Master of Science in Clinical Research Management
(Previously Entitled Medical Product Development Management)
College of Science
Program Planning Committee Report to the Provost

The Masters in Medical Product Development Management (MPDM) was established as a Special Session program designed to prepare professionals for project management roles within both the pharmaceutical and medical device industries. In the five years it has existed as a pilot program, the MPDM has developed a strong curriculum that not only relies heavily on input from industry professionals but that has also forged a strong educational alliance between the Colleges of Science and Business. The program is housed in the College of Science but not in a department. The program comprises of 33-units, with 12 units (four courses) being taught by faculty in the College of Business, and two online courses developed by San Diego State University. The MPDM admits a new cohort each fall semester as well as a few spring admissions. The curriculum of the MPDM is designed to prepare graduates for management roles in biomedical companies that design, research, develop, manufacture and market medical products such as drugs, biological, medical devices and medical diagnostic tests.

Strengths of the Program:

As noted by the program plan, external review report, and the dean's letter, the MPDM program is well conceived, constructed and meets the needs of the workforce. Students learn about the field through guest speakers, professional student interactions, and courses that are relevant to the actual roles, responsibilities and required skill sets the graduates will encounter on the job. Thus, the program is considered current and topical. Positive comments were received from graduates, students, instructors, and external advisory representatives. Below is a summary of the strengths:

- Industry relevant program.
- Appears to be a growing industry need.
- Provides students with career growth options as well as career changes.
- Students, graduates and external industry advisory give high praise.
- Science, business, industry-centric and practical experience is core to its value.
- Dedicated Director with related industry experience.
- Number of faculty who “tailor” classes to program needs and industry language.
- Staggered evening, weekend and online classes are convenient for working student.
- Faculty are responsive to feedback from students and industry advisors regarding course content and relevancy
- Inclusion of applied, job-related “soft skills” contributes to employability

Challenges of the Program:

As identified in the program plan and external review report, challenges to the program revolve around sustainability, enrollment, and improvement of assessment goals. (1) A central challenge includes the sustainability of the program where the enrollment goal of 16-20 students has not
been met during the duration of the program, but which is necessary to attain financial self-sufficiency. Efforts to increase enrollment in the program have been identified. (2) Other challenges to the current program center on the coursework, including overly concentrated course material in the core courses, misplaced emphasis of theoretical material without an application focus, and pedagogical quality. (3) A third challenge includes the need to develop a mission statement, program learning outcomes that are directly tied to the program mission, ongoing and direct assessment of student learning outcomes, and quality and relevance of individual courses. As would be expected in a new program, much of the attention has been focused on the development of new courses, bringing in qualified faculty, and recruitment of students. A formal assessment plan has been outlined. As suggested by the external review, assessments may include “pre” and “post” tests for selected courses or course sequences or at various times – even a pre and post program assessment to see if all the gained knowledge is accumulated.

The external review report has identified the following weaknesses:

- Faculty/instructors/administration are not part of a unified department for optimum success.
- Director is stretched too thin, especially with routine administrative tasks.
- Marketing/Promotion/Recruiting needs to be enhanced. Most heard by word of mouth.
- Admission process isn’t a priority at student services for self-support program.
- Several students felt neglected due to uncertain seating at commencement, lack of SJSU I.D., library privileges, etc.
- Low number of industry partners in “Partners Spotlight” and overall participation.

The assessment activities to date appear to be headed in the right direction. Feedback was requested from essential stakeholders, including students and industry advisors, an “assessment of assessment” has been conducted, and rubrics are being utilized to evaluate outcomes. Significant work in several areas will be needed to strengthen the assessment plan and activities: 1) It is important to develop clear statements regarding the mission and goals of the program and include each in all program materials. The mission and goals can provide an important foundation as ongoing improvements in the curriculum and training are considered and can also inform students and applicants regarding the expected benefits of the program; 2) As assessment of student learning depends on clear statements of expected outcomes, a revision of the Program Learning Outcomes (shown as SLOs in the report) should be considered. Information regarding expected outcomes is included in the SLOs, but seems imbedded within descriptions of capstone and course assignments. For example, although SLO-1 identifies a student product (a professional paper or presentation), it does not clearly specify a student learning outcome (e.g., “the student will apply appropriate research methodologies in clinical research at an advanced level”); 3) it may be helpful to develop a curriculum map that aligns each individual course with program learning outcomes; this will help clarify the developmental aspects of student learning as they progress through the program, provide the foundation for further development of course learning outcomes, and create more explicit alignments between course and program learning goals and outcomes; 4) greater clarity is needed regarding planned faculty engagement in assessment at the course and program levels, with evidence of broad participation; and 5) More direct measures of learning outcomes should be developed and/or utilized at both the course and program levels.

The action plan detailed for MPDM include: 1) increase the content relevancy of the Data Management and Statistical Methods courses, 2) originate the on-line Regulatory Affairs from the SJSU College of Science (accomplished), 3) increase the depth and rigor of the core symposia taught
by the program director, 4) add a year-round marketing activity and 5) decrease the routine
administrative workload of the program director. Finally, and as funds allow, increase the delivery
of content on-line throughout the MPDM. The curricular improvements and enhancements above
require the 33-unit MS degree program to become a 36-unit MS degree program with the title
Clinical Research Management (CRM), which they feel is more widely-used and recognizable by the
general public.

The final step in the program planning process is a scheduled meeting with Provost Junn (or
designee), AVP of Undergraduate Studies Jaehne, AVP of Graduate Studies and Research Stacks,
Dean Parrish, and Director Green. The following topics of discussion are summarized from the
reports:

• Plans to improve admissions process
• Plans to increase marketing and promotion, and maintain enrollment at sustainable levels
• Plans for external and internal resource development
• Requirements for administrative support
• Timeline for development of program website
• Further development of assessment plan

The Program Planning Committee recommends acceptance of the Program Plan. The Program Plan
provided a detailed examination of current, and ongoing issues. The next Program Plan will be due
to Dean Parrish in Fall 2016.

Fall 2012 University Planning Committee Members

Charles Whitcomb   Amy D’Andrade   Yasue Kodama Yanai
Dennis Jaehne      Mary Calegari (Acting Co-chair) Anthony Raynsford
Pam Stacks         Alaka Rao       Debra Caires
Sutee Sujitparapitaya Lou Larwood Julio Soto
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Linda Main         Jinny Rhee (Acting chair) Mary Wilson
Diana Wu           Michael Crump

CC: Tonya Green, Director, MPDM
    Michael Parrish, Dean, College of Science
    Elaine Collins, Associate Dean, College of Science
    Dennis Jaehne, AVP Undergraduate Studies
    Pam Stacks, AVP Graduate Studies and Research
    Charles Whitcomb, Vice Provost for Academic Administration & Personnel
Appendix (11/30/12)
(MPDM) Master of Science in Clinical Research Management

Description of Department and Programs
The Masters in Medical Product Development Management (MPDM) was established as a Special Session program designed to prepare professionals for project management roles within both the pharmaceutical and medical device industries. It is not a Profession Science Masters (i.e. PSM). The curriculum of the MPDM is designed to prepare graduates for management roles in biomedical companies that design, research, develop, manufacture and market medical products such as drugs, biological, medical devices and medical diagnostic tests. The program is currently required to apply for status as a permanent program before its 5-year pilot period is over.

Program Modifications
The name of the program, previously known as Medical Product Development Management (MPDM) has been changed to Clinical Research Management (CRM). In addition, curricular changes (including more rigorous capstone experience and hybrid courses) are planned, and the total units for the program will increase from 33-units to 36-units. Finally, year-round program marketing and the hire of an administrative assistant for the Program Director are planned.

Faculty
The program is not housed in its own department, but is housed within the College of Science. The program draws upon College of Science and College of Business faculty. The curriculum description indicates that 4 full-time faculty from Business, and 6 full-time faculty from Science (including the Program Director) currently participate in the program.

Scholarly, University, and Professional Activity
All graduates of the program are required to publish a paper in their field, or present their work at a relevant conference. The program has had 14 graduates to date. Scholarly activities of participating faculty are not explicitly described.

Part-time Faculty/Lecturers
There are currently no part-time faculty or lecturers in the program.

Internal and External Funding
The planning and pre-launch of the program received some grant support from the CSU under the Alfred P. Sloan Foundation. Additional funds were received from Abbott Laboratories, IES, and the CSU Commission for Extended University.

Clerical Support
The program currently has a Program Director, Tonja Green, who has 20-years of experience in the field.

Use of Technology, Equipment and Facilities
The program currently has two online courses in their curriculum, developed by San Diego State University, with mixed reviews. The program plans to transition them to a hybrid format within San Jose State University. It is assumed that they will use the campus resources to do so, but is not explicitly stated.

College Committee Summary
NA

External Reviewer (Key Points)
The external reviewer found extremely positive comments about the program from graduates, students, instructors, and external advisory members. Of particular note were the industrial need satisfied by the program, the qualifications of the Program Director, the rigor of the curriculum, and the excellent retention and graduation rate. His recommendations for the future include the following:

- To help in the guiding principles of the program, a mission statement or strong purpose should be developed and posted on a program website and included in program materials.
- The SLOs should be reworded to reflect gained knowledge by students.
- The internship experience should be evaluated, which the evaluator feels is a key feature of this program.
- The possibility of using adjunct faculty and outside instructors to augment current full-time instructors participating in program should be explored.
- Further administrative support is needed to offload current Program Director.
- Enrollment in each cohort needs to be increased to 15 for sustainable operation of program.
- External resources are needed for program, and should be the responsibility of the Program Director.
- Greater emphasis on online courses could expand market reach of program.
- Recognition and occasional gathering of participants and faculty is needed.

External Reviewer
Albert P. Kern, CSU San Marcos, Extended Learning

Dean's Report
The letter from Dean Parrish dated June 19, 2012, reiterated the strengths of the program noted in the program plan and external evaluator’s report, as well as the challenges, including the structural challenges associated with all interdisciplinary programs not housed in a department, the need to increase enrollment, streamlining administrative processes, and strengthening the online component of the curriculum.