

**Commission on Graduate Studies and Policies
CGS&P Resolution 2006-07C
Resolution for the Establishment of a Master of Science Degree
in Biomedical Technology Development and Management**

Approved by GCC	October 26, 2006
Second Reading CGSP	February 7, 2007
First reading by University Council:	Waived by a $\frac{3}{4}$ affirmative Vote
Approved by University Council:	February 19, 2007
Approved by the President:	February 19, 2007
Approved by the Board of Visitors:	March 26, 2007
Effective Date:	Spring Semester 2008

WHEREAS, the aging of the population and the focus on health issues will drive demand for pharmaceuticals and medical devices, leading the Department of Labor to project a greater than 27% increase in biomedical industry employment opportunities between 2004 and 2014; and

WHEREAS, a significant shift is emerging in the way pharmaceutical and biotechnology innovations evolve that emphasizes multi-disciplinary research and thus multi-disciplinary training; and

WHEREAS, the focus of the proposed joint degree program will be on developing a cadre of well-rounded professionals, trained in integrating science with technology, management, ethics, and public policy, and possessing a variety of analytical tools including modeling and simulation for business decision-making; and

WHEREAS, the creation of this proposed joint degree between Virginia Tech and Georgetown University reflects the ongoing efforts of these two universities to create a mutually beneficial partnership; and

WHEREAS, the proposed degree program is consistent with Virginia Tech's strategic goal to "Enhance graduate and professional degree value through national partnerships and joint degrees."

THEREFORE BE IT RESOLVED that the Master of Science Degree in Biomedical Technology Development and Management be approved and the proposal forwarded to the President, the Board of Visitors, and the State Council of Higher Education for Virginia (SCHEV) for approval.

Master of Science Degree in Biomedical Technology Development and Management Proposal Summary

A significant shift is emerging in the way pharmaceutical and biotechnology innovations evolve and ultimately come to market. Industry insiders are arguing that a more integrated approach—one which brings together elements of discovery and development and emphasizes multidisciplinary research—is becoming the standard for realizing improved product quality and efficiencies of scale in bringing drugs and devices to market.

In response to future imperatives for medical product discovery and development, and the emerging needs of industry, regulatory agencies, and education therein, Virginia Tech and Georgetown University have committed to creating a world-class graduate level program built on integrating science with technology, management, ethics, and public policy.

1. Proposed Graduate Curriculum

The degree will require 30 semester hours to include either a 3-hour project and report option plus an elective course, or a 6-hour research and thesis option.

The core of the program consists of 18 credit hours as follows:

- Scientific Core Courses
 - COS 5204 General Human Physiology (2)
 - COS 5214 Human Immunology in Health and Disease (2)
 - COS 5224 Principles of Pharmacology (2)
 - MSE 4574 Biomaterials (3)
- BIT 5474 Computer Based Decision Support Systems (3)
- STAT 5674 Clinical Biostatistics (3)
- COS 5234 Preclinical & Clinical Product Evaluation (3)

Two complementary tracks address multiple career objectives:

Management of Information Technology Track (12 hours)

- BIT 5624 Program Management and Project Leadership (3)
- BIT 5654 Decision Making and Risk Analysis (3)
- COS 5994 Research and Thesis (3 or 6)
- Elective course (3) – *if selecting the 3-hour project and report option*

Discovery & Product Development Track (12 hours)

- COS 5244 Biomedical Device Discovery & Development (3)
- COS 5254 Drug Discovery and Product Development (3)
- COS 5994 Research and Thesis (3 or 6)
- Elective course (3) – *if selecting the 3-hour project and report option*

2. Learning Objectives

a. Assessment of Student Achievement

Each student will select a Graduate Advisory Committee to be approved by the program director. The committee will include track grades in individual courses as well as the students' progress towards completing their plans of study.

Each degree candidate must complete and successfully defend either a research paper or a project and report which demonstrates in-depth knowledge of a particular topic as well as the ability to analyze information, think critically and communicate effectively. The student's Advisory Committee will act as the examination committee.

b. Program Assessment

The advisory committee will continuously collect data to facilitate program assessment. This is necessary to allow the steering committee to make modifications that will improve outcomes. In addition to collecting numerical data on program outcomes such as program completion rates and time to completion, stakeholders will be asked for qualitative feedback to help generate specific suggestions for program enhancement.

1. Current Students. In addition to normal course evaluations, feedback from current students will be collected once a year about their experience with the program including course availability and program administration.
2. Alumni. One year and five years after graduation, alumni will be surveyed to determine their employment outcomes and to collect data on how appropriate their training was for the job they now hold.
3. Faculty. Faculty teaching in the program will be contacted yearly to give the program feedback on whether students have appropriate preparation (both in terms of courses taken prior to enrollment in this program and also preparation from courses in the program) to succeed in their courses and to provide the steering committee with other suggestions.
4. Industry Contacts. Employers of program alumni will be contacted at least six months after hiring new graduates for data on whether the skills of our graduates are appropriate to their needs. In addition, we will maintain a relationship with the FDA and persons in private industry to make certain that our program is staying current with trends in this field.

3. Relation to Other Programs

Across the United States and internationally, there are several centers and institutes offering certificate and graduate-level degree programs and conducting related scholarship in the areas of drug development, medical devices, clinical investigation,

drug development regulatory affairs, and pharmaceutical quality assurance. These programs are relatively few in number and relatively narrow in scope. None of the centers, institutes, and programs identified significantly mirror the mission and vision of the proposed Virginia Tech-Georgetown joint degree.

4. Justification for the Proposed Program

The creation of the joint degree between Virginia Tech and Georgetown University reflects the ongoing efforts of these two universities to create a mutually beneficial partnership. The partnership closely aligns with the strategic priorities of both institutions—a shared commitment to academic excellence and research that brings international acclaim. Within this stated commitment, each institution has identified a unique target for guiding resource decisions: Virginia Tech’s attainment of heightened research reputation; Georgetown’s successful implementation of the Medical Center’s “Restaging Plan.”

The focus of the educational programs will be on developing a cadre of professionals with superior competencies in a variety of analytical tools including modeling and simulation for business decision-making. The program will utilize a cross-discipline approach to address the industry-recognized need to produce well-rounded professionals, conversant in multiple disciplines.

5. The Needs of the Commonwealth

Research in biotechnology holds the potential to improve both the physical and economic health of the Commonwealth. Virginia has a track record of commitment to technology development that has successfully allowed the Commonwealth’s economy to replace old industries and maintain economic vitality. The Center for Innovative Technology, a nonprofit organization formed to support research and development leading to the creation of new technology companies, targets biotechnology as one of its strategic focus areas. Virginia is currently home to more than 175 biotechnology, equipment, pharmaceutical and medical device companies. The proposed degree program would support both existing business and future development by creating a skilled workforce that has received innovative training matching employer needs.

6. Evidence of Occupational Demand

The most compelling evidence of demand for graduates is that the Food and Drug Administration’s Center for Devices and Radiological Health has contracted with Virginia Tech and Georgetown University to offer this coursework to their current employees. Through a separate Memorandum of Understanding, the institutions have taught six semesters (11 courses) to a cohort of approximately 20 students. These students are receiving graduate credit and will enroll in this program once approved.

More broadly, the drug and medical product development industry in the United States comprises more than 2,500 places of employment, with companies engaging in a range of activities related to the design and development of pharmaceutical preparations or finished drugs, biological products, chemicals, and diagnostic products. According to the Bureau of Labor Statistics, Occupational Outlook Handbook 2002–2003 Edition, most of these organizations are pharmaceutical firms although government agencies such as the FDA and NIH have an ongoing need for specially trained graduates in these fields.

7. Revenue and Revenue Sharing

Because students will be able to enroll in this program at either Virginia Tech or Georgetown University, tuition rates must be consistent regardless of institution. Tuition will be set at a level commensurate with appropriate professional degrees. Revenue to each university will flow from tuition paid by individual students enrolled in a course given by that institution. In other words, revenue for Virginia Tech is based on the actual number of students taught, not on the number of students enrolled by Virginia Tech into the joint degree program.

The differential between Virginia Tech's tuition rate and the rate charged for the degree will be used to cover the direct and indirect costs of instruction. Additional revenues will be directed to the Provost's office for allocation.