

MASTER OF REGULATORY COMPLIANCE (MSRC)

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 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.