

MS in Management of Drug Development

The MS program in the Management of Drug Development (MDD) at USC is a novel degree program designed for students with a background in preclinical biological and/or pharmaceutical sciences. It aims at producing entry- and mid-level practitioners with the knowledge and skills appropriate for professional practice in translational research, with particular emphasis on the area of transition between early stage preclinical drug discovery and clinical drug development. This area, commonly referred to as the “valley of death,” represents one of the most challenging and important areas in translational research, yet programs designed to train and educate future translational science leaders are lacking.

Program Structure

The MDD is designed as a twenty four-month program with eighteen-months of course work and a six-month practicum for students with no previous laboratory or industry experience. Full-time students can take the course work in a single intensive period immediately preceding the practicum. Part-time students can take the courses over a period of 2-5 years preceding the practicum. If students have no experience directly relevant to the degree, they must be prepared to spend a concentrated period in a practicum setting, possibly in their present workplace prior to graduation.

Material for the academic calendar was developed and approved by the university. Course listings are posted on the Regulatory Sciences web site each semester. All courses will be available in on-site and distance formats.

The MDD program offices are the Health Sciences campus of USC in the School of Pharmacy. Students have access to a state-of-the-art dedicated computer-learning laboratory. The MDD program includes team-taught, interactive discussions of current issues focused on drug discovery and development, including issues of ethics and safety. The program includes coursework delivered in nontraditional formats such as intensive weekend sessions and distance learning.

The MS (MDD) program relies on the participation of several faculty members from the School of Pharmacy as well as faculty members from other USC academic divisions. In addition, experts from the governmental and private sectors participate in the program, giving students direct contact with people working at the forefront of the drug discovery and drug development fields.

The MS (MDD) program is unique in its own scope in that it is ideal for individuals who have completed an undergraduate degree in one of the fields of science. Other students that will benefit from this program include Ph.Ds and Pharm.Ds who want to strengthen their expertise in the drug discovery and drug development arenas. MDD students will have the opportunity to design, critically evaluate and optimize a broad range of drug development strategies. Students will begin with the earliest stages of drug design and discovery, and will learn the many steps that one follows to successfully prosecute novel drug targets. Notably, this knowledge will provide students with the necessary foundations that will allow them to make critical decisions in their professional capacity on how to most effectively move drug discoveries to market in order to reach patients.

Course Requirements

Field of Preparation	Recommended Choices	Units
Business –one course minimum	RSCI 601 Biomedical Commerce, or equivalent business course	3
Introductory Translation –one course minimum	RSCI 530 Translational Medicine: An Overview	2
Advanced translation – two courses minimum, three recommended	RSCI 531 Industrial Approaches to Drug Discovery RSCI 532 Early Stage Drug Development CXPT 609 Preclinical Experimental Therapeutic Drug Development PSCI 664 Drug Discovery and Design	6-8
Quality Assurance –one course minimum	RSCI 525 Introduction to Drug and Food Toxicology MPTX 526 Chemistry manufacturing and Controls	3
Clinical Research –one course minimum	PM 523 Design of Clinical Studies MPTX 517 Structure and Management of Clinical Trials	3-4
Biostatistics–one course minimum (if not taken in previous programs)	PM 510L Biometry Principles	4
Introductory Regulation	MPTX 511 Introduction to Medical Product Regulation MPTX 512 Regulation of Pharmaceutical and Biological Products	3
Directed Research	RSCI 590	3
Electives		To add to 32

In addition, depending on the student's interest, additional course(s) could focus on strategic, policy and regulatory aspects that one would encounter during the translational investigation of medical products. The student will be allowed to choose from a number of existing Regulatory Sciences courses that will complement their overall needs in the Preclinical Development certificate program. Examples of such classes would be RSCI 525 Introduction to Drug and Food Toxicology, MPTX 602 Science, Research, & Ethics, MPTX 526, Chemistry and Manufacturing Controls or MPTX 511, Introduction to Medical Product Regulation. *Other courses can only be substituted with the approval of the program director. However, the flexibility identified here will facilitate the integration of this*

certificate with other initiatives currently underway in translational studies such as those currently being developed by the Clinical and Translational Science Initiative, where courses may be given during the week in more traditional formats for PhD and MS graduate students.

Below is an example of a proposed curriculum for a full-time student in the MDD graduate program.

Year 1

FALL	SPRING	SUMMER
RSCI 530 – Translational Medicine (2, Fa)	RSCI 531 – Pre-clinical Drug Discovery (4, Sp) or	RSCI 532 – Pre clinical Drug Development (3)
MPTX 526 – Chemistry manufacturing and Controls (3, Fa)	CXPT 609 (4, Sp) RSCI 601 – Biomedical Commerce (4, Sp)	

Year 2

FALL	SPRING	SUMMER
MPTX 517 – Structure and Management of Clinical Trials (4, FaSpSm)	MPTX 512 – Regulation of Pharmaceutical and Biological Products (4)	PM 510L – Principles of Biostatistics (4)
MPTX 516 – Medical Products and the Law (3, F)	RSCI – Application of Risk Management Tools & Techniques (2) <i>Also Suggested for course – CXPT 609</i>	RSCI 590 – Directed Research (3)