## Classes designed and taught by industry experts

- Distinguished professionals in regulatory affairs, reimbursement and biostatistics
- Insights and context derived from extensive experience bringing medical products to market
- Valuable networks of regulatory professionals and leaders
- Our faculty members are
   passionate about regulatory affairs,
   committed to student success and
   excited to be advancing careers in the medical device industry.



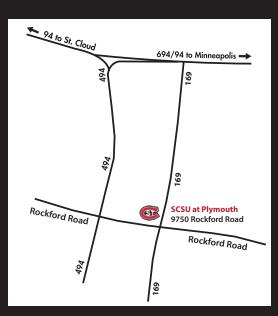
- · Board members are regulatory executives (past and present).
- Board members have vast global networks established when working at medical device companies such as 3M, Abbott, Boston Scientific, Medtronic, NeoVasc, RCRI, and Smiths Medical.

More information about each of our instructors and advisory board Members can be found online at www.msras.com.



Master's degree graduates with Director Cathy Krier, former Director Charles Swanson and Provost Dan Gregory

## Attend classes online or in person at St. Cloud State at Plymouth







### **MINNESOTA STATE**

St. Cloud State University,
A member of Minnesota State



#### For more information

320.308.2167 www.msras.com

ras@stcloudstate.edu

## College of Science and Engineering

145 Robert H. Wick Science Building St. Cloud State University 720 Fourth Avenue South St. Cloud, Minnesota 56301-4498 www.stcloudstate.edu/cose

cose@stcloudstate.edu

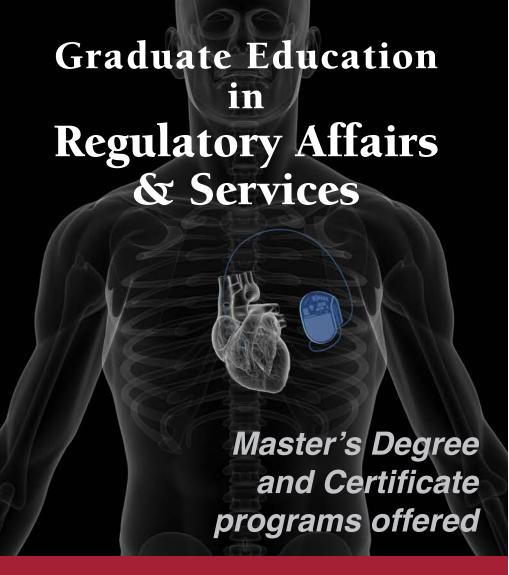
#### St.Cloud State at Plymouth

9750 Rockford Road, Suite 100 Plymouth, MN 55442 (Off Rockford Road and Hwy 169) www.stcloudstate.edu/plymouth



St. Cloud State University is committed to legal affirmative action, equal opportunity, access and diversity of its campus community. (http://scsu.mn/scsuoea)

## Classes now held in Plymouth, Minnesota







'Participating in the RAS program at St. Cloud State University opened an entirely new career path for me. Learning about the medical device regulatory profession was a challenging and engaging process. I have taken advantage of the opportunities and responsibilities that have come mv wav. None of this would have been possible without the knowledge that I obtained from the RAS program."

## www.msras.com

## It's about having options

#### For students in the Twin Cities and beyond...

- · In-person class held at the St. Cloud State at Plymouth academic center located in the Minneapolis suburb of Plymouth, Minnesota.
- Class participation is available in person and remote to engage students in synchronous class participation when traveling for work and for students located in other cities.
- · Courses are offered weekday evenings and Saturday mornings.

#### Three credential pathways...

- Graduate Certificate
  - Can be obtained in one year.
  - All coursework may be applied toward the MS degree.
- · Master's Degree full time program with internship
  - Can be obtained in two years.
  - The first year is focused on full time study.
  - The second year students devote approximately 20 hours per week to an industry internship.
- Master's Degree part time program with culminating project
  - Can be obtained in two years.
  - Designed for working professionals.
  - After completing 21 credits of coursework, students begin to work with their employer or a host company to complete a culminating project.

# Regulatory Affairs & Services Focusing on Medical Devices

The regulatory affairs profession is critical to ensuring safe and effective medical products are available to patients, and the demand for regulatory professionals is growing as medical product regulation expands worldwide.

The RAS program, now entering its ninth year, does more than teach medical product regulations. Our students learn how to:

- interpret and apply regulatory requirements to different types of medical products
- develop strategies to gain market approval for new products
- · keep marketed products in compliance.

RAS courses are taught by experienced industry professionals in regulatory, quality, clinical and reimbursement.

We are constantly striving to provide meaningful, relevant and up-to-date content that meets the needs of industry and our students. The RAS curriculum, focusing on medical devices, was developed under the guidance and support of our industry advisory board. Courses are reviewed annually to incorporate new and changing regulatory requirements.

If you are considering a career in regulatory affairs or looking to expand your expertise in this field, consider applying for the RAS master's program. Working in the highly regulated medical products industry also requires that the understanding of requirements extend beyond regulatory affairs. So, depending on their responsibilities, individuals in clinical, quality, product development, manufacturing and marketing may also benefit from individual RAS courses.

#### Courses Information

**RAS 621:** Legal Basis for Medical Device Product Regulation (3 credits)

RAS 623: Regulatory Routes to Market: 510(k)s (3 credits)

RAS 625: Regulatory Routes to Market: PMAs (3 credits)

RAS 627: International Regulatory Affairs: European Union, Eastern Europe, Australia and Canada (3 credits)

RAS 631: IDE Regulations and Clinical Trial Design (4 credits)

RAS 633: Quality Systems for Regulated Industry (3 credits)

**RAS 635:** Regulatory Affairs Compliance (3 credits)

RAS 641: Health Policy and the Medical Technology Industry (3 credits)

RAS 643: Reimbursement and Cost Management for Medical Technology (3 credits)

**RAS 651:** Regulation of Combination Products (3 credits)

RAS 653: Ethics in Regulatory Affairs and Clinical Trials (3 credits)

RAS 655: International Regulatory Affairs: Japan, Other Asia, Latin America and Middle East (3 credits)





## Things to consider

#### Qualifications

- Undergraduate GPA 2.75
- Bachelor's degree in engineering, science, biochemistry, biostatistics, public health, nursing, or other appropriate and relevant area is recommended
- Three to five years or more post-undergraduate working experience
- Completed application form
- Graduate school review and approval

#### Independent Enrollment

Courses may be taken on an independent basis without enrollment in the degree program.

To apply, visit the MSRAS website application page:

www.stcloudstate.edu/gradadmissions/application/default.aspx