

QUALITY ASSURANCE & REGULATORY SCIENCE (QARS)

biological products. Students examine the newly implemented steps to harmonize international regulations. Students who complete this course will be prepared to research, identify and track the status of the regulations and guidance documents that impact the drug and/or biologics life cycle, as well as serving as valuable cross-functional team members representing regulatory affairs in a clinical operations setting.

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.

QARS 421-DL Applied Quality & Regulatory Practices (1 Unit)

Explores quality standards and compliance regulations governing the manufacture and quality control testing of products with a focus on the laboratory setting. Emphasis on the laboratory function, course covers how controls are identified and implemented, including quality control testing in accordance with Good Manufacturing Practices (GMP). Topics include design control, risk management, equipment qualification and validation, out-of-specification results, the CAPA (corrective action and preventive action) system, supplier controls, change control, and document control. By the end of the course, students will have demonstrated the ability to synthesize knowledge to create a comprehensive plan to control and test product quality.

QARS 425-DL Quality Assurance Project Management (1 Unit)

Students will gain and apply skills in developing and leading projects that create value in any area, but with specific focus on improving quality, service, and regulatory compliance. Apply critical thinking to projects and determine which tools to use from a broad array of proven methodologies. Review current research in effective project management. Review of Total Quality Management (TQM), Malcolm Baldrige Criteria, and ISO Quality Management Systems will be performed to ensure that projects can deliver results that create the highest value by supporting the overall objectives of a quality/regulatory organization. Key concepts of leadership, talent management, and risk management will be integrated for successful project management.

QARS 450-DL Medical Device Regulations (1 Unit)

Provides an analysis of global medical device development and approval requirements, concentrating on the preparation of global medical device strategies. Covers the medical device classification and regulation by ministries of health around the world. FDA regulation of medical devices including Investigational Device Exemption (IDE), 510(k), and PMA will be taught as a foundation for looking at global regulatory submission pathways. In addition to FDA regulations, covers medical device regulations for the European Union, Canada, and other major markets. Students will be exposed to common post-market challenges such as change control and import/export issues.

QARS 460-DL Drug and Biologics Regulations (1 Unit)

Students in this quality systems course discuss current policies and guidelines under which pharmaceutical, biological and medical device products are developed for human use and regulated while in commerce. Topics include regulatory requirements for patented and generic pharmaceuticals, over-the-counter drugs, legal and ethical issues, and