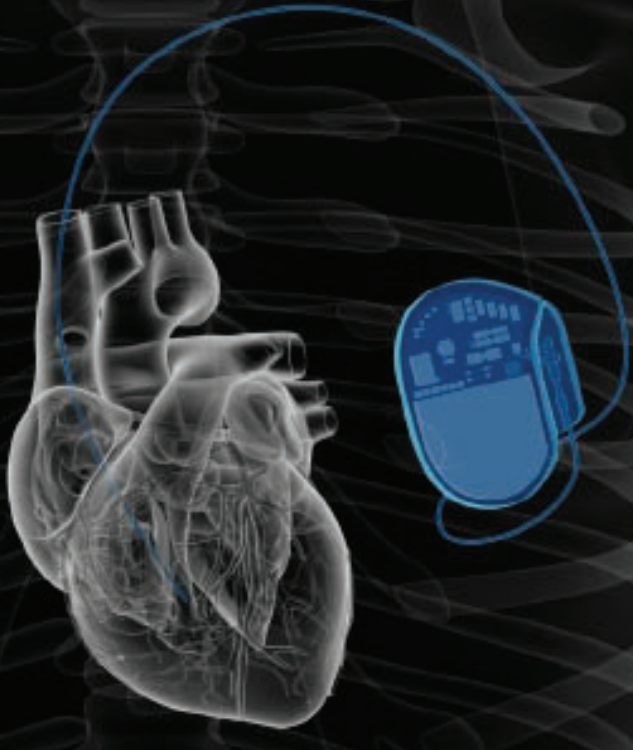
Master of Science in Regulatory Affairs and Services



The first in the country for medical devices.

Master of Science in Regulatory Affairs and Services

The regulatory affairs profession is critical to making safe and effective medical products available to patients worldwide.

St. Cloud State University's new M.S. RAS focuses on the specific educational and career development needs of employees responsible for managing the required regulatory approval processes in the medical device industry. The intent of the program is to prepare students to take leadership roles within the regulatory departments of medical device organizations.

Designed to meet the specific needs of working professionals, the classes are held evenings and weekends at North Hennepin Community College in the Twin Cities.

The program is organized to be completed in six semesters over two years.

For more information, visit:
www.msras.com

COURSES (33 credits):

Regulatory Affairs

RAS 621.	Legal Basis for Medical Device Product Regulation	3 credits
RAS 623.	Investigational Medical Device Regulations, Standards, and Guidelines	3 credits
RAS 625.	Regulatory Submission/Application Requirements for Medical Devices: Routes to Market	3 credits
RAS 627.	International Regulatory Affairs: European Union, Canada, Japan, and Australia	3 credits

Clinical Trials and Quality Systems

RAS 631.	Clinical Study Design, Implementation, and Analysis	3 credits
RAS 633.	Quality Systems for Regulated Industries	3 credits
RAS 635.	Regulatory Affairs Compliance	3 credits

Health Economics

RAS 641.	Health Policy and the Medical Technology Industry	3 credits
RAS 643.	Cost Management of Regulated Health Care Technology	3 credits
RAS 645.	Reimbursement for Medical Technology	3 credits

Culminating Experience

RAS 690.	Regulatory Affairs Culminating Project	3 credits

This course may be taken over one to three semesters, for a total of three credits. Required for degree completion.

ST. CLOUD STATE UNIVERSITY™

M.S. RAS Program Instructors and Developers

Charles "Chuck" Swanson, Ph.D. (Program Director)
Retired Vice President, Corporate Regulatory Affairs — Medtronic
- In 28 years at Medtronic provided strategic regulatory leadership and helped to shape FDA regulation of medical devices.

Maria Brittle, Ph.D., RAC
Director, Regulatory Affairs — Lumen Biomedical, Inc.
- 25 years in the medical device industry in regulatory and clinical affairs at several companies with numerous U.S. (PMA, 510k) and international submissions.

Steve C. deBaca
Vice President of Quality — Boston Scientific Corporation
- Responsible for the quality assurance system and over 400 person organization at Maple Grove/Plymouth, Minn., and two California facilities and for the design assurance functions for new product development for the Cardiovascular division.

Mark DuVal
President — DuVal and Associates, P.A.
- Over 15 years general counsel to 3M Pharmaceuticals, 3M Drug Delivery Systems, and later FDA and compliance counsel at Medtronic before starting his private practice specializing in FDA law and representing medical device, pharmaceutical and nutritional supplement companies.

Frank Freedman, Ph.D.
Consulting Partner – Alliancz Medical Consultants
- An adjunct professor at several Twin City academic institutions, he has over 30 years of experience involving medical device clinical studies and regulatory submissions.

Fred Halverson
Retired Vice President, Corporate Regulatory Strategy — Medtronic
- 30 years at Medtronic in regulatory affairs, helping to shape Medtronic's regulatory program and strategy with extensive experience in OUS regulatory strategy.

Mary Beth Henderson, Ph.D.
Principal Advisor — Regulatory and Clinical Research Institute, Inc. (RCRI)
- More than 20 years in the medical device and biotechnology industries with experience in global regulatory requirements, quality systems, product and process development, tech transfer & IP management.

Judith M. Hickey
President & Co-founder — Princeton Reimbursement Group
- More than 20 years in reimbursement and health care policy in the medical device and diagnostics industries.

Rich Jansen, Pharm. D.
President — Silver Pine Consulting
- 16 years specializing in spinal implant devices regulatory and clinical affairs. Previously a hospital pharmacist / clinical researcher and IRB chairman.

Mark Job
Owner / Reviewer — Regulatory Technologies Services, LLC
- Eight years performing third-party reviews of 510(k) under the FDA Accredited Person Program, completing more than 300 510(k) submissions.

Christopher Lyle, M.S.
Principal Advisor and Director of Biostatistics & Information Systems — RCRI
- Directs data analysis and database development for RCRI and consults on clinical trial design, analysis plan development and economic analyses.

Jennifer Marrone
Executive Vice President / Senior Principal Advisor & Co-founder — RCRI
- Significant experience in regulatory submissions and working with government to obtain IDE clinical study approval as well as pre-market approval (PMA) for many types of devices.

Carla Monacelli
Managing Partner & Co-founder — Argenta Advisors, LLC
- Nearly 20 years experience in policy, reimbursement and government affairs for the life sciences industries, including serving as the senior director of healthcare affairs for Conceptus Inc.

Sue Norenberg
Senior Principal Research Consultant / CRO Manager — Medtronic
- More than 25 years in the medical device industry, including R&D, clinical trial management, pre-clinical, IDE and post market domestic and international studies, as well as regulatory compliance.

Stephan Norsted, Ph.D., MPH
President and CEO — RCRI
- Epidemiologist who has worked in the design and analysis of clinical trials since 1980, is a frequent lecturer at national conferences and universities and is currently the president of one of the largest CROs in the US.

Susan Petersen-Stejskal
Vice President, Clinical Research — Cardiac Concepts, Inc.
- More than 25 years as research nurse clinician and manager and has three original panel track FDA PMA submissions with more than 20 PMAs requiring prospective clinical data.

Scott Sardeson
International Regulatory Manager — 3M
- With more than 12 years experience in the device industry, he currently manages registrations and assures compliance with 3M subsidiaries around the world.

Monica Schultz
Director of Reimbursement — RCRI
- More than 15 years in the medical device industry in reimbursement and post-approval studies and has served as research analyst for Blue Cross Blue Shield of Minnesota.

Deborah Shatin, Ph.D.
Principal — Shatin Associates, LLC
- More than 25 years in the health care industry including conducting domestic and international clinical trials at Medtronic and at UnitedHealth Group, directing pharmacoepidemiology studies, therapy safety surveillance for FDA, and health services research.

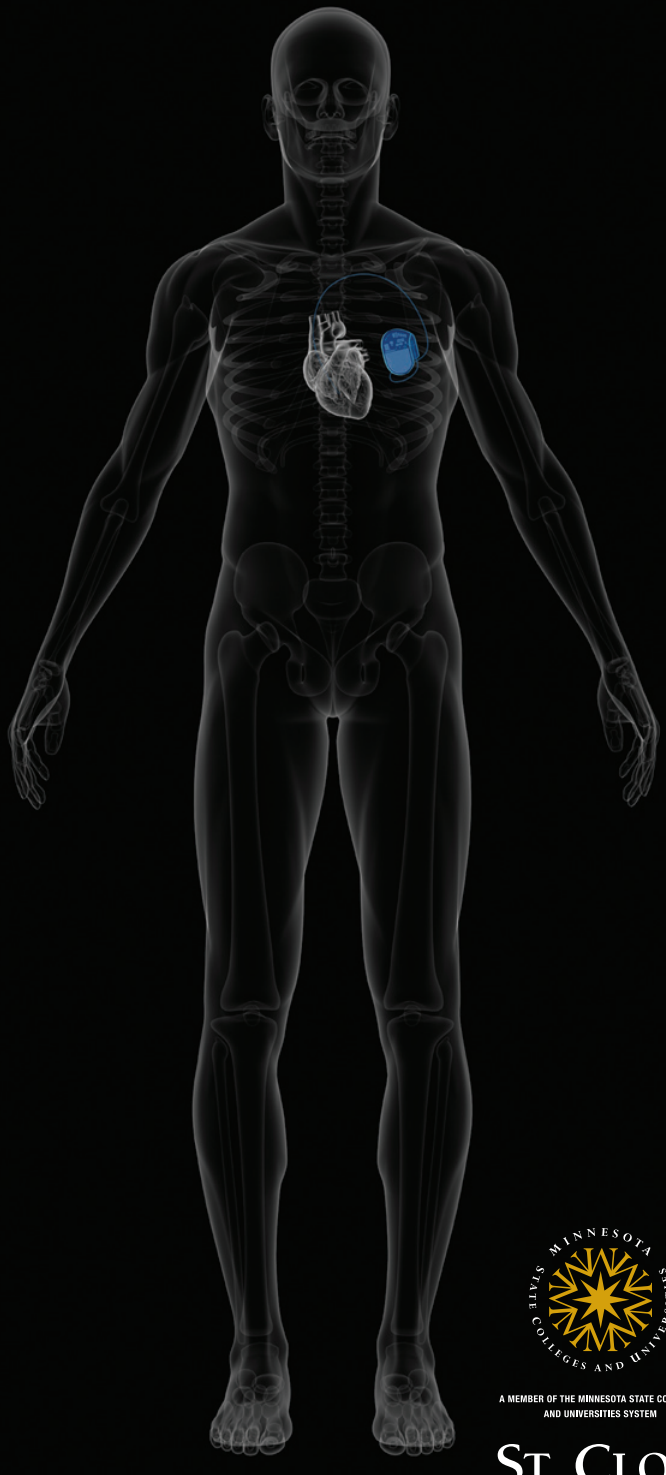
Charmaine Sutton
President and Principal Consultant — The Tamarack Group
- Expert in gaining market authorization of Class II and III devices and in development and implementation of ISO 13485 and FDA QSR quality systems.

David A. Teicher, Esq.
Associate Attorney — DuVal and Associates, P.A.
- Nearly 30 years in regulatory affairs starting as a biomedical engineer investigator with the FDA for 11 years, then device companies, and for the last three years as an attorney at DuVal.

Barb Veath
Senior Reimbursement Manager — Medtronic, CRDM
- Over 20 years in the health care industry currently focusing on clinical trial reimbursement compliance and health policy for Medtronic's Cardiac Rhythm Disease Management Division.

Richard R. Wilson, M.D.
- Over 30 years in developing drugs and medical devices.
- Medical director and chief medical officer for pharmaceutical and medical device firms.
- Co-founder of three medical device companies.

Winifred Wu
Vice President, Regulatory Affairs and Vigilance — Medtronic, Neuromodulation
- More than 25 years in the device and pharmaceutical industries in regulatory, clinical, quality and program management.



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