Choose one</b>	
MSRC 498-DL	Capstone
MSRC 590-0	Thesis Research