

# ST. CLOUD STATE UNIVERSITY

## College of Science and Engineering

### Proposed Program Summary:

## Master of Science in Medical Technology Quality (MS-MTQ)

This medtech industry focused program is designed to provide students with the necessary tools and competencies needed to be effective professionals and leaders in medical technology Quality. It will build a solid foundation for students wishing to enter this profession and help to expand and strengthen the knowledge of current Quality professionals. The program focuses on the fundamentals of Quality for the medtech industry, the medtech Regulatory impact, Quality Systems development and implementation, design and manufacturing process development and validation, and the overall management of Quality for the medtech industry.

- All courses are required for degree completion.
- The program is designed for working professionals and will be taught on evenings and weekends by medical technology industry quality professionals in collaboration with university professors
- Courses will also be offered on a standalone basis for non-degree students.
- Program courses will be offered at the SCSU Twin Cities Graduate Center, in Maple Grove.
- If the program is approved, courses will be offered starting in 2012.
- The program is designed to be completed in two years with two classes each fall and spring semesters and one each summer.

Course #	Course Title	Semester	Credits
<b>Foundational Courses for Medical Technology Quality:</b>			
MTQ-620	Medical Device Quality & Regulatory Fundamentals	1	3
MTQ-622	Quality Engineering	2	3
MTQ-624	Risk Management	2	3
MTQ-626	Medical Technology Quality Systems	1	3
<b>Design and Process Development and Validation:</b>			
MTQ-628	Design Control & Product Development	3	4
MTQ-630	Design Verification, Validation, & Clinical Evaluation	4	3
MTQ-632	Manufacturing Process Development & Validation	4	3
<b>Quality Systems Execution and Application:</b>			
MTQ-634	Corrective Action and Preventive Action (CAPA)	5	3
MTQ-636	Process Control & Monitoring	5	3
MTQ-638	Supplier Development and Management	6	3
MTQ-698	Culminating Experience	4-6	2

## **Course Descriptions:**

**MTQ 620: Medical Device Quality and Regulatory Fundamentals:** Introduction to basic concepts of quality and medical device regulatory requirements for both FDA and international regulations and standards. 3 Credits

**MTQ 622: Quality Engineering:** Quality tools and applications in design and manufacturing of medical devices, application of predictive statistics for sampling, statistical process control, and how to address multiple variables through Design of Experiments (DOE). 3 Credits

**MTQ 624: Risk Management:** Risk management process in the development and use of medical devices to protect patients, operators, and medical professionals from harm. Applicable standards, regulations, methods, and tools for identifying, analyzing, and controlling risks/hazards. 3 Credits

**MTQ 626: Medical Technology Quality Systems:** Medical technology Quality Management Systems application, management responsibilities, planning concepts, relevant US and international standard requirements, and current document control processes in the development, manufacture and distribution of medical devices. 3 Credits

**MTQ 628: Design Control and Product Development:** FDA and ISO design control requirements for medtech product development, translation of user needs into product design, risk management in the design process, and how design reviews and using a phased approach help assure designs are safe, robust, and effective. 4 Credits

**MTQ-630: Design Verification, Validation, and Clinical Evaluation:** Expand on design control requirements by focusing on design verification, design validation, and clinical studies using FDA Quality System Regulation (CFR Part 820) and ISO 13485 requirements and how risk management, statistical sampling, and technical reporting are interwoven. Also learn how end user needs are confirmed via design validation and clinical studies. 3 Credits

**MTQ 632: Manufacturing Process Development and Validation:** Use of Quality Tools to validate that a manufacturing process is well characterized, tested, capable, and controlled to demonstrate compliance, control risks and costs. Also, developing manufacturing processes, characterization, and optimization using Designed Experiments and determining sample size, protocol, report writing, and ongoing validation requirements to insure product quality. 3 Credits:

**MTQ 634: Corrective Action and Preventive Action (CAPA):** Methodologies medical technology companies use to prevent product failures, anticipate potential problems, and correct them when they occur as well as approaches for continuous Quality improvement. 3 Credits:

**MTQ 636: Process Control and Monitoring:** Fundamentals and application of Process Control and Monitoring Principles towards maintaining process capability and output quality through statistically-based process control and monitoring plans and reaction plans. 3 Credits:

**MTQ 638: Supplier Development and Management:** Select and develop productive relationships with suppliers. Audit and rate suppliers, create specifications that are complete and understandable, and learn how to work with suppliers on corrective actions and create effective quality agreements. 3 Credits

**MTQ 698: Culminating Experience:** Culminating project, starred paper, and seminar. Student will develop, carry out and report [in written and oral format] on an individual research project related to the content of the program courses.

Project requires approval of instructor. If an industry related research project cannot be identified an alternative is a research paper demonstrating integration and understanding of information

acquired in at least three courses, a comprehensive written examination covering medical technology quality regulations and standards, and an oral examination demonstrating Quality leadership and critical thinking. **Prerequisite:** This course can be started earlier but cannot be completed before the final semester of the program. 2 Credits