St. Cloud State University

Master of Science
in
Medical Technology Quality
(MSMTQ)

www.msmtq.com

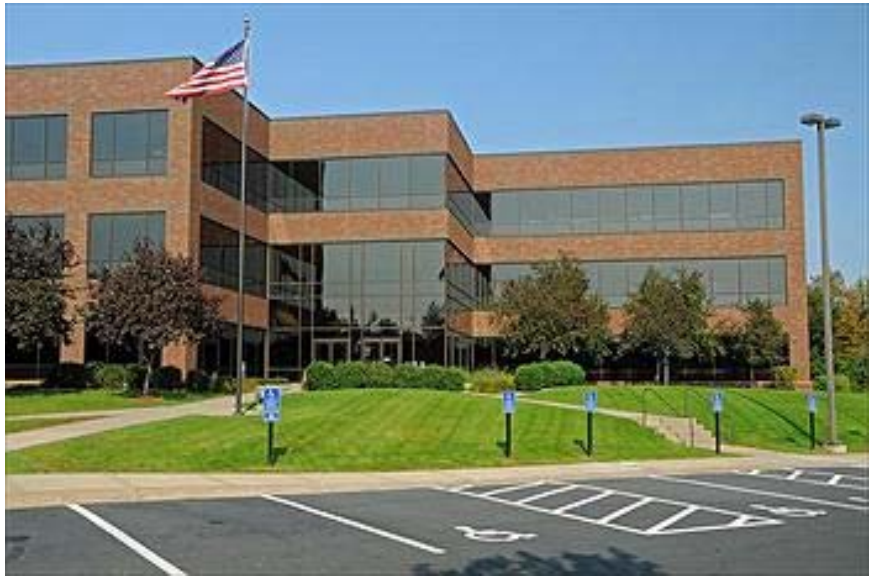
St. Cloud State University:

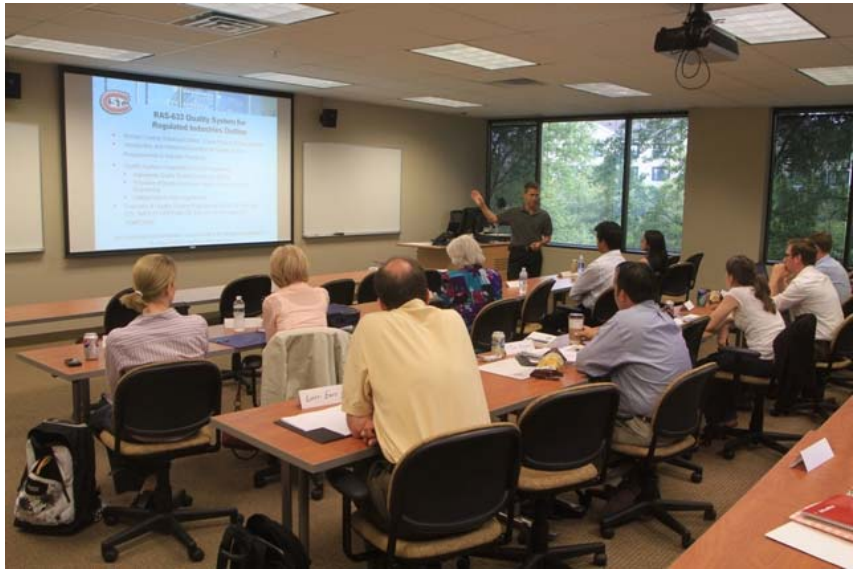
- 2nd largest University in MN & largest MnSCU
- Over 16,000 students
- MnSCU system > 250,000 students
- SCSU charter includes focus on applied education
- Twin Cities Graduate Center (TCGC) opened in 2009
- TCGC offers **MSMTQ, MSACR**, **MSRAS**, & other degrees

SCSU
Twin Cites Graduate Center:

Maple Grove at:
6401 Sycamore Ct. N.

Near the intersection of:
I-494 & Bass Lake Road





College of Science & Engineering

Masters in Medical Technology:

Started in: 2007	2010	2012
Master of Science In Regulatory Affairs & Services	**Master of Science In Applied Clinical Research**	**Master of Science In Medical Technology Quality**
Director: Chuck Swanson	**Associate Director:** Patty Feulner	**Associate Director:** Brian Rembish

Master of Science in Medical Technology Quality

- Unique new program & curriculum, focused on meeting medtech industry needs
- Probably no equivalent program in the world
- Designed by medical device industry Quality leaders & experts in collaboration with academia.
- Designed as a win/win/win for students/industry/University
- Program focus on providing very strong applied learning

Medtech Program Creation:

- **SCSU Medtech Industry Advisory Board:**
  - Initial advisory group started in late 2005
  - Formal Advisory Board established in Fall 2007
  - Made up of top industry leaders in Regulatory, Clinical, and Quality http://stcloudstate.edu/ras/advisoryboard.asp
  - Identified programs as critical education needs for the industry
  - Helped connect SCSU with other industry experts
  - Reviewed & provided vital feedback on the program designs
  - In 2008 the Advisory Board identified the need for Quality education
  - The Quality Education Committee was assembled in June 2009

Advisory Board Members:

(Current)

- **Vicki Bebeau**, Vice President, Clinical Affairs, Velomedix
- **David Cannistraci**, VP of Regulatory Affairs, Coviden (ev3)
- **Susan Danielson**, Director of Regulatory Affairs & Quality, 3M
- **Will Donovan**, Division Quality Manager, 3M Dental
- **Mark DuVal**, Attorney, DuVal & Associates
- **Jeff Fecho,** VP of Global Quality, St. Jude Medical
- **Larry Getlin**, VP Legal, Corporate Compliance, & Quality, AMS (retired)
- **Chris Harrold,** VP of Quality, Medtronic
- **Debra Kridner**, VP Clinical Research & Regulatory Affairs, Sunshine Heart, Inc.
- **Michael Morton,** VP, Corporate Regulatory Affairs, Medtronic
- **Steve Norsted**, CEO & President, RCRI
- **Dan Schaber**, VP of Clinical Research, Medtronic CRDM
- **Steve Theissen**, Quality Assurance Director, American Contract Systems

Quality Education Committee

- **Steve C de Baca**, VP of Quality, Boston Scientific (now Global VP of Quality for Beckman Coulter)
- **Brett Demchuck**, VP of Quality, Vascular Solutions
- **Jeff Fecho**, VP of Quality, St. Jude (now Global VP)
- **Dr. Ben Baliga**, Director of Masters in Engineering Management, SCSU
- **Katie Foran**, Regulatory and Quality Manager, 3M Healthcare
- **Michael Geary**, Director of Quality Systems, ev3 (now Covidien)
- **Neil Anderson**, Senior Quality Manger, Nonin Medical
- **Steve Gompertz**, Quality Systems Manager, Vital Images
- **Jill Knudson**, Director, Product Reliability and Quality Engineering, ev3 (now Covidien)
- **Dave Pettijohn**, Commercial Release Manager, Medtronic
- **Sara Rottunda**, Senior Director of Audit and Quality Training, Medtronic
- **Brian Rembish**, President, MedTech Leadership, Inc.

Quality Education Committee

Objective: Develop the best Master's in Quality program content possible for the medical device industry

- A committee with a wide range of industry experience
  - Small and large companies
  - Class 1, 2, & 3 devices
  - Both senior and middle management in Quality
- Identify all key content areas from these multiple perspectives
- Roughly 100 topic areas were identified for the curriculum
- Developed the needed courses, curriculum, and delivery
- Major focus on applied learning

Quality Education Committee

- Final curriculum developed and submitted in fall 2011
- Full academic approval June 20th 2012
- Classes started fall 2012
- Classes taught on weekday evenings & Saturday mornings @ Maple Grove
  - Weekday evenings from 5:00 – 9:00 p.m.
  - Saturday mornings from 9:00 a.m. – 1:00 p.m.
- Degree designed to be completed in 2 years
- **Classes may also be taken on an independent basis**
- For more detailed info go to **www.msmtq.com,**

MS in Medical Technology Quality Program – Press Release

Jeff Fecho – VP Global Quality – St. Jude:

"In today's competitive environment, especially in the Minnesota medical device sector, identifying and hiring competent and well-informed personnel in the quality profession is becoming more and more difficult. The Medical Technology Quality program, coupled with the already active Regulatory and Clinical programs at SCSU, provides us with a readily available and credible source specifically geared toward the medical device industry. This program has global appeal and is a key educational component in assuring that our employees have what they need to keep us compliant and competitive."

Master of Science in

Medical Technology Quality

Graduate Objective: To become a medical device Quality expert in the full range of areas for this industry field.

Program Focus:

- Comprehensive understanding of medical product quality
- Regulatory impact
- Quality Engineering tools & skills
- Quality systems development & implementation
- Product design control, verification, and validation
- Manufacturing process development & validation
- Process control
- Supplier management
- Etc.

Master of Science in

Medical Technology Quality

Program Requirements

- Two Years/33 Credits
- Ten Core Courses
- Culminating Project

Expert Faculty

- Industry Professionals in Quality, Engineering, & Regulatory

Focus Primarily on Medical Devices

MSMTQ Curriculum – Year 1

Fall

- MTQ-620: Medical Device Quality and Regulatory Fundamentals (3 credits)
  - Introduction to basic concepts of quality and medical device regulatory requirements for both FDA and international regulations and standards.
  - Learn the principles & responsibilities of roles in medical device Quality

- MTQ-626: Medical Technology Quality Systems (3 credits)
  - Medtech Quality systems with emphasis on FDA-QSR and ISO-13485
  - Also covers Good Manufacturing Practices (GMP), Good Laboratory Practices, and Good Clinical Practices (GCP), etc.

MSMTQ Curriculum – Year 1

Spring

- MTQ-622: Quality Engineering (3 credits)
  - Develop solid understanding of quality tools and applications in both design & manufacturing of medical devices
  - Learning of statistics and applications including Six Sigma

- MTQ-624: Risk Management (3 credits)
  - Learning to understand and reduce potential device hazards and risks
  - Control risks and ways to monitor the effectiveness.

Summer

- MTQ-628: Design Control & Product Development (4 credits)
  - FDA & ISO requirements for design control of medical devices
  - Manage the integration of user needs and design process
  - Using a phased approach – help assure designs are safe, robust & effective

MSMTQ Curriculum – Year 2

Fall

- MTQ-630: Design Verification, Validation, and Clinical Studies
  - Evaluate and apply FDA-QSR & ISO-13485 requirements
  - Focus on design verification, validation and clinical studies

- MTQ-632: Manufacturing Process Development and Validation
  - Use of Quality tools to validate manufacturing processes to demonstrate compliance, control risks, and costs.
  - Design experimentation to characterize and optimize a manufacturing process, etc.

Spring/Summer

- MTQ-698: Culminating Project (2 credits)

MSMTQ Curriculum – Year 2

Spring

- MTQ-634: Corrective Action and Preventative Action (CAPA)
  - Device industry requirements and methods to avoid process and product nonconformance.
  - Manage customer complaints while meeting regulatory requirements.

- MTQ-636: Process Control and Monitoring
  - Application of principles towards maintaining process capability & output Quality.
  - Development and implementation of effective process control, monitoring and reaction plans.

Summer

- MTQ-638: Supplier Development and Management
  - Effectively assess, audit, & rate suppliers.
  - Develop productive relationships with suppliers & effective agreements
  - Clear and complete specifications

Value of This Degree

- Fills potential knowledge gaps vs. on-the-job training
- Gives students solid understanding in Quality fields
- Provides valuable knowledge for professionals:
  - looking to enter the medical product industry
  - or advancing in this profession
- Can help increase career success
- Program students in high demand from device industry
- Medtech Masters Job Fair attracts 15-20 companies – including the 6-7 industry largest in Minnesota

Single Course Value

Value for Individuals:

- Expanding capabilities & career options
  - Professionals in these fields or
  - Other functions
- Training for new or expanded responsibilities
- Training for new medical device professionals
- Give independent students a clearer perspective of the full degree.
- Can later be applied to taking the full degree

Degree Application Process:

Criteria:

- BS in science, math, engineering, or health care preferred.
- Three to five years of working experience preferred
- Completed application form

To Apply: Go online to: **www.stcloudstate.edu/mtq/apply.asp**

Timing:

- Degree applications due by June 1st, sooner is better
- Classes start this fall on 9/6/14

Questions: **Brian Rembish,** Associate Director of MSMTQ Program
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