



UNIVERSITY OF WASHINGTON

The Graduate School

G-1 Communications

Box 353770

Seattle, Washington 98195-3770

Telephone: (206)543-5900

Fax: (206)685-3234

May 11, 2015

To: Sean D. Sullivan, Dean, School of Pharmacy

From: David L. Eaton, Vice Provost and Dean
Rebecca Aanerud, Associate Dean for Academic Affairs

RE: Review of the Master of Science in Biomedical Regulatory Affairs (2013-2014)

This memo outlines the recommendations from the review of the Master of Science in Biomedical Regulatory Affairs offered by the Department of Pharmacy in the School of Pharmacy. Detailed comments on the review can be found in the documents that were part of the following formal review proceedings:

- Charge meeting between review committee, program, and administrators (March 19, 2014)
- Review committee report (October 17, 2014)
- Program response to the review committee report (February 18, 2015)
- Graduate School Council consideration of review (April 2, 2015)

The review committee consisted of:

Larry Kessler, Professor and Chair, UW Department of Health Services

Beth Traxler, Associate Professor, UW Department of Microbiology

This review was conducted in response to recommendations made during the 2009-2010 School of Pharmacy academic program review. The committee's charge for the 2013-2014 review was to assess the degree program, focusing on specific issues raised during the 2009-2010 review.

A subcommittee of the Graduate School Council presented findings and recommendations to the full Council at its meeting on April 2, 2015. After discussion, the Council recommended subsequent review as part of the regularly scheduled School of Pharmacy program review (2019-2020), with an interim report submitted to the Dean of the School of Pharmacy and the Graduate School Council by the end of Autumn Quarter 2015. Specific recommendations are articulated at the end of this memo.

Comments and recommendations regarding the program include the following:

Program Strengths

- Demand. The program fills an important niche in education in regulatory and pharmaceutical sciences and there is significant demand for the program;
- Institutional support. The School of Pharmacy strongly supports the program;
- Financial support. The program has a solid financial foundation.

Program Challenges & Risks

The review committee raised several significant areas of concern:

- Faculty issues
 - Lack of a clear succession plan for program leadership, with reviewers recommending a national search;
 - Variability in course instruction quality;
 - Need for comprehensive internal evaluation of program faculty, including clear definitions of criteria for success and for improving faculty performance;
 - Concerns about overworked faculty;
- Connections to other programs. Limited connection to academic and research programs in the School of Pharmacy; increasing connections would improve the program and ensure sustainability;
- Quality of students. Early on, almost all who applied were admitted, although this appears to be shifting toward higher selectivity;
- Sustainability. Competition due to growth of similar programs in the US.

Areas of Concurrence

Areas where reviewers and program respondents concur include the following:

- Full-time status. In response to concerns about international students not having full-time (10 credit) programs of study each quarter to satisfy the Graduate School's interpretation of Homeland Security's "full-time" status, the program curriculum was changed to require a minimum of 10 credits per quarter;
- Faculty issues. In response to concerns about faculty workload and quality of instruction, the program developed a resource plan to do a national search to add a regulatory affairs faculty Assistant Director position;
- Instructional quality. There have been improvements in both systematic evaluation of instructors and in the ratings of these instructors by students. The FTE of program faculty has been increased;

- Program enhancements. The program states that program enhancements made in response to the 2009-2010 program review recommendations have been implemented.

Areas of Disagreement

Areas of the review about which reviewers and program respondents disagree include the following:

- Connections to other programs. The program articulates that the lack of connections to other programs is due to the nature of the Biomedical Regulatory Affairs program, with its evening delivery; full-time and non-traditional students; and faculty working full-time in industry. Regardless, the program will work to mitigate this issue through a "Program Enhancement Proposal" that includes mixing of students from this and other School of Pharmacy programs in seminars;
- National faculty search. The program describes a national dearth of people with the "academic pedigree" to fulfill their expectations. The "Program Enhancement Proposal" will improve program options in this regard;
- Student quality. The program believes student quality is sufficient given admissions requirements, applicant/enrolled data, in-program student performance, and employment following graduation;
- Sustainability. The program is financially sustainable, and there are over 50,000 open positions nationwide in regulatory affairs, clinical research, and quality assurance for which their graduates may compete.

Graduate School Council Recommendations

The Graduate School Council recommends that the Master of Science in Biomedical Regulatory Affairs continue its stated efforts to strengthen the program, which should be reviewed in coordination with the next School of Pharmacy academic program review (2019-2020).

In addition, the Council wishes to ensure that rapid action is taken on the plans the program has articulated to address the questions about leadership succession and instructional quality.

The Council recommends that the program develop and submit to the Dean of the School of Pharmacy and the Graduate School Council, by the end of Autumn Quarter 2015, a report that describes:

- 1) Steps that have been taken to implement the leadership succession plan, including but not limited to a plan to search nationwide for the next program director;
- 2) How the program has implemented faculty evaluations and defined criteria for success and improving faculty performance, when necessary;
- 3) Steps that have been taken to mitigate the challenges of connecting program instructors, research, and students with other School of Pharmacy programs.

We concur with the Council's comments and recommendations.

cc: Gerald Baldasty, Interim Provost and Executive Vice President
Patricia Moy, Associate Vice Provost for Academic and Student Affairs
Lingtak-Neander Chan, Interim Chair, Department of Pharmacy
Thomas Hazlet, Director, Master of Science in Biomedical Affairs Program
Members of the academic program review committee
Members of the Graduate School Council
David Canfield-Budde, Director, Academic Affairs & Interdisciplinary Programs, The
Graduate School
GPSS President