

ST. CLOUD STATE UNIVERSITY

Major: Regulatory Affairs and Services

Application for Semester Program Approval: MASTER OF SCIENCE

Student ID Number _____ Date _____

Name in Full _____ Email address _____

Local Address _____
City State Zip

Local Phone _____ Business Phone _____

I request the following graduate courses be transferred from: **(Official transcripts of all transfer credits which have been completed are required in the Graduate Office before program can be approved)**

Name of College or University Address of College or University

| <u>Dept. and Course No.</u> | <u>Name of College or University</u> | <u>Sem./Qtr. Hours</u> | <u>Grade</u> | <u>Date Taken</u> |
|-----------------------------|--------------------------------------|------------------------|--------------|-------------------|
| _____ | _____ | _____ | _____ | _____ |
| _____ | _____ | _____ | _____ | _____ |
| _____ | _____ | _____ | _____ | _____ |
| _____ | _____ | _____ | _____ | _____ |
| _____ | _____ | _____ | _____ | _____ |

(The area below the broken line should not be filled in by applicant)

I certify that this student is eligible for the proposed program approval and that I approve the program outlined in this application.

Signature of Adviser _____

The program outlined in this application complies with the minimum course requirements set by this university for the Master of Science degree.

Signature of Graduate Dean _____

Student Notified: _____

PROPOSED SEMESTER PROGRAM OF GRADUATE STUDIES

Plan B (Minimum 33 Cr.)

Major: Regulatory Affairs and Services

| Dept. Number | Name of Course | Sem./Yr. | Credits | Grade |
|--|--|----------|---------|-------|
| Regulatory Affairs – Federal State Legislation | | | | |
| RAS 621. | Legal Basis for Medical Device Product Regulation | _____ | _3_ | _____ |
| RAS 623. | Regulatory Routes to Market: 510(k)s | _____ | _3_ | _____ |
| RAS 625. | Regulatory Routes to Market: PMA's | _____ | _3_ | _____ |
| RAS 627. | International Regulatory Affairs: European Union, Eastern Europe, Australia and Canada | _____ | _3_ | _____ |
| Clinical Trials and Quality Systems | | | | |
| RAS 631. | IDE Regulations and Clinical Trial Design | _____ | _4_ | _____ |
| RAS 633. | Quality Systems for Regulated Industries | _____ | _3_ | _____ |
| RAS 635. | Regulatory Affairs Compliance | _____ | _3_ | _____ |
| Health Economics | | | | |
| RAS 641. | Health Policy and the Medical Technology Industry | _____ | _3_ | _____ |
| OR | | | | |
| RAS 643. | Reimbursement and Cost Management for Medical Technology | _____ | _3_ | _____ |
| Culminating Experience | | | | |
| RAS 690 | Regulatory Affairs Culminating Project | _____ | _2_ | _____ |
| Elective Courses | | | | |
| RAS 651. | Regulation of Combination Products | _____ | _3_ | _____ |
| RAS 653. | Regulatory and Clinical Ethics Involving Medical Devices | _____ | _3_ | _____ |
| RAS 655. | International Regulatory Affairs: Japan, Other Asia, South America and Middle East | _____ | _3_ | _____ |
| RAS 657. | Advanced Reimbursement and Cost management for Medical Technology | _____ | _3_ | _____ |

TOTAL CREDITS: 33 GPA: _____

Total Credits in Program: _____

Signature of Applicant

PROGRAM REQUIREMENTS:

1. Credit limitation on transfer and extension credits (combined)--10 Cr.
2. Credit limitation on Workshop--Plan B, 7 Cr.
3. Required: one-half of minimum requirements for program must be completed in 600-level courses.