August 2, 2016

PROFESSOR JAMES McKERROW, Dean
Skaggs School of Pharmacy and Pharmaceutical Sciences

SUBJECT: Proposed MS in Drug Development and Product Management

The Graduate Council approved the revised proposal to establish a new self-supporting program of study leading to a Master of Science (MS) in Drug Development and Product Management. The Council will forward the proposal to the San Diego Division’s Academic Senate Chair for placement on a Representative Assembly agenda in Fall Quarter 2016. Please note the following:

1. The School may not accept applications to the program or admit students until systemwide review of the proposal is complete and UC President Janet Napolitano has issued a final outcome.
2. The Committee on Planning and Budget also reviewed the revised proposal and raised some additional questions about the budget. These are attached in Appendix 1. We ask that the School prepare and submit a response to these questions by September 2, 2016 that can be included with the proposal as these questions may be raised by Representative Assembly or the Systemwide Academic Senate’s Coordinating Committee on Graduate Affairs (CCGA). Please submit the response to Lori Hullings, Senate Analyst, at lhullings@ucsd.edu.
3. If the MS program receives final systemwide approval, the Council approved conducting the first graduate program review three years after the program is established. At that time, the Council will look for evidence of self-supporting status, enrollment reports (projected and actual), graduate placement, faculty participation, an update on the internship requirement, and an update on plans to move to a fully online learning format.
4. The Council’s approval to establish a new MS program in Drug Development and Product Management does not include approval for offering the program in a fully online format. We are supportive of the general concept outlined in the School’s proposal for the MS degree and request that the School submit a more detailed proposal to the Council at least one year prior to admitting students intending to complete all course and degree requirements through off-site study. In addition to obtaining the Graduate Council’s approval, the School must also obtain approval from the Western Association of Schools and Colleges (WASC). WASC considers offering 50% or more of a degree program online to be a substantive change that requires its approval. Barbara Sawrey, Associate Vice Chancellor for Academic Affairs and Dean of Undergraduate Education, is UCSD’s Accreditation Liaison Officer to WASC. Please contact AVC/Dean Sawrey for more information regarding the WASC review and approval process.
5. Approval from the Graduate Council is required to offer individual courses through an alternative technologically-mediated mode of instruction (e.g. an online or distance learning format). If the School plans to offer any individual courses online prior to submitting a proposal to offer the program completely online, the School is advised to review the Academic Senate’s Policy on Remote and Distance Instruction. The Policy defines the criteria for remote and distance learning courses and specifies what supplementary information is required when submitting a request to offer an individual course through remote or distance learning.

If you have any questions, please contact Lori Hullings, at lhullings@ucsd.edu.

Sincerely,

David Salmon, Chair
Graduate Council

cc: M. Allen K. Barrett R. Continetti W. Ettouati J. Hirsch T. Mallis
S. Ramamoorthy R. Rodriguez K. Roy B. Sawrey
Appendix 1: Additional Questions on the Proposal’s Appendix E: Financial Projections/Cost Analysis

1. Line 7 is labeled “Total Faculty Compensation (from Table 13 submission)”. What is Table 13 and what information is included in it?
2. The charges included in year 1 of Line 20, Indirect Charges paid by Program to Chancellor (including ASSA Assessment) are $29,225 but they jump to $285,120 in years two and three. What is the cause for such an increase?
3. Why are Extension’s administrative costs listed as an indirect cost in Line 18 rather than include them as a direct cost?
Question 1: Line 7 is labeled “Total Faculty Compensation (from Table 13 submission)”. What is Table 13 and what information is included in it?

Response (from the campus Budget Office): Regents Budget Table 13 (RBT13) is an annual submission to OP that reports on faculty compensation related to their efforts on Self Supporting Programs (SSP). The purpose of the report is to ensure the faculty efforts on SSP are charged to SSP funds, not state funds. Line 7 on the OP cost analysis template must match the total reported on RBT 13 (which has been renamed to RBT 4).

Question 2: The charges included in year 1 of Line 20, Indirect Charges paid by Program to Chancellor (including ASSA Assessment) are $29,225, but they jump to $285,120 in years two and three. What is the case for such an increase?

Response: The lower charges paid to the Chancellor in year one are the result of voluntary reduced assessment to offset a program financial deficit until 48 FTE enrolled students is achieved in the second year.

Question 3: Why are Extension’s administrative costs listed as an indirect cost in Line 18 rather than include them as a direct cost?

Response (from the campus Budget Office): The cost template was designed by OP. Its structure is somewhat confusing but we are looking to work with OP this year to make improvements. Extension’s administrative cost is treated as an indirect charge, but on the template it is included in the Direct Cost section along with the other “indirect charges” and then backed out at the end, which does not make sense. We have followed up with OP and had made suggestions to reassess the construction of the template.
PROPOSAL FOR A SELF-SUPPORTING PROGRAM
OF GRADUATE STUDIES IN
DRUG DEVELOPMENT AND PRODUCT MANAGEMENT
FOR THE MASTER OF SCIENCE DEGREE

June 9, 2016
Contact Information

Submitter: James McKerrow, MD, PhD
Dean
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Dr.
Mail Code 0657
La Jolla, CA 92093
(858) 822-7801
jmckerrow@ucsd.edu

Program
Academic Director: Jan Hirsch, BS Pharm, PhD
Associate Professor of Clinical Pharmacy
Executive Director, Partners in Medication Therapy
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Dr.
Mail Code 0714
La Jolla, CA 92093
(858) 822-5562
janhirsch@ucsd.edu

Program
Managing Director: Williams Ettouati, PharmD
Director, Industrial Relations and Development
Health Sciences Associate Clinical Professor, N.S.
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Dr.
Mail Code 1177
La Jolla, CA 92093
(858) 699-5489
wettouati@ucsd.edu
PROPOSAL FOR A MASTER OF SCIENCE DEGREE IN
DRUG DEVELOPMENT AND PRODUCT MANAGEMENT

Table of Contents

Executive Summary 4

1.0 Introduction 6
   1.1 Program aims, objectives and features 6
   1.2 Historical development of the field 6
   1.3 Strength of UCSD in this field 7
   1.4 Timetable for development of the program 8
   1.5 Relationship to existing UCSD and UC programs 9
   1.6 Program evaluation plan 10

2.0 Program 10
   2.1 Degree type 10
   2.2 Admissions requirements 11
   2.3 Program of study 12
   2.4 Capstone requirement (internship) 13
   2.5 Student Advising 14
   2.6 Student Evaluation 14
   2.7 Pace of study options, sample program 15
   2.8 Online learning 15

3.0 Projected Need 16
   3.1 Market assessment 16
   3.2 Placement estimates and enrollment projections 18

4.0 Faculty 19

5.0 Courses 26

6.0 Resource Requirements and Impact on the Academic Unit 33

7.0 Graduate Student Support 36
   7.1 Financial assistance 36
   7.2 Enhancing diversity and accessibility 36

8.0 Governance 37

9.0 Changes in Senate Regulations Required 37

Appendices:
   A. Program and Pace of Study
   B. Market Assessment
   C. Faculty Vitae
   D. Course Approval Forms
   E. Financial Projections/Cost Analysis
   F. Letters of Endorsement
   G. Catalog Copy
   H. Suggested UC and external reviewers
   I. Admissions Criteria and Scoring
Executive Summary

Pharmaceutical products provide tremendous value to the health and welfare of society worldwide. The process for developing safe and successful products is costly, however, and thus a high-risk venture. Likewise, the task of managing utilization and the cost of expensive marketed products is an enormous challenge for health plans and systems worldwide. As a result, pharmaceutical companies and managed care systems demand high levels of interdisciplinary planning and collaboration among their employees in order to ensure success. Most academic preparation for individuals working in these environments, unfortunately, is focused on either pharmaceutical science or on individually-distinct professions, rather than on knowledge of the breadth of drug development and utilization management challenges and processes for collaborative innovation.

The proposed master’s degree program in drug development and product management (DDPM) has three aims: first, to give experienced professionals insight into the process of successful drug product development and deployment; second, to endow students with requisite knowledge and skill to collaborate effectively in the ongoing management of drug products; and third, to provide a solid, practical bridge to employment opportunities in pharmaceutical and managed care industries or related government agencies such as the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA).

Distinctive features of the program include instruction by a combination of faculty who possess scholarly understanding and industry experience, a case and project-oriented approach to learning, options in professional focus, online and face-to-face course delivery alternatives, exposure to student colleagues with varied professional backgrounds, and connections with employers through a practice-oriented internship at their site.

This program will be offered in a fully-online format to a global audience in Fall of 2021, although the degree will first be offered in 2018. The delivery method during this initial stabilization period (2018-2020) will be exclusively face-to-face, with students in residence at UCSD, but with the introduction of recorded lectures and online learning activities to supplement the teaching and learning process (“hybrid” or “flipped” format), while confidence regarding market, faculty, curriculum, and student placement is established. Although trends suggest that preference for the online format will predominate once it is available, the option for fully-residential study will continue in a hybrid format.

A desire at UCSD to contribute to the innovative capacity of the drug development industry is represented in the Center for Drug Discovery Innovation at the Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS), which will participate in the management of this degree program. The effort to create a globally-accessible graduate program in drug development and product management is also an important component for the UCSD Division of Health Sciences Clinical and Translational Research Institute (CTRI) that received a Clinical Translational Science Award (CTSA) recently funded by the NIH. The introduction of the DDPM degree will contribute to developing UCSD as a world-class institution.

---

class center for clinical and translational research, since drug development and management is a key part of the translational research process. The degree is also a high campus priority because it is part of a strategy to recruit more graduate-level professionally-oriented students, and thus more completely serve the biotech and pharmaceutical industry so closely tied to the work at UCSD.

All UCSD Graduate Division and Graduate Council requirements for master’s degrees will apply to this program. No GRE exam will be required as the target audience is working adults; work experience and achievements will be considered instead. A minimum of three years of work experience in a relevant field will be required. The program will strive to strike a student balance between legal, scientific, medical, and business management backgrounds or interests as part of the learning design.

The degree requires 72 total units over six quarters, and thus is eligible for an international student ("F") visa. The program provides 36 units of general classroom study and 24 units of specialized professional study. Finally, 12 units of on-site practice internship work with an industry sponsor are required. Per UC San Diego Senate requirement 700-C, all students must pass a Masters Examination, so successful completion of the exam will also be necessary to participate in on-site practice internships.

Academic advising is critical to student success. The program will strive to maintain a ratio of one advisor for no more than twelve students. Suitable university as well as industry advisors will be recruited and compensated to assist the program’s core faculty advising team in this important function.

The program is fully self-funded. Based on a market assessment and the strength of anticipated student placement, the program is confident it can obtain 24 new students each year during the stabilization phase. Furthermore, projections to obtain 48 new students once a global online format is available are also well within reach. The budget meets all direct and indirect financial commitments, including assigned assessments for the division, the relevant vice chancellor, and the office of the chancellor.

This program will be managed by the Skaggs School of Pharmacy and Pharmaceutical Sciences. SSPPS will have full control over all curriculum, faculty selection and review, admissions, and student evaluation. CTRI will contribute when needed in the oversight of program directors, selection of learning objectives, curriculum topics, and relations with industry and employers in order to ensure the effort is well coordinated and supportive of overall Health Sciences strategy.

Administrative support for the program will be provided by UCSD Extension. Under the direction of SSPPS, Extension will manage student recruitment, develop and execute program administrative policies, oversee financial management, and provide instructor and student servicing. Extension has extensive experience in administering self-supporting professionally-oriented degree programs at UCSD.
1.0 Introduction

1.1 Program aims, objectives and features
Pharmaceutical products provide tremendous value to the health and welfare of society worldwide. The process for developing safe and successful products is costly, however, and thus a high-risk venture. Likewise, the task of managing utilization and the cost of expensive marketed products is an enormous challenge for health plans and systems worldwide. As a result, pharmaceutical companies and managed care systems demand high levels of interdisciplinary planning and collaboration among their employees in order to ensure success. Most academic preparation for individuals working in these environments, unfortunately, is focused on either pharmaceutical science or on individually-distinct professions, rather than on knowledge of the breadth of drug development and utilization management challenges and processes for collaboratory innovation.

The proposed master’s degree program in drug development and product management (DDPM) has three aims: first, to give experienced professionals insight into the process of successful drug product development and deployment; second, to endow students with requisite knowledge and skill to collaborate effectively in the ongoing management of drug products; and third, to provide a solid, practical bridge to employment opportunities in pharmaceutical and managed care industries or related government agencies such as the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA).

Distinctive features of the program include instruction by a combination of faculty who possess scholarly understanding and industry experience, a case and project-oriented approach to learning, options in professional focus, online and face-to-face course delivery alternatives, exposure to student colleagues with varied professional backgrounds, and connections with employers through a practice-oriented internship at their site.

1.2 Historical development of the field

While technology has led to amazing drug discoveries that can save and improve human lives the cost to develop a prescription drug that gains market approval is estimated to be $2.6 billion, a 145% increase from 2003. New medications offering breakthrough benefits can be expensive for both healthcare systems as well as patients. For example Praluent™, a new drug approved in 2015 to treat high levels of LDL cholesterol, is priced at almost $15,000 per year compared to current therapy available at about $100 per year generic statins.

Employees with knowledge and skills needed to manage processes that range from drug discovery to marketing to develop safe and successful products in a cost-efficient manner are essential to the pharmaceutical industry. After a product

2 (http://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html)
is marketed similar knowledge and skills are needed to manage utilization and the ultimate cost of medications to health plans and systems worldwide.

Unfortunately, development of these types of employees is often left to the employer, through on-the-job training. In response, many universities are creating professionally-oriented graduate degree programs in specialized fields that reflect the needs of employers and the practical realities of industry dynamics. A recent study by the Education Advisory Board, Academic Affairs Forum, explains that the fastest growing segment of higher education is professional master’s programs focused on specific job knowledge and skills that help students obtain a new job or advance in an existing position.

1.3 Strength of UCSD in this field

UC San Diego has both depth and breadth in the field of drug discovery and product management. Foremost, is the success and capability of the Skaggs School of Pharmacy and Pharmaceutical Sciences. Created in July of 2000, and currently with a steady-state enrollment is 240 Pharm.D. students, 60 Ph.D. students and 30 pharmacy residents, the school offers an innovative and flexible curriculum taught by a stellar health sciences faculty in a program closely associated with the outstanding clinical, research and academic programs of the School of Medicine.

Complementing the Skaggs School is the UC San Diego Clinical and Translational Research Institute (CTRI). The Institute is one of 64 organizations in the US receiving funds from the NIH to speed the translation of research discovery into improved patient care. CTRI is among the leaders in this effort, with years of impressive achievements. CTRI is committed to transforming education in clinical and translational science by coordinating disparate programs, providing breadth of education from high school through pre-doctoral students, and providing training to postdoctoral fellows and faculty. The institute also transforms the conduct of clinical research by providing guidance and support from initial planning through data analysis and sharing. This structure fosters development of novel technologies to facilitate clinical research and provide support for the services and resources necessary to conduct clinical investigation and improve health. CTRI places a special emphasis on several areas of strength, such as imaging, biomarkers, community outreach and the translation of basic science discoveries to clinical science. In addition, when UC San Diego researchers discover the cause of a disease, they also identify new opportunities to create therapies. The Center for Drug Discovery Innovation (cDDI) helps researchers bring these opportunities to fruition by connecting promising projects with the information and capabilities needed to make real progress. Finally, UC San Diego Center for Translational Computer-Aided Drug Discovery & Project Management is fundamental in helping scientist create new molecular entities to target novel drug targets and creating innovative new therapies.

---

4 EAB, Understanding the Changing Market for Professional Master’s Programs, 2015.
UC San Diego Health Sciences has robust relationships with pharmaceutical companies, managed healthcare systems, and government agencies. San Diego ranks third in the nation as an engine for the development of biotechnology products. Surrounding the UCSD campus are numerous research and development companies devoted to biotechnology and pharmaceutical development, including many developed by or with UCSD faculty. Furthermore, San Diego hosts five award-winning healthcare systems, and is among the most successful and progressive geographic regions for research and patient care. Faculty, students, and administrators at UCSD actively partner with the professional community to solve scientific and professional challenges. The SSPPS Applied Pharmacoeconomic and Outcomes Research Forum, now in its ninth year, is an example of an initiative that facilitates problem-solving for cost-effective drug development and management across stakeholder groups, including pharmaceutical/biotech, managed care organizations, government agencies, medical centers, and academia.

1.4 Timetable for development of the program
This program will be offered in a fully-online format to a global audience in Fall of 2021, although the degree will first be offered in 2018. The delivery method during this initial stabilization period (2018-2020) will be exclusively face-to-face, with students in residence at UCSD, but with the introduction of recorded lectures and online learning activities to supplement the teaching and learning process (“hybrid” or “flipped” format), while confidence regarding market, faculty, curriculum, and student placement is established. Although trends suggest that preference for the online format will predominate once it is available, the option for fully-residential study will continue in a hybrid format.

Approval and introduction of this program does not affect the campus enrollment plan, as it is entirely self-funded. The program does, however, strongly contribute to the stated UCSD strategy of growing graduate enrollment through new Master’s degree programs with global reach.

The specific timeline for the evolution of the program is as follows:
- Review and endorsement by VCHS Summer 2015 (completed)
- Preliminary review by Chancellor Summer 2015 (completed)
- Health Sciences faculty review and approval Oct 2015 - Apr 2016 (completed)
- UCSD academic senate review and approval May 2016 – Oct 2016
- UCSD administrative review and approval Nov 2016 - Dec 2016
- Systemwide and WASC proposal review and approval Jan 2017 - June 2017
- CPEC, and OP review and approval July 2017 - Dec 2017
- Develop program courses during late 2017
- Recruit first cohort of 24 students early 2018
- Application and admissions late Spring 2018
- Begin courses Fall of 2018
- Develop and introduce online learning elements during 2019
- Place first cohort in internships Spring of 2020
1.5 Relationship to existing UCSD and UC programs

The proposed degree program draws primarily upon faculty of the Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS), although some faculty from the School of Medicine may also participate. This degree program will not affect the existing graduate degree programs because faculty participating in this program will be teaching via overload, and compensated accordingly. A list of faculty participating in the program, including their teaching and/or advising commitments, is included in section 4.0 of this document. Also, a letter from Dr. Joan Heller Brown, head of Pharmacology at the School of Medicine, endorsing the creation of this program can be found in Appendix F of this document.

The effort to create a globally-accessible graduate program in drug development, project and product management is an important component of the CTRI. The introduction of such a degree will contribute to developing UCSD as a world-class center for clinical and translational research, since drug development and management is a key part of the translational research process. The degree is also a high campus priority because it is part of a strategy to recruit more graduate-level professionally-oriented students, and thus more completely serve the science industries so closely tied to the work at UCSD. A letter from Gary S. Firestein, MD, Dean and Associate Vice Chancellor of Translational Medicine at UC San Diego (CTRI), further delineating the importance of this program to UCSD can be found in Appendix F of this document.

With regard to other programs at UCSD, overlap between this program and product development and management courses at other professional schools is minimal. At the Rady School of Management, innovation coursework is purposely broad to allow students to explore innovation in a wide variety of industries, and it emphasizes the application of analytical frameworks to validate the market potential of any type of new product idea, as opposed to the specific process-oriented framework to launch and manage drug products covered in this proposed program. In fact, the proposed program will serve as an academic compliment to the work at the business school, and will further solidify UCSD’s commitment to the biotech, pharmaceutical and managed care industries.

Any other programs at UC San Diego related to biology, pharmacology, or biotechnical topics are primarily scientific in focus, and thus serve a different purpose, target market, and industry need than does this program.

This program is not duplicated at any other UC campus. Furthermore, a review of graduate degree programs in the California region reveals only tangentially-oriented Master of Science degrees at the University of Southern California. One degree at that school focuses exclusively on the "chemical evolution,
implementation of quality systems and testing in animals and people” as part of the process of drug development, and another degree focuses exclusively on regulatory affairs. In contrast the proposed UCSD MS in Drug Development and Product Management spans the breadth of drug development within a pharmaceutical company and beyond to the management of drug products within healthcare systems.

1.6 Program evaluation plan
Program evaluation will consist of six elements.

First, the success of each course offering, including faculty teaching performance, will be evaluated by each student, and results will be shared and reviewed with the instructor and the program management committee.

Second, students will be encouraged to give feedback to their academic advisor on a regular basis, regarding individual courses and/or the overall learning experience.

Third, the program will solicit feedback from students, and from their industry sponsors, during and following each practice internship, with results shared and reviewed by the program management committee.

Fourth, the performance of students in each course, as well as their performance on the Master’s examination are indications of the quality of instruction and the success of students in mastering the material. Most courses in the program will use the standard letter grading system, although selected courses like the internship will use the alternate Satisfactory/Unsatisfactory grading framework.

Fifth, the ultimate measure of program and student success is subsequent employment of graduates. The program will maintain ongoing communication with program alumni, to monitor and report employment and professional achievements.

Sixth, the program will adhere to the standard 8-year academic senate program review cycle

2.0 Program

2.1 Degree type
This degree will be a Master of Science in Drug Development and Product Management. Although this program is intended to be professional in nature, comparable programs throughout the country (see section 3.1 Market Assessment) all use the MS degree designation. Likewise, degrees associated with science-based professions (like drug development) are usually expected to
carry a science designation. This program would clearly be at a competitive disadvantage if a degree designation other than Master of Science were used.

2.2 Admissions requirements
All UCSD Graduate Division and Graduate Council requirements for master’s degrees will apply to this program. No GRE exam will be required as the target audience is working adults; work experience and achievements will be considered instead. A minimum of three years of work experience in a relevant field will be expected.

As all instruction will take place in English, and students will be from throughout the world, the program will require an advanced TOEFL score of 85 for admission (higher than the current UCSD minimum requirement of 80).

Applicants will be required to submit a statement outlining their intended career focus (i.e., “statement of purpose”) during the program, and a description of any current or potential employer relationships they already have to aid in arranging the practice internship. The statement will also explain their plan for leveraging the degree to achieve their career pursuits.

Three letters of reference, including at least one from a relevant employer will be required in connection with the application. The program will strive to strike a student balance between legal, scientific, medical, and business management backgrounds or interests as part of the learning design. Diversity of the students’ backgrounds is an important priority for this program, so that graduates will address the needs of the diverse market for this knowledge. Active recruitment efforts and the fact that this is a self-funded program should lead to a continued diversified student base in terms of professional, academic and ethnic backgrounds. The program will remain steadfast in efforts to encourage application from highly qualified applicants from all sectors and levels within relevant industries so that the resulting applicant pool will meet diversity objectives.

Appendix I includes a scoring rubric that will be used for all program applicants. The rubric takes into account all of the elements described above, and also reflects consideration of factors obtained during an interview with each qualified applicant (i.e., scoring 70 or better) as part of the overall admissions process. The program will not allow revenue considerations to influence admissions decisions.

There is no foreign language competency requirement

An admissions committee of core faculty will review all applicants and make all admission recommendations.
2.3 Program of study

The program consists of 72 total units over six quarters (12 units per quarter), and thus is eligible for an international student (“F”) visa. All 72 units are necessary for graduation, and all courses are required, there are no elective courses. The list of courses and pace of study is delineated in Appendix A of this document.

The program provides 36 units of general classroom study during the first year. In addition, 24 units of specialized study are required during the second year. Although the initial set of second-year courses is prescribed (see Table 2 in section 5.0), as the program matures, new electives may be added to the second year menu of courses based on the preparation and career interests of admitted students, as well as the expressed needs of employers. Any such courses and changes to the program plan would be presented to the Graduate Council for review and approval at that time.

Twelve units of on-site practice internship work with an industry sponsor are also required. Per the prescribed pace of study, the internship is available in the final quarter of the program.

Per UC San Diego Senate requirement 700-C, all students must pass a Masters Examination, so successful completion of the exam will be a requirement to receive the degree. Successful completion of the exam will also be necessary to participate in on-site practice internships. The exam will be administered at the end of the fifth quarter of the program, just before internships begin. The exam will be in written form, covering material presented throughout the program. Some amount of case analysis and practice-based problem solving will also be inserted in the exam to allow students to demonstrate their ability to integrate curriculum in an applied manner. All testing of students, either in residence or remote via online learning, will be done in the presence of a proctor. The Steering Group of the program (see section 4.0) will appoint an evaluation committee at the beginning of each academic year to construct exam questions and to conduct the student evaluation process. The committee will construct a rubric for scoring qualitative questions, and apply the rubric in evaluating and grading each exam.

Students may advance to candidacy and receive the degree only in their last registered quarter in the program.

No units of research may be applied to meet degree requirements.

There are no licensing or certification requirements in connection with the program. There is no field or qualifying examination.

There is no duplication between the courses of the SSPPS PharmD degree and this degree program; they meet separate needs for separate student profiles.
2.4 Capstone requirement (Internship)

Twelve units (one quarter) of on-site practice internship work with an industry sponsor will be required. The Internship is a directed, highly-individualized experience designed to help an individual acquire practical skills for the type of career they want to pursue. The intern trains under the close direction and instruction of a qualified industry preceptor. The experience complements the didactic instruction received during the Master’s program.

Students will be prepared during the program for an internship with a pharmaceutical, biotech, or managed care company, or with the FDA in regulatory affairs science, project management, drug product management and pharmacoeconomics. For example, if a student pursues an internship with a manager in drug development, the student will learn how to provide project management in support of one or more drug development teams spanning the transition from discovery to development through to post-approval lifecycle management. The student will help establish and maintain an interdisciplinary team and serve as a project advocate within the organization. The student will be involved with analyzing project challenges, identifying and recommend solutions, convening and guiding team discussions, and communicating project status and issues to ensure accurate project information is available to the broader organization and to enable timely and prudent pipeline and milestone decisions.

Program directors and staff will make every effort to ensure that each student admitted to the program obtains a suitable internship during the requisite period. When potential students apply to the program they will be asked to identify and describe an organization and assignment for their internship. To assist them in this task, UCSD and individuals associated with this program have already established, and will continue to establish strong ties with employers for this purpose, both within the San Diego region and elsewhere. Opportunities of varying career interest, and organizations of various sizes will be represented in the database of potential internship partners provided to applicants.

As the program progresses, students will be introduced to many of these employers through receptions, guest speakers, and other activities during their first year in the program. During the second year, students will take the initiative to contact and probe specific internship opportunities during their work in the Analysis of Industry Needs in Drug Development and Product Management course (see section 5.0 Courses). Furthermore, internship placement and success during the internship will be a priority for each student’s faculty advisor.

Internships for all students, whether within or outside of the San Diego region, will be carefully managed. As a student approaches the time of their internship, the program steering committee will confirm the internship parameters via the sponsoring employer. Preceptors will provide their full CV and the program directors will have one-on-one discussions (either face to face or by video conference) with each industry preceptor to ensure their qualification based on
PROPOSAL FOR A MASTER OF SCIENCE DEGREE IN
DRUG DEVELOPMENT AND PRODUCT MANAGEMENT

their experience, relevant degree, and their commitment to providing a meaningful learning experience. While the student performs their internship, they will be guided by their industry preceptor and via regular interactions with their faculty advisor to ensure the experience meets program requirements, and results in a valuable experience for everyone involved.

2.5 Student Advising
Academic advising is critical to student success. The program will strive to maintain a ratio of one advisor for no more than twelve students. As the program approaches the planned “steady state” enrollment level of 96 students, at least 8 advisors will be necessary to maintain this goal. Suitable university as well as industry advisors will be recruited and compensated to assist the program’s core faculty advising team in this important function. The Skaggs School of Pharmacy currently has about 50 voluntary faculty from industry, managed care, and government so this figure is well within the school’s capability. Academic and industry advisors will participate in ongoing orientation, coordination, and other meetings to share best practices and enhance their abilities.

Academic advising will consist of monthly conversations with each student via a combination of email and desktop teleconferencing tools (e.g., Google Hangout, FaceTime, GoToMeeting, Skype). In addition to these methods, the program will explore software such as Virbela that allows real-time participation and communication for interaction between faculty and students. Advisors will be guided in conducting these interviews through assessment rubrics, checklists, and student achievement data provided by program directors, in order to track student progress and identify any performance concerns. Advisors will also discuss plans and progress toward identifying, confirming, and detailing the internship experience throughout the student’s time in the program.

In addition to advisor interaction, students will have access to course assistants who will be available online several times a week.

2.6 Student evaluation
Student evaluation will primarily be conducted in connection with individual coursework. All courses will have a final examination. Most courses in the program will use the standard letter grading system, although selected courses like the internship will use the alternate Satisfactory/Unsatisfactory grading framework.

The required comprehensive Master’s examination will also serve to evaluate student achievement. All testing of students in connection with online coursework will be done with the oversight of a proctor.

Internship work is evaluated via a face-to-face (e.g., Skype) summary presentation to the faculty advisor, plus a confidential written evaluation of the
student’s performance from their industry sponsor. Evaluations will occur at the mid-point and end of the internship.

2.7 Pace of study options, sample program
The program consists of 72 total units over six quarters, thus the normative time to complete the degree is two academic years. Each student is assigned a full-time load (12 units) of coursework each quarter, so the program is eligible for an international student (“F”) visa. Courses will be scheduled in late afternoon or evening hours, however, to allow a student to maintain a job while pursuing the degree. The program and pace of study is provided in Appendix A of this document.

2.8. Online Learning
A critical element of the program’s sustainable success will be its ability to extend its reach globally. The pharmaceutical industry conducts business across national boundaries and cultures as a matter of necessity, and it recruits and selects professional talent accordingly. Although this program includes curriculum with a global perspective, that curriculum alone is insufficient to produce either the quantity or sophistication of successful graduates that are needed. The program must attract promising individuals who are already well-versed and imbedded in the cultures and professional nuances of the communities served by the pharmaceutical industry around the world. Asking those types of individuals to leave their work and home for two years, to take on the financial burden of not only program tuition and fees but also living expenses in La Jolla (which exceeds the cost of the program), is a daunting challenge.

To achieve the reach and affordability necessary, this proposal includes the intent move to a fully-online learning format in year four and beyond, after instructional and experiential elements of the design have been proven and refined. This initial period of three years also provides time to track and examine student success, and to develop media and activities suitable for learning in remote and asynchronous fashion. Coincidentally, in addition to enabling the program to scale and reach students globally in an affordable fashion, an online learning option will also allow local professionals to consider engaging with the program while also working part-time.

Online learning is not new to higher education nor to graduate education. Although concerns regarding student comprehension and evaluation remain, they are being dealt with rapidly by respected institutions, and confidence in the medium is growing. This program envisions use of all best practices for online education to ensure that students who engage through that format experience no decline in comprehension, ability, or career success versus residential students.

Generally speaking, the program will use all of the resources currently available at UCSD to produce high-quality online learning experiences. The campus Teaching and Learning Commons, which includes the Office for Online and Technology
Enhanced Education (OTEE), employs a campus version of the Blackboard learning management system platform and this will be used by the program. OTEE likewise has trained instructional designers, as well as extensive studio and classroom equipment to devise, capture, edit, produce, and deliver excellent instructional material. Where additional resources may be needed, Extension likewise possess instructional designer, equipment, and technology-enhanced classrooms to supplement the demands of course development.

With regard to course design, each course will include (1) lecture material, captured either live during residential session or in-studio depending on the nature of the topic being delivered, (2) carefully-designed discussions and peer-to-peer learning activities to enhance networking and build upon the varied perspectives and backgrounds of the student body, (3) links to supplemental learning material such as articles, readers, video, and other media made available in digital realms, and (4) self-assessment quizzes to ensure students feel confident in their grasp of key concepts prior to the final examination for the course. Each course coordinator will be compensated by the program to engage with and be assisted by an instructional designer to adapt their curriculum to match this general design. Course coordinators and instructional support staff will be available during virtual office hours, and on-demand as possible, to assist each student with questions or challenges they face during the course.

Unless or until the campus feels confident in biometric and other technology affirming the presence of each student during remote examination, final examinations will be in writing, with the oversight of a proctor, and submitted to the instructor by the proctor. Proctoring services are available through commercial and educational institutions worldwide, including the UCOP-approved “Proctor U” contract proctoring service. Proctoring will be arranged by the program for each online student as part of their admissions and orientation process.

This proposal cannot describe each detail regarding each online course at present because it recognizes that requirements regarding graduate online learning are evolving at UC and UCSD, as is the technology, and will likely change before 2021 (the date at which the first students in this program would be admitted for fully-online study). Confidently, however, the program expects to be able to respond during 2020 to any and all questions and prescribed practices in order to obtain final approval to begin online coursework.

3.0 Projected Need

3.1 Market assessment
During the Fall of 2015, the UCSD Center for Research on the Regional Economy performed an assessment of the market for a program such as the one being proposed. The assessment includes a review of government projections for job opportunities in this field, examination of comparable or substitute programs of
study, surveys and interviews with potential students and employers, and an analysis of the probable return on educational investment for individuals who complete the program. The complete assessment is included in Appendix B of this document.

The assessment’s executive summary is as follows:

The proposed Masters of Science in Drug Development and Product Management is geared towards individuals who need to have managerial, regulatory and legal knowledge regarding the drug development process as well as have a background in pharmacy, nursing, medicine and other related biomedical sciences. This program is intended for experienced professionals with advanced degrees to gain managerial and collaborative skills in order to effectively monitor the multiple facets of the drug product development process from "bench to bedside" in the workplace.

Based on data from comparable programs and survey responses, UC San Diego leadership should target potential students who are looking at advancing within their careers. Most comparable programs prefer students to have 2 to 5 years of professional experience. The majority of comparable Master’s programs offer an internship component as an elective in their curriculum, with only two programs requiring students to complete this supplementary training. Additionally, university leadership may want to focus on recruiting students from a specific industry. The following report provides an analysis on three potential industry segments: 1) Life Sciences and Biotechnology, 2) Pharmaceutical and 3) general health industry segments. Students will likely enroll from all these three industry segments, however, by focusing on a specific industry UC San Diego leaders can ensure that the target student population’s educational programmatic preferences are addressed.

Comparable programs range from 18 months to 2 years of instruction, with the vast majority being 2 years in length. Employers showed a strong interest in a two-year delivery format. Meanwhile, students’ preferences were evenly split in terms of their preference for a 1 or 2 year program model. However, the preferred program length did vary when looking at students employed in specific industries.

The Return on Investment (ROI) for career advancers varied depending on the program length. Regardless, both the one- or two-year program models provided a reasonable ROI within the next ten years of a student’s career.

Overall, moving forward with the Master’s in Science in Drug Development and Product Management appears to be a viable option in terms of employer and student appeal. The majority of employers found the degree would be useful or very useful. Similarly, the majority of potential students also expressed finding the degree appealing or “maybe” finding it, with very few individuals not finding it
appealing. Based on this research, in the United States there are eight comparable Master’s programs that exist proving that there is a market.

----------

In addition to the market assessment, a number of industry leaders have been consulted regarding the proposed program. They have heartily given their endorsement of the concept and effort. Specific letters of endorsement from many of these individuals can be found in Appendix F of this document.

Furthermore, the managing director for this proposed degree program has experience offering online curriculum. In 2013 and 2014 the director offered a non-credit drug product development and commercialization course on Coursera (a commercial online learning platform with global reach). Our course attracted over 50,000 students worldwide, with several thousand performing well enough to receive validated documentation of their work. The experience with Coursera demonstrates that there is a strong global interest in learning the process of drug product development and management.

A desire at UCSD to contribute to the innovative capacity of the drug development industry is represented in the Center for Drug Discovery Innovation at the Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS), which will participate in this degree program. The effort to create a globally-accessible graduate program in drug development and product management is also an important component for the UCSD Division of Health Sciences and The Center for Translational Research Institute (CTRI) that received a Clinical Translational Science Award (CTSA) recently funded by the NIH. The introduction of the DDPM degree will contribute to developing UCSD as a world-class center for clinical and translational research, since drug development and management is a key part of the translational research process. The degree is also a high campus priority because it is part of a strategy to recruit more graduate-level professionally-oriented students, and thus more completely serve the biotech and pharmaceutical industry so closely tied to the work at UCSD.

3.2 Placement estimates, and enrollment projections
The internship component of the degree program is a key benefit for employers as it allows them to attract potential employees and assess their talent. It also helps students see whether or not they would enjoy working in a particular organization. According to a 2015 survey by the National Association of Colleges and Employers (NACE), the internship conversion rate is currently 51.7% which means that over half of students interns receive employment in the same organization where they do their internship. Thus, the internship component of the degree program provides strong confidence that students will find career placement upon completion of the program.
Regarding program enrollment projections, based on the initial market assessment and the strength of anticipated student placement, the program is confident it can obtain 24 new students each year during the stabilization phase and beyond. Furthermore, projections to obtain 48 new students each year once a global online format is available are also well within reach. Specifically, the program projects enrollment as outlined in Table 1.

### Table 1
Projected Enrollment Through Year Five (Steady State)

<table>
<thead>
<tr>
<th>Format/Cohort</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residential</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort 1</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Cohort 2</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Cohort 3</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort 4</td>
<td>24*</td>
<td>24*</td>
<td></td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Cohort 5</td>
<td>24*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Online</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort 6</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort 7</td>
<td></td>
<td></td>
<td></td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td><strong>Total/FTE students</strong></td>
<td>24</td>
<td>48</td>
<td>48</td>
<td>72</td>
<td>96</td>
</tr>
</tbody>
</table>

* hybrid format using online elements

The demands of the program make simultaneous full-time employment impractical. Thus, the mix of residential students is anticipated to be one-third local students, one-third visiting domestic students, and one-third visiting international students. The mix of online students is anticipated to be almost entirely students from outside the region, although as the program matures, local students may find the online format preferable in accommodating a part-time work schedule.

### 4.0 Faculty

The program relies upon a combination of current ladder-rank and adjunct faculty, supplemented by rotating speakers from industry. One new faculty member with expertise in regulatory science will be hired before the program begins, and will teach two courses in the program as part of their duties. The anticipated course coordination load for existing faculty will be very modest (one course per year in most cases), so that it will not negatively impact current duties, but specific statements from many of the faculty regarding the impact of this program on their overall workload of are included with their CV in Appendix C of this document. The SSPPS faculty committee on educational programs has reviewed each of these statements and has endorsed the participation of their faculty who are listed in this section.

All faculty work in the program will be funded directly from the program. The program budget also includes support for assistance to a course coordinator when the number
of student or specific course workload justifies that additional support. Assistance is anticipated to be provided by Fellows or PhD students within Health Sciences.

The Curriculum Vitae of each faculty member committed to participate in the program can be found in Appendix C of this document (separate file).

**Steering Group**

The following individuals will serve as steering group members, overseeing all elements of the curriculum, faculty selection and performance, student advising, and industry relations. They will also coordinate courses, teach, serve on the admissions committee, and advise students. Members of the Steering Committee serve for a three year term, which may be repeated. They are appointed by the Dean of the Skaggs School of Pharmacy and Pharmaceutical Sciences.

**Jan D. Hirsch, BS Pharm, Ph.D.**

Dr. Hirsch’s role in the program as the Faculty Director will be to provide oversight of faculty selection and performance, as well as academic policy and decisions, including student evaluation. In addition she will teach in classes related to pharmacoeconomics and outcomes research.

Currently, she is Associate Professor of Clinical Pharmacy in the Skaggs School of Pharmacy and Pharmaceutical Sciences and Executive Director of Partners in Medication Therapy (PMT), an outreach program of the school to provide medication therapy management services in the community. She is also a Clinical Pharmacist Specialist at the Veterans Affairs of San Diego Healthcare System where she is involved with formulary management activities within the VA to improve clinical outcomes and responsibly manage medical costs. Prior to joining the UCSD faculty, she spent 14 years in the pharmaceutical and managed care industry where she was responsible for establishing and managing outcomes research departments for two global pharmaceutical companies and a US pharmacy benefit management company.

**Williams S. Ettouati, Pharm.D.**

Dr. Ettouati’s role in the program as the Managing Director will be supervising day-to-day operations (including program related student interactions), recruiting student mentors, and overseeing student internships. He will be the primary contact with industry advisors and employers. In addition he will teach in classes in pharmaceutical marketing, product management, and business development, managing innovation and creating new biotech companies.

Dr. Ettouati is currently Director, Industry Relations and Development and Health Sciences Associate Clinical Professor at the Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) at the University of California San Diego. Dr. Ettouati’s role at the Skaggs School of Pharmacy and in Health Science School of Medicine is to develop and secure strategic collaborations, ranging from drug discovery to corporate sponsored fellowships for Pharm.D. students with
PROPOSAL FOR A MASTER OF SCIENCE DEGREE IN  
DRUG DEVELOPMENT AND PRODUCT MANAGEMENT

pharmaceutical and biotechnology companies.

Before joining the Skaggs School of Pharmacy and Pharmaceutical Sciences, Dr. Ettouati spent twenty years in the pharmaceutical and biotechnology industry in senior leadership roles (e.g. CEO, President & Co-Founder, Director, Chief Business Officer). Dr. Ettouati has proven and extensive experience encompassing multiple functional disciplines in pharmaceutical executive management, in areas such as business development, licensing, marketing and new product planning strategy in biotech and pharmaceutical companies.

**Jeremiah Momper, Pharm.D., PhD**

Dr. Momper’s role in the program will be to teach classes in regulatory sciences. He will also participate in academic policy decisions and matters of program marketing and design strategy as a key member of the program steering committee.

Currently, he is Assistant Professor of Clinical Pharmacy in the Skaggs School of Pharmacy and Pharmaceutical Sciences where his research is focused on mechanistically understanding alterations in drug disposition and response in special populations. Studies investigating pharmacokinetic-pharmacodynamic relationships of antiviral nucleotide analogs in transplant recipients with opportunistic infections are ongoing. In addition, Dr. Momper is pursuing the application of novel clinical pharmacology tools, such as physiologically based pharmacokinetic modeling, to support scientific decision making during pediatric drug development. Prior to joining UCSD Dr. Momper worked at FDA and completed Commissioner’s Fellowship (2011-2013) Office of Clinical Pharmacology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

**Core Faculty**

The following individuals will coordinate courses in the program, teach, serve on the admissions committee, and may serve as student advisors.

**Brookie Best, Pharm.D. MAS**

Dr. Best’s role in the program will be to chair or co-chair a course in Pharmaceutics for Small Molecules and Macromolecules, and to give lectures in areas related to her expertise in Phase 1 and 2 clinical studies, pharmacokinetics, and designing dosing regimens in various patient populations, including infants, children, non-pregnant adults, and pregnant and lactating women.

Dr. Best is Professor of Clinical Pharmacy in the Skaggs School of Pharmacy and Pharmaceutical Sciences where she specializes in pharmacokinetics – the processes by which a drug is absorbed, distributed, metabolized and eliminated by the body – and pediatric clinical pharmacology research. Her research efforts have focused on studying anti-HIV drugs in infants, children, adolescents, non-pregnant adults, and
pregnant women. She also studies drugs used to treat Kawasaki disease, the leading cause of acquired heart disease in children. She has specific interests and expertise in maternal-fetal clinical pharmacology, therapeutic drug monitoring of antiretrovirals, antiretroviral pharmacogenomics, and penetration of antiretrovirals into the central nervous system.

Hubert C. Chen, MD
Dr. Chen in the program will be to co-chair the course in Biologics and BioSimilar. Dr. Chen is a Physician-scientist with 12 years of research & development experience in multiple therapeutic areas in the biotech industry, and six years of basic research, clinical care, and teaching experience in academia. Dr. Chen experience as an executive at Amgen and in start-up enterprises demonstrated proven ability to work in a fast-paced, matrix environment, both as a strategic leader and a “roll-up-the-sleeves” tactician. Dr. Chen led and supervised multiple projects through key stages of research and development, including target selection (two programs), clinical candidate nomination (seven), IND submission (nine), clinical proof-of-concept (four), and phase 3 start-up (two). Dr. Chen is Board certified in both Internal Medicine and Endocrinology, Diabetes & Metabolism. Dr. Chen is currently Chief Medical Officer at Pfenmex Inc.

Vish Krishnan, Ph.D.
Dr. Vish Krishnan is an accomplished scholar and an award-winning educator with substantial industrial and academic experience. For over two decades, he has worked with the senior leadership at cutting-edge global firms, served in editorial positions at the top academic journals, and has been named the Most Valuable Professor multiple times by his students. Besides working in software and automotive companies, he has consulted with senior managers and executives at multi-national companies such as 3M, Dell, HP, Qualcomm, Sony, Ford, Nissan, Zeiss, and Microsoft. He has also been a visiting Professor at the Harvard Business School, and has been invited to deliver seminars at many major Universities including MIT, Harvard, Stanford, INSEAD, University of Chicago and UCLA.

Vish Krishnan received his doctorate degree from the Massachusetts Institute of Technology, and is currently Chaired Professor and a founding faculty at the University of California, San Diego’s Rady School of Mgmt. He teaches and specializes on the topics of Innovation & Entrepreneurship, Growth Strategy, New Product Development, and Supply Chain/Operations Mgmt. He has developed and launched Rady’s signature MBA curriculum, “Lab to Market”.

Joseph D. Ma, Pharm.D.
Dr. Ma’s role in the program will be to chair a course in early stage clinical development processes and requirements and to give lectures in related content. Dr. Ma will also co-chair a course in Biologics and BioSimilar

He is an Associate Professor of Clinical Pharmacy in the Skaggs School of Pharmacy and Pharmaceutical Sciences. His current research interests are evaluating in vivo
drug metabolizing enzyme activity and opioid pharmacokinetic variability. His current clinical practice is the Doris A. Howell Pain and Palliative Care Service at the UC San Diego Moores Cancer Center, where he specializes in symptom management. Prior to joining UCSD Dr. Ma worked at Amgen in early clinical trial development where he was responsible to help develop drugs to IND and manage proof of concept clinical trials.

**Morton Printz, PhD.**
Dr. Printz is professor of Pharmacology at UCSD School of Medicine in the department of Pharmacology. Dr Printz role will be to lead and coordinate the course in System Pharmacology and Toxicology.

Dr. Printz research focuses on finding the genes that are responsible for adverse stress-induced effects on the cardiovascular/autonomic system and then figuring out their molecular mechanisms. Dr. Printz has been teaching for over thirty years at UCSD in the Biomedical Sciences graduate program in Health Sciences.

**Chantal Reed, Ph.D.**
Dr. Reed’s role in the program will be to chair or co-chair a course in Pharmaceutics for small molecules and macromolecules, and to give lectures in areas related to her expertise.

Dr. Reed has a Ph.D. in Bioengineering, currently a pharmaceutical executive and volunteer Faculty at SSPPS. Her research focused on the complexation of synthetic, pH-responsive polymers with proteins in order to enhance the endosomal release of targeted biomolecules, thereby increasing their therapeutic efficacy. in the area of drug delivery and product quality for antisense oligonucleotides, small molecule. While working with biotech companies her responsibilities included developing novel formulation research to qualify new dosage forms appropriate for specific therapeutic indications and routes of administration. She focused on novel (liposomal and polymeric) dosage forms, aseptically prepared parenteral solutions and nasal sprays. She designed and led animal studies to ascertain the effectiveness of novel formulations. In addition, her responsibilities included optimizing transfection conditions in new and difficult cell types, including primary cells, investigating cell-type specific parameters which affect the efficiency of in vitro transfection.

**Andy Sarkin, PhD**
Director of Evaluation Research
Health Services Research Center
UC San Diego
Dr. Sarkin’s role in the program will be to chair and teach lectures in the Health Outcomes Evidence: Prospective Trials, Claims Data and Predictive Models course. In addition he will advise the Steering Committee on program content and internship opportunities based on his experiences teaching students in the UCSD CREST program and his collaborative research with pharmaceutical companies and community based health systems.
Dr. Sarkin is Director of Evaluation Research at the UCSD Health Services Research Center where he oversees a staff of 25 people who collectively provide a wide variety of health research services to other organizations in academia, pharmaceutical industry, and community partners (e.g. County of San Diego Adult Mental Health System). He also serves as course director of the Research Project Management course in the UCSD CREST program and Graduate Seminar in Program Evaluation at San Diego State University.
He is well published and serves on several editorial and advisory boards related to his program evaluation research expertise.

Additional Faculty

The following individuals will teach in the program, and may serve as student advisors.

Steve Duff, MS

Mr. Duff’s role in the program will be to provide lectures within the project management course related to health economic and reimbursement issues from early development through utilization management for marketed drug products within managed healthcare systems. In addition he will advise the Steering Committee on program content and internship opportunities based on his experiences and relationships within the pharmaceutical, biotech, device and managed care industry.

Mr. Duff is founder of Veritas Health Economics Consulting, and has spent over eighteen years providing health economic and reimbursement consulting services to pharmaceutical, biotechnology, medical device, and diagnostic companies. Mr. Duff provides to his clients a unique combination of health economics expertise with clinical knowledge and product development experience gained through various positions in the consulting and pharmaceutical industries. Prior to founding Veritas Health Economics Consulting, Mr. Duff spent eight years as a consultant with Covance Health Economics and Outcomes Services where he focused on medical technology assessment, economic modeling, and development of dossiers, manuscripts, and strategic plans. His clients ranged from small start-ups to Fortune 500 companies with technologies in various stages of development and marketing. In addition to his consulting experience, Mr. Duff also has held various positions in pharmaceutical research and clinical development. He spent seven years in research and development at Kendall McGaw and Allergan, primarily in the field of pharmacokinetics.

Bimal V. Patel, Pharm.D., M.S.

Dr. Patel's role in the program will be to provide lectures within the project management course related to managing utilization and the cost of marketed drug products within managed healthcare systems. In addition he will advise the Steering
Committee on program content and internship opportunities based on his experiences and relationships within the managed care industry.

Dr. Patel is Director, Health Outcomes & Advanced Analytics at MedImpact, where he is responsible for the application of health outcomes and advanced analytic concepts into prescriptive analytics, clinical programs and product development. His work encompasses understanding patient/prescriber behavior, impact of pharmacy benefits, effectiveness of clinical program, development and application of predictive models and understanding the impact of health policy on population health. Dr. Patel is a volunteer Assistant Clinical Professor for UCSD’s Skaggs School of Pharmacy and Pharmaceutical Sciences; serves as a co-chair of the Quality Metric Expert Panel for Pharmacy Quality Alliance and is an Academy of Managed Care Pharmacy representative for the Interpreting Modeling Studies for Health Care Decisions Task Force within the Comparative Effectiveness Research Collaborative Initiative.

**Dr. Jonathan H. Watanabe, Pharm.D. Ph.D.**

Assistant Professor of Clinical Pharmacy  
Dr. Watanabe’s role in the program will be to provide lectures related to health economic issues and analyses using large databases (public and private) to inform product development, utilization and reimbursement decisions from early development through utilization management for marketed drug products within managed healthcare systems. His efforts will be particularly directed to the Health Outcomes Evidence: Prospective Trials, Claims Data and Predictive Models course. In addition he will advise the Steering Committee on program content and internship opportunities based on his experiences and relationships within the pharmaceutical, biotech, device and managed care industry.

Dr. Watanabe is Assistant Professor of Clinical Pharmacy in the Skaggs School of Pharmacy and Pharmaceutical Sciences where he specializes in determining the impact and determinants of compromised medication adherence on clinical and economic outcomes. His investigations include exploring the effect of copayment and copayment pricing on adherence; measuring influence of polypharmacy on adherence; measuring the influence of pharmacy benefit on health services utilization; and contrastiing methods used in health services investigations applying large national databases. His past experience includes fellowship within the pharmaceutical industry focused on application of outcomes research data and tools to guide early product development decisions within pharmaceutical company through marketed product utilization decisions in managed care. He currently serves as course coordinator of the Pharmacy & Therapeutics course and liaison with the Academy of Managed Care Pharmacy for the Skaggs School of Pharmacy, as well as serving as the the American Association of Colleges of Pharmacy delegate to the Pharmacy Quality Alliance workgroup for Long Term Care.
5.0 Courses

The full list of courses to be taught in the program follows. All of the course listed are new and will be developed specifically for this program. The listing indicates the course coordinator, and details regarding the content of the course. Parameters regarding course length, units of credit, etc. can be found in the Academic Senate course approval requests included in Appendix D of this document.

As the program is self-funded, state tuition payments are not applied. Consequently, although courses in the program are open to any admitted UCSD graduate student, separate fees must be assessed to that student (or a sponsoring department).

System Pharmacology and Toxicology (DDPM 201). M. Printz.
This new course is designed to provide students an introduction and survey of pharmacological concepts, constructs and essential considerations necessary through the multiplicity of stages in new drug design, development, testing and therapeutic trials and testing. The course presents a core body of knowledge in pharmacology and toxicology to students with varying academic backgrounds of didactic and/or experiential learning and experiences. Such a body of knowledge should enable future managers to better guide their efforts in drug discovery and clinical testing. This course will seek to “segment” the issues and challenges in new drug design based on known pharmacological and pharmaco-therapeutic principles and knowledge.

Specific topics in the course include:
- Origin, history and basic principles of pharmacology, pharmacokinetics and toxicology.
- Cardiovascular and cardiac pathophysiology
- Pulmonary and immunology
- Cancer and growth dysfunctions
- Behavioral and sensory disorders

Pharmaceutics for Small Molecules and Macromolecules (DDPM 202). B Best
The course has the following key objectives: (1) to examine the systemic bioavailability of drugs following various routes of administration and the bioequivalence of drug products; (2) to delineate the physiologic processes determining the rate and extent of drug absorption; (3) to summarize the physicochemical properties of a drug and the formulation factors influencing the rate and extent of drug absorption; (4) to present the pharmacokinetic principles used to summarize and predict the time course of drug in the body; (5) to understand the process used by companies to take a newly identified drug candidate to a commercial product preformulation, excipients, manufacturing, packaging); (6) to be able to evaluate and select an appropriate dosage form, including (a) understanding the chemical, physical chemical and physiologic barriers that must be considered in the design of the dosage form, (b) understanding the processes used to manufacture the dosage forms, and (c) being aware of the critical factors associated with the integrity of dosage forms; (7) to
become familiar with devices and formulations being used to effectively administer drugs.

Descriptive elements of the course are outlined below:
- Introduction to topic (vocabulary and definitions) and team projects
- Regulatory agencies/considerations/global
- The Drug (API overview) – Small molecule and biologics
- Excipient functionalities
- Preformulation studies
- Site of administration to systemic circulation
- Oral absorption: anatomic and physiologic considerations
- Capsules, tablets, manufacturing (including laboratory)
- Systemic exposure and assessment of drug absorption
- IV/invasive delivery
- Sterility considerations
- Extravascular administration
- Repeated dosing/accumulation
- Novel delivery formulations and systems (SR, ER, etc.)
- Issues and regulatory perspectives in BA and BE
- Pharmaceutic considerations for generics/Biosimilars
- Stability
- SISPQ
- Dissolution (as related to bioequivalence)

Pre-Clinical and Clinical Regulatory Submissions (DDPM 203). J. Momper
This course provides an overview of the common regulatory filings during pre-clinical and clinical development, including Investigational New Drug Applications and New Drug Applications. Using a case study format, the student will gain an understanding of the regulations governing pharmaceutical and biologic products in the United States and globally. The process of writing multidisciplinary reports and submissions to regulatory agencies is reviewed. Generic drug regulation is also be explored.

The course objectives are:
- Describe the timeline of regulatory submissions to move drug products and biologics toward approval
- Examine key elements for successful regulatory filings, including INDs, BLAs, NDAs, sDNAs
- Understand the role of project managers and other regulatory professionals in the drug development process
- Conduct case studies to illustrate the potential pitfalls in interacting with regulatory agencies in the United States and abroad
- Understand harmonization of the drug development process from a global perspective

Early Stage Clinical Trials (DDPM 204). J. Ma
At the completion of this course the students will be able to have a better understanding of early stage clinical drug development. Students will learn the
process of drug development through specific examples of case studies to better understand the issues facing the challenges of delivering a new drug on the market.

The course objectives will be:
- Be able to describe early stage drug development clinical trials such as Phase 0, Phase 1, drug-drug interaction, drug-food interaction, and bioequivalence trials.
- Identify outcomes and/or endpoints differences between a Phase 0 vs. Phase 1 vs. drug-drug interaction vs. bioequivalence trial.
- Incorporate study design methods for consideration in the design of clinical protocols to access safety, tolerability, and efficacy in multiple therapeutic areas.
- Understand the challenges and bias related to the conduct of clinical research and/or clinical trials.

**Principles of Drug Development (DDPM 205).** (New clinical science faculty)
This course presents principles underlying preclinical and clinical development of new therapeutic drugs, and biomarkers. The course uses a case-study approach to identify and solve practical, theoretical, and technical problems in human drug studies. In addition the course analyzes an experimental design for a new drug candidate. It also includes legal and ethical regulations that apply to drug development.

**Patent Strategy and Freedom to Operate (DDPM 206).** Tbd
The Patent Strategy & Freedom to Operate course explains how to maximize Pharmaceutical Patent Life Cycles in the pharma and biotech industry. Unprecedented patent losses starting in 2016 on small molecule pharmaceutical products having values in excess of $100 billion annually will occur in the next few years.

This course will:
- Provide fundamental concepts in patent law as they relate to pharmaceuticals.
- Explain patent terminology to enable better understanding of patent law concepts presented in the course.
- Inform and analyze on patent life cycle management for both small and now large molecule pharmaceutical products.
- Cover both US PTO and European Patent office.
- Describes the major components of a patent document and how the invention is incorporated into the patent application.
- Explain how pharma and biotech are using IP assists to increase value and monetize their IP portfolio, compared to the software industry for example.
- Provides a historical perspective, along with provisions for generic companies to challenge patents covering brand name drugs; Including topics such as patent validity and infringement.
- Cover and discuss how Pharma R&D vertical fragmentation creates transformational IP paradigm for the companies. If not managed properly, this can increase risks to the company and, as an industry trend, can actually lead to destabilisation over the longer term. Potential IP increased risk caused by allocation of control and inherent conflicts of interest in licensing arrangements.
PROPOSAL FOR A MASTER OF SCIENCE DEGREE IN
DRUG DEVELOPMENT AND PRODUCT MANAGEMENT

- Analyze recent critical cases affecting patent life cycle planning using case study.
- Assess the impact of PTO procedures under the AIA on Hatch-Waxman strategies relative to Patent Life Cycle Management.
- Explain how Biosimilars development and approval will influence pharmaceutical patent life cycle and portfolio strategies in view of the further implementation of Biologics Price Competition and Innovation Act of 2009 (BPCIA) and the inevitability of the patent cliff.
- Present and discuss key pharmaceutical cases decided by the Supreme Court that could have a major effect on drug development.
- Understand the impact of negotiations from the Trans-Pacific Partnership and Trans-Atlantic Trade & Investment Partnership and impact on patent laws on pharmaceutical products.

Foundations of Project Management for BioMedical & Pharmaceutical Product Development (DDPM 207). V. Krishnan
Using multiple case studies and real-world examples, this course describes the complexity of today’s project management in a global drug development effort. We discuss how the underlying risk in particular makes it very challenging to manage drug development and how project management can help mitigate risk. We then define project success and how different types of projects may emphasize different dimensions of success. A phased approach to projects is introduced for structure and consistency. Discussions cover Project Planning and Scheduling Essentials: Critical Path and Schedule Risk Management. The course then closes with an in-depth coverage of project execution issues, including managing teams, meetings, and the psycho-social issues of project management.

Key objectives of the course include:
- Communicate the key role of project management in the drug development success.
- Describe how project portfolio management guides the drug development effort to make it more efficient and effective.
- Learn the central project management concepts of critical path and critical chain planning and scheduling as well as detailed methods/tools that help implement these concepts.

Marketing Strategy, Product Management & Life Cycle Product Management (DDPM 208). W. Ettouati
The course has four key objectives: (1) Explain key components of global drug marketing strategy in a highly regulated environment; (2) Explore portfolio strategy as it relate to drug product management; (3) Describe and explain LCSP process including what happens once the patent on a drug goes generic and what are the strategies to protect the brand; and (4) Provide students with multiple case study describing the complexity of today brand management on a global basis, and how pharmaceutical drugs are commercialized in today’s environment.

A description of course content is outlined below:
• Define and cover the Four P’s of drug marketing; Place, Product, Price, Promotion
• Define the Four C’s explaining the complexity of marketing today, Customer solutions, Customer Cost, Communication, Convenience
• Analysis and understand of market research principles and factors influencing marketing strategy
• Discuss and analyze pharmaceutical marketing strategy tools
• Maximizing tactical plan including utilization of Social media
• Increasing impact through effective segmentation & targeting
• Building competitive advantage through creative product positioning, to ensure successful product launch
• Role and application of branding
• Building an effective and engaging marketing plan & promotional mix
• Discuss and analyze what constitute a highly differentiated drug product profile
• Review principles and process of launching a brand successfully, including key stages of launch planning and priorities for each stage
• Explain and discuss the role of the launch Team Leader, consider leadership skills and qualities for working with and leading cross-functional launch team
• Define importance of customer, market understanding and segmentation on how to optimize customer focus and successful launch
• Learn about measuring marketing effectiveness
• Discuss and analyze purpose of portfolio management

This course provides an overview and understanding of the types of analyses that contribute to developing a body of cost effectiveness evidence demonstrating product value. The student will advance from basic understanding of analysis types, to ability to critically analyze the strengths and weaknesses or published cost-effectiveness evidence, on to conducting their own cost-effectiveness analysis.

The course objectives are:
• Illustrate basic types of analyses that contribute to a body of cost-effectiveness evidence, including clinical, economic and humanistic data
• Examine the requirements for cost effectiveness evidence to support reimbursement decisions by payers across major global markets
• Understand the role of cost-effectiveness analyses throughout the drug development and marketing process
• Critically evaluate the common types of cost effectiveness studies presented in the medical literature to determine quality and relevance to decision-making needs
• Conduct a cost effectiveness analysis using cost data from public sources and effectiveness data from the published literature.
**Biologics & Biosimilars Drug Development (DDPM 210).** J. Ma and H. Chen

The Biologics and Biosimilars course has three key objectives: (1) explain how biologics are developed and commercialized as therapeutics, (2) explore how the process differs from the traditional pharmaceutical approach for small molecules, and (3) outline the challenges and opportunities for producing more affordable generic equivalents, also known as biosimilars.

A description of course content is summarized below.

- Define basic concepts of recombinant DNA technology and terminology
- Describe key phases of biologics research and development, from target identification through the end of clinical testing and regulatory approval
- Compare and contrast the biologics process with that for small molecule pharmaceuticals
- Explain the scientific and regulatory challenges that have limited the development and approval of follow-on equivalents of biologics, or biosimilars
- Review recent advances in analytical and regulatory sciences that facilitate the development of biosimilars
- Highlight regulatory pathways available for biosimilars approval in the US, Europe, and other key geographic regions
- Outline opportunities and areas of uncertainty for the development and commercialization of biosimilars
- Explore how biosimilars development and approval will influence pharmaceutical patent life cycle and portfolio strategies

**Principles of Regulatory Science (DDPM 211).** (New clinical science faculty)

This course provides an overview of U.S. FDA regulations governing drug and biologic development and post-approval marketing. Practices in access to regulatory information, submissions, FDA inspections, and good practice quality guidelines (GLP, GCP, GMP) are covered. Using a case study format, the student will gain an understanding of the legal and scientific considerations for moving a product through the development process.

The course objectives are:

- Describe risk management strategies in the drug development setting
- Understand the FDA jurisdiction of drug law, including historical context
- Identify current U.S. and international regulatory guidance documents to reach scientifically justifiable conclusions
- Explain critical regulatory milestones in the product development process

**Analysis of Industry Needs in Drug Development and Product Management (DDPM 212).** W. Ettouati, J. Hirsch, J. Momper

This course prepares students to identify, obtain, and succeed at a practice-based internship. Accepting a collection of individual and group assignments to research corporations and public agencies in drug development and product management field,
students learn and share their findings regarding current industry challenges and concerns, workforce dynamics, and specific business opportunities.

Key objectives of the course include:
- Identifying suitable organizations and positions for practice-based internships
- Learning and practicing skills to define and secure a productive internship experience
- Identifying current scientific and business challenges facing the industry, as they relate to development and management of drug products.
- Identifying current practice in the industry regarding talent acquisition and retention, workforce development, distribution of professional responsibilities, organization structure, and salary structure
- Identifying currently promising areas of drug development, as well as current opportunities and threats with regard to the expansion of approved drugs
- Sharing information and generalizing findings to understand the current scope of industry business practice

**Health Outcomes Evidence (DDPM 213). A. Sarkin**
This course examines the breadth of data and study types that build evidence of a product’s value from potential estimates during the early development stages through to post marketing actual value realized over time in various populations.

The course objectives are to:
- Review common sources of health outcomes evidence including clinical, economic and humanistic outcomes.
- Examine the application, strengths and weaknesses of value evidence data from Phase 2, 3 and 4 clinical trials
- Describe common analysis techniques and strategies for assessing product value using pharmacy and medical claims utilization data
- Describe modeling methodologies, including regression, decision analytic, and Markov techniques, commonly used to examine product value post marketing
- Discuss appropriateness, limitations and strategic utilization of different types of data and analyses across the drug development and management continuum.

**Pharmaceutical Business Development & Managing R&D Innovation (DDPM 214). W. Ettouati**
This course has three key objectives: (1) learning the entire process and language of deal making within the pharmaceutical and biotech industries, from search and evaluation to closing the deal, (2) acquiring principles of negotiation strategy, valuation and how to best manage the contract phase and how to avoid the financial and legal pitfalls that can break a deal, and (3) understanding effective alliance management and the importance for a successful relationship between partners.

Descriptive elements of the course include:
- Learn the language, the concepts and tools from an executive’s point of view including search selection criteria
Understand the processes for in-Licensing vs. out-Licensing
Profile product opportunities that will the most suitable depending on each company’s profile
Quantify and differentiate BD opportunities and gain insight using benchmarking and SWOT analysis Strength weakness opportunity and threat
Develop analytical and personal skills necessary to become a successful BD executive
Learn valuation; risk and return analysis and the difficulties in forecasting
Pricing and reimbursement in valuing BD transactions
Analyze and understand different deal structures: joint ventures, licensing, M&A, options...
Discussion and analysis of successful and failed deals
Learn what makes up a good “Term Sheet” and how to assess those from other parties.
Effective negotiation planning: key success factors in the process including dos & don’ts during negotiation meetings
The final contract: what it should include to avoid problems and address dispute resolution
The deal is closed now each companies need to manage the relationship; students will learn alliance man

Comprehensive Analysis of Key Principles in Drug Development and Product Management (DDPM 215). Selected Steering Group members.
This course assists students in obtaining an integrated and comprehensive view of all of the key principles presented in the program, so they are able to articulate issues and practices in a professional manner, and continue to develop new knowledge in the field after they complete the program. The course is presented prior to the comprehensive exam for the degree. In the course, students work individually and in groups to review and present key elements of previous courses, while also identifying new concepts that arise from integration of key principles across subjects.

Practice-based Internship (DDPM 216). Various (student advisors)
This course consists of a full-time, three month supervised internship with a suitable company or public organization. Students apply the knowledge they have obtained in the program to assist their internship host in managing drug development projects and/or constructing and implementing product management strategies. The internship includes frequent research and analytical assignments. Students meet weekly to their academic advisor and their practice supervisor to review progress on assignments, challenges and questions, and overall performance.

6.0 Resource Requirements and Impact on the Academic Unit

Using the approved UCOP template for graduate program financial reporting and fee requests, Appendix E of this document outlines financial projections for this self-funded program.

The budget for this degree program meets all direct and indirect financial commitments, including assigned assessments for the division (SSPPS), the relevant vice chancellor (VCHS), and the office of the chancellor. Current UCSD policy for assessments on new master’s programs states that Graduate Division and ASSA
assessments will be covered as part of the assessments to the vice chancellor and chancellor. The UCOP assessment for this program will be covered as part of the overall Extension assessment addressed by the EVCAA.

No library acquisitions are required for this program, nor any special computing costs or special equipment. Standard campus support of an online learning platform is included in program assessments. Test proctoring services (for online students) will be funded by the program.

No special space or capital facilities are required as the program plans to use existing classrooms assigned to Health Sciences for face-to-face instruction, and the remaining instruction will be online.

Administrative support for the program will be provided by UCSD Extension. Under the direction of SSPPS, Extension will manage
- student recruitment
- admissions counseling and assistance
- development and execution of program administrative policies
- program finances
- instructor and student servicing
- coordination of online course development and hosting.

Extension has extensive experience in administering self-supporting professionally-oriented degree programs at UCSD. This arrangement will ensure no adverse administrative impact on SSPPS.

Extension, as administrative partner in the program, will establish accounts for this program on an Extension-managed fund, including a program reserve account for any program surplus or deficit accumulated over time, and maintain complete separation of those monies from any other Extension activities. All fee income program expenses will be managed and processed on the Extension fund, including any compensation to faculty who teach on overload, recharges to departments who assign faculty as part of their regular load, or “buy-outs” of faculty time. Campus assessments are also recharged to the program. The program is subject to annual review and approval by UCOP for program fees and overall financial viability.

Development Costs Associated with Movement to Online Delivery
Costs associated with developing and offering the program online are not reflected in the Appendix E Cost Analysis since they are one-time expenses, reimbursed through reduced assessments to the Chancellor and Vice Chancellor, producing no net impact on program finances.

Development costs consist of two elements. First, lead faculty will be compensated a one-time stipend of $10,000 per 4-unit course to work with online learning instructional design and technology support personnel to capture lectures and create suitable online learning activities, supplemental learning material, and self-assessment quizzes.
Course exams for online learning remain the same as in residential courses. This stipend may be allocated among a number of faculty associated with a course if that is deemed appropriate. The DDPM 216 course (internship) does not require development of an online course, so 15 courses in all will be developed for fully-online delivery, totaling $150,000 in faculty compensation stipends.

Second, $7,000 per course is being set aside for instructional design and technology support staff assistance. Although the campus Office of Online and Technology Enhanced Education does not require a recharge fee for their services, the program is budgeting for the contingency of needing additional contract staff for this project, or unique equipment, or access to additional/unique facilities, or capture of on-site footage at appropriate pharmaceutical facilities to enhance lecture and student learning, and/or increased technical assistance to students and instructors during the launch of each course. The average $7,000/course figure is based on the experience at Extension in launching new courses with complex design and significant student support. The overall set aside for this element is $105,000.

Also, aside from production and testing of online learning materials, promotion of the program to an international audience will require dedicated attention. The development budget includes a half-time contract position for nine-months prior to year four, to supplement Extension marketing resources, and the purchase of promotional attention (primarily digital ads and sponsored social media). The total cost of initial promotion of the fully-online delivery option is estimated to be $48,125. Ongoing annual international promotional costs are incorporated into the Appendix E Cost Analysis.

All of these one-time development costs will be assigned to the Extension fund, and reimbursed through program fees, specifically foregone assessments to the Chancellor and Vice Chancellor. The actual costs will likely be incurred during years two and three as the program learns from the initial years of practice, and approaches the planned launch of the online option. When development costs are incurred, assessments will be reduced/reassigned in that same period.

Other ongoing costs associated with movement to online delivery include academic advising and administrative support to students. The Appendix E Cost Analysis includes a $1,500 per-student stipend to faculty advisors, both during the residential and the dual delivery periods of program maturity, so the cost is fully variable with program enrollment. This stipend includes responsibility for advising and evaluating a student during their internship experience. The cost analysis also includes compensation for a course assistant for each course offered online as well as a 25% increase in faculty compensation to handle increased student interaction. Exam proctoring fees are the direct responsibility of each student (charged by each approved proctoring vendor), and are not processed through the program.

Should the program never achieve enough surplus to recoup the start-up costs or operating deficits, the Vice Chancellor of Health Sciences and the Dean of Extension have agreed to absorb the unreimbursed expense from other non-state fund reserves.
7.0 **Graduate Student Support**

7.1 **Financial Assistance**
Although students pursuing self-funded graduate programs are eligible for federal student financial loans, they are not eligible for state (i.e., taxpayer-funded) financial assistance. In order to provide suitable financial assistance options to students, this program will forego 10% of all fee income to offer program fee reductions of 50%. Based on current enrollment and financial projections, that equates to five 50% fee discounts for each incoming cohort each year (i.e., 20%+ of each cohort being supported, at least in part, through program-generated financial assistance).

The program will provide no employment, research, teaching, or training grants to students. Many students will be in overseas locations as they pursue the program, and some will be working, so grants of this nature are impractical or unnecessary. Students may be paid by an employer during their practice internship, at the discretion and judgment of the employer, consistent with visa and/or IRS rules. UCSD makes no commitment to students regarding this practice, nor will the university be involved in the employment or compensation process.

7.2 **Enhancing Diversity and Accessibility**
This program is committed to being inclusive and active in pursuing diversity both in student profiles and in the approach in instruction. Financial assistance offered by the program will be merit-based and open to individuals from a wide variety of academic and professional backgrounds, so that graduates will address the needs of the diverse market for this knowledge.

Active recruitment efforts and the fact that this is a self-funded and global program should lead to a continued diversified student base in terms of professional, academic and ethnic backgrounds. The program will remain steadfast in efforts to encourage application from highly qualified applicants from all sectors and levels within relevant industries so that the resulting applicant pool will meet diversity objectives.

8.0 **Governance**

This program will be managed by the Skaggs School of Pharmacy and Pharmaceutical Sciences, in cooperation with the UCSD Clinical and Translational Research Institute. SSPPS will have full control over all curriculum, faculty selection and review, admissions, and student evaluation. CTRI be consulted periodically in the oversight of program directors, selection of learning objectives, curriculum topics, and relations with industry and employers in order to ensure the effort is well coordinated and supportive of overall Health Sciences strategy.
Dr. Jan Hirsch, Associate Professor of Clinical Pharmacy and Executive Director of Partners in Medication Management, will be the faculty director of the program, providing oversight of faculty selection and performance, as well as academic policy and decisions, including student evaluation. Dr. Williams Ettouati, Health Sciences Associate Clinical Professor and Director of Industry Relations and Development, will be managing director of the program, supervising day-to-day operations (including course related student interactions), recruiting student mentors, and overseeing student internships. Dr. Jeremiah Momper, Assistant Professor of Clinical Pharmacy, will also be part of the program steering committee, participating in academic policy decisions and matters of program marketing and design strategy.

SSPPS does not currently award any MS degrees, so a new degree authorization for SSPPS will be required as part of this proposal.

The program also will receive oversight from the SSPPS Council on Educational Policy and the UC San Diego Graduate Council regularly.

9.0 Changes in Senate Regulations Required

No changes in Senate regulations are required at the systemwide level.

This proposal seeks approval to be offered in both residential and online formats now, but we expect that the program should be evaluated by the Graduate Council prior to moving online based on residential success.
## Appendix A: Program and Pace of Study

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Course</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1 (Fall)</td>
<td>System Pharmacology and Toxicology</td>
</tr>
<tr>
<td></td>
<td>Pharmaceutics for Small Molecules and Macromolecules</td>
</tr>
<tr>
<td></td>
<td>Pre-Clinical and Clinical Regulatory Submissions</td>
</tr>
<tr>
<td>Quarter 2 (Winter)</td>
<td>Early Stage Clinical Trials</td>
</tr>
<tr>
<td></td>
<td>Principles of Drug Development for BioMedical &amp; Pharmaceutical Product</td>
</tr>
<tr>
<td></td>
<td>Development</td>
</tr>
<tr>
<td></td>
<td>Patent Strategy and Freedom to Operate</td>
</tr>
<tr>
<td>Quarter 3 (Spring)</td>
<td>Foundations of Project Management</td>
</tr>
<tr>
<td></td>
<td>Marketing Strategy, Product Management, and Life Cycle Product</td>
</tr>
<tr>
<td></td>
<td>Management</td>
</tr>
<tr>
<td></td>
<td>Principles of Cost Effective Analysis in Drug Development and Markets</td>
</tr>
<tr>
<td>Summer Off</td>
<td></td>
</tr>
<tr>
<td>Quarter 4 (Fall)</td>
<td>Biologics and Biosimilars Drug Development</td>
</tr>
<tr>
<td></td>
<td>Principles of Regulatory Science</td>
</tr>
<tr>
<td></td>
<td>Analysis of Industry Needs in Drug Development and Product Management</td>
</tr>
<tr>
<td>Quarter 5 (Winter)</td>
<td>Health Outcomes Evidence</td>
</tr>
<tr>
<td></td>
<td>Pharmaceutical Business Development and Managing R&amp;D Innovation</td>
</tr>
<tr>
<td></td>
<td>Comprehensive Analysis of Key Principles in Drug Development and Product</td>
</tr>
<tr>
<td>Between quarters</td>
<td>COMPREHENSIVE EXAM</td>
</tr>
<tr>
<td>Quarter 6 (Spring)</td>
<td>Practice-Based Internship</td>
</tr>
</tbody>
</table>
PROPOSAL FOR A MASTER OF SCIENCE DEGREE IN
DRUG DEVELOPMENT AND PRODUCT MANAGEMENT

Appendix B: Market Assessment
[This page was intentionally left blank.]
The proposed Masters of Science in Drug Development and Product Management is geared towards individuals who need to have managerial, regulatory and legal knowledge regarding the drug development process as well as have a background in pharmacy, nursing, medicine and other related biomedical sciences. This program is intended for experienced professionals with advanced degrees to gain managerial and collaborative skills in order to effectively monitor the multiple facets of the drug product development process from “bench to bedside” in the workplace.

Based on data from comparable programs and survey responses, UC San Diego leadership should target potential students who are looking at advancing within their careers. Most comparable programs prefer students to have 2 to 5 years of professional experience. The majority of comparable Master’s programs offer an internship component as an elective in their curriculum, with only two programs requiring students to complete this supplementary training. Additionally, university leadership may want to focus on recruiting students from a specific industry. The following report provides an analysis on three potential industry segments: 1) Life Sciences and Biotechnology, 2) Pharmaceutical and 3) general health industry segments. Students will likely enroll from all these three industry segments, however, by focusing on a specific industry UC San Diego leaders can ensure that the target student population’s educational programmatic preferences are addressed.

Comparable programs range from 18 months to 2 years of instruction, with the vast majority being 2 years in length. Employers showed a strong interest in a two-year delivery format. Meanwhile, students’ preferences were evenly split in terms of their preference for a 1 or 2 year program model. However, the preferred program length did vary when looking at students employed in specific industries.

The Return on Investment (ROI) for career advancers varied depending on the program length. Regardless, both the 1 or 2 year program models provided a reasonable ROI within the next ten years of a student’s career. Overall, moving forward with the Master’s in Science in Drug Development and Product Management appears to be a viable option in terms of employer and student appeal. The majority of employers found the degree would be useful or very useful. Similarly, the majority of potential students also expressed finding the degree appealing or “maybe” finding it, with very few individuals not finding it appealing. Based on this research, in the United States there are eight comparable Master’s programs that exist proving that there is a market.
# Table of Contents

The Research........................................................................................................................................................................ 5  
Introduction.......................................................................................................................................................................... 6  
Master’s in Drug Development and Product Management.................................................................................................. 8  
    Competitive Analysis........................................................................................................................................................ 9  
    Employers Outlook......................................................................................................................................................... 12  
    Potential Students......................................................................................................................................................... 16  
    Return on Investment Framework............................................................................................................................... 24  
    Occupational Outlook................................................................................................................................................... 28  
    Potential Student Profiles........................................................................................................................................... 29  
    Final Recommendations.......................................................................................................................................... 30  
    Next Steps............................................................................................................................................................... 31  
Appendix A: Methodology................................................................................................................................................ 35  
Appendix B: Comparable Programs......................................................................................................................................... 36  
Appendix C: Occupations List............................................................................................................................................ 37  
Appendix D: Occupational Profiles..................................................................................................................................... 38  
Appendix E: Industry Clusters in San Diego County........................................................................................................... 45  
Appendix F: Industry Associations ..................................................................................................................................... 50
The UC San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences commissioned UC San Diego Extension to conduct a market research study to look at the viability of creating a master's degree in Drug Development and Product Management.

This study was conducted by UC San Diego Extension’s Center for Research on the Regional Economy (CRRE). UC San Diego Extension is the professional education and public service division of UC San Diego. The organization is focused on being a major catalyst for the continued economic, intellectual, and cultural growth of the San Diego and Baja California region. Core offerings include professional education and training, cultural enrichment, and regional economic solutions. The CRRE is Extension’s research arm, which focuses on technological innovations, researching global trends, and industry developments shaping regional economies. The department places specific emphasis on regional workforce trends.

The Master’s in Drug Development and Product Management market research study consisted of a competitive landscape analysis looking at similar Master’s programs throughout the nation. This analysis includes a comprehensive look at the curriculum, course delivery formats, program costs and student demographics for each of these comparable programs. To gain a comprehensive understanding of potential employers perception of the proposed degree, the research team interviewed and surveyed potential employers to ask them about their perception of the proposed degree and the potential skill sets learned through the program. A larger pool of potential students were surveyed (industry professionals) to understand their viewpoint of the proposed Master’s programs and the potential skill sets learned. In addition to this primary data collected, the research team used external data such as Bureau of Labor Statistics data to capture wage information and occupational growth projections; Burning Glass data to determine the top technical and soft skills required by specific occupations that each proposed master’s degree may target; and Economic Modeling Specialists, International data to determine the demographic profile for potential students. (See Appendix A for detailed methodology.) In addition, the research team created a Return on Investment (ROI) framework to calculate the potential benefit of the proposed Master’s degrees for individuals in various occupations. The market research study provides the reader with the research team’s final recommendations for the proposed Master’s degree. Finally, a list of potential next steps analysis is included to help UC San Diego Skaggs School leadership with their final program design.

At the end of this report is a comprehensive appendix, with detailed information regarding occupations, industry clusters in San Diego County, and industry associations that UC San Diego leaders may want to contact when moving forward with the Master’s in Drug Development and Product Management program.

Research Authors:
Josh Shapiro, Ph.D.
Gladys Bustos-Selfridge

Research Advisors:
Mary Walshok, Ph.D.
Bruce Dunn, M.B.A.
Jan Hirsch, BSPharm, Ph.D.
Jeremiah Momper, Pharm.D., Ph.D.
Williams Etouati, Pharm.D.

Research Assistants:
Caylen Garrie
Gina Carton

For questions please contact Dr. Josh Shapiro at jshapiro@ucsd.edu.
Introduction

In the last two decades, enrollment in higher education has increased significantly. The growth of individuals earning Master’s degrees increased by 47 percent between 1995 and 2005 and is only expected to grow more in the next decade. By 2022, experts predict that masters’ degrees will account for nearly one-third of all higher education degrees awarded.¹

Even with this increase of students enrolled in Master’s degree programs, historically popular Master’s degree programs in business, education, and law disciplines have experienced slower growth rates or a decline in enrollment. The demand for MBAs has experienced a slower than average growth rate (the average growth rate of Master’s programs is 6.2 percent in degree programs), while business programs have only experienced a 3.1 percent growth rate between 2009 and 2014.² Meanwhile, Master’s in education and JD admissions have declined by 0.6 percent and 17.6 percent respectively.³

<table>
<thead>
<tr>
<th>Master’s Degrees Growth Rate (2009 - 2014)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Master’s Degrees</td>
</tr>
<tr>
<td>↑ 6.2%</td>
</tr>
<tr>
<td>Business</td>
</tr>
<tr>
<td>↑ 3.1%</td>
</tr>
<tr>
<td>Education</td>
</tr>
<tr>
<td>↓ -0.6%</td>
</tr>
<tr>
<td>Law</td>
</tr>
<tr>
<td>↓ -17.6%</td>
</tr>
</tbody>
</table>

The programs seeing significant growth are niche Master’s programs that tend to focus on specific job skills, with many of these crossing traditional fields and disciplines. These niche programs are designed differently than traditional Master’s programs; they tend to be interdisciplinary and are designed around employers’ hiring needs and many times constructed in conjunction with industry.⁴

Professional Master’s programs appeal to a segment of students who have work experience and are focused on specific job skills they want to learn. Many of these programs are tied to geographic industry markets and their needs. However, even with this geographic focus, online delivery can expand a market’s reach.

The research team identified three main target student segments that enroll in Master’s programs. These include individuals starting careers, usually recent graduates seeking a graduate degree prior to entering the workforce (Career Starters). There are also mid-career professionals looking to advance their career (Career Advancers). In addition to these two groups there are also people that are looking at changing careers. This is a much more difficult demographic to capture as potential students are often mid-career professionals looking to transition

⁴ “Understanding the Changing Market for Professional Master’s Programs.” The Education Advisory Board. 2015.
from a variety of different industries and backgrounds. This report does not focus its research on this potential student population but is important to mention as a potential opportunity and could be tracked and analyzed over time.

Students in each of these market segments have different preferences for program structure. Some prefer accelerated delivery formats, while others prefer flexible delivery to accommodate their professional and personal commitments. If it’s not feasible for a program design to offer all the delivery formats for each student segment, programs should be designed to meet the needs of their target student demographic group.

Career Starters
Recent graduates with little to no industry experience seeking professional degree for additional experience/knowledge.

Career Advancers
Mid-career professionals looking for professional degree to advance their career or get a raise.

Career Changers
Mid-career professionals looking for professional degree to move into a new industry or career field.

Introduction

As more programs are targeted towards working professionals, there has been an increase in demand and availability of online programs. Even with this increase of programs, evidence shows that students prefer to enroll in a reputable university whose name they recognize within their state of residence.5

This report provides a market research analysis of a Masters in Drug Development and Product Management. The research team conducted a competitive landscape analysis, industry/employer outlook, potential student outlook, and an occupational outlook analysis (see Appendix A for methodology). Additionally, the research team created a Return on Investment (ROI) calculation for each of the potential student markets.

The proposed Masters of Science in Drug Development and Product Management is geared towards individuals who need to have managerial, regulatory and legal knowledge regarding the drug development process as well as have a background in pharmacy, nursing, medicine and other related biomedical sciences. This program is intended for experienced professionals with advanced degrees to gain managerial and collaborative skills in order to effectively monitor the multiple facets of the drug product development process from “bench to bedside” in the workplace. For the purpose of this report we analyze data looking at three industry segments, 1) Life Sciences and Biotechnology, 2) Pharmaceutical, and 3) other industries including health, government regulatory agencies, and other industries hat may be interested in this degree in the field of drug product development and management. Figure 1 shows examples of the types of occupations within these industry segments.

**Figure 1: Examples of occupations for industry**

<table>
<thead>
<tr>
<th>Life Sciences &amp; Biotechnology</th>
<th>Pharmaceutical</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical/Biological scientists</td>
<td>Clinical research manager</td>
<td>Business developers</td>
</tr>
<tr>
<td>Product directors</td>
<td>Medical and health services managers</td>
<td>Marketing managers</td>
</tr>
<tr>
<td>Natural sciences managers</td>
<td>Pharmaceutical scientist</td>
<td>Financial analysts</td>
</tr>
</tbody>
</table>

**Key Findings:**

- The majority of comparable programs are 2 years in length. Survey respondents were pretty evenly split between preferring a 1 year or 2 year model, student preferences varied depending on industry.

- The Master’s program should target Career Advancers in a specific industry segment. Students can vary from multiple industries, however, by targeting a specific industry university leaders can ensure that these students programmatic preferences are addressed.

- The majority of potential students found the degree appealing and would prefer full-time enrollment.

- The Master’s in Drug Development and Product Management would provide Career Advancers with a reasonable Return on Investment (ROI).
COMPETITIVE ANALYSIS

The research team identified fifteen programs similar to the Master’s in Drug Development and Product Management described above. These programs include ten Master’s programs, two PhD programs, and three certificate programs. Two of the Master’s programs and the two PhD programs will be excluded from the remainder of the analysis due to differing program structures and student targets.\(^6\)

Comparable programs are typically housed within the pharmacy schools or are collaborative efforts between the business schools and extended studies. Only one program is housed within the medical school. Programs focus their curricula on teaching regulatory, managerial, financial/economic, and ethics of overseeing drug development from lab to market. They also concentrate on leadership skills, identification of problems and solutions in a variety of settings, and critical problem analysis. They provide students with key resources and networks to obtain entry-level or mid-level careers in biotechnology or pharmaceutical companies, government regulatory agencies, nonprofit organizations, technology/consulting companies, financial companies or academic institutions. Appendix B shows a list of the 15 comparable programs.

The majority of comparable Master’s programs are designed to be completed within two years. However, programs offering intensive instructional delivery formats can be completed in as little as 18 months (San Diego State University) or in 12 months (University of Southern California) assuming full-time enrollment. Master’s programs range from $21,720 to $77,800 while certificate programs cost between $5,196 and $19,536.\(^7\) The average cost for a two-year Master’s program and certificate program is $40,495 and $11,244 respectively. Three of the Master’s programs are offered on-campus and two are available online. The remaining three programs allow students to choose among traditional, online, or hybrid instructional delivery formats. USC’s certificate offers a hybrid delivery format while SDSU’s is available online.

Six of the programs offer flexible admissions cycles where students can apply for the fall, spring or summer terms. The remaining two programs offer one admissions cycle.

CURRICULUM

Comparative Master’s programs require students to complete 24 to 66 credits, consisting of foundational core courses and electives. Common core courses and themes include statistics, business (biomedical commerce, principles of accounting and finance for science and technology), project management, early stage drug development, drug discovery, quality assurance, clinical research (design of clinical studies and structure). Elective classes are extremely diverse, ranging from scientific writing to fundamentals in intellectual property, health care law, and bioinformatics. In addition to meeting a certain number of credits, some programs require students to complete supplementary training and gain work experience through summer internships and/or practicums. Twenty-five percent of programs require an internship while fifty percent offer optional internships that are highly encouraged. All programs require a capstone project or a thesis.

---

\(^6\) The two programs offered at the University College London will not be included in the remaining analysis of the report due to its structure, a one year program, being specific to the UK. The program is more specific to the UK pharmaceutical industry thus making it not comparable to the identified programs in the US. The PhD programs will also be excluded from the analysis due to program structure.

\(^7\) Tuition for resident students enrolled full-time. This excludes other mandatory costs, such as administrative fees, health insurance, transportation, housing, etc.
STUDENT DEMOGRAPHICS
Most comparative programs require students to have a background in pharmacy, nursing, medicine, or other related biomedical science fields. Programs require or prefer students with a Bachelor’s degree in pharmacy or in chemistry of the biological sciences, a Doctor of Pharmacy, or a PhD with all incoming students having adequate preparation in mathematics.

Some programs emphasize at least 2 to 5 years of relevant work experience in the biotechnology, pharmaceutical, or other relevant healthcare industries. Students enrolled in the programs generally work full-time, part-time, or intern due to course flexibility. The majority of the Master’s programs are designed for career advancers with only one program geared toward career starters, career advancers, and career changers, and one program geared for career starters, the Keck Graduate Institute’s program.

INDUSTRY RELATIONSHIPS
Given the importance of specific skills being taught and ensuring students are prepared to obtain a job upon completion, the need to have industry advisors at the tables when programs are creating and revising their curriculum is an essential component for the majority of the programs. Program curricula are developed with assistance from leading biotechnology and pharmaceutical firms that are in proximity to the universities as well as other academic departments within the universities such the business schools, the public health schools and the medical schools.

LEADERS IN THE FIELD
San Jose State University’s Master of Science in Medical Product Development Management is a prime example of a degree geared towards the business aspect of medical product development. The program combines customized technical classes with MBA level business and management courses to better prepare students for leadership roles in the biomedical industry.

The University of Southern California’s Master’s in Management of Drug Development most closely resembles the proposed Master of Science in Drug Development and Product Management at UC San Diego. The emphasis of the program is to bring regulatory and basic science together to bridge the gap of drug discovery and clinical drug development in order to develop commercially viable drug products to market. The program is 32 credits and requires students without lab or industry experience to complete a six month practicum. While the program is designed to be 24 months, students can choose to complete the Master’s in one-year by enrolling in the fast track option. This allows students to take more courses at one time to complete their education within 1 year.
The Keck Graduate Institute’s Master of Bioscience is an example of a degree that emphasizes industry experience and networking. The program requires students to participate in a team-based capstone program called the Team Masters Project in addition to a mandatory paid summer internship at a bioscience company. This project showcases the students’ abilities to collaborate amongst their team members as well as with leading industry experts to produce a report for assigned sponsoring companies addressing the business and the technical aspects in the biosciences sector. Students are also responsible for presenting a confidential presentation at the site of the sponsoring company with the submission of a comprehensive report to their assigned faculty advisor. Students are required to complete 66 units in order to graduate. Lastly the Keck Graduate Institute serves as the national model for the Professional Science Master’s degrees.

Rutgers University’s Master of Business & Science with a concentration in Drug Development and Discovery focuses on the business facet of drug development and discovery. The program combines MS and MBA courses, requiring students to complete 24 credits in the sciences and 19 credits in business. Courses focus on teaching students about the pharmaceutical development processes as well as the communication and analytical skills necessary for managerial and staff positions in relevant industries. Additionally the Rutgers program has established a strong connection with the business community through the industry advisory and affiliates. The program is comprised of companies who work with the Rutgers faculty and administrators to create a curriculum relevant to industry. Additionally these companies provide internship and networking opportunities for the students and present lectures and seminars on the latest industry topics. Each curriculum area/concentration also has an advisory board particular to the scientific area.

---

9 This project represents about 33% of the students final year of academic work
9 “Professional Science Master’s degrees provide advanced training in science or math while simultaneously developing high-valued workplace skills. Today PSM degrees are offered at more than 300 institutions around the country.” Keck Graduate Institute Annual Report: 2014-2015.
EMPLOYERS OUTLOOK

The research team surveyed and interviewed 14 employers to understand their perception of the proposed Master’s in Drug Development and Product Management. Figure 2 illustrates employers’ perceived value of the degree. The majority (71 percent of respondents) found the degree to be useful or very useful in gaining employment at their respective organizations. The remaining 29 percent felt neutral about the proposed degree. None of the employers felt that the program would be of little or no use.

![Figure 2: Employers Perceived Value of Degree](n=14)

Very Useful 7%
Neutral 29%
Useful 64%

Employers were asked to rate a number of skillsets to be included in the proposed Masters degree program (Figure 3). Project Management was the most valued skillset by employers, followed by communication and writing skills; principles of drug discovery, design, development, and commercialization; regulatory knowledge; and on-site practice internship experience. Two employers also emphasized the need for understanding legal, patent, and intellectual property protection in the U.S. and worldwide. One employer in the regulatory sector emphasized that his company expects candidates to have a Master’s or at least certification in Regulatory, as well as experience in the pharmaceutical industry.
The following skillsets were suggested by employers as also being important for the proposed program:

- Address the global nature of drug development and how to manage teams internationally.

- As a part of the clinical data analysis, statistics, quantitative analysis and visual graphical analysis should be included as well as the ability to translate and synthesize a value story out of complex information.

- Leadership and negotiation skills.

- Health policy knowledge.
Employers emphasized that they perceived the proposed degree as an “add on” degree that could potentially provide individuals with an advantage over other candidates. They reported placing a higher priority on employees’ technical qualifications (often M.D. or Ph.D.). Employers would consider a person with a Master’s in Drug Development and Product Management and the required technical education for a more advanced role (or project management role).

Employers were also asked to provide the value they placed on program length and instruction model. For program length, employers were asked to select which of the following options their company would value more:

- A one-year program where students gain foundational general knowledge in drug product development and management.
- A two-year program where students can learn more specialized skills and can focus on one of two tracks (regulatory or project management).

The majority of respondents (86 percent) placed more value on a two-year instruction model (see Figure 4).

Figure 4: Program Length More Valued
(n=14)
In addition, employers provided their perceived value of the different format instructions. Ninety-three percent of respondents placed a higher value on the program being offered in a hybrid format (described as having some in-person classes and some online classes).

Twenty-one percent of employers would give candidates with the proposed degree a preference when selecting final candidates, with the remaining 79 percent reporting that they might do so depending on other factors. Eighty-six percent of employers also reported that they might give a job applicant with the proposed degree a higher salary, with only fourteen percent reporting they would not do so.

Furthermore, employers were asked to think of their most successful hires and the kind of profiles these candidates had. The following are summaries of employers’ responses:

- Well-rounded individuals that have highly technical and analytical skills with excellent interpersonal skills, good written and verbal communication skills.

- Individuals with work experience and a wide network.

- Self motivation with a constant willingness to learn and contribute.

- Clinical assessment skills, business sense, and negotiation skills.

- Ability to integrate transverse view, ability to define a critical path and have a solid logical approach to decision making/decision tree.

“I believe this Master’s program should supplement another graduate degree such as PharmD, PhD, MD or advanced nursing (ANP) to be of value when hiring for clinical positions. For regulatory Affairs position the Master’s degree with a 2nd year focus on Regulatory Affairs should be sufficient for an entry level hire.” - Employer
POTENTIAL STUDENTS
There are three potential target student demographics, Career Starters, Career Advancers, and Career Changers. Most of the comparable programs are geared towards Career Advancers with 2 to 5 years of work experience seeking graduate degrees for career advancement and promotions.

CAREER STARTERS AND CAREER CHANGERS
Career starters are potential students with little to no experience with industry. The Keck Graduate Institute is the only program targeting this subgroup of potential students. Because this potential market of students is challenging to identify for surveying purposes there is no survey analysis of this potential student demographic. However, it is worth noting that even though the focus of this report is not on this student population this is a possible outlier student segment that may enroll in this degree program, with the hope of getting hands-on experience and knowledge.

Career changers are those potential students that are changing tracks in their career (either industry or occupations). This is also a more difficult population segment to capture as they come from multiple occupations with different experiences. Part of this student segment is captured in the Career Advancers: Other analysis in the proceeding section.

CAREER ADVANCERS
The surveyed career advancers consisted of professionals employed in industries such as life sciences and biotechnology, pharmaceutical, and health services. The highest education attained by survey respondents consisted of 36 percent with at least a Bachelor’s degree, 22 percent acquired Master’s degree, and 42 percent had doctoral or other professional degree. Fifty-two percent of career advancers found the program appealing, 6 percent did not, and 42 percent expressed maybe. Figure 5 illustrates the appeal of the degree and Figures 6, 7, and 8 show the students’ preferences regarding the structural components of the Master’s in Drug Development and Product Management. Of the 42 percent who responded they maybe interested in pursuing this degree, they reported their willingness would be determined by the cost, skills learned, and the ability to build connections to industry and jobs. Less than half of these respondents were concerned with industry recognition and value of the degree. Respondents also indicated that the degree would be appealing if it included relevant certifications/qualifications with governing bodies as well as connections with the U.S. Food and Drug Administration (FDA). Many also indicated that their enrollment would depend upon course flexibility to accommodate work schedules as well as financial assistance.

The top reasons why career advancers find the program appealing is because respondents believed that the degree would facilitate career advancement and increase their marketability. Figure 9 shows a breakdown of the top five reasons selected. As seen in Figure 10, those who expressed disinterest in the Master’s largely indicated that they had no time at this point in their career to pursue such a degree. One respondent mentioned that they do not possess the skills needed to succeed in this type of program while another respondent stated that they have already taken sufficient courses related to this topic.
“The Master of Science in Drug Development and Product Management degree can be very valuable to industry professionals who need to develop their skills in a more holistic manner to break through the glass cone of overspecialized and isolated departmental silos.” - Managing Director
A CLOSER LOOK
Of the survey respondents, the research team identified three potential student segments: 1) individuals with a life sciences and biotechnology background, 2) individuals with a pharmaceutical background and 3) individuals with a variety of backgrounds from health services, manufacturing, regulatory agencies to managed care. Programmatic preferences varied depending on the student segment. The following are closer looks at each of these potential student populations.

A CLOSER LOOK: LIFE SCIENCES AND BIOTECHNOLOGY PROFESSIONALS
Survey respondents from the life sciences and biotechnology industry were primarily between the ages of 25 and 34, with 95 percent working full-time. Twenty-one percent of these respondents have a Bachelor’s degree, 19 percent have a Master’s degree, and 36 percent have a doctorate degree. Figure 11 illustrates the appeal of the degree. Fifty-five percent of respondents expressed finding the degree appealing, with 28 percent reporting they may be interested, and 17 percent reporting not being interested. Of the 28 percent that reported maybe reported their willingness would be determined by cost and building connections to industry and jobs, the largest determining factor, followed by industry’s recognition of the degree, skills learned and the length of the program. Figures 12, 13 and 14 show Life Sciences and Biotechnology Professionals preferences regarding different the components of the Master’s program.

“I believe that the Master's would be a great way to advance in my career and would also make me much more marketable.” - Head Researcher
Figure 11: Would the degree be appealing to you? (Career Advancers: Life Sciences and Biotechnology Professionals) (n=42)

- Yes: 55%
- Maybe: 28%
- No: 17%

Figure 12: Full-time or Part-time Enrollment (Career Advancers: Life Sciences and Biotechnology Professionals) (n=42)

- Full-time: 71%
- Part-time: 29%

Figure 13: Preferred Delivery Model (Career Advancers: Life Sciences and Biotechnology Professionals) (n=42)

- Traditional Model: 36%
- Hybrid Model: 71%
- Online Model: 19%

Figure 14: Preferred Program Length (Career Advancers: Life Sciences and Biotechnology Professionals) (n=42)

- One year: 43%
- Two years: 57%

Figure 15 shows the top reasons why careers advancers in the life sciences and biotechnology industry find the program appealing. Eighty-one percent believed that the degree allowed for the opportunity to gain greater knowledge. Many also believed that the degree was appealing because it would enable them to advance in their industry as well as enhance job security.
A CLOSER LOOK: PHARMACEUTICAL PROFESSIONALS

Survey respondents from the pharmaceutical industry are primarily between the ages of 25 and 34, with 92 percent working full-time. Forty-two percent of these individuals have a Bachelor’s degree, 21 percent have a Master’s degree, and 37 percent have a doctorate or professional degree. Figure 16 illustrates the appeal of the degree. Sixty-two percent of respondents expressed finding the proposed degree appealing, with 38 percent stating they may be interested, and zero respondents not finding it interesting. Of those that expressed that they maybe interested their willingness was primarily dependent on cost, followed by skills learned and the length of the program. Figures 17, 18, and 19 show respondents preferences regarding the components of the Master’s program.
Drug Development and Product Management

Figure 18: Preferred Delivery Model
(Career Advancers: Pharmaceutical Professionals)
(n=24)

Figure 19: Preferred Program Length
(Career Advancers: Pharmaceutical Professionals)
(n=24)

Figure 20 lists the reasons why career advancers in the pharmaceutical industry find the program appealing. Eighty percent believed that the degree was appealing because it would enable career advancement and 73 percent thought that the pharmaceutical industry would recognize the value of the degree as well as improve performance or pay in their current job or field. Many also thought it would help secure employment and thought that managed care employers would recognize and value the degree.

Figure 20: Why does this degree appeal to you
(Career Advancers: Pharmaceutical Professionals)
(n=15)

- Be able to advance in my industry/profession (n=12) 80%
- Think pharmaceutical industry would recognize the value of types of courses in degree (n=11) 73%
- Personal interest enrichment (n=10) 67%
- Gaining greater knowledge (n=10) 67%
- Will help me in the future to get employment (n=10) 67%
A CLOSER LOOK: OTHER PROFESSIONALS
Forty-six percent of survey respondents were primarily employed in the following industries: health services, government regulatory agencies, academic or higher institutions, manufacturing, marketing, managed care, and health plans. Respondents are largely between the ages of 25 and 34, with 85 percent employed full-time. Forty-one percent have a Bachelor’s degree, 23 percent have a Master’s degree, and 36 percent have a doctorate or professional degree. Figure 21 illustrates the appeal of the degree. Forty percent of respondents found the proposed degree appealing, with 49 percent stating they may be interested, and 11 percent not finding the degree appealing. Of those that expressed maybe finding the degree appealing, their willingness would be determined by the skills/knowledge learned, cost, and improvements in performance or pay. One respondent believed that the degree would be most valuable if it incorporated industry-related practical skills. Another indicated potential interest if the Master’s provided a flexible schedule to accommodate those concurrently enrolled and employed. Figures 22, 23, and 24 show the respondents’ preferences regarding the structural components of the Master’s program.

Figure 21: Would the degree be appealing to you? (Career Advancers: Other Professionals) (n=65)

- Yes: 40%
- Maybe: 49%
- No: 11%

Figure 22: Full-time or Part-time Enrollment (Career Advancers: Other Professionals) (n=65)

- Full-time: 63%
- Part-time: 37%

“Since my background in the industry is medical affairs, all aspects of the drug development are relevant such principles governing pharmacovigilance, compliance, grant analysis, impact of changes in healthcare policies, role of study publication planning in the drug life cycle management- medical communication, effective communication of clinical data, best sharing practices, global differences in regulatory and marketing, marketing analysis, intellectual property strategies, etc. However, hands-on experience is what matters in the industry.” - Student
Figure 23 lists the reasons why career advancers in these diverse industries find the program appealing. Sixty-five percent found the degree appealing because of industry recognition, followed by an equal 58% that thought the Master’s would provide greater knowledge in drug development and management as well as the opportunity to advance in current industry or profession.
RETURN ON INVESTMENT (ROI) FRAMEWORK

Pursuing a Master’s degree requires a financial and time commitment. The research team developed a Return on Investment (ROI) framework to allow potential students to calculate the potential ROI on earning a Master’s degree for the proposed program. The ROI framework takes the following into consideration:

<table>
<thead>
<tr>
<th>Current Earning power</th>
<th>Current income (or most probable income if not currently employed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Existing outstanding student debt</td>
<td>Any existing student debt</td>
</tr>
<tr>
<td>Tuition cost to complete Master’s program</td>
<td>Cost to complete Master’s program (for entire length of program)</td>
</tr>
<tr>
<td>University administrative fees, health ins., and other educational costs for Master’s program</td>
<td>Administrative and miscellaneous fees charged by university</td>
</tr>
<tr>
<td>Living costs (net of employment income)</td>
<td>Housing, food, and other living expenses costs (particularly important if relocating for program)</td>
</tr>
<tr>
<td>Earning power after Master’s programs</td>
<td>Potential salary after obtaining Master’s degree</td>
</tr>
</tbody>
</table>

The calculations assume students are enrolled in a full-time program without working. It is important to note that the framework does not take into consideration any potential loss of income that a student may experience if they leave their existing employment to pursue their master’s education (it also excludes any potential income from internships). Calculations also assume students will complete loan repayment within 10 years (or 120 months). Students can then adjust the time-frame in which they expect to stay within their employment field to determine the ROI of their educational investment.

The total monthly student debt payment as a percent of income is also calculated. In general, guidelines vary by different agencies on the percentage of income that should go towards paying student debt. The following are a sample of those guidelines:

- Forbes rule of thumb is that total student debt should not be more than annual earning power.
- Government mortgage underwriting guidelines state that total debt payment not to exceed 43% of monthly income.
- Credit counselor guideline: 50% maximum of after-tax income on housing, insurance, transportation, food and debt payments.

It’s important to note that the ROI calculator is intended to show students the potential economic impact the Master’s degree could have on their income over time. However, this is not to say that students could only achieve this type of ROI by enrolling in the proposed Master’s program. There are multiple variables that cannot be captured in a calculator such as experience, aptitude, and connectivity.
The following are examples of how the ROI calculator could apply to the following target groups:

**Career Advancer: Medical Scientist**

A medical scientist more established in their career earning approximately $76,980 (within the median salary range) could earn a potential of $107,250 annually in the same existing role (75th percentile).

Based on a one-year program model, the ROI calculator estimates that he or she would have a benefit of $222,900 over the course of 10 years. (This is assuming that he or she stays in the same role and does not assume a leadership position with a different salary.) Figure 26 shows the calculations. It should also be noted that the student would have to allot 10 percent of their income to pay their student debt (based on the assumption costs).

![Figure 26: Medical Scientist 1-year Program ROI Calculation](image)

<table>
<thead>
<tr>
<th>Factors Influencing ROI</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current earning power (most probable annual income)</td>
<td>$76,980</td>
</tr>
<tr>
<td>Tuition cost to complete the program</td>
<td>$30,000</td>
</tr>
<tr>
<td>Administrative fees, health ins., and other educational costs</td>
<td>$6,000</td>
</tr>
<tr>
<td>Living costs (net of employment income)</td>
<td>$24,000</td>
</tr>
<tr>
<td>Debt acquired for the program</td>
<td>$60,000</td>
</tr>
<tr>
<td>Earning power after the program (most probable annual income)</td>
<td>$107,250</td>
</tr>
</tbody>
</table>

**Total Benefit** $222,900

Monthly student debt payment as a percent of income: 10%

Based on a two-year program model, the ROI calculator estimates that the medical scientist would have a benefit of $143,100 over the course of 10 years. (Taking the same assumptions as above.) Figure 27 shows the calculations. The student would have to allot 17 percent of their income to pay their student debt.

![Figure 27: Medical Scientist 2-year Program ROI Calculation](image)

<table>
<thead>
<tr>
<th>Factors Influencing ROI</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current earning power (most probable annual income)</td>
<td>$76,980</td>
</tr>
<tr>
<td>Tuition cost to complete the program</td>
<td>$60,000</td>
</tr>
<tr>
<td>Administrative fees, health ins., and other educational costs</td>
<td>$12,000</td>
</tr>
<tr>
<td>Living costs (net of employment income)</td>
<td>$48,000</td>
</tr>
<tr>
<td>Debt acquired for the program</td>
<td>$120,000</td>
</tr>
<tr>
<td>Earning power after the program (most probable annual income)</td>
<td>$107,250</td>
</tr>
</tbody>
</table>

**Total Benefit** $143,100

Monthly student debt payment as a percent of income: 17%

---

A medical and health services manager more established in their career earning approximately $88,580 (within the median salary range) could earn a potential of $114,920 annually in the same existing role (75th percentile).

Based on a one-year program model, the ROI calculator estimates that he or she would have a benefit of $183,600 over the course of 10 years. (This is assuming that he or she stays in the same role and does not assume a leadership position with a different salary.) Figure 28 shows the calculations. It should also be noted that the student would have to allot 9 percent of their income to pay their student debt (based on the assumption costs).

Based on a two-year program model, the ROI calculator estimates that the medical and health services manager would have a benefit of $103,800 over the course of 10 years. (Taking the same assumptions as above.) Figure 29 shows the calculations. The student would have to allot 16 percent of their income to pay their student debt.

---

**Factors Influencing ROI**

<table>
<thead>
<tr>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current earning power (most probable annual income)</td>
</tr>
<tr>
<td>Tuition cost to complete the program</td>
</tr>
<tr>
<td>Administrative fees, health ins., and other educational costs</td>
</tr>
<tr>
<td>Living costs (net of employment income)</td>
</tr>
<tr>
<td>Debt acquired for the program</td>
</tr>
<tr>
<td>Earning power after the program (most probable annual income)</td>
</tr>
<tr>
<td><strong>Total Benefit</strong></td>
</tr>
<tr>
<td>Monthly student debt payment as a percent of income</td>
</tr>
</tbody>
</table>

**Factors Influencing ROI**

<table>
<thead>
<tr>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current earning power (most probable annual income)</td>
</tr>
<tr>
<td>Tuition cost to complete the program</td>
</tr>
<tr>
<td>Administrative fees, health ins., and other educational costs</td>
</tr>
<tr>
<td>Living costs (net of employment income)</td>
</tr>
<tr>
<td>Debt acquired for the program</td>
</tr>
<tr>
<td>Earning power after the program (most probable annual income)</td>
</tr>
<tr>
<td><strong>Total Benefit</strong></td>
</tr>
<tr>
<td>Monthly student debt payment as a percent of income</td>
</tr>
</tbody>
</table>

---

COMPARISON TWO UNIVERSITIES: USC COMPARED TO UC SAN DIEGO

The USC program was the one that resembled the proposed UC San Diego program the most. The following is an example of how the ROI calculator could apply to the a Medical Scientist professional upon enrollment in the Master of Science in Management and Drug Development at the University of Southern California.

A medical scientist more established in their career earning approximately $76,980 (within the median salary range) could earn a potential of $107,250 annually in the same existing role (75th percentile).

Based on USC’s two-year program model, the ROI calculator estimates that he or she would have a benefit of $156,400 over the course of 10 years. (This is assuming that he or she stays in the same role and does not assume a leadership position with a different salary.) Figure 30 shows the calculations. It should also be noted that the student would have to allot 16 percent of their income to pay their student debt (based on the assumption costs).

The ROI for USC is slightly more economically beneficial than compared to the UC San Diego estimated cost. The UC San Diego program (figure 24 in preceding page) shows a total benefit of $143,100 for medical scientist. The ROIs are fairly comparable with USC's program being slightly more beneficial due to it’s slightly lower program cost ($50,000 for USC compared to $60,000 for UC San Diego).

---

**Figure 30: Medical Scientist**

USC 2-year Program ROI Calculation

<table>
<thead>
<tr>
<th>Factors Influencing ROI</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current earning power (most probable annual income)</td>
<td>$76,980</td>
</tr>
<tr>
<td>Tuition cost to complete the program</td>
<td>$50,000</td>
</tr>
<tr>
<td>Administrative fees, health ins., and other educational costs</td>
<td>$12,000</td>
</tr>
<tr>
<td>Living costs (net of employment income)</td>
<td>$48,000</td>
</tr>
<tr>
<td>Debt acquired for the program</td>
<td>$156,400</td>
</tr>
<tr>
<td>Earning power after the program (most probable annual income)</td>
<td>$107,250</td>
</tr>
<tr>
<td><strong>Total Benefit</strong></td>
<td>$156,400</td>
</tr>
<tr>
<td>Monthly student debt payment as a percent of income</td>
<td>16%</td>
</tr>
</tbody>
</table>

---

**OCCUPATIONAL OUTLOOK**

The industry and occupation outlook for life sciences, biotechnology, and pharmaceutical careers are projected to experience an average growth rate of 20.4 percent from 2012 to 2022. According to the Bureau of Labor Statistics (BLS), this growth rate is higher than the national 10.8 growth rate. Figure 31 shows the average projected growth. Appendix D lists occupational profiles for the Master’s in Drug Development and Product Management including occupational growth, salary ranges, technical and soft skill sets sought by employers.

---

**Figure 31: Occupational Growth Rate**

---

**POTENTIAL STUDENT PROFILES**

**LIFE SCIENCES AND BIOTECHNOLOGY CAREER ADVANCERS**

Interested in degree due to ability to gain greater knowledge in drug development and management, industry recognition, and industry/professional advancement.

71% of students preferred full-time enrollment and were willing to commit to the two-year model.

71% favored a hybrid format and 36% preferred a traditional model of learning.\(^{16}\)

Determining factors in students deciding to pursue degree include cost, connections to industry, and skills learned.

**PHARMACEUTICAL CAREER ADVANCERS**

Interested in degree due to industry/professional advancement, industry recognition, and personal enrichment.

75% preferred full-time enrollment and were willing to commit to the one-year model.

54% valued a hybrid format and 25% equally preferred an online and/or traditional model of learning.\(^{17}\)

Determining factors in students deciding to pursue degree include cost, skills learned, and length of program.

**OTHER PROFESSIONAL CAREER ADVANCERS**

Interested in degree due to industry recognition, ability to gain greater knowledge in drug development and management, and industry/professional advancement.

63% preferred full-time enrollment and 52% were willing to commit to the one-year model.

65% valued a hybrid format and 38% preferred a traditional delivery format.\(^{18}\)

Determining factors in students deciding to pursue degree include skills learned, costs, and improvements in performance or pay.

---

\(^{16}\) n = 42  
\(^{17}\) n = 24  
\(^{18}\) n = 65
Final Recommendations

Employers and students had a positive response to the potential Masters of Science in Drug Development and Product Management degree at UC San Diego.

Seventy-seven percent of employers thought the degree would be useful or very useful for their organization. They made clear that this degree would be most valuable for people who already have the technical educational background (often PharmD, M.D., Ph.D.). Of the 131 potential students surveyed, 52 percent thought the degree would be very useful in terms of career advancement and skills learned, with another 42 percent responding as being possibly interested, their willingness would be determined by the cost, skills learned, and the ability to build connections to industry and jobs. Less than half of these respondents were concerned with industry’s recognition and value of the degree. Respondents also indicated that the degree would be appealing if it included relevant certifications/qualifications with governing bodies and industry connections through capstone project and additional collaborating opportunities. One student mentioned that the degree should address a holistic approach to managing risk when developing drug products:

“I believe too much emphasis in the drug development and commercialization industry is place on compliance. Whilst it is important to comply with all the relevant regulations at national and internal level, taking into account the current situation and future market access, it has to be stressed that mere compliance does not assure safety... The Master of Science in Drug Development and Product Management degree can be very valuable to industry professionals who need to develop their skills in a more holistic manner to break through the glass cone of overspecialized and isolated departmental silos.” - Managing Director

Most of the comparable programs range from 18 months to 2 years of instruction. With employers showing a strong preference for a two-year instruction model (with 86 percent preferring a two-year model), and students preference almost split down the middle (with 49 percent preferring a two-year model).

As mentioned in the introduction, the programs that have the fastest growth are those that target niche fields and distinct market segments. Those that would highly value the program as well as financially benefit are Career Advancers with prior work experience. Focusing student recruiting efforts for Career Advancers working in a niche industry for this Master’s program could be beneficial. San Diego is known for having a strong Pharmaceutical, Life Science and Biotechnology industry in the region and UC San Diego has a highly regarded reputation of being a world class institution for the pharmaceuticals and the sciences. The University can leverage its reputation and the region’s strength in industry clusters to create a Master’s in Drug Development and Product Management program that will benefit professionals.

Most comparable programs require 2 to 5 years of work experience.
NEXT STEPS
The following are next steps for the proposed Master’s of Science in Drug Development and Product Management program. It should be noted that these next steps are not taking into consideration the input of employers. The following factors are interdependent and will impact decisions for the degree program.

NICHE MARKET
Competitive Master’s programs target students who already have a strong background in science fields such as students with an academic background in preclinical biology and pharmaceutical sciences as well as those with industry relevant experience in pharmaceutical or life sciences and biotechnology industries. Since a majority of the programs are tailored to address the needs of career advancers, many programs require or recommended that students have two to five years of relevant work experience as well as prefer candidates that have completed a graduate degree in science, engineering or business as well as PhDs or PharmDs.

POTENTIAL STUDENT SEGMENTS
The most successful Master’s programs target a specific set of students to attract to their programs. The core target student demographic will be critical in identifying the delivery format and design of the Master’s program, as each of the student segments has their own preferences. Comparable programs enroll students from a variety of backgrounds and points in their career, however, they focus their efforts on a specific core student population. The following is an analysis for potential student segments:

<table>
<thead>
<tr>
<th>Career Starters:</th>
<th>Positives</th>
<th>Negatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Students can gain hands-on experience through internships</td>
<td>Employers prefer candidates with experience. Although internships may help, it will not substitute for years of experience. Career Starter graduates will likely gain entry level positions</td>
<td>Students will not have the industry knowledge or experience to be able to fully leverage this program</td>
</tr>
</tbody>
</table>

| Career Advancers: | | |
|-------------------| | |
| 52 percent of respondents found the degree appealing | ROI for students is above $100,00 over ten-year time frame | Considering factors (neutral): dependent upon skills/knowledge learned, improving performance or pay in current job field, cost of the degree program and length of the degree program. |
## ATTRACTING STUDENTS

With UC San Diego recognized as a highly regarded national and international institution especially in the life science and biotechnology and pharmaceutical sciences fields, the University is well positioned to attract a high caliber of students. UC San Diego can attract students by the following methods:

- Industry associations
- Industry conferences
- Employers/Non-profits
- Current university students (seniors) in specific majors
- University alumni in specific majors

## PROGRAM LENGTH

Comparable Master’s programs primarily take 18 months to two years of full-time enrollment to complete. In general programs targeting industry professional have a part-time option, as many individuals in the program will remain employed during the course of the degree or have an internship. The following are the positives and negatives for each of these scenarios:

<table>
<thead>
<tr>
<th>Positives</th>
<th>Negatives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>One year program:</strong></td>
<td></td>
</tr>
<tr>
<td>More affordable</td>
<td>Not as appealing to employers and potential students working in Life Sciences and Biotechnology, and possibly students with less industry experience</td>
</tr>
<tr>
<td>More appealing to potential students working in Pharmaceutical industry</td>
<td>Challenging to complete project work experience component</td>
</tr>
<tr>
<td>Better ROI for students</td>
<td>Need to recruit cohorts each year. Fiscally not as secure as two-year program for University</td>
</tr>
<tr>
<td><strong>Two year program:</strong></td>
<td></td>
</tr>
<tr>
<td>Valued significantly more by employers</td>
<td>Not as appealing to potential students working in Pharmaceutical industry</td>
</tr>
<tr>
<td>More appealing to potential students working in Life Sciences and Biotechnology</td>
<td>If students enrolled part-time, would be challenging to complete work experience component</td>
</tr>
<tr>
<td>Allows time for project work experience component if full-time</td>
<td>ROI not as appealing as one-year program for students (but still worthwhile)</td>
</tr>
<tr>
<td>Second year cohort a sustaining group.</td>
<td>More sustainable financial program for University</td>
</tr>
</tbody>
</table>

*List of industry associations available for relevant occupations in Appendix F.*
COURSE DELIVERY

Employers and potential students were asked to indicate their preferred methods of course delivery for the Master’s of Science in Drug Development and Product Management program. The majority of employers and potential students indicated a preference towards a hybrid delivery model (taking courses online and in-person). This type of delivery format allows students to have some flexibility with their online courses, but also gives students the opportunity to interact with fellow students, network and meet with prominent industry leaders. The majority of comparable Master’s program allow students the opportunity to choose between a fully online program, fully on-campus program or hybrid. There are two programs that are only offered in a traditional delivery format.

<table>
<thead>
<tr>
<th>Positives</th>
<th>Negatives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Traditional Delivery Format:</strong></td>
<td>Students may have to budget for relocation costs</td>
</tr>
<tr>
<td></td>
<td>Limited to students within a specific geographic boundary</td>
</tr>
<tr>
<td><strong>Online Delivery Format:</strong></td>
<td>Students will not have to consider relocation cost to pursue Master’s degree</td>
</tr>
<tr>
<td></td>
<td>Challenging to manage project work experience component if students located nationwide or globally</td>
</tr>
<tr>
<td></td>
<td>Program can be expanded exponentially without geographic limitations</td>
</tr>
<tr>
<td><strong>Hybrid Delivery Format:</strong></td>
<td>Appealing to the majority of employers</td>
</tr>
<tr>
<td></td>
<td>Student geographic limitations if traditional in person classes are required</td>
</tr>
<tr>
<td></td>
<td>Appealing to the majority of potential students (industry professionals and current students)</td>
</tr>
</tbody>
</table>
CLASS SIZE
Class size should be selected dependent on the host department’s infrastructure including faculty available to teach industry relevant topics, as well as the department’s administrative support capabilities. The typical master’s degree class size ranges form 6 to 20 per cohort, though online options are enabling some Master’s programs to not follow a cohort-based model.

COST
Tuition for comparable Master’s programs varies widely depending on the type of institution (public/private) and its reputation. Tuition ranges from $21,720 to $77,800. The average tuition for a two-year master’s program is $40,495. The highest priced comparable program is a full-time only on campus program at the Keck Graduate Institute. Because of UC San Diego’s national and international reputation (especially with the target student demographic), the University could likely charge in the upper quartile of the two year scales.
The research design utilized both qualitative and quantitative approaches to determine the viability and scope of the proposed Master’s degrees in Drug Development and Product Management. The research study relied on a combination secondary research, surveys and interviews to elucidate the major phases of research described below.

(1) Competitive Landscape Analysis
To capture comparable existing masters’ degree programs the research team mined online databases, performed web searches, and spoke with program directors. Upon identification of comparable programs, outreach was conducted with program representatives to inquire regarding program student demographics, program location, instructional delivery formats, fees, curriculum overview, program length, student occupational placement, and institutional ranking (if available).

(2) Occupational Outlook
Occupational outlook data was collected using secondary data from Economic Modeling Specialists, International (EMSI) which provides national occupational projections statistics using Bureau of Labor Statistics (BLS), Employment Development Department (EDD), and other sources. In addition, the research team utilized Burning Glass job market intelligence data to analyze online job postings for top specialized skills in demand for the occupations identified.

(3) Employers Outlook
Potential employers were interviewed to capture their perception of the proposed master’s degrees. Individual interviews allow the research team to collect a wide swath of information about individual employer’s attitudes and perceptions, but also enables for collective themes to emerge. Topics included a) labor market evaluation, b) skills and expertise prioritized by employers, c) willingness to provide release time and/or tuition reimbursement, d) perceptions of instructional delivery formats (online, in-person, hybrid), e) perceived value of proposed degree for candidates, and f) willingness to increase position or pay of successful candidates.

(4) Potential Students Outlook
The research team reached out to potential students populations to assess their level of interest in the proposed master’s degree programs through surveys. The survey was sent through Qualtrics panels in which college graduates between the ages 22 years and 54 years old within specific occupations were identified and surveyed. The survey had a common core of items relating to a) perceived value of skill sets learned through proposed degree, b) program length preference, c) instructional delivery formats (online, in-person, hybrid) preference, d) appeal of proposed degree program, and e) perceived value of proposed degree for candidates. Surveys were also sent to current UC San Diego undergraduate students (career starters).

The surveys enabled a comprehensive understanding of potential students’ perceptions and allowed the research team to create student profiles of potential students at various stages in their careers.

(5) Return on Investment (ROI) Framework
A framework for assessing costs and returns on education was created. The ROI framework looked at expected salary increases, current employment, salary, living expenses and tuition to determine cost benefit analysis.
## Appendix B - Comparable Programs

<table>
<thead>
<tr>
<th>University</th>
<th>Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Southern California</td>
<td>MS in Management of Drug Development</td>
</tr>
<tr>
<td>San Jose State University</td>
<td>Certificate in Preclinical Drug Development</td>
</tr>
<tr>
<td>University of Cincinnati</td>
<td>M.S. in Pharmaceutical Sciences with Drug Development Specialization</td>
</tr>
<tr>
<td>University of Cincinnati</td>
<td>MS Drug Development Sciences</td>
</tr>
<tr>
<td>University of Cincinnati</td>
<td>PhD Drug Development Sciences</td>
</tr>
<tr>
<td>Drexel University</td>
<td>Master of Science in Drug Discovery &amp; Development</td>
</tr>
<tr>
<td>Rutgers University</td>
<td>Master of Business &amp; Science with a concentration in Drug Development and Discovery</td>
</tr>
<tr>
<td>University of Arizona</td>
<td>Doctor of Philosophy in Pharmaceutical Sciences with an emphasis in Drug Discovery and Development</td>
</tr>
<tr>
<td>Keck Graduate Institute</td>
<td>Master of Bioscience</td>
</tr>
<tr>
<td>University College London</td>
<td>MSc Drug Discovery and Pharma Management</td>
</tr>
<tr>
<td>San Diego State University</td>
<td>Master of Science in Regulatory Affairs</td>
</tr>
<tr>
<td>San Diego State University</td>
<td>Certificate in Regulatory Affairs</td>
</tr>
<tr>
<td>Occupation Title</td>
<td>SOC Code</td>
</tr>
<tr>
<td>------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Biological Scientists, All Other</td>
<td>19-1029</td>
</tr>
<tr>
<td>Market Research Analysts and Marketing Specialists</td>
<td>13-1161</td>
</tr>
<tr>
<td>Marketing Managers</td>
<td>11-2021</td>
</tr>
<tr>
<td>Media and Communication Workers, All Other</td>
<td>27-3099</td>
</tr>
<tr>
<td>Medical and Clinical Laboratory Technologists</td>
<td>29-2011</td>
</tr>
<tr>
<td>Medical and Health Services Managers</td>
<td>11-9111</td>
</tr>
<tr>
<td>Medical Records and Health Information Technicians</td>
<td>29-2071</td>
</tr>
<tr>
<td>Medical Scientists, Except Epidemiologists</td>
<td>19-1042</td>
</tr>
<tr>
<td>Medical Transcriptionists</td>
<td>31-9094</td>
</tr>
<tr>
<td>Natural Sciences Managers</td>
<td>11-9121</td>
</tr>
<tr>
<td>Operations Research Analysts</td>
<td>15-2031</td>
</tr>
<tr>
<td>Statisticians</td>
<td>15-2041</td>
</tr>
<tr>
<td>Training and Development Managers</td>
<td>11-3131</td>
</tr>
</tbody>
</table>
Appendix D - Occupational Profiles

Biological Scientists, All Others

Projected National Growth (2012-2022)  
-0.6%

National Employment (2012)  
34,300

Conduct research using bioinformatics theory and methods in areas such as pharmaceuticals, medical technology, biotechnology, computational biology, proteomics, computer information science, biology and medical informatics. May design databases and develop algorithms for processing and analyzing genomic information, or other biological information.

Sample of reported job titles: Bioinformaticist; Bioinformatics Scientist; Director of Bioinformatics and Trait Discovery; Director of Translation and Experimental Medicine Bioinformatics; Director, Informatics; Research Scientist; Scientific Database Curator; Scientific Informatics Project Leader; Senior Research Associate; Senior Scientist

Market Research Analysts and Marketing Specialists

Projected National Growth (2012-2022)  
31.6%

National Employment (2012)  
415,700

Research market conditions in local, regional, or national areas, or gather information to determine potential sales of a product or service, or create a marketing campaign. May gather information on competitors, prices, sales, and methods of marketing and distribution.

Sample of reported job titles: Business Development Specialist, Client Service and Consulting Manager, Client Services Vice President, Communications Specialist, Market Analyst, Market Research Analyst, Market Research Consultant, Market Research Manager, Product Line Manager, Project Manager

---

Marketing Managers\textsuperscript{23}

<table>
<thead>
<tr>
<th>Projected National Growth (2012-2022)</th>
<th>12.7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Employment (2012)</td>
<td>180,500</td>
</tr>
</tbody>
</table>

Plan, direct, or coordinate marketing policies and programs, such as determining the demand for products and services offered by a firm and its competitors, and identify potential customers. Develop pricing strategies with the goal of maximizing the firm's profits or share of the market while ensuring the firm's customers are satisfied. Oversee product development or monitor trends that indicate the need for new products and services.

Sample of reported job titles: Account Supervisor, Brand Manager, Business Development Director, Business Development Manager, Commercial Lines Manager, Market Development Executive, Marketing Coordinator, Marketing Director, Marketing Manager, Product Manager

<table>
<thead>
<tr>
<th>Salary</th>
<th>10th</th>
<th>25th</th>
<th>Median</th>
<th>75th</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>$62,650</td>
<td>$85,740</td>
<td>$119,480</td>
<td>$160,810</td>
<td></td>
</tr>
</tbody>
</table>

Median Employment (2012): 180,500

Note: O*NET data is not available for this title.

Media and Communication Workers, All Others\textsuperscript{24}

<table>
<thead>
<tr>
<th>Projected National Growth (2012-2022)</th>
<th>4.9%</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Employment (2012)</td>
<td>30,700</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Salary</th>
<th>10th</th>
<th>25th</th>
<th>Median</th>
<th>75th</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>$23,510</td>
<td>$31,670</td>
<td>$45,160</td>
<td>$66,580</td>
<td>$87,430</td>
</tr>
</tbody>
</table>

Median Employment (2012): 30,700

Note: O*NET data is not available for this title.


\textsuperscript{24} Data not available for occupation title.
Medical and Clinical Laboratory Technologists

Projected National Growth (2012-2022) 13.8%
National Employment (2012) 164,300

Perform complex medical laboratory tests for diagnosis, treatment, and prevention of disease. May train or supervise staff.

Sample of reported job titles: Chief Medical Technologist; Clinical Laboratory Scientist (CLS); Clinical Laboratory Technologist; Histologist Technologist; Medical Laboratory Technologist (Medical Lab Tech); Medical Technologist (MT); Medical Technologist, Clinical Laboratory Scientist; Microbiologist; Microbiology Technologist; Research Assistant

Medical and Health Services Managers

Projected National Growth (2012-2022) 23.2%
National Employment (2012) 315,500

Plan, direct, or coordinate medical and health services in hospitals, clinics, managed care organizations, public health agencies, or similar organizations.

Sample of reported job titles: Clinical Director, Director of Nursing, Health and Social Service Manager, Medical Records Manager, Mental Health Program Manager, Nurse Manager, Nutrition Services Manager, Office Manager, Practice Administrator, Program Manager

Salaries:

Medical and Clinical Laboratory Technologists:
- 10th Percentile: $39,580
- 25th Percentile: $48,610
- Median: $57,580
- 75th Percentile: $68,930
- 90th Percentile: $78,900

Medical and Health Services Managers:
- 10th Percentile: $53,940
- 25th Percentile: $69,160
- Median: $88,580
- 75th Percentile: $114,920
- 90th Percentile: $150,560

Notes:

Appendix D - Occupational Profiles (continued)

Medical Records and Health Information Technicians\(^{27}\)

<table>
<thead>
<tr>
<th>Projected National Growth (2012-2022)</th>
<th>22.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Employment (2012)</td>
<td>186,300</td>
</tr>
</tbody>
</table>

**Medical Records and Health Information Technicians**

- Compile, process, and maintain medical records of hospital and clinic patients in a manner consistent with medical, administrative, ethical, legal, and regulatory requirements of the healthcare system. Process, maintain, compile, and report patient information for health requirements and standards in a manner consistent with the healthcare industry's numerical coding system.

- Sample of reported job titles: Coder, Health Information Clerk, Health Information Specialist, Health Information Technician (Health Information Tech), Medical Records Analyst, Medical Records Clerk, Medical Records Coordinator, Medical Records Director, Medical Records Technician (Medical Records Tech), Registered Health Information Technician (RHIT)

<table>
<thead>
<tr>
<th>Salary</th>
</tr>
</thead>
<tbody>
<tr>
<td>$22,250</td>
</tr>
<tr>
<td>10th</td>
</tr>
</tbody>
</table>

**Medical Scientists, Except Epidemiologists\(^{28}\)**

<table>
<thead>
<tr>
<th>Projected National Growth (2012-2022)</th>
<th>13.3%</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Employment (2012)</td>
<td>103,100</td>
</tr>
</tbody>
</table>

**Medical Scientists, Except Epidemiologists**

- Conduct research dealing with the understanding of human diseases and the improvement of human health. Engage in clinical investigation, research and development, or other related activities. Includes physicians, dentists, public health specialists, pharmacologists, and medical pathologists who primarily conduct research.

- Sample of reported job titles: Associate Director, Experimental Medicine; Clinical Laboratory Scientist; Clinical Pharmacologist; Investigator; Laboratory Director; Post-Doctoral Fellow; Research Scientist; Scientist; Senior Research Scientist; Senior Scientist


Appendix D - Occupational Profiles (continued)

Medical Transcriptionists

Projected National Growth (2012-2022) 7.6%
National Employment (2012) 84,100

Transcribe medical reports recorded by physicians and other healthcare practitioners using various electronic devices, covering office visits, emergency room visits, diagnostic imaging studies, operations, chart reviews, and final summaries. Transcribe dictated reports and translate abbreviations into fully understandable form. Edit as necessary and return reports in either printed or electronic form for review and signature, or correction.

Sample of reported job titles: Clinical Medical Transcriptionist, Documentation Specialist, Medical Language Specialist, Medical Secretary, Medical Transcriber, Medical Transcription, Medical Transcription Supervisor, Medical Transcriptionist, Radiology Transcriptionist, Transcriptionist

<table>
<thead>
<tr>
<th>10th</th>
<th>25th</th>
<th>Median</th>
<th>75th</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>$22,400</td>
<td>$27,650</td>
<td>$34,020</td>
<td>$40,820</td>
<td>$47,250</td>
</tr>
</tbody>
</table>


Natural Sciences Managers

Projected National Growth (2012-2022) 5.7%
National Employment (2012) 51,600

Plan, direct, or coordinate clinical research projects. Direct the activities of workers engaged in clinical research projects to ensure compliance with protocols and overall clinical objectives. May evaluate and analyze clinical data.

Sample of reported job titles: Clinical Program Coordinator, Clinical Program Manager, Clinical Research Administrator, Clinical Research Associate (CRA), Clinical Research Coordinator, Clinical Research Manager, Clinical Research Nurse Coordinator, Clinical Trial Coordinator, Clinical Trial Manager, Research Coordinator

<table>
<thead>
<tr>
<th>10th</th>
<th>25th</th>
<th>Median</th>
<th>75th</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>$65,040</td>
<td>$88,750</td>
<td>$115,730</td>
<td>$156,720</td>
<td></td>
</tr>
</tbody>
</table>
### Operations Research Analysts\(^1\)

<table>
<thead>
<tr>
<th>Projected National Growth (2012-2022)</th>
<th>26.7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Employment (2012)</td>
<td>73,200</td>
</tr>
</tbody>
</table>

**Salary**

- 10th: $40,550
- 25th: $53,120
- Median: $72,100
- 75th: $97,170
- 90th: $129,490

Formulate and apply mathematical modeling and other optimizing methods to develop and interpret information that assists management with decision making, policy formulation, or other managerial functions. May collect and analyze data and develop decision support software, service, or products. May develop and supply optimal time, cost, or logistics networks for program evaluation, review, or implementation.

Illustrative examples: Procedure Analyst, Operations Analyst, Process Analyst

---

### Statisticians\(^2\)

<table>
<thead>
<tr>
<th>Projected National Growth (2012-2022)</th>
<th>26.7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Employment (2012)</td>
<td>27,600</td>
</tr>
</tbody>
</table>

**Salary**

- 10th: $42,220
- 25th: $55,360
- Median: $75,560
- 75th: $99,340
- 90th: $121,890

Develop and apply biostatistical theory and methods to the study of life sciences.

Sample of reported job titles: Associate Director of Biostatistics, Biostatistician, Biostatistics Director, Consultant/Associate Professor of Biostatistics, Principal Biostatistician, Principal Statistical Scientist, Professor of Biostatistics, Research Associate Professor, Research Scientist, Senior Biostatistician/Group Leader

---


## Training and Development Managers

<table>
<thead>
<tr>
<th>Projected National Growth (2012-2022)</th>
<th>11.2%</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Employment (2012)</td>
<td>28,600</td>
</tr>
</tbody>
</table>

### Salary

<table>
<thead>
<tr>
<th></th>
<th>10th</th>
<th>25th</th>
<th>Median</th>
<th>75th</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salary</td>
<td>$54,070</td>
<td>$72,020</td>
<td>$95,400</td>
<td>$126,720</td>
<td>$164,640</td>
</tr>
</tbody>
</table>

Plan, direct, or coordinate the training and development activities and staff of an organization.

Sample of reported job titles: Development Manager, Director of Education, Director of Educational Services, Director of Staff Development, Education and Development Manager, Learning Manager, Manager of Staff Training and Development, Training and Development Coordinator, Training Director, Training Manager.

---

San Diego County's economy is very diverse and has multiple industry clusters in which it employs the region's workforce. The following are analyses of the sub-clusters that exist within each one of the major industry clusters. All employment data and charts for industry clusters and their sub-clusters are from the U.S. Cluster Mapping project.

San Diego County Top 10 Industry Clusters

<table>
<thead>
<tr>
<th>Industry Cluster</th>
<th>Employment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitality</td>
<td>56,284</td>
</tr>
<tr>
<td>Education</td>
<td>37,880</td>
</tr>
<tr>
<td>Marketing</td>
<td>30,164</td>
</tr>
<tr>
<td>ICT</td>
<td>23,089</td>
</tr>
<tr>
<td>Aerospace &amp; Defense</td>
<td>16,745</td>
</tr>
<tr>
<td>Water Transportation</td>
<td>11,432</td>
</tr>
<tr>
<td>Communications</td>
<td>7,488</td>
</tr>
<tr>
<td>Biopharmaceuticals</td>
<td>6,578</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>5,702</td>
</tr>
<tr>
<td>Recreational Goods</td>
<td>4,289</td>
</tr>
</tbody>
</table>

Hospitality and Tourism Cluster

Employment by Subcluster, 2013

Appendix E - Industry Clusters in San Diego County

Education and Knowledge Creation Cluster

Rank in US

Research Organizations – 3
Colleges, Universities, and Professional Schools – 32
Training Programs – 6
Educational Support Services – 25
Professional Organizations – 20

Employment by Subcluster, 2013

Highlighting indicates a Strong Subcluster in the region.
A strong cluster is a cluster that has high employment specialization in a region.

Marketing, Design, and Publishing Cluster

Rank in US

Advertising Related Services – 2
Other Marketing Related Services – 15
Publishing – 16
Design Services – 10

Employment by Subcluster, 2013

Highlighting indicates a Strong Subcluster in the region.
A strong cluster is a cluster that has high employment specialization in a region.

Appendix E - Industry Clusters in San Diego County (continued)

Information Technology and Analytical Instruments Cluster

Employment by Subcluster, 2013

Rank in US

Software Publishers - 6
Computers and Peripherals - 3
Process and Laboratory Instruments - 6
Electronic Components - 5
Medical Apparatus - 21
Semiconductors - 32
Audio and Video Equipment - 8
Software Reproducing - 36

Employment, 2013

Highlighting indicates a Strong Subcluster in the region.
A strong cluster is a cluster that has high employment specialization in a region.

Aerospace Vehicles and Defense Cluster

Employment by Subcluster, 2013

Rank in US

Aircraft - 8
Search and Navigation Equipment - 15
Missiles and Space Vehicles - 20

Employment, 2013

Highlighting indicates a Strong Subcluster in the region.
A strong cluster is a cluster that has high employment specialization in a region.

Appendix E - Industry Clusters in San Diego County

Water Transportation Cluster
Employment by Subcluster, 2013

- Boat Building and Repairing: 3
- Marine Transportation Services: 53
- Water Passenger Transportation: 87

Communications Equipment and Services Cluster
Employment by Subcluster, 2013

- Communications Services: 14
- Communications Equipment: 7
- Communications Equipment Components: 18

Biopharmaceuticals Cluster
Employment by Subcluster, 2013

- Biopharmaceutical Products: 8
- Diagnostic Substances: 1
- Biological Products: 26

Appendix E - Industry Clusters in San Diego County (continued)

---


44. [Graphs and data visualizations related to industry clusters in San Diego County, including Medical Devices Cluster and Recreational and Small Electric Goods Cluster.]
# Appendix F - Industry Associations

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Industry Association</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotechnology</td>
<td>Advanced Medical Technology Association</td>
<td><a href="http://advamed.org/">http://advamed.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Association for the Advancement of Science</td>
<td><a href="http://www.aaas.org/">http://www.aaas.org/</a></td>
</tr>
<tr>
<td>Biosciences</td>
<td>American Association of Pharmaceutical Scientists</td>
<td><a href="http://www.aaps.org/WhoWeAre/">http://www.aaps.org/WhoWeAre/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Board of Toxicology</td>
<td><a href="http://www.abtox.org/AboutABT.aspx">http://www.abtox.org/AboutABT.aspx</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Chemical Society</td>
<td><a href="http://www.acs.org/content/acs/en/about.html">http://www.acs.org/content/acs/en/about.html</a></td>
</tr>
<tr>
<td>Chemistry</td>
<td>American Chemistry Council</td>
<td><a href="http://www.americanchemistry.com/About/ContactUs">http://www.americanchemistry.com/About/ContactUs</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American College of Clinical Pharmacology</td>
<td><a href="http://www.accp.com/">http://www.accp.com/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American College of Laboratory Animal Medicine</td>
<td><a href="http://www.aclam.org/about-us/contact">http://www.aclam.org/about-us/contact</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Genetic Association</td>
<td><a href="http://www.asng.org/">http://www.asng.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Institute of Chemical Engineers</td>
<td><a href="http://www.aiche.org/">http://www.aiche.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Medical Writer’s Association</td>
<td><a href="http://www.amwa.org/">http://www.amwa.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Society for Biochemistry and Molecular Biology</td>
<td><a href="http://www.asbmb.org/ContactUs/">http://www.asbmb.org/ContactUs/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Society for Clinical Pharmacology and Therapeutics</td>
<td><a href="http://www.ascpt.org/">http://www.ascpt.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Society for Microbiology</td>
<td><a href="http://www.asm.org/">http://www.asm.org/</a></td>
</tr>
<tr>
<td>Pharmacology</td>
<td>American Society for Pharmacology and Experimental Therapeutics</td>
<td><a href="https://www.aspet.org/">https://www.aspet.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Society of Gene Therapy</td>
<td><a href="http://www.asgct.org/">http://www.asgct.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>American Veterinary Medical Association</td>
<td><a href="https://www.avma.org/Pages/home.aspx">https://www.avma.org/Pages/home.aspx</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Analytical, Life Science, and Diagnostics Associations</td>
<td><a href="https://thealda.org/">https://thealda.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Association for Assessment and Accreditation of Laboratory Animal</td>
<td><a href="http://www.aaalac.org/about/index.cfm">http://www.aaalac.org/about/index.cfm</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Association of Biomolecular Resource Facilities</td>
<td><a href="http://www.abrf.org/">http://www.abrf.org/</a></td>
</tr>
<tr>
<td>Chemistry</td>
<td>Association of Chemical Industry of Texas</td>
<td><a href="http://www.acit.org/pages/Contact-Us.html">http://www.acit.org/pages/Contact-Us.html</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Association of Clinical Research Professionals</td>
<td><a href="http://www.acrpnet.org/">http://www.acrpnet.org/</a></td>
</tr>
<tr>
<td>Life Sciences</td>
<td>Association of Commercial Professionals</td>
<td><a href="http://www.acp-ls.org/">http://www.acp-ls.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Association of Medical Diagnostics Manufacturers</td>
<td><a href="https://www.amdm.org/contact.html">https://www.amdm.org/contact.html</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>BIO (Biotechnology Industry Organization)</td>
<td><a href="https://www.bio.org/contact-us">https://www.bio.org/contact-us</a></td>
</tr>
<tr>
<td>Life Sciences</td>
<td>Biocom</td>
<td><a href="https://biocom.org/about_us/">https://biocom.org/about_us/</a></td>
</tr>
<tr>
<td>Biosciences</td>
<td>BioFlorida</td>
<td><a href="http://www.bioflorida.com/">http://www.bioflorida.com/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Biotechnology Association of Alabama</td>
<td><a href="http://bioalabama.com/">http://bioalabama.com/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Biotechnology Industry Organization</td>
<td><a href="https://www.bio.org/">https://www.bio.org/</a></td>
</tr>
<tr>
<td>Biosciences</td>
<td>California Life Sciences Association</td>
<td><a href="http://califesciences.org/">http://califesciences.org/</a></td>
</tr>
<tr>
<td>Category</td>
<td>Association</td>
<td>URL</td>
</tr>
<tr>
<td>------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Biotechnology</td>
<td>California Separation Science Society</td>
<td><a href="http://www.casss.org/general/?type=CONTACT">http://www.casss.org/general/?type=CONTACT</a></td>
</tr>
<tr>
<td>Chemistry</td>
<td>Chemical Industry Council of California</td>
<td><a href="http://cicc.org/">http://cicc.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Clinical Data Interchange Standards Consortium</td>
<td><a href="http://www.cdisc.org/">http://www.cdisc.org/</a></td>
</tr>
<tr>
<td>Biosciences</td>
<td>Colorado Bioscience Association</td>
<td><a href="http://www.cobioscience.com/">http://www.cobioscience.com/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Consumer Health Care Products Association</td>
<td><a href="http://www.chpa.org/">http://www.chpa.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Drug Information Association (DIA)</td>
<td><a href="http://www.diaglobal.org/en.aspx">http://www.diaglobal.org/en.aspx</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Environmental Mutagen Society</td>
<td><a href="http://www.emgs-us.org/">http://www.emgs-us.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>iBIO (Illinois Biotechnology Industry Organization)</td>
<td><a href="http://www.ibio.org/general/?type=CONTACT">http://www.ibio.org/general/?type=CONTACT</a></td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>International Federation of Pharmaceutical Manufacturer Associations</td>
<td><a href="http://www.ifpma.org/about-ifpma/welcome.html">http://www.ifpma.org/about-ifpma/welcome.html</a></td>
</tr>
<tr>
<td>Biosciences</td>
<td>Kansas Bioscience Organization</td>
<td><a href="http://www.kansasbio.org/">http://www.kansasbio.org/</a></td>
</tr>
<tr>
<td>Biosciences</td>
<td>Massachusetts Biotechnology Council</td>
<td><a href="http://www.massbio.org/">http://www.massbio.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Mid-Atlantic Directors and Staff of Scientific Cores</td>
<td>NA</td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Midwest Association of Core Directors</td>
<td><a href="http://sites.google.com/a/my.abrf.org/mwacd/">http://sites.google.com/a/my.abrf.org/mwacd/</a></td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>North Carolina Association for Biomedical Research</td>
<td><a href="http://www.scinemasters.com/ContactUs/tabid/64/Default.aspx">http://www.scinemasters.com/ContactUs/tabid/64/Default.aspx</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Northwest Regional Life Sciences Core Directors</td>
<td>NA</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>Pharmaceutical Business Intelligence Group</td>
<td><a href="http://www.pbirg.com/AboutUs/default.aspx">http://www.pbirg.com/AboutUs/default.aspx</a></td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>PhRMA</td>
<td><a href="http://www.phrma.org/about">http://www.phrma.org/about</a></td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>Premier Pharma Executive Talent Sourcing, LLC</td>
<td><a href="http://www.premierpharma.net/">http://www.premierpharma.net/</a></td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>Regulatory Affairs Professionals Society</td>
<td><a href="http://www.raps.org/">http://www.raps.org/</a></td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>San Diego Regulatory Affairs</td>
<td></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Society of Toxicology</td>
<td><a href="http://www.toxicology.org/index.asp">http://www.toxicology.org/index.asp</a></td>
</tr>
<tr>
<td>Chemistry</td>
<td>The Chemical Industry Council of Illinois</td>
<td><a href="http://www.cicil.net/">http://www.cicil.net/</a></td>
</tr>
<tr>
<td>Biosciences</td>
<td>Virginia Biotechnology Association</td>
<td><a href="http://www.vabio.org/">http://www.vabio.org/</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Washington Biotechnology And Biomedical Association</td>
<td><a href="http://www.washbio.org/?page=Our_Team">http://www.washbio.org/?page=Our_Team</a></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Western Association of Core Directors</td>
<td><a href="http://wacd.abrf.org/organizing_committee">http://wacd.abrf.org/organizing_committee</a></td>
</tr>
<tr>
<td>Management</td>
<td>The National Professional Science Master's Association</td>
<td><a href="http://www.npsma.org/">http://www.npsma.org/</a></td>
</tr>
</tbody>
</table>
Appendix D: Course Approval Forms

DDPM 201  System Pharmacology and Toxicology
DDPM 202  Pharmaceutics for Small Molecules and Macromolecules
DDPM 203  Pre-Clinical and Clinical Regulatory Submissions
DDPM 204  Early Stage Clinical Trials
DDPM 205  Principles of Drug Development for BioMedical and Pharmaceutical Product Development
DDPM 206  Patent Strategy and Freedom to Operate
DDPM 207  Foundations of Project Management
DDPM 208  Marketing Strategy, Product Management, and Life Cycle Product Management
DDPM 209  Principles of Cost Effective Analysis in Drug Development and Markets
DDPM 210  Biologics and Biosimilars Drug Development
DDPM 211  Principles of Regulatory Science
DDPM 212  Analysis of Industry Needs in Drug Development and Product Management
DDPM 213  Health Outcomes Evidence
DDPM 214  Pharmaceutical Business Development and Managing R&D Innovation
DDPM 215  Comprehensive Analysis of Key Principles in Drug Development and Product Management
DDPM 216  Practice-Based Internship

Note: Appendix C (Faculty CVs) is separate file not included with proposal
**UNIVERSITY OF CALIFORNIA, SAN DIEGO**
**REQUEST FOR COURSE APPROVAL**

<table>
<thead>
<tr>
<th>Subject &amp; Number</th>
<th>Units</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDPM - 201</td>
<td>4</td>
<td>System Pharmacology and Toxicology</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hours Per Week</th>
<th>Lec</th>
<th>Sem</th>
<th>Dis</th>
<th>Lab</th>
<th>Studio</th>
<th>Practicum</th>
<th>Tutorial</th>
<th>Med Clerk</th>
<th>Outside Prep</th>
<th>Other (describe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected of Student</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?

- **x** Single List of all students
- By Dis Section
- By Lab Section
- By Studio Section
- By Tut Section

Grading - Undergraduate:
- Standard Grading (letter or P/NP)
- P/NP Only

Grading – Graduate and SOM:
- **x** Standard Option (Graduate)
- S/U Permitted
- S/U Only
- H/P/F (SOM Core only)

May be taken for credit **1** time(s). If more than once, justify:

- **x** Final Exam Given
- If not, explain:

**COURSE DESCRIPTION** (In concise catalog description style, 40 word limit)

This new course provides students an introduction to pharmacological concepts, constructs and essential considerations in new drug design, development, testing and therapeutic trials and testing, enabling future managers to guide efforts in drug discovery and clinical testing.

Prerequisites: Student in MS-DDPM program or permission of department

**ENFORCEMENT** List prerequisites and other restrictions to be enforced by computer (see instructions). NA

Prerequisites that must be completed:

Co-requisites (must be concurrent):

Other restrictions: Student in MS-DDPM program or permission of department

Special course characteristics. Check all boxes that apply and see instructions for required explanations.

- Use of animals
- Use of computer resources
- IP Grading
- Cross listed with _______  
- Conjoined with _______

Instructor and title: Morton Printz, PhD  Professor – Department of Pharmacology

**JUSTIFICATION:** Required course in MS-DDPM program

Program Director

Department Chair/Program Director: date
Registrar: date

**APPROVALS – GRADUATE COURSE**

- Dean, School of Medicine: date
- Dean of Graduate Studies: date
- Graduate Council: date

**APPROVALS - UNDERGRADUATE COURSE**

- Council of Provosts: date
- CEP Subcommittee on Courses: date

Extent of approval:  
- Indefinite  
- Summer Only  
Expires at the end of ________ quarter, 20__

FO 2073 (REV. 12/11/09)
**REQUEST FOR COURSE APPROVAL**

- **Subject & Number**: DDPM - 202
- **Units**: 4
- **Title**: Pharmaceutics for Small Molecules and Macromolecules

<table>
<thead>
<tr>
<th>Hours Per Week</th>
<th>Lec</th>
<th>Sem</th>
<th>Dis</th>
<th>Lab</th>
<th>Studio</th>
<th>Practicum</th>
<th>Tutorial</th>
<th>Med Clerk</th>
<th>Outside Prep</th>
<th>Other (describe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected of Student</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?**
- [x] Single List of all students
- [ ] By Dis Section
- [ ] By Lab Section
- [ ] By Studio Section
- [ ] By Tut Section

**Grading - Undergraduate**
- [ ] Standard Grading (letter or P/NP)
- [ ] P/NP Only

**Grading – Graduate and SOM**
- [x] Standard Option (Graduate)
- [ ] S/U Permitted
- [ ] S/U Only
- [ ] H/P/F (SOM Core only)

**May be taken for credit**
- [1] time(s). If more than once, justify:
  - [x] Final Exam Given
  - If not, explain:

**COURSE DESCRIPTION** (In concise catalog description style, 40 word limit)
The course examines the tools used to assess the systemic bioavailability of drugs, delineates the processes determining drug absorption, summarizes the physicochemical properties of a drug, and presents pharmacokinetic principles used to predict the time course of a drug.

**Prerequisites**: Student in MS-DDPM program or permission of department

**ENFORCEMENT** List prerequisites and other restrictions to be enforced by computer (see instructions). NA

**Prerequisites that must be completed**: 

**Co-requisites (must be concurrent)**:

**Other restrictions**: Student in MS-DDPM program or permission of department

**Special course characteristics. Check all boxes that apply and see instructions for required explanations.**
- [ ] Use of animals
- [ ] Use of computer resources
- [ ] IP Grading
- [ ] Cross listed with
- [ ] Conjoined with

**Instructor and title**: 
Brookie Best, Pharm.D. MAS, Clinical Professor, SSPPS

**JUSTIFICATION**: Required course in MS-DDPM program.

---

**Approvals**

**Program Director**

---

**Department Chair/Program Director**

---

**Registrar**

---

**APPROVALS – GRADUATE COURSE**

- Dean, School of Medicine: date
- Dean of Graduate Studies: date
- Graduate Council: date

**APPROVALS – UNDERGRADUATE COURSE**

- Council of Provosts: date
- CEP Subcommittee on Courses: date

**Extent of approval**: 
- [ ] Indefinite
- [ ] Summer Only

Expires at the end of ________ quarter, 20____
UNIVERSITY OF CALIFORNIA, SAN DIEGO
REQUEST FOR COURSE APPROVAL

Subject & Number: DDPM - 203
Units: 4
Title: Pre-Clinical and Clinical Regulatory Submissions

Hours Per Week Expected of Student:

<table>
<thead>
<tr>
<th>Lec</th>
<th>Sem</th>
<th>Dis</th>
<th>Lab</th>
<th>Studio</th>
<th>Practicum</th>
<th>Tutorial</th>
<th>Med Clerk</th>
<th>Outside Prep</th>
<th>Other (describe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?

- [x] Single List of all students
- [ ] By Dis Section
- [ ] By Lab Section
- [ ] By Studio Section
- [ ] By Tut Section

Grading - Undergraduate:
- Standard Grading (letter or P/NP)
- [x] P/NP Only

Grading – Graduate and SOM:
- [x] Standard Option (Graduate)
- [ ] S/U Permitted
- [ ] S/U Only
- [ ] H/P/F (SOM Core only)

May be taken for credit ______1______ time(s). If more than once, justify:
- [x] Final Exam Given

If not, explain:

COURSE DESCRIPTION (In concise catalog description style, 40 word limit)

This course provides an overview of the common regulatory filings during pre-clinical and clinical development. Using a case study format, the student will gain an understanding of the regulations governing pharmaceutical and biologic products in the United States and globally.

Prerequisites: Student in MS-DDPM program or permission of department

ENFORCEMENT:
List prerequisites and other restrictions to be enforced by computer (see instructions). NA

Prerequisites that must be completed:

Co-requisites (must be concurrent):

Other restrictions: Student in MS-DDPM program or permission of department

Special course characteristics. Check all boxes that apply and see instructions for required explanations.

- [ ] Use of animals
- [ ] Use of computer resources
- [ ] IP Grading
- [ ] Cross listed with ___________
- [ ] Conjoined with ___________

Instructor and title: Jeremiah Momper, Pharm.D., PhD; Clinical Professor, SSPPS

JUSTIFICATION: Required course in MS-DDPM program.

Program Director

Department Chair/Program Director date Registrar date

APPROVALS – GRADUATE COURSE

Dean, School of Medicine date

Dean of Graduate Studies date

Graduate Council date

APPROVALS - UNDERGRADUATE COURSE

Council of Provosts date

CEP Subcommittee on Courses date

Extent of approval: Indefinite Summer Only Expires at the end of ________ quarter, 20____

FO 2073 (REV. 12/11/09)
**UNIVERSITY OF CALIFORNIA, SAN DIEGO**

**REQUEST FOR COURSE APPROVAL**

- **Subject & Number**: DDPM - 204
- **Units**: 4
- **Title**: Early Stage Clinical Trials

**Hours Per Week**

<table>
<thead>
<tr>
<th>Expected of Student</th>
<th>Lec</th>
<th>Sem</th>
<th>Dis</th>
<th>Lab</th>
<th>Studio</th>
<th>Practicum</th>
<th>Tutorial</th>
<th>Med Clerk</th>
<th>Outside Prep</th>
<th>Other (describe)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>

**If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?**

- [x] Single List of all students

**Grading - Undergraduate**

- Standard Grading (letter or P/NP)
- [x] P/NP Only

**Grading – Graduate and SOM**

- [x] Standard Option (Graduate)

**May be taken for credit**: 1 time(s). If more than once, justify:

- [x] Final Exam Given

**COURSE DESCRIPTION** (in concise catalog description style, 40 word limit)

Students will learn the process of drug development through specific examples of case studies to better understand the issues facing the challenges of delivering a new drug on the market.

**Prerequisites**: Student in MS-DDPM program or permission of department

**ENFORCEMENT** List prerequisites and other restrictions to be enforced by computer (see instructions). NA

**Prerequisites that must be completed**:

**Co-requisites (must be concurrent)**:

**Other restrictions**: Student in MS-DDPM program or permission of department

**Special course characteristics. Check all boxes that apply and see instructions for required explanations.**

- [ ] Use of animals
- [ ] Use of computer resources
- [ ] IP Grading
- [ ] Cross listed with ___________
- [ ] Conjoined with ___________

**Instructor and title**: Joseph D. Ma, Pharm.D.; Clinical Professor, SSPPS

**JUSTIFICATION**: Required course in MS-DDPM program.

**Program Director**

Department Chair/Program Director [date] Registrar [date]

**APPROVALS – GRADUATE COURSE**

- Dean, School of Medicine [date]
- Dean of Graduate Studies [date]

**APPROVALS - UNDERGRADUATE COURSE**

- Council of Provosts [date]
- CEP Subcommittee on Courses [date]

**Extent of approval**: Indefinite

Expires at the end of ________ quarter, 20____

FO 2073 (REV. 12/11/09)
# UNIVERSITY OF CALIFORNIA, SAN DIEGO

## REQUEST FOR COURSE APPROVAL

- **New Course**: Yes
- **Subject & Number**: DDPM - 205
- **Units**: 4
- **Title**: Principles of Drug Development
- **Quarter**: Winter
- **Year**: 2019
- **Change In Course**: Yes
- **Nature of Change**: Effective

### Course Details

<table>
<thead>
<tr>
<th>Hours Per Week</th>
<th>Lec</th>
<th>Sem</th>
<th>Dis</th>
<th>Lab</th>
<th>Studio</th>
<th>Practicum</th>
<th>Tutorial</th>
<th>Med Clerk</th>
<th>Outside Prep</th>
<th>Other (describe)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expected of Student</strong></td>
<td>4</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?**
  - [x] Single List of all students
  - [ ] By Dis Section
  - [ ] By Lab Section
  - [ ] By Studio Section
  - [ ] By Tut Section

- **Grading - Undergraduate**: Standard Grading (letter or P/NP)
- **Grading – Graduate and SOM**: [x] Standard Option (Graduate)
- **May be taken for credit**: 1 time(s)
- **Final Exam Given**: Yes

### Course Description

This course presents principles underlying preclinical and clinical development of new therapeutic drugs, and biomarkers. The course uses a case-study approach to identify and solve practical, theoretical, and technical problems in human drug studies, including legal and ethical regulations.

**Prerequisites**: Student in MS-DDPM program or permission of department

**Enforcement**: List prerequisites and other restrictions to be enforced by computer (see instructions). NA

**Prerequisites that must be completed**:

**Co-requisites (must be concurrent)**:

**Other restrictions**: Student in MS-DDPM program or permission of department

### Special Course Characteristics

- [ ] Use of animals
- [ ] Use of computer resources
- [ ] IP Grading
- [ ] Cross listed with
- [ ] Conjoined with

**Instructor and title**: TBD (new faculty hire)

**Justification**: Required course in MS-DDPM program.

---

**Program Director**

**Date**

**Department Chair/Program Director**

**Date**

**Registrar**

**Date**

**Approvals – Graduate Course**

- Dean, School of Medicine: Date
- Dean of Graduate Studies: Date
- Graduate Council: Date

**Approvals – Undergraduate Course**

- Council of Provosts: Date
- CEP Subcommittee on Courses: Date

**Extent of approval**: Indefinite

Expires at the end of __________ quarter, 20__

---

FO 2073 (REV. 12/11/09)
**UNIVERSITY OF CALIFORNIA, SAN DIEGO**

**REQUEST FOR COURSE APPROVAL**

- **New Course**: Yes
- **Subject & Number**: DDPM - 206
- **Units**: 4
- **Title**: Patent Strategy and Freedom to Operate
- **Expected of Student**: 4

**COURSE DESCRIPTION**

This course explains how to maximize pharmaceutical patent life cycles in the pharma and biotech industry. Patent losses on pharmaceutical products have a multi-billion dollar detrimental impact in the industry each year.

**Prerequisites**: Student in MS-DDPM program or permission of department

**ENFORCEMENT**

List prerequisites and other restrictions to be enforced by computer (see instructions). NA

**Prerequisites that must be completed:**

- **Co-requisites (must be concurrent):**

**Other restrictions**: Student in MS-DDPM program or permission of department

**Special course characteristics. Check all boxes that apply and see instructions for required explanations.**

- Use of animals
- Use of computer resources
- IP Grading
- Cross listed with
- Conjoined with

**Instructor and title**: TBD (faculty member not yet selected)

**JUSTIFICATION**: Required course in MS-DDPM program.

---

**APPROVALS – GRADUATE COURSE**

- Dean, School of Medicine: date
- Dean of Graduate Studies: date

**APPROVALS - UNDERGRADUATE COURSE**

- Council of Provosts: date
- CEP Subcommittee on Courses: date

**Extent of approval**: Indefinite

Expires at the end of ________ quarter, 20____
UNIVERSITY OF CALIFORNIA, SAN DIEGO
REQUEST FOR COURSE APPROVAL

<table>
<thead>
<tr>
<th>Subject &amp; Number</th>
<th>Units</th>
<th>Title</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Hours Per Week</th>
<th>Lec</th>
<th>Sem</th>
<th>Dis</th>
<th>Lab</th>
<th>Studio</th>
<th>Practicum</th>
<th>Tutorial</th>
<th>Med Clerk</th>
<th>Outside Prep</th>
<th>Other (describe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected of Student</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?

- [x] Single List of all students
- [ ] By Dis Section
- [ ] By Lab Section
- [ ] By Studio Section
- [ ] By Tut Section

Grading - Undergraduate

- [ ] Standard Grading (letter or P/NP)
- [ ] P/NP Only

Grading – Graduate and SOM

- [x] Standard Option (Graduate)
- [ ] S/U Permitted
- [ ] S/U Only
- [ ] H/P/F (SOM Core only)

May be taken for credit [ ] 1 time(s). If more than once, justify:

- [x] Final Exam Given
- [ ] If not, explain:

COURSE DESCRIPTION (in concise catalog description style, 40 word limit)

Using multiple case studies and real-world examples, this course describes the complexity of today’s project management in a global drug development effort. Development risk, defining success, phased development approaches and project scheduling, and project execution issues are all presented.

Prerequisites: Student in MS-DDPM program or permission of department

ENFORCEMENT List prerequisites and other restrictions to be enforced by computer (see instructions). NA

Prerequisites that must be completed:

- Co-requisites (must be concurrent):
- Other restrictions: Student in MS-DDPM program or permission of department

Special course characteristics. Check all boxes that apply and see instructions for required explanations.

- Use of animals
- Use of computer resources
- IP Grading
- Cross listed with _________
- Conjoined with _________

Instructor and title: Vish Krishnan, Ph.D.; Professor, Rady School of Management

JUSTIFICATION: Required course in MS-DDPM program.

Program Director

Department Chair

Registrar

APPROVALS – GRADUATE COURSE

Dean, School of Medicine

date

Council of Provosts

date

Dean of Graduate Studies

date

CEP Subcommittee on Courses

date

Graduate Council

date

Extent of approval: [ ] Indefinite [ ] Summer Only Expires at the end of _________ quarter, 20____

FO 2073 (REV. 12/11/09)
Request for Course Approval

**Subject & Number**
DDPM - 208

**Units**
4

**Title**
Marketing Strategy, Product Management, and Life Cycle Product Management

**Nature of Change:**

- New Course
- Change in Course

**Effective Quarter & Year**
Spring 2019

**Hours Per Week**

<table>
<thead>
<tr>
<th>Lec</th>
<th>Sem</th>
<th>Dis</th>
<th>Lab</th>
<th>Studio</th>
<th>Practicium</th>
<th>Tutorial</th>
<th>Med Clerk</th>
<th>Outside Prep</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?**

- [x] Single List of all students
- [ ] By Dis Section
- [ ] By Lab Section
- [ ] By Studio Section
- [ ] By Tut Section

**Grading - Undergraduate**

- [ ] Standard Grading (letter or P/NP)
- [ ] P/NP Only

**Grading – Graduate and SOM**

- [x] Standard Option (Graduate)
- [ ] S/U Permitted
- [ ] S/U Only
- [ ] H/P/F (SOM Core only)

**May be taken for credit**

- [x] 1 time(s)

**Final Exam Given**

- [x] If not, explain:

---

**COURSE DESCRIPTION**
The course explains global drug marketing strategy in a highly regulated environment, explores portfolio strategy as it relates to drug product management, describes the complexity of global brand management, and considers how pharmaceutical drugs are commercialized in today’s environment.

**Prerequisites:** Student in MS-DDPM program or permission of department

**ENFORCEMENT**
List prerequisites and other restrictions to be enforced by computer (see instructions). NA

**Prerequisites that must be completed:**

**Co-requisites (must be concurrent):**

**Other restrictions:**
Student in MS-DDPM program or permission of department

**Special course characteristics.**
Check all boxes that apply and see instructions for required explanations.

- [ ] Use of animals
- [ ] Use of computer resources
- [ ] IP Grading
- [ ] Cross listed with ___________
- [ ] Conjoined with ___________

**Instructor and title:**
Williams S. Ettouati, Pharm.D.; Adjunct Professor, SSPPS

**JUSTIFICATION:**
Required course in MS-DDPM program.

---

**Program Director**

**Department Chair/Program Director**

**Registrar**

**APPROVALS – GRADUATE COURSE**

- Dean, School of Medicine
- Dean of Graduate Studies
- Graduate Council

**APPROVALS - UNDERGRADUATE COURSE**

- Council of Provosts
- CEP Subcommittee on Courses

**Extent of approval:**

- [ ] Indefinite
- [ ] Summer Only

**Expires at the end of _______ quarter, 20____

---

FO 2073 (REV. 12/11/09)
UNIVERSITY OF CALIFORNIA, SAN DIEGO
REQUEST FOR COURSE APPROVAL

New Course ☑
Reinstatement ☐
Deletion ☐
Renumbering: old number__________
Summer Session Only ☐
Change In Course ☐
Nature of Change:

Subject & Number
DDPM - 209

Units
4

Title
Principles of Cost Effective Analysis in Drug Development and Markets

Hours Per Week
Expected of Student
Lec 4
Sem 1
Dis
Lab 0
Studio 1
Practicum 8
Tutorial 0
Med Clerk 0
Outside Prep 0
Other (describe) 0

If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?
[ ] Single List of all students
[ ] By Dis Section
[ ] By Lab Section
[ ] By Studio Section
[ ] By Tut Section

Grading - Undergraduate
Standard Grading (letter or P/NP) ☐
P/NP Only ☐

Grading – Graduate and SOM
Standard Option (Graduate) ☑
S/U Permitted ☐
S/U Only ☐
H/P/F (SOM Core only) ☐

May be taken for credit ______1______ time(s). If more than once, justify:
[ ] Final Exam Given
If not, explain:

COURSE DESCRIPTION (In concise catalog description style, 40 word limit)
This course provides an overview and understanding of the types of analyses that contribute to developing a body of cost
effectiveness evidence demonstrating product value. The student will achieve the ability to conduct their own cost-
effectiveness analysis.

Prerequisites: Student in MS-DDPM program or permission of department

ENFORCEMENT List prerequisites and other restrictions to be enforced by computer (see instructions). NA

Prerequisites that must be completed:

Co-requisites (must be concurrent):

Other restrictions: Student in MS-DDPM program or permission of department

Special course characteristics. Check all boxes that apply and see instructions for required explanations.
[ ] Use of animals
[ ] Use of computer resources
[ ] IP Grading
[ ] Cross listed with ___________
[ ] Conjoined with ___________

Instructor and title: Jan D. Hirsch, BS Pharm, Ph.D.; Clinical Professor, SSPPS

JUSTIFICATION: Required course in MS-DDPM program.

Program Director

Department Chair/Program Director
date
Registrar
date

APPROVALS – GRADUATE COURSE

Dean, School of Medicine
date
Council of Provosts
date

Dean of Graduate Studies
date
CEP Subcommittee on Courses
date

Graduate Council
date

APPROVALS – UNDERGRADUATE COURSE

Extent of approval:
[ ] Indefinite
[ ] Summer Only
Expires at the end of ________ quarter, 20____

FO 2073 (REV. 12/11/09)
UNIVERSITY OF CALIFORNIA, SAN DIEGO
REQUEST FOR COURSE APPROVAL

Subject & Number  DDPM - 210
Units  4
Title  Biologics and Biosimilars Drug Development

If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?
- Single List of all students  x
- By Dis Section
- By Lab Section
- By Studio Section
- By Tut Section

Grading - Undergraduate
- Standard Grading (letter or P/NP)
- P/NP Only  x

Grading – Graduate and SOM
- Standard Option (Graduate)  x
- S/U Permitted
- S/U Only
- H/P/F (SOM Core only)

COURSE DESCRIPTION (In concise catalog description style, 40 word limit)
This course explains how biologics are developed and commercialized as therapeutics, explores how the process differs from the traditional pharmaceutical approach for small molecules, and outlines the challenges and opportunities for producing more affordable generic equivalents, also known as biosimilars.

Prerequisites:  Student in MS-DDPM program or permission of department

ENFORCEMENT  List prerequisites and other restrictions to be enforced by computer (see instructions).  NA

Prerequisites that must be completed:

Co-requisites (must be concurrent):

Other restrictions:  Student in MS-DDPM program or permission of department

Instructor and title:  Joseph D. Ma, Pharm.D; Clinical Professor, SSPPS, and Hubert C. Chen, MD; Project Scientist, Department of Bioengineering

JUSTIFICATION: Required course in MS-DDPM program.

Program Director

Department Chair/Program Director  date  Registrar  date

APPROVALS – GRADUATE COURSE

Dean, School of Medicine  date

Dean of Graduate Studies  date

Graduate Council  date

APPROVALS – UNDERGRADUATE COURSE

Council of Provosts  date

CEP Subcommittee on Courses  date

Extent of approval:  Indefinite  Summer Only  Expires at the end of ________ quarter, 20___

FO 2073 (REV. 12/11/09)
**UNIVERSITY OF CALIFORNIA, SAN DIEGO**

**REQUEST FOR COURSE APPROVAL**

<table>
<thead>
<tr>
<th>Subject &amp; Number</th>
<th>Units</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDPM - 211</td>
<td>4</td>
<td>Principles of Regulatory Science</td>
</tr>
</tbody>
</table>

**Hours Per Week Expected of Student**

<table>
<thead>
<tr>
<th>Lec</th>
<th>Dis</th>
<th>Lab</th>
<th>Studio</th>
<th>Practicum</th>
<th>Tutorial</th>
<th>Med Clerk</th>
<th>Outside Prep</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8</td>
</tr>
</tbody>
</table>

If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?

- [x] Single List of all students
- [ ] By Dis Section
- [ ] By Lab Section
- [ ] By Studio Section
- [ ] By Tut Section

Grading - Undergraduate

- [x] Standard Grading (letter or P/NP)
- [ ] P/NP Only

Grading – Graduate and SOM

- [x] Standard Option (Graduate)
- [ ] S/U Permitted
- [ ] S/U Only
- [ ] H/P/F (SOM Core only)

May be taken for credit ______1______ time(s). If more than once, justify:

- [ ] Final Exam Given

If not, explain:

**COURSE DESCRIPTION** (In concise catalog description style, 40 word limit)

This course provides an overview of U.S. FDA regulations governing drug and biologic development and post-approval marketing. Practices in information access, submissions, FDA inspections, and quality guidelines (GLP, GCP, GMP) are be covered.

Prerequisites: Student in MS-DDPM program or permission of department

**ENFORCEMENT** List prerequisites and other restrictions to be enforced by computer (see instructions). NA

**Prerequisites that must be completed:**

**Co-requisites (must be concurrent):**

**Other restrictions:** Student in MS-DDPM program or permission of department

**Special course characteristics. Check all boxes that apply and see instructions for required explanations.**

- [ ] Use of animals
- [ ] Use of computer resources
- [ ] IP Grading
- [ ] Cross listed with _________
- [ ] Conjoined with _________

Instructor and title: TBD (new faculty hire)

**JUSTIFICATION:** Required course in MS-DDPM program.

Program Director: 

Department Chair/Program Director: 

Registrar: 

**APPROVALS – GRADUATE COURSE**

- Dean, School of Medicine: 
  - Date: 

- Dean of Graduate Studies: 
  - Date: 

- Graduate Council: 
  - Date: 

**APPROVALS - UNDERGRADUATE COURSE**

- Council of Provosts: 
  - Date: 

- CEP Subcommittee on Courses: 
  - Date: 

Extent of approval: 

- [ ] Indefinite
- [ ] Summer Only

Expires at the end of _________ quarter, 20____
**UNIVERSITY OF CALIFORNIA, SAN DIEGO**  
**REQUEST FOR COURSE APPROVAL**

- **Subject & Number**: DDPM - 212
- **Units**: 4
- **Title**: Analysis of Industry Needs in Drug Development and Product Management

### Hours Per Week

<table>
<thead>
<tr>
<th>Lec</th>
<th>Sem</th>
<th>Dis</th>
<th>Lab</th>
<th>Studio</th>
<th>Practicum</th>
<th>Tutorial</th>
<th>Med Clerk</th>
<th>Outside Prep</th>
<th>Other (describe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Nature of Change:
- **Change In Course**: New Course
- **Effective Quarter Year**: Fall 2019
- **Summer Session Only**: False

### Subject & Number

- **Subject & Number**: DDPM - 212

### Units

- **Units**: 4

### Title

- **Title**: Analysis of Industry Needs in Drug Development and Product Management

### Hours Per Week

- **Lectures (Lec)**: 4
- **Semester (Sem)**: 4
- **Discussion (Dis)**: 0
- **Laboratory (Lab)**: 0
- **Studio**: 0
- **Practicum**: 0
- **Tutorial**: 0
- **Med Clerk**: 0
- **Outside Prep**: 8

### If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?
- **Single List of all students**

### Grading - Undergraduate

- **Standard Grading (letter or P/NP)**
- **P/NP Only**

### Grading – Graduate and SOM

- **Standard Option (Graduate)**
- **S/U Permitted**
- **S/U Only**
- **H/P/F (SOM Core only)**

### May be taken for credit

- **1 time(s)**

### Final Exam Given

- **If not, explain**: Student are evaluated based on research papers submitted and presentations given during class.

### COURSE DESCRIPTION

This course prepares students to identify, obtain, and succeed at a practice-based internship. Through individual and group research assignments, students learn and share their findings regarding current industry challenges and concerns, workforce dynamics, and specific business opportunities.

**Prerequisites:** Permission of the instructor, also student in MS-DDPM program or permission of department.

**ENFORCEMENT**

- List prerequisites and other restrictions to be enforced by computer (see instructions). NA

**Prerequisites that must be completed:**

**Co-requisites (must be concurrent):**

**Other restrictions:** Student in MS-DDPM program or permission of department

### Special course characteristics.

- **Use of animals**
- **Use of computer resources**
- **IP Grading**
- **Cross listed with**
- **Conjoined with**

### Instructor and title:

Jan D. Hirsch, BS Pharm, Ph.D., Clinical Professor, SSPPS, and Williams S. Ettouati, Pharm.D., Adjunct Professor, SSPPS.

### JUSTIFICATION

Required course in MS-DDPM program

______

Program Director

_______ date _______ date

**Department Chair/Program Director**

**Registrar**

### APPROVALS – GRADUATE COURSE

- **Dean, School of Medicine**: date
- **Dean of Graduate Studies**: date
- **Graduate Council**: date

### APPROVALS – UNDERGRADUATE COURSE

- **Council of Provosts**: date
- **CEP Subcommittee on Courses**: date

### Extent of approval:

- **Indefinite**
- **Summer Only**

**Expires at the end of quarter, 20__**

---

FO 2073 (REV. 12/11/09)
### UNIVERSITY OF CALIFORNIA, SAN DIEGO
### REQUEST FOR COURSE APPROVAL

<table>
<thead>
<tr>
<th>Subject &amp; Number</th>
<th>Units</th>
<th>Title</th>
<th>Hours Per Week</th>
<th>Expected of Student</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDPM - 213</td>
<td>4</td>
<td>Health Outcomes Evidence</td>
<td>Lec 4</td>
<td>Sem Dis Lab Studio Practicum Tutorial Med Clerk Outside Prep</td>
</tr>
</tbody>
</table>

- If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?
  - x Single List of all students
  - By Dis Section
  - By Lab Section
  - By Studio Section
  - By Tut Section

- Grading - Undergraduate
  - Standard Grading (letter or P/NP)
  - P/NP Only

- Grading – Graduate and SOM
  - x Standard Option (Graduate)
  - S/U Permitted
  - S/U Only
  - H/P/F (SOM Core only)

May be taken for credit ___1____ time(s). If more than once, justify:

- x Final Exam Given

**COURSE DESCRIPTION** (In concise catalog description style, 40 word limit)

This course examines the breadth of data and study types that build evidence of a product’s value from potential estimates during the early development stages through to post marketing actual value realized over time in various populations.

**Prerequisites:** Student in MS-DDPM program or permission of department

**ENFORCEMENT** List prerequisites and other restrictions to be enforced by computer (see instructions). NA

**Prerequisites that must be completed:**

**Co-requisites (must be concurrent):**

**Other restrictions:** Student in MS-DDPM program or permission of department

**Special course characteristics. Check all boxes that apply and see instructions for required explanations.**

- Use of animals
- Use of computer resources
- IP Grading
- Cross listed with ________
- Conjoined with _______

**Instructor and title:** Andrew Sarkin, PhD; Professor, Department of Family Medicine and Public Health

**JUSTIFICATION:** Required course in MS-DDPM program.

---

Program Director

Department Chair/Program Director ____________ date ____________

Registrar ____________ date ____________

**APPROVALS – GRADUATE COURSE**

- Dean, School of Medicine ____________ date ____________
- Dean of Graduate Studies ____________ date ____________
- Graduate Council ____________ date ____________

**APPROVALS - UNDERGRADUATE COURSE**

- Council of Provosts ____________ date ____________
- CEP Subcommittee on Courses ____________ date ____________

**Extent of approval:**

- Indefinite
- Summer Only

Expires at the end of ________ quarter, 20____

---

FO 2073 (REV. 12/11/09)
UNIVERSITY OF CALIFORNIA, SAN DIEGO
REQUEST FOR COURSE APPROVAL

Subject & Number
DDPM - 214

Units
4

Title
Pharmaceutical Business Development and Managing R&D Innovation

Hours Per Week
Expected of Student
Lec 4
Sem 8
Dis 8
Lab 8
Studio 8
Practicum 8
Tutorial 8
Med Clerk 8
Outside Prep 8
Other (describe)

If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?

- Single List of all students
- By Dis Section
- By Lab Section
- By Studio Section
- By Tut Section

Grading - Undergraduate

Standard Grading (letter or P/NP)  P/NP Only

Grading – Graduate and SOM

- Standard Option (Graduate)
- S/U Permitted
- S/U Only
- H/P/F (SOM Core only)

May be taken for credit

1 time(s). If more than once, justify:

- Final Exam Given
- If not, explain:

COURSE DESCRIPTION (In concise catalog description style, 40 word limit)
This course has three objectives: (1) learning the process deal making within the pharmaceutical and biotech industries, (2) exploring negotiation strategy, valuation and how to manage the contracting phase of a deal, and (3) understanding effective alliance management.

Prerequisites: Student in MS-DDPM program or permission of department

ENFORCEMENT List prerequisites and other restrictions to be enforced by computer (see instructions). NA

Prerequisites that must be completed:

Co-requisites (must be concurrent):

Other restrictions: Student in MS-DDPM program or permission of department

Special course characteristics. Check all boxes that apply and see instructions for required explanations.

- Use of animals
- Use of computer resources
- IP Grading
- Cross listed with
- Conjoined with

Instructor and title: Williams S. Ettouati, Pharm.D., Adjunct Professor, SSPPS

JUSTIFICATION:

Program Director

Department Chair/Program Director

Registrar

APPROVALS – GRADUATE COURSE

Dean, School of Medicine

date

Council of Provosts

date

Dean of Graduate Studies

date

CEP Subcommittee on Courses

date

Graduate Council

date

Extent of approval: Indefinite Summer Only Expires at the end of _________ quarter, 20____

FO 2073 (REV. 12/11/09)
UNIVERSITY OF CALIFORNIA, SAN DIEGO
REQUEST FOR COURSE APPROVAL

<table>
<thead>
<tr>
<th>Subject &amp; Number</th>
<th>Units</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDPM - 215</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

**Title:** Comprehensive Analysis of Key Principles in Drug Development and Product Management

<table>
<thead>
<tr>
<th>Hours Per Week</th>
<th>Expected of Student</th>
<th>Lec</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>4</td>
</tr>
</tbody>
</table>

If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?

- [x] Single List of all students
- [ ] By Dis Section
- [ ] By Lab Section
- [ ] By Studio Section
- [ ] By Tut Section

**Grading - Undergraduate:**

- [ ] Standard Grading (letter or P/NP)
- [ ] P/NP Only

**Grading – Graduate and SOM:**

- [x] Standard Option (Graduate)
- [ ] S/U Permitted
- [ ] S/U Only
- [ ] H/P/F (SOM Core only)

May be taken for credit ______1______ time(s). If more than once, justify:

- [ ] Final Exam Given
  If not, explain: Student are evaluated based on papers submitted and presentations given during class.

**COURSE DESCRIPTION** (In concise catalog description style, 40 word limit)

Students work individually and in groups to review and present key elements of prior courses, while also identifying new concepts that arise from integration of principles across subjects. Students learn to articulate issues and practices in a professional manner.

**Prerequisites:** Permission of the instructor, and student in MS-DDPM program or permission of department

**ENFORCEMENT** List prerequisites and other restrictions to be enforced by computer (see instructions). NA

**Prerequisites that must be completed:**

**Co-requisites (must be concurrent):**

**Other restrictions:** Student in MS-DDPM program or permission of department

**Special course characteristics. Check all boxes that apply and see instructions for required explanations.**

- [ ] Use of animals
- [ ] Use of computer resources
- [ ] IP Grading
- [ ] Cross listed with ___________
- [ ] Conjoined with _________

**Instructor and title:** Jan D. Hirsch, BS Pharm, Ph.D., Clinical Professor, SSPPS; Williams S. Ettouati, Pharm.D., Adjunct Professor, SSPPS; Jeremiah Momper, Pharm.D., PhD, Clinical Professor, SSPPS

**JUSTIFICATION:** Required course in MS-DDPM program.

---

**Program Director**

**Department Chair/Program Director**

**Registrar**

**APPROVALS – GRADUATE COURSE**

- Dean, School of Medicine
  - date
- Dean of Graduate Studies
  - date
- Graduate Council
  - date

**APPROVALS – UNDERGRADUATE COURSE**

- Council of Provosts
  - date
- CEP Subcommittee on Courses
  - date

**Extent of approval:**

- [ ] Indefinite
- [ ] Summer Only

Expires at the end of _______ quarter, 20____

FO 2073 (REV. 12/11/09)
REQUEST FOR COURSE APPROVAL

UNIVERSITY OF CALIFORNIA, SAN DIEGO

x New Course  Reinstatement  Deletion  Renumbering: old number__________  Summer Session Only

Change In Course  Nature of Change:

Effective Quarter Year Spring 2020

Subject & Number
DDPM - 216

Units
12

Title
Practice-based Internship

Hours Per Week
Expected of Student
Lec  Sem  Dis  Lab  Studio  Practicum  36  Tutorial  Med Clerk  Outside Prep  Other (describe)
36  4  4  4  4  4  4  4  4  4

If the course has multiple discussion or other sections, how should the grade reports be printed (check one)?

x Single List of all students  By Dis Section  By Lab Section  By Studio Section  By Tut Section

Grading - Undergraduate
Standard Grading (letter or P/NP)  P/NP Only

Grading – Graduate and SOM
Standard Option (Graduate)  S/U Permitted  x S/U Only  H/P/F (SOM Core only)

May be taken for credit ______2______ time(s). If more than once, justify: Some students and employer sponsors may opt for a 6-month internship.

Final Exam Given  If not, explain: Internship evaluation in lieu of final exam

COURSE DESCRIPTION (In concise catalog description style, 40 word limit)
Students apply the knowledge they have obtained in the DDPM program to assist their internship host in managing drug development projects and/or constructing and implementing product management strategies. The internship includes frequent research and analytical assignments.

Prerequisites: Permission of the instructor and department, and successful completion of the masters examination

ENFORCEMENT  List prerequisites and other restrictions to be enforced by computer (see instructions).  NA

Prerequisites that must be completed:

Co-requisites (must be concurrent):

Other restrictions: Student in MS-DDPM program or permission of department

Special course characteristics. Check all boxes that apply and see instructions for required explanations.

Use of animals  Use of computer resources  IP Grading  Cross listed with ___________  Conjoined with _________

Instructor and title: Various (academic advisor serves as internship instructor)

JUSTIFICATION: Required course in the MS-DDPM program.

Program Director

Department Chair/Program Director  date  Registrar  date

APPROVALS – GRADUATE COURSE

Dean, School of Medicine  date

Dean of Graduate Studies  date

Graduate Council  date

APPROVALS - UNDERGRADUATE COURSE

Council of Provosts  date

CEP Subcommittee on Courses  date

Extent of approval:  Indefinite  Summer Only  Expires at the end of _________ quarter, 20____

FO 2073 (REV. 12/11/09)
PROPOSAL FOR A MASTER SCIENCE IN
DRUG PRODUCT DEVELOPMENT AND MANAGEMENT

Appendix E: Financial Projections/Cost Analysis
### Cost Analysis for Self-Supporting Program Fee Proposals

**Campus:** San Diego  
**Program:** Drug Development and Product Management

<table>
<thead>
<tr>
<th>FTE ENROLLMENT:</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Year-average Program Enrollment</td>
<td>24</td>
<td>48</td>
<td>48</td>
</tr>
<tr>
<td>2 Year-average Campus Enrollment (State + Self-Supporting Programs) est.</td>
<td>34,000</td>
<td>35,000</td>
<td>37,000</td>
</tr>
</tbody>
</table>

### REVENUE

<table>
<thead>
<tr>
<th>Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Fee (per unit)</td>
<td>$825</td>
<td>$825</td>
<td>$825</td>
</tr>
<tr>
<td>Student Services Fee</td>
<td>$1,021</td>
<td>$1,072</td>
<td>$1,126</td>
</tr>
<tr>
<td>Campus-Based Fees</td>
<td>$739</td>
<td>$776</td>
<td>$815</td>
</tr>
<tr>
<td>Health Insurance</td>
<td>$3,569</td>
<td>$3,747</td>
<td>$3,935</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Fee Revenue Generated: $712,800, $1,425,600, $1,425,600

### COSTS

#### A. Program Direct Costs (provided by the School)

<table>
<thead>
<tr>
<th>Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faculty FTE Equivalent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student-Faculty Ratio</td>
<td>8.00</td>
<td>8.00</td>
<td>8.00</td>
</tr>
<tr>
<td>Total Faculty Compensation (from Table 13 submission)</td>
<td>$190,000</td>
<td>$280,000</td>
<td>$280,000</td>
</tr>
<tr>
<td>Total Staff Salaries</td>
<td>$103,922</td>
<td>$103,922</td>
<td>$103,922</td>
</tr>
<tr>
<td>Faculty and Staff Benefits</td>
<td>$75,961</td>
<td>$84,961</td>
<td>$84,961</td>
</tr>
<tr>
<td>General Assistance</td>
<td>$10,000</td>
<td>$51,000</td>
<td>$51,000</td>
</tr>
<tr>
<td>S&amp;E</td>
<td>$136,184</td>
<td>$70,245</td>
<td>$70,245</td>
</tr>
<tr>
<td>Financial Aid</td>
<td></td>
<td>$142,560</td>
<td>$142,560</td>
</tr>
<tr>
<td>Other (Describe: Campus-based fee-funded activities if any)</td>
<td></td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Equipment</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Travel</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Financial Aid</td>
<td>$71,280</td>
<td>$142,560</td>
<td>$142,560</td>
</tr>
<tr>
<td>Indirect Charges paid by Program to Skaggs SPPS</td>
<td>$49,896</td>
<td>$99,792</td>
<td>$99,792</td>
</tr>
<tr>
<td>Indirect Charges paid by Program to Extension</td>
<td>$35,640</td>
<td>$70,245</td>
<td>$70,245</td>
</tr>
<tr>
<td>Indirect Charges paid by Program to EVHS (incl. OGS assessment)</td>
<td>$10,692</td>
<td>$228,096</td>
<td>$228,096</td>
</tr>
<tr>
<td>Indirect Charges paid by Program to Chancellor (incl. ASSA Assessment)</td>
<td>$29,225</td>
<td>$285,120</td>
<td>$285,120</td>
</tr>
<tr>
<td>Campus Assessment paid by Program to Campus (ASSA) - see line 20</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Direct Costs: $712,800, $1,416,976, $1,416,976

#### B. Campus Indirect Costs

<table>
<thead>
<tr>
<th>Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Mission Components (Schedule B, total funds)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Campus Total Instruction</td>
<td>$775,000,000</td>
<td>$798,250,000</td>
<td>$822,197,500</td>
</tr>
<tr>
<td>Campus Total Research</td>
<td>$797,000,000</td>
<td>$820,910,000</td>
<td>$845,537,300</td>
</tr>
<tr>
<td>Campus Total Public Service</td>
<td>$21,000,000</td>
<td>$21,630,000</td>
<td>$22,278,900</td>
</tr>
<tr>
<td>Campus Total Clinical Services/Medical Center</td>
<td>$1,181,035,000</td>
<td>$1,216,466,050</td>
<td>$1,252,960,032</td>
</tr>
<tr>
<td>Subtotal</td>
<td>$2,774,035,000</td>
<td>$2,857,256,050</td>
<td>$2,942,973,732</td>
</tr>
<tr>
<td>Instruction as a % of campus basic mission components</td>
<td>27.94%</td>
<td>27.94%</td>
<td>27.94%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic Support</td>
<td>$70,000,000</td>
<td>$72,100,000</td>
<td>$74,263,000</td>
</tr>
<tr>
<td>Institutional Support</td>
<td>$140,000,000</td>
<td>$144,200,000</td>
<td>$148,526,000</td>
</tr>
<tr>
<td>Operation and Maintenance of Plant</td>
<td>$85,000,000</td>
<td>$87,550,000</td>
<td>$90,176,500</td>
</tr>
<tr>
<td>Subtotal</td>
<td>$295,000,000</td>
<td>$303,850,000</td>
<td>$312,965,500</td>
</tr>
<tr>
<td>Instruction Share of Support Functions (line 35 x line 39)</td>
<td>$82,416,047</td>
<td>$84,888,529</td>
<td>$87,435,185</td>
</tr>
<tr>
<td>Student Services</td>
<td>$110,000,000</td>
<td>$102,870,872</td>
<td>$108,323,028</td>
</tr>
<tr>
<td>Student Health Insurance</td>
<td>$40,000,000</td>
<td>$44,160,000</td>
<td>$48,752,640</td>
</tr>
<tr>
<td>TOTAL CAMPUS INDIRECT COSTS</td>
<td>$152,416,047</td>
<td>$143,599,401</td>
<td>$147,005,573</td>
</tr>
</tbody>
</table>

Annual Cost per FTE Student: $24,473, $15,264, $15,264

### TOTAL PROGRAM COST BEFORE ASSESSMENTS (line 1 x line 41)

<table>
<thead>
<tr>
<th>Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Direct Costs (line 22 / line 1)</td>
<td>$29,700</td>
<td>$29,520</td>
<td>$29,520</td>
</tr>
<tr>
<td>Less Indirect Charges paid by Program (line 17 and 18/ line 1)</td>
<td>($3,564)</td>
<td>($3,564)</td>
<td>($3,564)</td>
</tr>
<tr>
<td>Less Campus Indirect and Assessments paid by Program (line 19, 20 and 21/line 1)</td>
<td>($1,663)</td>
<td>($10,692)</td>
<td>($10,692)</td>
</tr>
<tr>
<td>TOTAL COST PER FTE STUDENT (w/o indirect charges or assessment)</td>
<td>$24,473</td>
<td>$15,264</td>
<td>$15,264</td>
</tr>
</tbody>
</table>

### TOTAL PROGRAM COST BEFORE ASSESSMENTS

<table>
<thead>
<tr>
<th>Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Direct Costs (line 22 / line 1)</td>
<td>$29,700</td>
<td>$29,520</td>
<td>$29,520</td>
</tr>
<tr>
<td>Less Indirect Charges paid by Program (line 17 and 18/ line 1)</td>
<td>($3,564)</td>
<td>($3,564)</td>
<td>($3,564)</td>
</tr>
<tr>
<td>Less Campus Indirect and Assessments paid by Program (line 19, 20 and 21/line 1)</td>
<td>($1,663)</td>
<td>($10,692)</td>
<td>($10,692)</td>
</tr>
<tr>
<td>TOTAL COST PER FTE STUDENT (w/o indirect charges or assessment)</td>
<td>$24,473</td>
<td>$15,264</td>
<td>$15,264</td>
</tr>
</tbody>
</table>

### ANNUAL COST PER FTE STUDENT

<table>
<thead>
<tr>
<th>Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Direct Costs (line 22 / line 1)</td>
<td>$29,700</td>
<td>$29,520</td>
<td>$29,520</td>
</tr>
<tr>
<td>Less Indirect Charges paid by Program (line 17 and 18/ line 1)</td>
<td>($3,564)</td>
<td>($3,564)</td>
<td>($3,564)</td>
</tr>
<tr>
<td>Less Campus Indirect and Assessments paid by Program (line 19, 20 and 21/line 1)</td>
<td>($1,663)</td>
<td>($10,692)</td>
<td>($10,692)</td>
</tr>
<tr>
<td>TOTAL COST PER FTE STUDENT (w/o indirect charges or assessment)</td>
<td>$24,473</td>
<td>$15,264</td>
<td>$15,264</td>
</tr>
</tbody>
</table>

UCOP-Budget (Drug Product Development cost analysis - Appendix E.xlsx)  
Version: 1/22/2016  
page 1 of 1
<table>
<thead>
<tr>
<th>line #</th>
<th>FTE ENROLLMENT:</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Year-average Program Enrollment</td>
<td>72</td>
<td>96</td>
</tr>
<tr>
<td>2</td>
<td>Year-average Campus Enrollment (State + Self-Supporting Programs) est.</td>
<td>38,000</td>
<td>39,000</td>
</tr>
</tbody>
</table>

### REVENUE

<table>
<thead>
<tr>
<th>Line</th>
<th>Description</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Annual Fee Per Student (Fee detail is optional)</td>
<td>$825</td>
<td>$825</td>
</tr>
<tr>
<td></td>
<td>Program Fee (per unit)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Student Services Fee</td>
<td>$1,182</td>
<td>$1,241</td>
</tr>
<tr>
<td></td>
<td>Campus-Based Fees</td>
<td>$855</td>
<td>$898</td>
</tr>
<tr>
<td></td>
<td>Health Insurance</td>
<td>$4,132</td>
<td>$4,338</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Total Fee Revenue Generated</td>
<td>$2,138,400</td>
<td>$2,851,200</td>
</tr>
<tr>
<td>5</td>
<td>Total Other Funds (describe: )</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>6</td>
<td>TOTAL PROGRAM REVENUE</td>
<td>$2,138,400</td>
<td>$2,851,200</td>
</tr>
</tbody>
</table>

### COSTS

**A. Program Direct Costs (provided by the School)**

<table>
<thead>
<tr>
<th>Line</th>
<th>Description</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Faculty FTE Equivalent</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Student-Faculty Ratio</td>
<td>8.00</td>
<td>8.00</td>
</tr>
<tr>
<td>8</td>
<td>Total Faculty Compensation (from Table 13 submission)</td>
<td>$314,740</td>
<td>$345,400</td>
</tr>
<tr>
<td>9</td>
<td>Total Staff Salaries</td>
<td>$128,922</td>
<td>$128,922</td>
</tr>
<tr>
<td>10</td>
<td>Faculty and Staff Benefits</td>
<td>$91,503</td>
<td>$103,161</td>
</tr>
<tr>
<td>11</td>
<td>General Assistance</td>
<td>$51,000</td>
<td>$87,000</td>
</tr>
<tr>
<td>12</td>
<td>S&amp;E</td>
<td>$122,145</td>
<td>$123,986</td>
</tr>
<tr>
<td>13</td>
<td>Equipment</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>14</td>
<td>Financial Aid</td>
<td>$213,840</td>
<td>$285,120</td>
</tr>
<tr>
<td>15</td>
<td>Campus-based fee-funded activities (if any)</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>16</td>
<td>Other (Describe: campus recharge for online tech support)</td>
<td>$14,400</td>
<td>$24,000</td>
</tr>
<tr>
<td>17</td>
<td>Indirect Charges paid by Program to Skaggs SPPS</td>
<td>$149,688</td>
<td>$199,584</td>
</tr>
<tr>
<td>18</td>
<td>Indirect Charges paid by Program to Extension</td>
<td>$106,920</td>
<td>$142,560</td>
</tr>
<tr>
<td>19</td>
<td>Indirect Charges paid by Program to EVHS (incl. OGS assessment)</td>
<td>$342,144</td>
<td>$456,192</td>
</tr>
<tr>
<td>20</td>
<td>Indirect Charges paid by Program to Chancellor (incl. ASSA Assessment)</td>
<td>$427,680</td>
<td>$570,240</td>
</tr>
<tr>
<td>21</td>
<td>Campus Assessment paid by Program to Program to Campus (ASSA) - see line 20</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>22</td>
<td>TOTAL DIRECT COSTS</td>
<td>$1,962,982</td>
<td>$2,466,165</td>
</tr>
</tbody>
</table>

**B. Campus Indirect Costs**

<table>
<thead>
<tr>
<th>Line</th>
<th>Description</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>Basic Mission Components (Schedule B, total funds)</td>
<td>3.0%</td>
<td>3.0%</td>
</tr>
<tr>
<td></td>
<td>Campus Total Instruction</td>
<td>$822,197,500</td>
<td>$846,863,425</td>
</tr>
<tr>
<td>24</td>
<td>Campus Total Research</td>
<td>$845,537,300</td>
<td>$870,903,419</td>
</tr>
<tr>
<td>25</td>
<td>Campus Total Public Service</td>
<td>$222,789,000</td>
<td>$229,548,832</td>
</tr>
<tr>
<td>26</td>
<td>Campus Total Clinical Services/Medical Center</td>
<td>$1,252,960,032</td>
<td>$1,290,548,832</td>
</tr>
<tr>
<td>27</td>
<td>Subtotal</td>
<td>$2,942,973,732</td>
<td>$3,031,262,943</td>
</tr>
<tr>
<td>28</td>
<td>Instruction as a % of campus basic mission components</td>
<td>27.94%</td>
<td>27.94%</td>
</tr>
<tr>
<td>29</td>
<td>Campuswide support functions (Schedule C, unrestricted funds)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Academic Support</td>
<td>$76,490,890</td>
<td>$78,785,617</td>
</tr>
<tr>
<td>30</td>
<td>Institutional Support</td>
<td>$152,981,780</td>
<td>$157,571,233</td>
</tr>
<tr>
<td>31</td>
<td>Operation and Maintenance of Plant</td>
<td>$92,881,795</td>
<td>$95,668,249</td>
</tr>
<tr>
<td>32</td>
<td>Subtotal</td>
<td>$322,354,465</td>
<td>$332,025,099</td>
</tr>
<tr>
<td>33</td>
<td>Instruction Share of Support Functions (line 35 x line 39)</td>
<td>$90,058,240</td>
<td>$92,759,987</td>
</tr>
<tr>
<td>34</td>
<td>Student Services</td>
<td>$110,000,000</td>
<td>$112,000,000</td>
</tr>
<tr>
<td>35</td>
<td>Student Health Insurance</td>
<td>$53,822,915</td>
<td>$59,420,498</td>
</tr>
<tr>
<td>36</td>
<td>TOTAL CAMPUS INDIRECT COSTS</td>
<td>$146,235,326</td>
<td>$145,339,490</td>
</tr>
<tr>
<td>37</td>
<td>Campus Indirect Costs per Student</td>
<td>3,848</td>
<td>3,727</td>
</tr>
</tbody>
</table>

### ANNUAL COST PER FTE STUDENT

<table>
<thead>
<tr>
<th>Line</th>
<th>Description</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>38</td>
<td>Program Direct Costs (line 22 / line 1)</td>
<td>$27,264</td>
<td>$25,689</td>
</tr>
<tr>
<td>39</td>
<td>Less Indirect Costs paid by Program (line 17 and 18/ line 1)</td>
<td>($3,564)</td>
<td>($3,564)</td>
</tr>
<tr>
<td>40</td>
<td>Less Campus Indirect and Assessments paid by Program (lines 19, 20 and 21/line 1)</td>
<td>($10,692)</td>
<td>($10,692)</td>
</tr>
<tr>
<td>41</td>
<td>TOTAL COST PER FTE STUDENT (w/o indirect charges or assessments)</td>
<td>$13,008</td>
<td>$11,433</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Line</th>
<th>Description</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>42</td>
<td>TOTAL PROGRAM COST BEFORE ASSESSMENTS (line 1 x line 41)</td>
<td>$936,550</td>
<td>$1,097,589</td>
</tr>
<tr>
<td>43</td>
<td>PRE-ASSESSMENT SURPLUS (DEFICIT) (line 6 minus line 42)</td>
<td>$1,201,850</td>
<td>$1,753,611</td>
</tr>
<tr>
<td>44</td>
<td>PRE-ASSESSMENT SURPLUS (DEFICIT) PER HEADCOUNT STUDENT</td>
<td>$16,692</td>
<td>$18,267</td>
</tr>
</tbody>
</table>
Appendix F:  Letters of Endorsement

Faculty Committees
SSPPS Committee on Educational Policy (CEP)

Health Sciences Graduate Professional Education Council (GPEC)

Health Sciences Faculty Council (HSFC)

Industry
Arena Pharmaceuticals

Biocom

Johnson and Johnson Innovation

PFEnex.inc

Pfizer Oncology

UC San Diego
Dr. David Brenner, Vice Chancellor, Health Sciences

Dr. Gary Firestein, Director, Clinical and Translational Research Institute

Dr. Joan Heller Brown, UCSD Department of Pharmacology

Center for Drug Discovery and Innovation

Moores Cancer Center
4 March, 2016

To: Bob Carter, MD, Ph.D.
Chair, Health Sciences Faculty Council

From: Shirley Tsunoda, Pharm.D.
William Gerwick, Ph.D.
Chairs, SSPPS Committee on Educational Policy (CEP)

Re: Request for Endorsement: Masters of Science Degree Program in Drug Development and Product Management

On behalf of the SSPPS CEP, we are requesting that the HSFC endorse the MS degree program in Drug Development and Product Management. At our February 24th meeting, the SSPPS CEP approved this proposal unanimously. The proposal is comprehensive and backed by market research to suggest that graduates would be well positioned for careers within the pharmaceutical industry. This program harnesses expertise from our SSPPS faculty and will provide a unique set of skills to a variety of learners. We enthusiastically support this proposal and look forward to its continued progress through the approval process and development as a degree program within the SSPPS, UCSD.
DATE: January 26, 2016

TO: Jan Hirsch, BS Pharm, PhD
    Associate Professor of Clinical Pharmacy

FROM: T. Mike Hsieh, M.D.
      Chair, Graduate Program Education Committee (GPEC)

SUBJECT: Proposal for a Program of Graduate Studies in Drug Development and Product Management for the Master of Science Degree

This letter is to endorse your proposal for a Master’s in Drug Development and Product Management. At the January 21, 2016 Graduate Program Education Committee meeting, the committee reviewed the full proposal. At the conclusion of the meeting, the committee unanimously approved the program as proposed by the Skaggs School of Pharmacy.

cc: James McKerrow, Dean – Skaggs School of Pharmacy and Pharmaceutical Sciences
    Williams Ettouati, Director – Industry Relations and Development
April 6, 2016

WILLIAMS ETTOUATI, PharmD
Director, Industry Relations and Development
Skaggs School of Pharmacy and Pharmaceutical Sciences
MC 1177

Subject: Proposal for MS in Drug Development and Product Management

Dear Dr. Ettouati:

I am pleased to inform you that the Health Sciences Faculty Council (HSFC) has voted unanimously to endorse the proposal to pursue the development of a Master of Science degree in Drug Development and Product Management.

The HSFC thanks you for presenting at last night’s meeting. We wish you success as you continue your efforts in creating this program.

Sincerely,

Bob S. Carter, M.D., Ph.D.
Chair, Health Sciences Faculty Council

c: David A. Brenner, M.D., Vice Chancellor, Health Sciences
James McKerrow, Dean, SSPPS
Jan Hirsch, SSPPS
Bruce Dunn, University Extension
December 23, 2015

Williams S. Ettouati, Pharm.D.
Director, Industrial Relations & Development
Health Sciences Associate Clinical Professor, N.S.
University of California San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Drive #0714
La Jolla, CA 92093-0714

Dear Dr. Williams:

It is my pleasure to write a letter in support of the new Health Science Master of Science in Drug Development & Product Management proposal being submitted to UCSD review committees Program.

With the current proposed curriculum for the course, students should be in a solid position to better understand small molecule and biotherapeutic product development in the pharmaceutical R&D paradigm. Specifically, students will be exposed to critical concepts that go into the drug development process, namely Pharmacology/Toxicology activities, worldwide regulatory affairs activities and clinical development aspects, to name a few. The blend of the proposed course curriculum will better enable students pursuing a career in the pharmaceutical environment (large pharma and biotech). This level of education to professional students entering industry or transitioning to industry for the first time will better position students to quickly engage and contribute in the pharmaceutical work environment.

I fully support the efforts of the Skaggs School of Pharmacy and Pharmaceutical Sciences as they seek approval to support a program such as the MS in Drug Development & Product Management. The proposed MS program will greatly benefit students, the UCSD campus, and enhance the marketability of students entering the pharmaceutical or regulatory environment.

Sincerely,

R.J. Christopher, Ph.D., D.A.B.T., FCP
Vice President, Preclinical Development
December 21, 2015

Williams S. Ettouati, Pharm.D.
Director, Industrial Relations & Development
Health Sciences Associate Clinical Professor, N.S.
University of California San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Drive #0714
La Jolla, CA 92093-0714

Dear Williams

It is my pleasure write a letter in support of the new Health Science Master of Science in Drug Development & Product Management proposal being submitted to UCSD review committees Program.

As the life science trade association representing over 700 companies in Southern California and beyond, Biocom, and its workforce development arm, the Biocom Institute are acutely aware of the workforce needs of the industry. Through a biennial statewide workforce survey published in 2014 and subsequent conversations with our member companies, it is our opinion the proposed Master of Science in Drug Development & Product Management will fill a critical regional need.

In conclusion, Biocom fully support the efforts of the Skaggs School of Pharmacy and Pharmaceutical Sciences as they seek approval to support a program such as the MS in Drug Development & Product Management. I believe that this program is well designed to give students unique skills that can be applied in developing their knowledge and improve their careers. This program will help provide students get new jobs or be promoted in their companies, in the pharmaceutical and biotech industry as well as with managed care organizations and government agencies like the Food and Drug Administration and the European Medicine Agency.

In summary I believe that this MS program will greatly benefit students, campus, and the community at large.

Sincerely,

Joe Panetta
CEO, Biocom

Liisa Bozinovic
Executive Director, Biocom Institute
December 21, 2015

Williams S. Ettouati, Pharm.D.
Director, Industrial Relations & Development
Health Sciences Associate Clinical Professor, N.S.
University of California San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Drive #0714
La Jolla, CA 92093-0714

Dear Williams,

It is my pleasure to write a letter of support for the new Health Science Master of Science in Drug Development & Product Management proposal being submitted to the UCSD Review Committee Program.

I fully support the efforts of the Skaggs School of Pharmacy and Pharmaceutical Sciences as they seek approval for support of a program such as the MS in Drug Development & Product Management. I believe that this program is well-designed to give students unique skills. This program will help enable students to pursue new positions or be promoted within their current companies in the pharmaceutical and biotech industry, as well as, with managed care organizations and government agencies like the Food and Drug Administration and the European Medicine Agency.

In summary I believe that this Master of Science program will greatly benefit the students, campus, and community at large.

Sincerely,

G. Diego Miralles, M.D.
Head of Innovation, Johnson & Johnson
December 17, 2015

Williams S. Ettouati, Pharm.D.
Director, Industrial Relations & Development
Health Sciences Associate Clinical Professor, N.S.
University of California San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Drive #0714
La Jolla, CA 92093-0714

Dear Williams:

It is my pleasure to write a letter of support for the proposed Health Science Master of Science in Drug Development & Product Management program being submitted to UCSD review committees.

I believe the program addresses a significant unmet need for professionals seeking a career in drug development and product management. In contrast to well-established educational pathways that can lead to research and discovery opportunities in the biotech and pharmaceutical industries, there is a dearth of similar programs and educational credentials for those interested in drug development and product management. Having worked in the biotech industry for over a decade, I can attest to the fact that all of my drug development experience have been obtained through “on-the-job” training, although I would have welcomed a more formal educational experience to solidify and expand my understanding of the process. In my current role as Chief Medical Officer of Pfenex and hiring manager for job openings in drug development and product management, I would welcome an expanded pool of applicants who are educated and certified by a highly-regarded institution such as UCSD.

I therefore fully support the efforts of the Skaggs School of Pharmacy and Pharmaceutical Sciences as it seeks approval for the Master of Science in Drug Development & Product Management program. I believe that this unique and well-designed program will provide students with a solid knowledge base and a practical skill set in the drug development and product management process. This program will help graduates transition into new jobs or assume greater responsibilities, not only in the pharmaceutical and biotech industries, but also with managed care organizations and regulatory agencies such as the Food and Drug Administration and the European Medicines Agency.
Please feel free to contact me if I can be of further assistance in the review process.

Sincerely,

Hubert C. Chen, M.D.
Chief Medical Officer
Pfenex Inc.
10790 Roselle St.
San Diego, CA 92121
Telephone: (858) 352-4358
E-mail: hchen@pfenex.com
Dear Williams,

It is my pleasure to write a letter in support of the new Health Sciences Master of Science in Drug Development & Product Management proposal being submitted to UCSD review committee program.

The current training curriculum of many academic institutions unfortunately does not include any drug development and project management courses which in my opinion is a basic training needed for staff members in Pharma. In absence of the above, pharmaceutical companies spend a significant amount of time on training their new hires (MD, PharmD and PhD) in drug development and project management. From a pharma point of view I believe the proposed MSc program could be of significant value for the candidates either on its own or in combination with another graduate degree (MD, PharmD or PhD).

In conclusion, I fully support the efforts of the Skaggs School of Pharmacy and Pharmaceutical Sciences as they seek approval to support a program such as the MSc in Drug Development & Product Management. I believe that this program is well designed to give students unique skills that can be applied in developing their knowledge and improving their careers. This program could help students securing new jobs or advancing their careers, in the pharmaceutical and biotech industry as well as with managed care organizations and government regulatory agencies like the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

In summary I believe that this MS program will greatly benefit students, campus, and the community at large.

Sincerely,

Kourosh Parivar, M.Pharm.
Vice President & Head
Clinical Pharmacology
Pfizer Oncology
February 4, 2016

Graduate Council
MC 0002

Re: Masters Program in Drug Development

As Vice Chancellor for Health Sciences at the University of California San Diego, I have met with the committee launching the new Master of Science Program in Drug Development and Product Management.

I have discussed and reviewed their proposal, and I am pleased to endorse its launch at UCSD and supports its efforts.

Sincerely,

David A. Brenner, MD
Vice Chancellor for Health Sciences
Dean, School of Medicine
University of California San Diego
March 8, 2016

Williams S. Ettouati, Pharm.D.
Director, Industrial Relations & Development
Health Sciences Associate Clinical Professor, N.S.
University of California San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Drive, MC 0714
La Jolla, CA 92093-0714

Dear Williams:

It is my pleasure to write a letter in support of the new Health Science Master of Science in Drug Development & Product Management proposal being submitted to UCSD review committees.

As you know from our previous meetings and discussions, the Clinical and Translational Research Institute (CTRI) is dedicated to train scientist, MDs and pharmacists in clinical development and translational research to improve patient care.

Your plan captures an area of career development that is truly underserved and that it will attract a broad range of students. For our part, the proposed MS program will help to insure that the high profile of the CTRI, and its strong interaction with the Skaggs School of Pharmacy and Pharmaceutical Sciences, remains nationally and globally visible.

With the current proposed curriculum for the course, students should be in a solid position to better understand small molecule and biotherapeutic product development in the pharmaceutical R&D paradigm. Specifically, students will be exposed to critical concepts that go into the drug development process, namely pharmacology and toxicology activities, worldwide regulatory affairs activities and clinical development aspects, to name a few.

The proposed course curriculum will better enable students pursuing a career in in the pharmaceutical and biotech industry as well as with managed care organizations and government agencies like the Food and Drug Administration, the European Medicine Agency and Academia. This level of education to professional students entering industry or transitioning to industry for the first time will better position students to quickly engage and contribute in the pharmaceutical work environment.

Accordingly I fully support approval of the MS in Drug Development & Product Management.

Sincerely,

Gary S. Firestein, M.D.
December 22, 2015

Williams S. Ettouati, Pharm.D.
Director, Industrial Relations & Development
Health Sciences Associate Clinical Professor, N.S.
University of California San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Drive #0714
La Jolla, CA 92093-0714

Dear Williams

It is my pleasure write a letter in support of the new Health Science Master of Science in Drug Development & Product Management proposal being submitted to UCSD review committees.

As you know from our previous meetings and discussions, the Department of Pharmacology had considered the possibility of developing our own Master of Science Program, based on what we perceived as a significant interest in training for jobs in the pharmaceutical industry. I believe your plan captures an area of career development that is truly underserved and that it will attract a broad range of students. For our part, the proposed MS program will help to insure that the high profile of the UCSD Department of Pharmacology, and its strong interaction with the Skaggs School of Pharmacy and Pharmaceutical Sciences, remains nationally and globally visible. In addition the program affords some of our faculty with further teaching opportunities in the more basic principles of pharmacology course that our emeritus faculty member Dr. Morton Printz will help design and direct. Accordingly I fully support the efforts of the Skaggs School of Pharmacy and Pharmaceutical Sciences as they seek approval to support a program such as the MS in Drug Development & Product Management.

I believe that this program is well designed to give students unique skills that can be applied in developing their knowledge and improve their careers. This program will help provide students get new jobs or be promoted in their companies, in the pharmaceutical and biotech industry as well as with managed care organizations and government agencies like academia, the Food and Drug Administration and the European Medicine Agency.

In summary I believe that this MS program will greatly benefit students, campus, and the community at large.

Sincerely,

Joan Heller Brown, PhD
Distinguished Professor and Chair
Department of Pharmacology

jhbrown@ucsd.edu
January 13, 2016

Dear Williams,

We are pleased to write in strongest support of your innovative and visionary proposal to establish a new Health Sciences Master of Science in Drug Development and Product Management.

UCSD is nearly unique among top-flight universities in assembling, on a single campus, powerful research and training programs that span biomedicine, pharmaceutical sciences, clinical practice, chemistry, business management, and related disciplines. This unified structure creates opportunities to build interdisciplinary programs that are greater than the sums of their parts. Indeed, it is this setting which has led to development of the current campus-wide drug discovery initiative, with leadership by the Center for Drug Discovery Innovation (CDDI).

Your proposal would likewise draw upon strengths across our campus, and beyond, to create a remarkable, integrated training program that could not be replicated by a student merely enrolling in a miscellany of existing classes. The program is well designed to provide students with key fundamentals, along with up to date information on emerging trends in drug development and product management, and, particularly through the project component, with currently relevant skills. It thus couples scholarly content with practicality, and we anticipate that it will attract particular interest from students aiming for personal and professional advancement in the pharmaceutical and biotech industries, managed care organizations, and government agencies like the Food and Drug Administration and the European Medicine Agency.

With its focus on drug development, your program also clearly helps to advance the goals of the CDDI, which include both research and education; and to enhance the visibility of UCSD as a center of activity in this field.

Please do not hesitate to call on us if we might be of help in advancing this important educational initiative.

Sincerely yours,

Michael K. Gilson, M.D., Ph.D.
Co-Director, CDDI
Professor of Pharmacy and Pharmaceutical Sciences

Thomas Hermann, Ph.D.
Co-Director, CDDI
Associate Professor of Chemistry & Biochemistry
Thursday, March 10, 16

Williams S. Ettouati, Pharm.D.
Director, Industrial Relations & Development
Health Sciences Associate Clinical Professor, N.S.
University of California San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences
9500 Gilman Drive #0714
La Jolla, CA 92039-0714

Dear Williams,

I am delighted to write a letter in support of the new Health Science Master of Science in Drug Development & Product Management proposal being submitted to UCSD review committees.

As you know from our previous meetings and discussions, the Moore Cancer Center (MCC)’s unique "bench-to-bedside" approach to cancer research and patient care supports the broadest range of cancer activities in the San Diego region. From research in molecular genetics to the most advanced treatments, MCC is dedicated to train MDs, Pharmacists and scientists in oncology clinical development, and cancer personalized medicine.

As the Senior Deputy Director for Clinical Science and Personalized Cancer Therapy, I believe your plan captures an area of career development that is truly underserved, and that it will attract a broad range of students including MDs and Pharm.Ds. For our part, the proposed MS program will help to insure that the high profile of the MCC and its strong interaction with the Skaggs School of Pharmacy and Pharmaceutical Sciences remain nationally and globally visible.

Your proposal would likewise draw upon strengths across our campus, and the San Diego biotech and pharmaceutical cluster in San Diego. It would create a remarkable, integrated multidisciplinary team-approach training program that could not be replicated by a student merely enrolling in a miscellany of existing classes. The program is well designed to provide students with key fundamentals, along with up-to-date information on emerging trends in drug development and product management, and, particularly through the project component, with currently relevant skills. I would anticipate that it will attract particular interest from students aiming for personal and professional advancement in the pharmaceutical and biotech industries, managed care organizations, and government agencies like the Food and Drug Administration and the European Medicine Agency as well as academia.

This level of education to professional students entering industry or transitioning to industry for the first time will better position students to quickly engage and contribute in the pharmaceutical work environment.
Accordingly I fully support the efforts of the Skaggs School of Pharmacy and Pharmaceutical Sciences as they seek approval to support a program such as the MS in Drug Development & Product Management.

In summary, I believe that this MS program will greatly benefit students, campus, and the community at large.

Sincerely,

Razelle Kurzrock, M.D.
Murray Professor of Medicine
Sr. Deputy Center Director, Clinical Science
Director, Center for Personalized Cancer Therapy,
Chief, Division of Hematology and Oncology
Appendix G: Catalog Copy

The Master of Science in Drug Development and Product Management

La Jolla Village Professional Center
8950 Villa La Jolla Dr., Suite A-212
(858) 534-9162
E-mail: ddpm@ucsd.edu
http://ddpm.ucsd.edu

All courses, faculty listings, and curricular and degree requirements described herein are subject to change or deletion without notice. Updates may be found on the Academic Senate website: http://senate.ucsd.edu/catalog-copy/approved-updates/.

Program Description

The Master of Science (MS) in Drug Development and Product Management has three aims: first, to give experienced professionals insight into the process of successful drug product development and deployment; second, to endow students with requisite knowledge and skill to collaborate effectively in the ongoing management of drug products; and third, to provide a solid, practical bridge to employment opportunities in pharmaceutical and managed care industries or related government agencies such as the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA).

Distinctive features of the program include instruction by a combination of faculty who possess scholarly understanding and industry experience, a case and project-oriented approach to learning, options in professional focus, online and face-to-face course delivery alternatives, exposure to student colleagues with varied professional backgrounds, and connections with employers through a practice-oriented internship at their site.

The MS in Drug Development and Product Management is a full-time, self-supporting degree program with a required course schedule that takes two academic years to complete. The UC San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences is responsible for the academic management of the curriculum. UC San Diego Extension administers the program and provides student advising and career counseling services.

Admission

New students are admitted in the fall each academic year. Prospective candidates should submit and complete the official UC San Diego online graduate application for admission
PROPOSAL FOR A MASTER OF SCIENCE DEGREE IN DRUG PRODUCT DEVELOPMENT AND MANAGEMENT

(which includes a detailed statement of personal intent regarding the program), the application fee, one set of official transcripts from each institution attended after high school, three letters of professional recommendation, and a current résumé or curriculum vitae. At the discretion of the admissions committee, a personal interview may be required. The GRE/GMAT is not required; candidates should have an undergraduate degree and a minimum of five years of full-time work experience at the professional level. International applicants must submit official scores from the Test of English as a Foreign Language (TOEFL). The application deadline is May 20, 2018.

Program of Study

The degree program is designed to be completed in two years, studying full time. Classes are typically scheduled in the late afternoons, evenings, or weekends to accommodate part-time employment. Students are required to complete seventy-two units of course work for the degree, which includes a one-quarter internship. Successful completion of a Masters Examination is also required.

Required Courses

- DDPM 201: System Pharmacology and Toxicology (4 units)
- DDPM 202: Pharmaceutics for Small Molecules and Macromolecules (4 units)
- DDPM 203: Pre-Clinical and Clinical Regulatory Submissions (4 units)
- DDPM 204: Early Stage Clinical Trials (4 units)
- DDPM 205: Principles of Drug Development for BioMedical & Pharmaceutical Product Development (4 units)
- DDPM 206: Patent Strategy and Freedom to Operate (4 units)
- DDPM 207: Foundations of Project Management (4 units)
- DDPM 208: Marketing Strategy, Product Management, and Life Cycle Product Management (4 units)
- DDPM 209: Principles of Cost Effective Analysis in Drug Development and Markets (4 units)
- DDPM 210: Biologics and Biosimilars Drug Development (4 units)
- DDPM 211: Principles of Regulatory Science (4 units)
- DDPM 212: Analysis of Industry Needs in Drug Development and Product Management (4 units)
- DDPM 213: Health Outcomes Evidence (4 units)
• DDPM 214: Pharmaceutical Business Development and Managing R&D Innovation (4 units)
• DDPM 215: Comprehensive Analysis of Key Principles in Drug Development and Product Management (4 units)
• DDPM 216: Practice-Based Internship (12 units)
Appendix H:  Suggested UC and External Reviewers

UC San Diego

Victor Nizet, M.D.
Professor of Pediatrics & Pharmacy
Center for Immunity, Infection & Inflammation
University of California San Diego School of Medicine
Skaggs School of Pharmacy & Pharmaceutical Sciences
Phone: 858-534-7408
E-Mail: vnizet@ucsd.edu

Michael K. Gilson, M.D., Ph.D.
Professor
Skaggs School of Pharmacy and Pharmaceutical Sciences
Co-Director, UCSD Center for Drug Discovery Innovation
Phone: 858-822-0622
E-Mail: mgilson@ucsd.edu

Deborah H. Spector, Ph.D.
Distinguished Professor
Chair, Biomedical Sciences Graduate Program
Director of the UCSD CTRI Translational Research Alliance
Department of Cellular and Molecular Medicine
School of Medicine and
Skaggs School of Pharmacy and Pharmaceutical Sciences
Phone: 858-822-4003
E-mail: dspector@ucsd.edu

Joan Heller Brown, Ph.D.
Distinguished Professor and Chair
Department of Pharmacology
Phone: 858 534-2595
E-mail: jhbrown@ucsd.edu

University of California

Robert Jacobs, Ph.D.
Professor of Pharmacology
UC Santa Barbara
E-Mail: rsjacobs@chem.ucsb.edu
http://www.coastalresearchcenter.ucsb.edu/cmi/Jacobs.html
Outside reviewers

**Academic**
Jeff Lee, Pharm.D., FCCP  
Associate Professor, Pharmacy Practice  
Lipscomb University College of Pharmacy  
Email: jeff.lee@lipscomb.edu  
Phone: (615) 966-7012 office; (615) 232-4828 cell

C. E. (Gene) Reeder, PhD, RPh  
Professor of Pharmacy Administration  
Presbyterian College School of Pharmacy  
Email: cereeder@presby.edu  
Phone: 864-938-3827  
[http://pharmacy.presby.edu/faculty-staff/faculty-overview/gene-reeder/](http://pharmacy.presby.edu/faculty-staff/faculty-overview/gene-reeder/)

Anne M. Libby, PhD  
Professor and Vice Chair for Academic Affairs  
University of Colorado Anschutz Medical Campus  
Email: anne.libby@ucdenver.edu  
Phone: 303-724-9630

Dr. Andras Gruber, M.D.  
Associate Professor  
OSHU  
Email: grubera@ohsu.edu  
Phone: 503 418-9308

**Industry**
Kourosh Parivar, M.Pharm.  
Vice President  
Head, Clinical Pharmacology  
Pfizer Oncology  
Pfizer Inc, La Jolla  
Phone: (858) 638-6235  
E-Mail: kourosh.parivar@pfizer.com

G. Diego Miralles, M.D.  
Head of Innovation  
Johnson & Johnson  
E-Mail: DMirall2@its.jnj.com

R.J. Christopher, Ph.D., D.A.B.T., FCP
PROPOSAL FOR A MASTER SCIENCE IN
DRUG PRODUCT DEVELOPMENT AND MANAGEMENT

Vice President, Preclinical Development,
Arena Pharmaceuticals, Inc.
Ph: (858) 453-7200 ext 1629
Email: rchristopher@arenapharm.com

Joe Panetta
CEO
BIOCOM
Phone: 858.455.0300
E-Mail: JPanetta@biocom.org
PROPOSAL FOR A MASTER SCIENCE IN
DRUG PRODUCT DEVELOPMENT AND MANAGEMENT

Appendix I:  Admissions Criteria and Scoring
### UCSD MASTERS IN DRUG DEV AND PRODUCT MNGT

#### Admissions Scoring Template

**PART ONE**
Grades, as measured by most recent cumm. GPA, based on a four-point grading scale (select one):

<table>
<thead>
<tr>
<th>Grades (select one)</th>
<th>Points Available</th>
<th>Candidate Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.75-4.0 (A or A+)</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>3.5-3.74 (A-)</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>3.25-3.49 (B+)</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>3.0 - 3.24(B)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>2.67-2.9 (B-)</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>2.33-2.66 (C+)</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>2.0 - 2.32 (C)</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Less than a 2.0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

#### Optional points

**Concurrent Enrollment in UCSD graduate course:**
- A or A minus (average) +7.5
- B or B+ average +5

**Work in very relevant class(es) at recognized institutions:**
- A or A minus (average) +10
- B or B+ (average) +5
- C or lower -5

**PART TWO**
Relevant education and experience, as communicated by their CV/resume and the responses on their application

<table>
<thead>
<tr>
<th>Degree (select one)</th>
<th>Points</th>
<th>Candidate Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional (MD, JD, PharmD, MBA, MAS, etc.)</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Academic graduate degree (PhD, MS, MA, etc.)</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Bachelors degree</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Minor US or lesser foreign institution</td>
<td>-3</td>
<td></td>
</tr>
</tbody>
</table>

**Business professional or legal functional experience (select one)**
- 3+ years | 15 |  |
- Graduate study and 1+ years less than 3 years | 10 |  |
- Graduate study and 1+ years more than 3 years | 5 |  |

**Pharmaceutical or medical science experience (select one)**
- 3+ years | 15 |  |
- Graduate study and 1+ years less than 3 years | 10 |  |
- Graduate study and 1+ years more than 3 years | 5 |  |

#### Optional points

- Significant directly relevant work experience +5
- Professional awards or recognition +5

**PART THREE**
Recommendations, as indicated by letter, or personal endorsement

| Articulation of student characteristics and achievements which instill confidence of success | up to 15 |
| Relevant and responsible title(s) of recommenders | up to 5 |

**PART FOUR**
Personal Preparation, as indicated by statement of purpose

| Articulation of achievable and meaningful professional outcomes from the program | up to 15 |
| Articulation of an existing employer relationship that can lead to an internship | +7 |

**PART FIVE**
Interview of those scoring 70 or more total points on parts one through four

| Clear and practical expectations with regard to location and type of eventual employment | up to 10 |
| Clear and practical expectations with regard to type of internship experience they can obtain | up to 10 |

**Total (20 maximum)**

**Total (15 maximum)**

**Total (25 maximum)**

**Total (40 maximum)**

**Total Points (all parts)**

**Total Points (parts 1-4)**

**Total Points (20 maximum)**

**Total (20 maximum)**

**Total (20 maximum)**

**Total (20 maximum)**

**NOTE:** English proficiency is a separate requirement for admission. Individuals for whom English is not their first language must achieve a TOEFL score of 82 (online) or 550 (paper). The score may be waived in exceptional circumstances via a personal interview.