

VII. STANDING COMMITTEES

A. Academic and Student Affairs Committee

Establishment of the Master of Science in Biomedical Regulatory Affairs

RECOMMENDED ACTION

It is the recommendation of the administration and the Academic and Student Affairs Committee that the Board of Regents grant authority to the Department of Pharmacy, in the School of Pharmacy, to offer the Master of Science in Biomedical Regulatory Affairs degree program, effective immediately. The degree program will have provisional status with a review to be scheduled in the 2011-2012 academic year. At such time that continuing status is granted, a ten-year review cycle would begin.

BACKGROUND

In September 2006, the Graduate School received a proposal from the graduate faculty in the Department of Pharmacy requesting authority to offer the self-sustaining Master of Science in Biomedical Regulatory Affairs degree program. Implementation is planned for Autumn Quarter 2007, with the program anticipating 20 new students per year.

The MS in Biomedical Regulatory Affairs was designed in response to a need for comprehensively trained personnel in fields related to the creation, development, regulation, and manufacture of pharmaceuticals and medical devices. There has been recent rapid growth in biotechnology activity in the Puget Sound Region, but despite the industry's vigor and the need for experts in regulatory affairs, virtually no one is specifically prepared for the work. Two existing certificate programs offered through UW Educational Outreach address specific aspects of the needed training, but the MS in Biomedical Regulatory Affairs will allow for more comprehensive and coherent education of professionals. The degree program will be offered during evening hours and on weekends on the UW campus and in locations accessible to working adults. Students will earn a Master of Science degree in 2 years.

Evidence of demand for education and training in the area of biomedical regulatory affairs comes from: (1) the success of the two existing UW Educational Outreach certificate programs, Biomedical Regulatory Affairs and Clinical Trials; (2) feedback from focus groups with industry representatives, UW faculty, and stakeholders from professional organizations and the FDA; and (3) an online survey of biomedical companies in the Puget Sound area.

In November, 2006, the Vice Provost and Dean of the Graduate School appointed two reviewers to evaluate the Master of Science in Biomedical Regulatory Affairs proposal. One reviewer directs a nationally recognized program offering a

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master's degree and certificate in Regulatory Affairs, and the other is the Director of Regulatory Affairs at a national pharmaceutical company. The reviewers both supported approval of the degree program, while each made several specific recommendations to improve the program's curriculum. The program provided a detailed response to these recommendations.

The Graduate School Council met on January 25, 2007, to discuss the MS in Biomedical Regulatory Affairs degree proposal. The Council recommended unanimously that, contingent on minor changes intended to bolster the ethics component and to assure that students exhibit a sufficient level of science competency, the proposal should be forwarded to the Higher Education Coordinating Board for review and approval. The Vice Provost and Dean of the Graduate School concurred with this recommendation.

On May 7, 2007, the Higher Education Coordinating Board Education Committee discussed the Master of Science in Biomedical Regulatory Affairs proposal, which was then considered by the full Higher Education Coordinating Board on May 24, 2007. The Board approved the proposal by the Department of Pharmacy at the University of Washington to offer the Master of Science in Biomedical Regulatory Affairs.

The Vice Provost and Dean of the Graduate School, the Dean of the School of Pharmacy, and the Provost have reviewed and approved the recommendation. The Higher Education Coordinating Board will be informed of the Board of Regents' action on the Master of Science in Biomedical Regulatory Affairs degree program.