

Courses in Regulatory Science

Are you interested in formal training in regulatory affairs, quality assurance or clinical research? The School of Pharmacy will offer a series of courses as part of its new Regulatory Science Program. These courses can be taken one of three ways:

- *As a part-time or full-time student in the Master's program in Regulatory Science.* These participants have preferential placement in the courses, and obtain credits towards the degree when they pass the course.
- *As a limited enrollment student.* Such participants also obtain credit for successful completion of the program that can in future be applied toward a graduate program, or may be used as continuing education credits to support professional credentials such as Regulatory Affairs Certification. *It is advised that limited-distance students should register at least 2 weeks before the 1st day of class.*
- *As an auditing student.* Such participants can be accommodated on a limited basis with the permission and special arrangement of the instructor.

Information about enrollment, application and tuition are available from Kathy Knodel, Regulatory Science Program Student Counselor, at regsci@usc.edu or (323) 442-3102. Further information about the content of these courses can be found at http://regulatory.usc.edu/program_Schedule.aspx.

MPTX 511 “Introduction to Medical Product Regulation” (3 units)

Are you interested in the way that the many regulatory agencies govern the development and commercialization of medical products? In this course, we examine the roles of a host of governmental bodies. By focusing on an unusual case-study, students will work in groups to identify how these many agencies overlap to oversee the production of medical and health-care products. Designed for students new to regulatory science, this course can serve as an overview for those who want a beginning flavor of the profession. Alternatively it can be a foundation for later courses in which particular aspects of medical product development are explored in detail.

MPTX 512 “Regulation of Drugs and Biological Products” (3 units)

Pharmaceuticals are amongst the most profitable of medical products. They are also one of the most demanding to commercialize and most subject to regulatory oversight. This course will explore the relationships between scientific discovery, testing and regulatory oversight. It will look at the rules governing prescription and over-the-counter drugs, and look at the changes that are introduced by the burgeoning influence of genetic engineering and biological product development. It will consider the practical issues facing regulatory specialists as they work with the FDA and other international regulatory bodies to secure and keep product approval.

MPTX 513 “Regulation of Medical Devices” (3 units)

Twenty years ago the bionic man was considered to be a science-fiction flight of fancy. Today, most people over the age of sixty will have at least one bionic part. Perhaps not surprisingly, new advances in science and engineering are changing the way that governments are looking at the regulation and payment for new medical technologies. This course will explore the developmental and regulatory path for new devices, and look at the way that products are governed once in the marketplace.

MPTX 514 “Regulation of Foods and Dietary Supplements” (3 units)

Globalization of the food supply and increased usage of dietary supplements imparts domestic and international demands on the regulations of these items such that the products are safe and the associated claims are truthful and not misleading. This course explores the regulatory dynamics of foods and their components, including intentional additives and possible contaminants, and dietary supplements, and examines the contentious nature of international regulations associated with these products. Experts share their expertise and address the current and future state of regulations that governed these products. Students experience the production and regulatory differences between foods and dietary supplements through field trips to production and manufacturing facilities of food products and dietary supplements, and critically review these differences through discussions, oral presentations, and written assessments.

MPTX 515 “Quality Assurance” (3 units)

If medical products fail, there can be life-threatening results. Quality assurance is a huge part of medical product development and constitutes a science in itself. In this introductory course, we will examine the way that different countries regulate the quality of medical products, from design and development to manufacturing and distribution. We will study the rules governing good laboratory and manufacturing practices, and explore how they mesh with ISO and European standards, CE marking and quality systems regulations. We will look at risk analysis and documentation, and participate in a real-life audit. Course requires a distance module to be completed by the last course date (allow two weeks minimum).

MPTX 516 “Medical Products and the Law” (3 units)

Laws governing medical products are the beginning point for regulations that identify how research, development and marketing of such products should be pursued. Almost every activity in the chain of product-development activities will have legal implications and liabilities. This course will explore the history of laws related to medical product development, commercialization and clinical use, and will consider relevant legal cases whose decisions have been important in establishing precedents and guiding interpretations of legal theory over the last two decades.

MPTX 517 “Structure and Management of Clinical Trials” (4 units)

Clinical trials are big business. They underlie the commercialization of most new drugs and invasive medical devices, products with enormous capability to harm as well as help. Over the last few years, highly publicized problems have put clinical trials under a regulatory microscope. In this course we will look at the bioethical and practical concerns that shape the design of clinical trials. We will examine how trials are carried out, and how they are managed and documented. This innovative course is designed with practitioners in mind. It has a distance component, with modules to be completed at least three weeks before the first day of class. This is an intensive four day weekend which focuses on more advanced concepts and problems presented by real-life clinical situations and challenges from experts in the field. The course requires a distance module (online slides and lectures) to be completed prior the first session in which homework assignments and a midterm on this information will be due on the morning of the first day of class.

MPTX 518 “Medical Writing Course” (3 units)

Written communication is so important for the work of regulatory and clinical professionals! In this course, we will review all of those rules for writing grammatically correct and stylistically compelling reports and submissions. We will examine in detail some of the tricky parts of submissions, and we will discuss time and project management skills needed to produce large multi-authored submissions to the FDA.

MPTX 519 “International Approaches to Medical Product Regulation” (3 units)

The marketplace for medical products is global. This advanced course in Regulatory Science is designed to compare the laws, regulations and institutions governing medical products in North America with those of several other countries and groups of countries. Particular attention will be paid to regulations that shape the developmental path and marketing applications for drugs, biologics, and medical devices. We will study the countries, including developing countries in which ethical considerations are often very important to understand.

RSCI 520 “Introduction to Risk Management for Health Care Products” (2 units)

Medical products are amongst the most highly regulated commodities on the market today because many can pose large potential risks to human health. Management of risk is a central part of quality assurance programs that are designed to ensure that products are safe and effective. Recent regulations in most developed countries insist on risk assessment and plans for risk management as a core requirement prior to approval of clinical trials or product commercialization. The goal of this course is to introduce the student to the formal language, historical development and theoretical underpinnings of risk management. Several formal methodologies exist to characterize and manage risks in product design, manufacture and use in target populations. The goal of these approaches is to prevent problems by anticipating and mitigating them. However, risk management strategies also include activities related to risk control such as recalls, crisis management insurance and legal actions.

MPTX 522 “Clinical Design” (3 units)

It is unknown how many promising compounds have been rejected because they were evaluated in a study with a poor design. Well-designed clinical trials are essential in the development process of a medication or device. Before developing and executing a clinical trial, essential features which must be considered include: 1) basic study design; 2) study population; 3) planned statistical analysis; 4) enrollment of subjects; 5) regulatory requirements; and 6) ethical issues. In this course the student will explore and become familiar with clinical research designs and statistical analyses utilized in medical-product research. The course will also highlight the unique features of clinical trials in specialized populations such as AIDS, cancer, pediatrics and psychiatry. Current trends for accelerating drug development will also be covered.

MPTX 524 “Food Science and Technology” (3 units)

The importance of safe and “healthy foods” in today’s society has resulted in an expansion of food science and technology applications. The science and the technology continue to employ the basic concepts of food science and food safety. Those concepts include, but not limited to, fundamental food chemistry, food composition and nutrient interactions, food processing, food engineering, food stability and preservation, food sensory qualities, food toxicology, food microbiology, and food biotechnology. These concepts encompass a variety of physical principles, physiological processes, and regulatory guidelines, which contribute to the introduction of more stable, nutritious products to feed our growing population. Students will discuss these concepts and experience their principles through classroom demonstrations, personal local grocery market surveys, and group projects.

RSCI 525 “Introduction to Drug and Food Toxicology” (3 units)

Drug and food safety is at the forefront of consumer concerns. The course examines the safety assessment of these products as the students develop a general understanding of the toxicological tools and regulations associated with drugs, botanicals and food components. The fundamental concepts of pharmacokinetics and absorption, distribution, metabolism and excretion (ADME) will be applied to historical and contemporary drug and food products. Students will develop critical thinking skills through discussions, critical problem-solving experiences, and case report analyses of drug and food components.

MPTX 526 “Chemistry Manufacturing & Controls” (3 units)

Chemistry, Manufacturing and Controls documentation reflect the scientific foundation for commercialization of new active pharmaceutical ingredients. The technical challenges coupled with the domestic and international regulatory dynamics place considerable demands on numerous key elements in the CMC process. Student experiences will develop a critical understanding of the CMC process and will craft essential CMC documents that encompass the breadth of this process. The details and demands of this process are presented and discussed by leaders from regulatory agencies, private industry, and academic institutions.

RSCI 527 “Medical Product Safety” (3 units)

It seems as though newspapers run stories about hazardous food and medical products weekly! In this course, we focus on the role of the medical product manufacturer and supplier in the management of safety. We define the regulatory expectations and the best-practices used to meet these expectations. Some of these practical approaches anticipate problems before they happen, at the level of manufacturing, packaging and labeling. Other approaches include corrective and preventive actions that are stimulated by field observations, complaints and other forms of pharmacovigilance. Finally, we will study specific approaches for managing product records and archiving information and product that might be needed in case of legal challenge. Crisis management plans and recall procedures will be reviewed with a particular focus on the special challenges faced by medical product manufacturers. The course will include hands-on practice using vigilance application tools, and the MedDRA and Med Watch data bases.

RSCI 528 “Safety in Health Care Environment” (3 units)

The objective of this course is to examine safety in the context of the end-users and facilities in which health care is delivered. We will explore how regulatory expectations affect principles and practices in managing health care facilities and services. Practical approaches include mock-up case studies of JCAHO certification, implementation of environmental risk management, and reduction of health hazards for health care facility. Special attention will be paid to management of medication and treatment errors that form a major threat to safety in the hospital environment.

RSCI 529 “Application to Risk Management Tools and Techniques” (2 units)

Management of risk is a central part of quality assurance programs. Medical products are designed to ensure that they are safe and effective. Risk management is emerging as a core requirement prior to approval of clinical trials or product commercialization in a range of fields including foods and medical products. In this course, a cohesive set of risk management tools are introduced. Students with a basic knowledge of biomedical science and regulatory structures will explore in depth how to apply these tools. Emphasis will be placed on tools in common use in the engineering and medical products arena, including functional analysis, fault-tree analysis, failure modes and effects analysis, hazard analysis and critical control point analysis and six sigma methods.

RSCI 530 “Translational Medicine: An Overview” (2 units)

An overview of principles and concepts underlying drug discovery and development, including terminology of translational science.

RSCI 531 “Drug Discovery” (4 units)

Examines the process of drug discovery from selection of disease and therapeutic target to characterization and validation of lead drug candidates.

RSCI 532 “Early Stage Drug Development” (3 units)

Explores the activities involved in transforming an early drug or biological candidate to a drug approved for marketing by regulatory authorities.

RSCI 601 “Biomedical Commerce” (4 units)

Introduction to business principles appropriate to medical products, including: supply and demand, product entry-exit strategies, financing, reimbursement, marketing and pricing in global marketplace. This transitional course will use a mix of distance and site-based delivery systems. Each site-based session will be an intensive day-long session, after which will be assigned about 3-4 streamed lectures to add other perspectives to the course. The output of the course will include a business plan and a number of smaller assignments.

MPTX 602 “Science, Research and Ethics” (2 units)

Recent advances in science and medicine have raised a plethora of issues concerning science, research and ethics. In this course, we will review the traditional approaches and concepts that underlie bioethical analysis. Using case studies, we will consider some of the major ethical issues facing basic scientists and clinical researchers. We will then expand our considerations to issues of financial management and conflict of interest, of product liability and managed care. The first day of the course will be more didactic. The last three days will center on student projects in each of several areas.

RSCI 603 “Managing Complex Projects” (3units)

Project management is central to the efficient, effective conduct of complex organization. In this course, we will evaluate some of the tools and methodologies that provide a common approach and language for product managers in a range of disciplines. We will then look at some of the particular challenges inherent to products in the medical products sector, including the need to manage innovation and scientific enterprise, the challenges of multifunctional teams that cross into clinical environments, the highly transnational nature of some projects and the implications of intellectual property and privacy concerns. Finally, we will study specific approaches for managing product records and archiving information that might be needed in case of legal challenge. Crisis management plans and recall procedures will be reviewed with a particular focus on the special challenges faced by medical product manufacturers. The course will include hands-on practice using project management methods.

RSCI 604 “Regulatory Strategy in Asia” (4 units)

Are regulatory standards developed and applied in different constituencies in Asia? At the beginning of the course, we will study in depth the regulatory rules and business climate in countries that differ markedly in their levels of development, regulatory maturity and socioeconomic features. Students will develop briefing packages on the different countries for the use of their colleagues. We will then travel to a subset of Asian countries as a delegation. By meeting with the principal regulatory authorities in each country we will have a first-hand opportunity to study the interplay between culture, management methods and regulatory expectations. We will then visit “typical” domestic and foreign medical-products companies to investigate what they see as the major challenges in medical product development and commercialization. (continued)

We will explore how regulatory expectations affect principles and practices in the delivery of health care and the expectations of society. We will also examine the stresses that are occurring in these rapidly evolving business environments, and consider approaches and solutions to working with Asian manufacturers and distributors.

RSCI 605 “Managing Organizations and Human Resources” (3 units)

This objective of this course is to study the way that people are organized and managed in organizations of different types and sizes. The course will focus first on management principles in general. We will consider the theoretical underpinnings of personnel management, organizational design and industrial relations. We will then bring that theoretical knowledge into practical situations, using case studies, discussions and role-playing. As part of this course, we will focus on management styles, leadership and negotiation capabilities. Particular attention will be paid to two types of very different organizations, the small, rapidly growing enterprise and the large, mature company with extensive global operations. Such organizations best typify the medical products industry.

RSCI 608 “Regulatory Strategy in Europe and the Americas” (4 units)

The purpose of this course is to acquaint students with the way in which regulations, laws, culture and business climate combine to affect the competitiveness and business environment for medical products in the EU, Canada and South America. The course builds upon a basic understanding of global regulations. Through both focused lectures and later travel to both EU and Canada, students will have the opportunity to talk to representatives of principal policy and rule-making bodies of the European commission and the individual countries themselves. We will study the way that regulations differ from elsewhere in the world and we will further study the differences that exist between the way that foods, drugs and devices are managed in Europe and Canada.

MPTX 630 “Directed Field-Research Project” (6 units)

“Book-learning” is important but equally important is the application of learned principles to the management of real-life regulatory, quality and clinical problems. For students without previous background in the field, an internship period in industry is offered during which trainees work alongside other professionals in industry and government. These internships are arranged with the help of the School of Pharmacy, and in consideration of the future career interests of the individual trainee. If trainees have already ideas about sites in which they wish to spend this period they should identify these interests early. In addition, individuals already in industry may be interested in conducting a research project in their home institution. We encourage such activities, but the arrangements must be approved before formally registering in the course.