Graduate School Review 17 October 2014
Biomedical Regulatory Affairs MS Program
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Executive Summary

The Biomedical Regulatory Affairs MS (BRAMS) Program was begun in 2008 in the Department of Pharmaceutical Sciences in the School of Pharmacy (SoP). This program has always been housed in the UW Educational Outreach program and is intended to be a self-sustaining program as is typical for UWEO programs.

We were asked to review the entire program and focus on several issues in particular that were raised as part of the School of Pharmacy review in 2009-2010. Those issues included the following:

a. Sustainability. Is there sufficient demand for the program to ensure sustainability?
b. Quality: Has the program been able to maintain student quality while enrolling a sufficient number of students to keep the program financially viable?
c. Faculty. Has the program adequately addressed the concern that the burden of the program is being shouldered by one tenure-track faculty and one senior lecturer? Is faculty selection, oversight, and evaluation appropriately defined and implemented?
d. Student issues. The report raised questions about student mentoring, program curriculum, practicum placements, and certification exam preparation.

We will address these in our summary comments here and in more detail in the body of our report.

Our overall conclusions about BRAMS

- **We believe that BRAMS should continue as a program.**
  - BRAMS fills an important niche in the education in the regulatory and pharmaceutical sciences that appears to have reasonably strong demand. BRAMS is doing so with good quality and with selected improvements and investments can be strengthened. We detail selected improvements in this report.
- **Faculty issues.**
  - There are several concerns about the faculty situation with BRAMS. First, a clear succession plan needs to be worked out between BRAMS and SoP/Dept of Pharmacy leadership. While we respect the efforts and the leadership of Dr. Thomas Hazlet as director of the BRAMS program, the current ideas about the future leadership of the program need more work. A successor to Dr. Hazlet should not be hand-picked and internal, but rather, the program should carry out a national search for such an appointment. It is not clear that is the plan of the program.
  - The quality of the course instruction in the program is quite variable. The faculty instructors in the program are clearly knowledgeable in their areas

of expertise. However, their connections to the rest of the Department and its activities, particularly the vibrant research programs in Pharmacy, are not uniformly strong.
    - Faculty evaluations need to be conducted for this program in a comprehensive fashion. Criteria for success and for improving faculty performance where necessary should be defined.
- **Improved connection to the academic and, especially research program, in Pharmacy is needed**
    - As noted above, there is a real opportunity to better leverage the excellent work done elsewhere in the SoP and connect faculty and students in BRAMS to those efforts. These ties must be strengthened for the program to improve and to ensure sustainability.
- **Quality of students remains a concern**
    - Our impression is that the program admits almost all who apply to the program. This is an indication that the program may need strengthening. While the fact that the program does attract some international students who are willing to travel a considerable distance to pursue the degree, improvements in the program and perhaps additional marketing efforts will result in a larger applicant pool from which to admit students.
- **Quality of instruction remains a concern**
    - The revamping of the curriculum for 2014 is a welcome move. In particular, the revised sequence for the Clinical Trials series will address the issues that have been raised concerning non-sequential arrangement of material. Other steps should be taken by Pharmacy: more routine evaluations of instructors in this program, where necessary, remedial action plans for instructors and criteria for success, and possible increase of active SoP faculty into the program, at least on a part-time basis.
- **Sustainability**
    - Our impression is that the program is successfully self-sustaining. However, the growth of similar programs in regulatory science throughout the US raises concerns about the longer-term viability of the program unless it is strengthened. We believe there is a role for this program and better integration with the faculty and programs of SoP will go a long way to improving the program quality and the longterm financial viability of BRAMS.

Our recommendations for the BRAMS leadership

- **Action items:** We suggest that Dr. Hazlet and Dr. Odegard work together to outline a succession plan for the leadership of BRAMS over the next year and discuss ways to strength the connections between BRAMS and the other units and activities within the Dept. of Pharmacy. *They should summarize these discussions in a letter to the Graduate School and the Dean of the SoP by Fall Qtr 2015*.

- **Planning for the next BRAMS review:** Assuming that the letter described above is transmitted to the Gradate School and the SoP Dean in a timely manner, we suggest that the next review for the BRAMS program should be done with the next SoP general review for the Graduate School.

Introduction:

The BRAMS program is offered by the UW Dept. of Pharmacy and graduated its first cohort of students in 2010. This relatively young program consists of a two-year curriculum designed for working professionals with a goal of gaining credentials for management of regulations, standard practices, and compliance issues relating to drugs and medical devices. During its short history, the program has been successful, attracting and educating qualified students and contributing to the School of Pharmacy community.

BRAMS admits *ca.* 20 students each fall, and approximately 15 students finish the BRAMS degree each year. The program has the capacity for 25 new students/year with the existing faculty participation. These students must take 14 required courses (45 credits), including a practicum (9 credits). There are not any elective choices among the classes offered under the BRAMS umbrella. The scope of the coursework required for the degree is designed to give the students a broad understanding in diverse aspects of regulatory affairs and clinical research relating to pharmaceuticals and medical devices.

The BRAMS students are mentored and taught by ten Dept. of Pharmacy faculty, staff and affiliates, who currently teach the required courses for the degree. Primary among the program's faculty is the BRAMS founding director, Dr. Thomas Hazlet, Associate Professor in the Dept. of Pharmacy.

Issues we raised during our review and our summary on each

- **Horizontal and vertical integration of material presented throughout the program.**
  - **Material that is presented, sometimes with conflicting information, in multiple classes by multiple instructors.**
    - The program responded that the Clinical Trials series has been completely revised, and overall responsibility for the series assigned to Mr. David Hammond. The redesign has specifically addressed the issues of integration, including the coordination of topics and lecturers between the Regulatory Affairs and Clinical Trials series of courses, conferencing with Regulatory Affairs series faculty, and in the end-of-year debriefing session. The program provided a revised schedule which can be found in their Q1 appendix in the document attached. We believe this has been very responsive to the concerns that we expressed and that had been identified by the students.
  - **Too many student presentations impinge on time better dedicated to classroom instruction.**
    - The program has modified their curriculum and decreased the focus on student presentations. The initial curriculum focused heavily on communication skills. That area remains a competency important to success in almost any graduate program; however, overemphasis in this context was inappropriate and seems to have been addressed.
  - **A need for broader viewpoints when covering topics.**
    - We are not certain the program has fully addressed this issue. The program claims and there is some objective evidence to support

that it has wide coverage of pharmaceuticals, devices, and biologics. It also has a module in international regulatory affairs that is uncommon. However, if the program is responsive to our recommendation to systematically approach and work with other faculty in Pharmacy, then we believe the issue of broader topics can be addressed.

- **Rigor – comparison to national "standards"**
  - According to the program, at this time, the BRAMS program aligns well with other Master's Degree programs in Biomedical Regulatory Affairs. The costs, time to completion and academic requirements are similar to the majority of the programs reviewed.
  - We note that this is very practical and largely content based knowledge. BRAMS does this well. There may be a few areas of expertise in SoP that can be brought to bear that would enrich the Master's degree, such as courses in benefit/risk analysis and methods to perform systematic reviews of the literature and synthesize that evidence.

- **Reevaluate curriculum in comparison to professional organization exams**
  - **Please clarify the mapping of the courses onto Table 1 (p10, etc) of the Hammond report (provided as a programmatic "self-study" document).**
  - **What was process for judging adequate coverage of concepts in non-UW cert programs?**
  - **Which courses map to which expectations for professional exams**
    - In a systematic review of the program by David Hammond, he stated the following: "As you can see from the tables in this section, the RAC exam is well covered by the classes taught in the BRAMS program. While it is never the intention of this program to teach to a certain examination and a student completing this program would still need employment experience in the field of regulatory affairs to qualify for the examination, this test represents the areas that RAPS feels are important for a professional in the field of regulatory affairs to have mastered. This table also demonstrates that the program goes well beyond what is to be studied for this test." The RAC Examination is a rigorous standard and a likely certification that many of the BRAMS graduates may wish to seek. Therefore, it is important that the program teach content that will allow students to pass this certification.
    - There are other certification exams, e.g., CCRP, CCRA, CCRC, where the coverage by BRAMS appears to be fairly solid. However, in the review by Hammond, there were certain areas that were either not covered (e.g., preparation of a trial master file) or were covered but could be improved (e.g., implementing corrective

action plans). It is beyond the scope of our review to verify all the assertions made in the review report by Hammond.

- In conclusion, we would say that the program appears to address many of the most important or crucial aspects of a certification examination and as this is a master's degree program, there will be areas that will not be explicitly addressed in the program for which a student wishing to get the credential may need to do some self-study.

- **Revised curriculum to be instituted Fall 2014**
  - **Please provide revised curriculum: Will the revised curriculum address the issue of non-sequential arrangement of the class materials in the Clinical Trials class?** The program provided detailed explanation of the global redesign of the clinical trials sequence. That addressed the non-sequential issue that we have raised. We recommend that the program review this aspect of the new design at the end of the year and provide a brief report to the Graduate School about the resolution of this issue.

  - **Practicum-- Please provide the revised instructions for practicum for Fall 2014 and describe the associated review process; provide a list of practicum sites and project titles.** The program provided details of the practicum process and also connections that can be made via the practicum. This process looks extensive and addresses the concerns that have been raised. There is also a very impressive list of practica that have been completed. There was very specific criticism leveled at faculty involved with the practicum. It is important for the program to have a plan to ensure quality is maintained and the students feel that they have a well running program. We believe this should be addressed and the resolution of these issues reported to the department chair and Dean.

- **General questions about the students**:
  - **Provide data on the mix of applicants, including representation from Puget Sound, international students, certificate applicants, and GNM applicants:** Each cohort consists of 12-15 US students and 5-8 international students. Since 2010, 73% of the program's students have come from Washington State, and 19% of the students were international students, largely from India, China, Taiwan, and Canada. International students are required to have a TOEFL score of 100 (above the UW Graduate School requirement of 92). We do not appear to have complete information on GNM students.
  - **What is the quality of student applicants and accepted students?**

The program has accepted about 75% of its applicants since 2010 (range from 70%-90%). While the accepted students have been qualified, the program would likely benefit from attracting a larger and stronger applicant pool.

- **Evaluate the blending of graduate students (BRAMS and otherwise) and certificate students in the Department of Pharmacy and in classes; include an assessment of GNM participants in BRAMS:**
  - The students associated with the BRAMS program should be better integrated into the Dept of Pharmacy student population, and invited to participate more fully in departmental life. BRAMS students would benefit from enhanced contacts to other departmental programs, particularly the Pharmaceutical Outcomes Research and Policy Program (PORPP). In addition, the leadership in the School of Pharmacy and the Dept of Pharmacy believe that the BRAMS program would be strengthened if the students were encouraged to engage in more robust scholarship and to publish their theses. Given the role of the University of Washington as a research university, the BRAMS program should educate its students in regulatory science in addition to regulatory affairs.
  - There are a few GNM students that currently take some of the BRAMS courses (in the Clinical Trails and Regulatory Affairs series). These students have done well in these courses, with an average GPA of 3.9. According to our interview with Dean Baillie, some PharmD students take BRAMS courses, but not many. This should be a topic of discussion with the new Dean after the report is delivered to SoP and BRAMS faculty.

- **Student competitiveness in relationship to competing programs**: This is one area where we could not assess. We recommend that the program examine this issue and report to the department chair and Dean.

- **BRAMS program fit into its school/department:** Department of Pharmacy chair Dr. Odegard enthusiastically supports the BRAMS program and would like to increase the profile of the program within the department as well as its connection to other faculty and programs in this department. A variety of efforts could help with this, including increasing the scholarship associated with the BRAMS program. Going forward, the program should use formal job searches for adding new BRAMS faculty as much as possible. The BRAMS program has produced two students that now participate as core instructors, Mr. David Hammond and Mr. Stephan Shipman. While these graduates are well respected

and are positive additions to the instructional faculty, the future of BRAMS program should not rely so heavily on its own trainees.

- **Succession plan:** Dr. Thomas Hazlet is the founding director of BRAMS and devotes most of his time to the program. Dr. Hazlet has substantial support from the administration, and has run the program with significant autonomy. While not an immediate need, a critical issue for BRAMS is the identification of a successor to Dr. Hazlet as the next director, with an appropriate training and transition period. The next BRAMS director should only be hired after a formal, national search.

- **Financial expectations for the BRAMS program going forward: Is the program meeting its financial targets? Is there a mechanism in place for revenue generated by BRAMS to return for re-investment in the program?** The BRAMS program needs to enroll at least 15 new students/year to meet its budgetary obligations. The program has exceeded this minimum and generated income ($194,500 in the 2011-2013 biennium). The Dean of the School of Pharmacy and the chair of the Department of Pharmacy each take 10% of the program's income. The remainder of the BRAMS income is set aside into a fund that is intended to endow a salary for the BRAMS director. This structure and these arrangements were clearly and consistently described by all of the stakeholders interviewed during the program review.

Conclusion:

BRAMS is a program that has an important role in the School and Department of Pharmacy and should be continued. There are key challenges that need to be, and can be met. These include increasing the profile of the program within the department, connection to other faculty and programs in the department, strengthening the teaching quality in the program, improve student evaluations, clarifying program goals for students, marketing the program more widely, developing a succession plan, and developing a plan for national level recruitments. In addition, it will be desirable to increase the scholarship associated with the BRAMS program.

Despite these challenges, there is significant merit and opportunity associated with the BRAMS program. It has responsive leadership and strong support within the SoP. It is educating its students for future success in an important and growing discipline and has a solid financial foundation. While keeping its sights on its strengths, the program should note the concerns outlined above and use the time before the next general SoP review to position the degree program for growth and greater achievements.