March 4, 2014

MEMORANDUM

TO: Darryll Pines  
   Dean, A. James Clark School of Engineering

FROM: Elizabeth Beise  
       Associate Provost for Academic Planning and Programs

SUBJECT: Proposal to Establish a Regulatory Science and Engineering Option for the Post-Baccalaureate Certificate in Engineering (PCC log no. 13037)

At its meeting on February 7, 2014, the Senate Committee on Programs, Curricula, and Courses approved your proposal to establish a Regulatory Science and Engineering Option for the Post-Baccalaureate Certificate in Engineering. A copy of the approved proposal is attached.

The change is effective Fall 2014. Please ensure that the change is fully described in the Graduate Catalog and in all relevant descriptive materials, and that all advisors are informed.

MDC/

Enclosure

cc: Marilee Lindemann, Chair, Senate PCC Committee  
    Sarah Bauder, Office of Student Financial Aid  
    Reka Montfort, University Senate  
    Erin Howard, Division of Information Technology  
    Pam Phillips, Institutional Research, Planning & Assessment  
    Anne Turkos, University Archives  
    Linda Yokoi, Office of the Registrar  
    Alex Chen, Graduate School  
    William Fourney, A. James Clark School of Engineering  
    William Bentley, Fischell Department of Bioengineering  
    George Syrmos, Office of Advanced Engineering Education
College/School: ENGR
Please also add College/School Unit Code-First 8 digits: 01320101

Department/Program: Office of Advanced Engineering Education
Please also add Department/Program Unit Code-Last 7 digits: 1322302

Type of Action (choose one):

- Curriculum change (including informal specializations)
- Renaming of program or formal Area of Concentration
- Addition/deletion of formal Area of Concentration
- Suspend/delete program

Other

Summary of Proposed Action:

Creation of an academic option in Regulatory Science and Engineering to the existing Post-Baccalaureate Certificate in Engineering program through the Office of Advanced Engineering Education.

APPROVAL. SIGNATURES - Please print name, sign, and date. Use additional lines for multi-unit programs.

1. Department Committee Chair (William Bentley, Chair, BIOE)
2. Department Chair (George Syrmos, Executive Director, OAEE)
3. College/School PCC Chair (Lima Bucci) 12/12/13
4. Dean (Petri) 12/13/13
5. Dean of the Graduate School (if required) 2/18/14
6. Chair, Senate PCC
7. University Senate Chair (if required)
8. Senior Vice President and Provost
Proposal for a New Specialization in Regulatory Science and Engineering in the Post-Baccalaureate Certificate in Engineering Program

I. Overview and Rationale

We propose the creation of a Post-Baccalaureate Certificate in Engineering (GCEN) in Regulatory Science and Engineering academic option that will be a complement to the research work being done by the Clark School of Engineering’s Center of Excellence in Regulatory Science and Innovation (CERSI). The center is a collaborative partnership between the University of Maryland, College Park, and the University of Maryland in Baltimore. Researchers from both campuses work with FDA staff to support the development of new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products. Through the CERSI, researchers, regulators and industry professionals can learn from one another in the effort to develop regulatory science practices that promote innovation in medical devices and pharmaceuticals, while also addressing critical safety concerns. See their website for detailed information - http://www.cersi.umd.edu/. The GCEN in Regulatory Science and Engineering is part of the MPowering the State collaborative program as there is a sister program in Regulatory Science in the UMB School of Pharmacy that focuses on drug discovery, development and clinical research. The UMCP Clark School of Engineering program focuses on medical devices with the goal to create a new Professional Master of Engineering academic option.

This program is independent of the FDA but it is designed to be complementary to their efforts to train their future workforce. We are in communication with the FDA regarding this program and have received much support. Based on this, we hope that the relationship of this program to the FDA will grow to become a key strength of the relationship between the FDA and the UMD.

II. Program Audience

Based on our internal review, which included discussions with faculty, research sponsors, experts in industry and government as well as evaluation of competing higher education institutions, we believe there is a high-demand for engineers and technical professionals with a graduate level expertise in Regulatory Science and Engineering, specifically in medical devices. Through the CERSI Consortia Members (AdvaMed, Cannon Life Sciences, MDMA, Siemens, Waters, BD, Lockheed Martin, MedStar Health, SAIC, Weinburg Medical Physics) as well as with the FDA and NIH in our area we believe the demand will continue and grow. Additionally, Mtech’s Maryland Industrial Partner’s program is a resource that identifies companies and start-up companies that require assistance in biotechnology development. We expect to utilize their contacts in biotech companies to reach out to the local community about the certificate program.

III. Program Administration

This new academic option will be administered through the Office of Advanced Engineering Education (OAEE) making sure that the necessary student services are
provided. As with all programs in OAEE, curriculum and academic oversight for the core and elective courses in the series will be through a faculty advisory committee that will collaborate with the OAEE Executive Director, making sure that both commitment to support this new specialization and academic excellence are in place. Evaluation and assessment of this option will be performed by the faculty and more specifically the Department Chair of the Fischell Department of Bioengineering and/or Director of CERSI and OAEE (see the attached Assessment Plan approved for all OAEE academic options). The new specialization will comply with all UMCP policies and requirements for graduate admission, time of study, and graduation requirements.

IV. Curriculum

The curriculum presented represents a fundamental overview of regulatory science and engineering. Students in the GCEN – Regulatory Science and Engineering program (4 courses or 12 credits) will complete three core courses (BIOE689R Introduction to Regulatory Affairs: Devices and Drugs, BIOE689Q Clinical Study Data Analysis, and BIOE689S Regulatory Law – Medical Devices). The elective course may be taken from Bioengineering, Statistics or another area within the Clark School of Engineering. Each student will need to have the approval of the academic advisor for the GCEN. Professor Keith Herold, BIOE, will be the initial academic advisor for the Regulatory Science and Engineering academic option.

REGULATORY SCIENCE AND ENGINEERING CORE COURSES

**BIOE 689R Introduction to Regulatory Affairs: Devices and Drugs** (3 credits)
Course Description: This course provides an introduction to regulatory affairs as related to US FDA regulation of devices and drugs. It covers a summary of the FDA procedures necessary to obtain FDA approval of devices and drugs. It covers a summary of ethical and legal issues related to regulatory affairs. It touches on the relationship between regulatory affairs and science and engineering, highlighting the opportunities for technical input to the regulatory process.

**BIOE689Q Clinical Study Data Analysis** (3 credits)
Statistical analysis and supporting activities required for an FDA regulated clinical trial. Present insight and information about statistical analysis of clinical trial results and activities that support that effort in an FDA-regulated company. The class applies to drugs, biologics and medical devices. Primary efficacy variables and sample size calculations. Regulations about electronic records.

**BIOE689S Regulatory Law – Medical Devices** (3 credits)
An introduction to legal issues pertinent to medical device regulation, Topics will include device classification, general and special controls, quality system regulation, 510(k) applications, clinical trials, IDEs (investigational device exemption) and MDRs (medical device reporting), recalls, labeling/advertising, enforcement.

REGULATORY SCIENCE AND ENGINEERING ELECTIVE COURSE
With the approval of the academic advisor, any course from the following categories:
• BIOE 400 level or above
• Engineering, Physical Science, or Mathematics courses, especially Statistics at the 400 level or above

V. Budget Resources

The Office of Advanced Engineering Education is a self-support program and the GCEN programs are administered through its resources. OAEE began offering the GCEN in 2000 to meet the needs of professionals who may already have a graduate degree, but wanted to complete a highly-specialized curriculum without obtaining another full Master’s or Doctoral degree. There are now over 250 recipients of the growing list of twenty-one academic options for the GCEN. We offer courses on campus, at remote education sites in Maryland, and completely online through the state-of-the-technology Siegel Learning Center. You can learn more about our programs at www.advancedengineering.umd.edu.

VI. Current Status

We offered BIOE 689R in Fall 2013 and had an enrollment of 11, including a mix of undergraduate and graduate students, ENPM students and FDA professionals. We plan to offer BIOE689Q and BIOE689S in Fall 2014. These two courses are currently under development, with instructors identified for both and a plan to offer them online.

VII. FUTURE PLANS

We anticipate that this certificate will evolve into a Master's Degree program which we envision to have the following core courses. This list provides a summary of the body of knowledge expected of graduates from the program in the field of medical device regulation. The certificate program will include a subset of this knowledge. We anticipate introducing these courses at the rate of 1-2 per year starting now. Thus, we expect that the certificate students will select their electives from this list. However, particularly at the beginning, we anticipate a transition period where the initial students in the program may not have access to this full set to choose from. Thus, the certificate proposal is written with flexibility for the 4th course.

**Regulatory Science Courses:**
- BIOE689R Introduction to Regulatory Affairs
- BIOE689Q Clinical Study Data Analysis
- BIOE689S Regulatory Law – Medical Devices
- BIOEyyy Medical Device Bench Testing
- BIOEzzz Medical Device Animal Testing
- BIOEsss Technology Trends

**Fundamental Science Courses**
- BIOEfff Human Physiology
- BIOEggg Pharmacology

**Elective Courses - 2**
Program Goals:

1. Address the continuing education needs of working engineers and technical professionals.

2. Deliver this program in a variety of ways so to make it accessible regardless of location.

Relevance of goals to the mission statements and/or strategic plans of the University, College, or Program as applicable:

The goals of the Professional Master of Engineering (ENPM) Program are directly related to the Clark School’s mission, which is to address the continuing education needs of working engineers and technical professionals. In particular, ENPM is a practice-oriented, part-time graduate program designed to assist engineers and technical professionals in the development of their careers and to provide the expertise needed in the rapidly changing business, government, and industrial environments. The Graduates of the ENPM Program will have acquired sufficient knowledge to “retool” and keep current with the latest technological developments in their field, or perhaps to develop a new area of expertise so as to further their careers. The ENPM Program provides a variety of delivery methods where students can take a class live, either on campus or at a remote site, web-assisted, or completely online.

Student Learning Outcomes
(list the three-to-five most important)

<table>
<thead>
<tr>
<th>Assessment Measures and Criteria</th>
<th>Assessment Schedule</th>
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<tbody>
<tr>
<td>(describe one or more measures for each outcome and criteria for success)</td>
<td>(initial year, and subsequent cycle)</td>
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<tr>
<td>1. Demonstrate knowledge of advanced principles in engineering.</td>
<td>Criterion: 90% of the Master of Engineering students should have a GPA equal or greater than 3.0</td>
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<tr>
<td>Measure: GPA.</td>
<td>2006, each semester</td>
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|   | 2. Demonstrate continued retention of students and progress towards degree completion. | Criterion: 80% enrollment by existing students each semester  
Measure: Registrar's Enrollment Records. | 2006, each semester |
|---|---|---|---|
|   | 3. Demonstrate completion of degree program. | Criterion: 80% graduation rate of students within the five year limit for Masters students.  
Measure: Registrar's Graduation Records | 2006, each semester |
|   | 4. Anonymous evaluation by students of each instructor in a course for feedback on course instruction and content. Results are tallied and summarized (using a 4.0 grading system) for each instructor and comments typed by the office staff and given to each instructor to give feedback regarding their classroom instruction. | Criterion: achieve a 3.0 grade for all instructors.  
Measure: Course Evaluations | 2006, each semester |
|   | 5. Point-of-graduation survey. The survey is a web based survey. Graduating students, prior to then end of the semester are sent the web site in which to fill in the appropriate information and submit the survey electronically. The survey seeks to ascertain a student's experiences in the ENPM program regarding the quality of courses, the general program, faculty, and staff. The survey also collects information on employment (position, salary, etc.) at graduation. | Criterion: 50% response rate by graduating students  
Measure: Graduation Survey | 2006, each semester |