



Announcing...

Our new Master's Program in Regulatory Science!

In May 2001, the USC School of Pharmacy began an innovative, cross-disciplinary Master's program in Regulatory Science. This program is an intensive course of study designed to produce graduates whose undergraduate and graduate backgrounds in science, engineering or law are enhanced by skills appropriate for research and practice in regulatory science. Its goal is to increase the skills of regulatory and clinical leaders who design, manage and evaluate research related to biomedical product development and commercialization. The program provides an opportunity for advanced preparation in a field in which industry and government cannot find sufficient numbers and quality of skilled personnel.

Centered in the School of Pharmacy, the program has a year-round curriculum developed jointly with the Schools of Engineering, Medicine, Independent Health Professions, Business and Public Policy. The program builds on the strong reputation of University of Southern California for scientific training and industry linkages. California is home to more than 2500 biomedical firms, most of which are located in the seven counties around Los Angeles. The program relies on the participation of professionals from public and private sectors with extensive experience in fields related to regulatory science.

The interdisciplinary curriculum provides students with advanced training in several subsectors including those related to pharmaceutical products, medical devices, foods and dietary supplements. The full-time program is structured to serve the needs of students with science-based undergraduate and graduate degrees. As part of our commitment to continuing education, the program will be structured to facilitate access for part-time students who may be already in the workforce. An international focus will encourage the development of broadly based skills, important in a sector that relies increasingly on global markets and multinational organization.

What is Regulatory Science?

Regulatory Science relates the regulatory and legal requirements of biomedical product development to the scientific research needed to ensure the safety and efficacy of those products. It is an emerging profession experiencing tremendous growth. The rapid expansion of biomedical industry in southern California has resulted in a particularly large and unmet demand for regulatory professionals. Such individuals have great opportunities for interesting careers at the boundaries between business, science and health delivery. The shortage of regulatory professionals can be judged from the bouyant salaries of current specialists. In the US, salaries have typically increased by 15-20% in the last two years and now average \$93-117,000 for individuals at the Director level (RAPS, 1999).

Why the new emphasis on Regulatory Professionals?

University programs in biomedical sciences have expanded rapidly over the last two decades. Much of this expansion has been driven by the belief that biomedical research will result in new medical products and practices to remediate injury and disease. Universities have become adept at training students in basic sciences where research creates new knowledge important ultimately for new medical therapies and products. However, a long developmental and regulatory path exists between new knowledge and the production of safe and efficacious medical products. The rate at which new products become accessible for public use depends upon the speed with which products can graduate through preclinical and clinical trials. The developmental period is long, costly and often inefficient, in part because individuals who understand regulatory requirements and research methods are difficult to find and expensive to hire.

The medical products sector is not like most other manufacturing sectors. What sets it apart is the extraordinary level of regulatory science and oversight needed to develop and market its products. For example, as early as 1990, developmental costs of a single marketed drug were estimated to equal or exceed \$US 500 million. Most investment is spent in the long preclinical and clinical phases of regulatory testing, which typically take 10-15 years! Inefficiencies in this path are costly for both the consumer and manufacturer. For the consumer, delays in the regulatory phase slow the market approval of potentially important therapies. For the company, they delay product marketing and thus the ability to offset R& D costs by product revenue. Delays have been known to bankrupt smaller companies and to affect the success of US products versus those from other countries. Problems in the regulatory phase result in a negative governmental and public image of the manufacturer, increase the subsequent level of scrutiny to which the manufacturer may be subjected, and potentially increase liability. Most importantly, poor planning and execution of preclinical and clinical trials may skew the company's ability to understand the safety, efficacy and contraindications of its product. For all of these reasons it is critically important that individuals in regulatory and clinical science be well-trained professionals who are highly capable.

Medical-product industries are a particularly significant source of economic growth in California; they are the second largest high-technology employer behind only electronic equipment and ahead of computer and film industries (CHI, 1999). Of these companies, 77 % focus on the development of medical devices and diagnostics, whereas the remaining companies develop pharmaceutical and biologically-based products. However, pharmaceutical companies tend to be larger, so that employment is split quite evenly between the two market segments. In California, at least 2,500 companies specialise in medical products. Export of these products account for more than \$4 billion annually, at a growth rate of more than 10% per year. Californian companies receive more approvals for new technologies from the Food and Drug Administration than any other state. If one in five of Californian companies hire a new regulatory administrator each year, we might estimate an annual demand for 500 individuals with regulatory training.

An increasing demand for regulatory experts has also been identified in other health-related institutions, such as governmental agencies, contract laboratories or consulting services. Also interested in regulatory-science specialists are the multibillion dollar foodstuffs and agribusiness industries. Not to be overlooked are the additional employment markets in the much larger range of original equipment manufacturers and service providers across the US and in the international arena.

Why not just learn on the job?

1. The range of regulatory guidelines and standards are passing the point where generalists can understand the system. The addition of new regulations will undoubtedly not be balanced by the equivalent removal of others. Students educated in this program will be able to interpret regulatory guidelines, then use their knowledge of research methods and first principles to solve problems and develop appropriate research plans.
2. Standards to which companies are held by the regulatory agencies have become more demanding than even a few years ago. Failure to comply with these standards has grave financial consequences in terms of denied approval of products, suspension of manufacturing operations, and legal liability. Students from this program will understand the policy-related and legal issues important for the types of research and developmental activities in which they are engaged.
3. The ability to shave time from the approvals process increases the value of patented products by extending the period in which commercialized products remain under patent protection. Regulatory experts are regarded increasingly as a source of competitive advantage. Students from this program will be equipped with a knowledge of business, project-management methods, and standard testing procedures that will increase the efficiency of product development.
4. Programs are needed that can serve as neutral educational resources for regulators, where new science and policies can be debated. Educational programs allow regulators to discuss their viewpoints and receive feedback in an environment less laden with vested interests.

What are the Admissions Criteria?

1. Baccalaureate or graduate degree in an appropriate discipline with a minimum grade point average of 3.0
2. Qualifying scores on the GRE of 1000 (combined verbal and quantitative score), or equivalent performance on MCAT or GMAT exams
3. Proficiency with the English language and excellent communication skills
4. Two letters of reference
5. One page letter explaining your career objectives

Preference will be given to applicants with graduate research experience or experience in related sectors of business or government. In the case of adult applicants who have considerable work experience, entrance criteria may be modified on a case-by-case basis.

Applications Deadlines: October 15; February 15 and June 15th for acceptance in the following term. International students are encouraged to apply earlier.

What Does the Program Involve?

It is possible to complete the program in as little as 4 terms (USC has 3 terms/year) or you can take up to 5 years to complete your degree. There is no minimum number of courses you must take each term.

Full-time students without industry or public sector experience must take a minimum of 30 units of coursework and complete a 6-unit practicum/research project.

Students with extensive research experience in industry may be allowed to substitute six units of additional coursework for the practicum component with the approval of the Admissions/academic committee of the program.

It is recognized that students will have diverse backgrounds with differing levels of preparation in fields relevant to the program under study. However, a core of eight courses from seven different focus areas will normally form the base of the program (Table 1). Additional courses can be selected from a list of recommended choices (Table 2) or the student can select any course that is applicable towards the degree (courses must be approved by the department). Students are strongly advised to consult with the program coordinator when making course selections! Up to twelve units of relevant coursework at USC may be taken prior to formal enrollment in the graduate program, or eight graduate units taken in a different university, may be credited to the requirements of the graduate program with the permission of the Admissions/academic committee. Exceptions to core course requirements may be made if students have already taken an equivalent course. Instead, optional courses can be substituted.

Required courses for MS in Regulatory Science

Introductory (1 of the following)

MPTX 511	Introduction to Medical Product Regulation	3 units	√
BME 416	Development & Regulation of Medical Products	3 units	

Advanced Regulatory (2 of the following)

MPTX 512	Regulation of Drugs and Biologics	3 units	√
MPTX 513	Regulation of Medical Devices	3 units	√
MPTX 514	Regulation of Food and Dietary Supplements	3 units	

Quality

MPTX 515	Quality Assurance	3 units	√
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Clinical (1 of following)

MPTX 517	Structure and Management of Clinical Trials	4 units	√
PM 523	Design of Clinical Studies	3 units	

Biostatistics (1 of following)

PM 510	Principles of Biostatistics	4 units	√
MPTX 522	Clinical Design Course	3 units	

Law

MPTX 516	Medical Products and the Law	3 units	√
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Business (1 of following)

BAEP 551	Introduction to New Ventures	3 units	√
BAEP 552	Cases in Feasibility Analysis	3 units	
BAEP 556	Technology Feasibility	3 units	
BEAP 557	Technology Commercialization	3 units	

Internship

MPTX 630	Directed Field Research Project	6 units	√
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Total units 32 units

Optional Courses offered through Regulatory Science Program

MPTX 518	Medical Writing	3 units	
MPTX 519	International Approaches to Regulation	3 units	
MPTX 520	Risk Management	3 units	
MPTX 521	Seminar in Regulatory Science	1-6 units	
MPTX 524	Food Science and Technology	3 units	
MPTX 526	Chemistry Manufacturing Control	3 units	
MPTX 602	Science, Research, and Ethics	2 units	

Optional Courses offered through other USC departments

ISE 527	Advanced Quality Control	3 units	
NURS 511	Health Care Delivery Systems	3 units	
PM 513	Experimental Designs	3 units	
PMEP 509	Research Design	4 units	
PMEP 519	Survey Research	4 units	
PMEP 529	Risk Probability and Preference	4 units	
PMEP 539	Economics of Health Care	4 units	
PMEP 538	Pharmaceutical Economics	4 units	
PSCI 664	Drug Discovery and Design	4 units	
PSCI 665	Drug Transport and Delivery	4 units	
PUAD 530	Problems and Issues in the Health Field	4 units	
PUAD 527	Public Policy Formulation	4 units	
PUAD 528	Public Policy Formulation and Implementation	4 units	

Total units 4 units

= 36 units for Degree Completion



Regulatory Science Program

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