RAPS ONLINE UNIVERSITY

Certificates and Courses

Introduction

Build a solid body of regulatory knowledge and advance your career with a RAPS Online University certificate. The **Dual Certificate Program in medical devices and pharmaceuticals** has the most comprehensive curriculum and includes **eight electives** you hand pick from dozens of options, spanning the topical areas of clinical, quality, pharmaceuticals and biologics, medical devices, and regulatory essentials.

Prefer to concentrate on one product sector? A RAPS Online University individual certificate program in either medical devices or pharmaceuticals might be right for you. Like the dual certificate, they feature a **core curriculum of essential courses, including ethics, the role of the regulatory professional, global regulatory strategy, and lifecycles and definitions.** Each individual certificate includes five electives, and learners can choose from all available courses regardless of product sector.

Interested in earning a dual certificate but not sure if you're ready to take on that much at once? You can start by enrolling in an individual certificate program and choose to **upgrade to the dual certificate when you're ready for more.**

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RAPS REGULATORY AFFAIRS CERTIFICATES

The Regulatory Affairs Certificate Program is an online series of courses you personalize to meet your professional development needs.

ONLINE UNIVERSITY COURSES

RAPS Online University provides you with education options to hone your skills in your area of expertise. We provide individual courses on a variety of regulatory topics, from the basics to product- and region-specific subjects

Essentials

Medical Devices

Pharmaceuticals

Quality

Clinical

(M) Denotes courses in the Medical Device Certificate curriculum (P) Denotes courses in the Pharmaceutical Certificate curriculum

RAPS Regulatory Affairs Certificate in Medical Devices

The RAPS Regulatory Affairs Certificate in Medical Devices provides a cost-effective, convenient option that will equip you with the tools and knowledge needed to progress as a regulatory professional and stay ahead of the competition. Written for regulatory professionals in their first five years in the regulatory field, this certificate program is comprehensive and flexible to meet your learning needs.

Program Details

This certificate is achieved by completing four core and five elective courses. After successfully completing all nine courses, you will receive a certificate recognizing your achievement.

You will have 12 months to complete all nine courses of the program.

Core Courses

The following four courses are required:

- Ethics
- Global Regulatory Strategy for Medical Devices
- Medical Devices: Definition and Lifecycle
- Role of the Regulatory Professional

Elective Courses

Choose five courses from our entire portfolio of programs that have the Ⓜ assigned to them. These courses are considered part of our Medical Device Certificate. You may add on additional courses outside the five Ⓜ courses you select at an additional charge.

Pricing

Member	Nonmember
$ 2,360	$2,950

SIGNUP NOW

RAPS Regulatory Affairs Certificate in Pharmaceuticals

Regardless of whether you are new to the regulatory profession or pharmaceutical industry, transitioning from a related discipline, or simply need to refresh your knowledge in your field of work, the RAPS Regulatory Affairs Certificate in Pharmaceuticals will help meet your individual learning needs or the needs of your entire team. Written for regulatory professionals in their first five years in the regulatory field, this flexible certificate program is comprehensive and customizable.

Program Details

This certificate is achieved by completing four core and five elective courses. After successfully completing all nine courses, you will receive a certificate recognizing your achievement.

You will have 12 months to complete all nine courses of the program.

Core Courses

The following four courses are required:

- Ethics
- Global Regulatory Strategy for Pharmaceuticals
- Pharmaceuticals: Definition and Lifecycle
- Role of the Regulatory Professional

Elective Courses

Choose five courses from our entire portfolio of programs that have the P assigned to them. These courses are considered part of our Pharmaceuticals Certificate. You may add on additional courses outside the five P courses you select at an additional charge.

Pricing

Member	Nonmember
$2,360	$2,950

SIGNUP NOW

RAPS Regulatory Affairs Dual Certificate in Medical Devices and Pharmaceuticals

The RAPS Regulatory Affairs Dual Certificate in Medical Devices and Pharmaceuticals provides a route for you to complete both tracks in an efficient manner. By taking all six core courses and selecting eight electives, you have the opportunity to extend your achievement with a dual certificate acquired within a 12-month timeframe.

Program Details

The Regulatory Affairs Certificate: Medical Devices and Pharmaceuticals is achieved by completing six core and eight elective courses. After successfully completing all 14 courses, you will receive a certificate recognizing your achievement.

You will have 12 months to complete all 14 courses.

Core Courses

The following six courses are required:

- Ethics
- Global Regulatory Strategy for Medical Devices
- Global Regulatory Strategy for Pharmaceuticals
- Medical Devices: Definition and Lifecycle
- Pharmaceuticals: Definition and Lifecycle
- Role of the Regulatory Professional

Elective Courses

Choose eight courses from our entire portfolio of programs. These courses can be labeled with an M or/and P. This means that these courses are valid electives in order to achieve the dual certificate.

Pricing

Member	Nonmember
$3,590	$4,490

SIGNUP NOW

Effective Regulatory Communication

3 RAC Credits

The intention of this course is to provide you with an understanding of the critical elements in effective communication from the regulatory professional's perspective, from influencing teams to managing meetings and everyday activities within and across the company. The course will explore how to make communication more effective in all interactions, including presentations, meetings and negotiations, and in written documents. Participants will come away with a better understanding of listening, influencing and achieving more effective results during all interactions.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Ethics—Essential Tools for Regulatory Professionals

4 RAC Credits

Making the right decision isn't always easy. Consumers today expect and demand integrity, honesty and transparency. Learn the importance of doing the right thing when product quality is at risk using actual cases that affected consumer safety and trust, so you're better prepared to deal with issues or situations that don't always involve easy answers or clear decisions. This course identifies and analyzes ethical issues regulatory professionals may encounter and provides a general introduction to complex concepts, principles and theories, including bioethics and legal principles. It highlights ethical issues in areas of product development, compliance and clinical testing. This course is intended to be a companion piece to the RAPS Code of Ethics, as well as your own institution's policies, procedures and training programs.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW

FDA Law and Regulation

4 RAC Credits

The US Food and Drug Administration (FDA) is authorized to regulate foods, dietary supplements, drugs, devices (including *in vitro* diagnostics), biologics, veterinary products, cosmetics and tobacco under the *Food, Drug, and Cosmetic Act (FD&C Act).* FDA regulation is subject to periodic reform by Congress and regulators, with input or challenges from other stakeholders. In addition, FDA regulation increasingly expands beyond US borders in light of the globalization of the supply chain for FDA-regulated products. This course provides an overview of FDA and its associated laws and regulations. It discusses the history of FDA's authority, compliance requirements for each category of regulated products, prohibited acts under the *FD&C Act* and actions that FDA may take when individuals or corporations violate the *FD&C Act*.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW

Intermediate Medical Writing: Investigational Applications

6 RAC Credits

Regulatory and medical writing is an integral part of the product development and approval process and plays a crucial role in assuring that submissions for new investigational products are well organized, accurate and reviewer-friendly. This course provides an overview of the variety of investigational applications prepared by regulatory and medical writers for both drugs/biologics and medical devices. Key investigational submissions covered include region-specific applications for drugs/biologics such as the Investigational New Drug Application (IND), Canadian Clinical Trial Application (CTA) and Investigational Medicinal Product Dossier (IMPD), as well as those required for investigational devices such as the Investigational Device Exemption (IDE), European CTA and Investigational Testing Authorization (ITA).

Pricing Member: $570 Nonmember: $790

SIGNUP NOW

Intermediate Medical Writing: Medical Devices

2 RAC Credits

Regulatory writing is an integral part of the product development and approval process and plays a crucial role in speeding product submission and supporting compliance. This course will provide an overview of some of the more complex documents prepared by regulatory and medical writers, including key sections of the Premarket Approval (PMA) and 510(k) Premarket Notification applications for medical devices. You will be introduced to the components of each of these documents and learn techniques for improving document quality in order to advance your career as a regulatory writer.

Pricing Member: $255 Nonmember: $350

SIGNUP NOW

Intermediate Medical Writing: Pharmaceuticals and Biologics

3 RAC Credits

Regulatory and medical writing is an integral part of the product development and approval process and plays a crucial role in assuring that submissions for new products are well organized, accurate and reviewer-friendly. This course will provide an overview of some of the more complex documents prepared by regulatory and medical writers, with a focus on the Common Technical Document (CTD). Key considerations associated with writing submissions in CTD format, including region-specific considerations for clinical sections in US New Drug Applications (NDA), US Biologics License Applications (BLA) and EU Marketing Authorisation Applications (MAA) will be discussed.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Introduction to Regulatory Affairs in the US and Canada

2 RAC Credits

This course provides an overview of healthcare product regulation across product lines in North America, specifically in the US and Canada. It highlights the agencies primarily responsible for regulating healthcare products—the US Food and Drug Administration (FDA) and Health Canada. The course highlights the applicable legislation that drives the regulatory processes.

Pricing Member: $255 Nonmember: $350

SIGNUP NOW

Introduction to Regulatory Affairs in the EU

1 RAC Credit

This course focuses on the development of healthcare product regulation in the European Union (EU). It discusses the responsibilities of agencies involved, processes employed and interactions among agencies. In addition, this course provides a basic understanding of the regulatory requirements for obtaining marketing approval for healthcare products. Also covered is the process for medical device approvals performed by notified bodies (NBs)—independent third parties notified to the European Commission (EC) by the national competent authorities (CAs) of the Member States—that carry out the Conformity Assessment Procedures (CAPs) for medical devices.

Pricing Member: $135 Nonmember: $185

SIGNUP NOW

Introductory Medical Writing

3 RAC Credits

Regulatory writing is a skill that must be honed and refined as one gains regulatory knowledge and experience. Regulatory professionals prepare highly detailed documents that are pivotal to the approval and marketing of healthcare products around the world. During this course, you will obtain an overview of the medical writing profession from a regulatory perspective, including an introduction to the basic skills important for medical writing in that field. You will gain a set of resources and a better understanding of the expectations and tasks that will be required of you to be a successful regulatory medical writer.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Project Management for Regulatory Professionals

4 RAC Credits

Commonly used in engineering and IT applications, project management principles, tools and techniques also can be used for better planning, control, monitoring and review of project tasks in the regulatory profession. This course provides guidance for effectively establishing a regulatory development project plan, including identifying resources and determining the effort and timing required to create project and budget reports. The course also provides, from the project management perspective, important tips on communication and meetings, such as how to set up and run meetings and how to use meetings to advance and monitor the project effectively.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW

Regulatory Due Diligence for Product Development

3 RAC Credits

This course will provide insight to better prepare the due diligence regulatory affairs team member by providing a basic understanding of the principles and practices of due diligence within the medical product environment. It covers a wide range of issues, including the reasons for performing due diligence, types of due diligence and responsibilities of a due diligence team. The processes and checklists commonly used in due diligence are also discussed and put into practice using a hypothetical case study. You will learn how best to contribute to the goals of the due diligence team, and by extension those of the company, if you are asked to represent the regulatory perspective.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Role of the Regulatory Professional

1 RAC Credit

Regulatory professionals advise on legal and scientific constraints and requirements, and collect, collate and evaluate the scientific data generated by research and development colleagues. They give strategic and technical advice at the highest levels in their companies, making important contributions both commercially and scientifically to the success of a development program and the company overall. This course discusses the evolution of the regulatory profession and the professional's roles and responsibilities. It also briefly outlines the critical events and their impact for each product lifecycle stage for drugs, biologics and medical devices.

Pricing Member: $25 Nonmember: $25

SIGNUP NOW

Supplier Management

1 RAC Credit

Supplier management—also known as vendor management—is a term encompassing a broad array of regulatory requirements and industry activities necessary to develop, manage and control active pharmaceutical ingredients, foods, pharmaceutical and biologic products, cosmetics, veterinary products and medical devices. This course provides a basic understanding of current supplier management practices and their impact on product quality and patient safety. It covers a wide range of issues, including why regulations and guidance documents targeting supplier oversight are increasing in rigor, how companies ensure compliance, what are the basic roles and responsibilities of regulatory and quality professionals, and which are the most common regulatory issues stemming from poor supplier performance and weak supplier management.

SIGNUP NOW

Pricing Member: $365 Nonmember: $500

Supply Chain Controls

3 RAC Credits

A supply chain is a series of linked activities and organizations that transform natural resources, raw materials, components, services and information into a finished product that is then delivered to the end customer. The increasingly globalized healthcare industry creates regulatory supply chain challenges that may not be addressed by current regulations, which may lag industry best practices. This course provides a review of common supply chain issues and addresses how agencies like the US Food and Drug Administration (FDA) encourage organizations to improve supply chain controls through guidance documents and regulatory harmonization activities. It also reviews key steps in supply chain control as well as advanced techniques for regulatory affairs and quality assurance executives to consider.

SIGNUP NOW

Pricing Member: $365 Nonmember: $500

Global Regulatory Strategy for Medical Devices

4 RAC Credits

The medical device market changes frequently in terms of technology, risk potential, marketing and reimbursement. Therefore, it is imperative for regulatory professionals to be aware of existing requirements and new developments in the global market. As a participant you will learn how to ask the right questions and adapt the course concepts to your own organization. This course provides a basic description of global regulatory strategy for medical devices and explains the relationships between regulatory strategy and product development.

SIGNUP NOW

Pricing Member: $465 Nonmember: $640

Medical Devices: Advertising and Promotion in the US

3 RAC Credits

Advertising and promotion are important tools used by medical device companies to educate consumers and healthcare professionals, and increase awareness about their products. This course provides information on the US agencies that regulate medical devices and their enforcement tools, as well as strategies to avoid enforcement actions. Included are guidelines on the information needed for a regulatory review of medical device advertising, methods used to identify claims in promotional materials and how to evaluate evidence to substantiate various types of claims. A review of current promotional issues and enforcement trends also is included.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Medical Devices: Canadian Regulations

3 RAC Credits

This course will provide a basic understanding of medical device regulations in Canada. It will address a wide range of compliance requirements, from the regulatory framework provided by Health Canada and the steps to submit an investigational testing application or a medical device licence application to postmarket activities. You will learn the classification rules applied to devices, selection of the appropriate licence type, submission requirements, quality systems and postmarket requirements.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Medical Devices: China, Japan, Singapore and South Korea Regulatory Overview

4 RAC Credits

Navigating global regulatory markets in Asia can be a challenge, particularly when each country has unique regulations and requirements. Every country has its own body or system of legal requirements for bringing medical devices to market. Therefore, understanding the laws and regulations of the various Asian nations is the key to successful registration of products. This course examines and introduces medical device regulations and registration requirements in China, Japan, Singapore and South Korea. You will learn how to obtain and maintain product approvals, and receive the most up-to-date information about premarket and postmarket regulations.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW

Medical Devices: Compliance and Audits

5 RAC Credits

Auditing is a requirement in the world of medical devices. There are many types of audits, including, but not limited to, first-party, internal, second-party, supplier, external and agency audits. Regardless of the audit's nature and scope, the purpose is basically the same—to assess compliance with the Quality Management System (QMS) requirements. Typical audit outcomes require manufacturers to take some sort of action to come into compliance with standards or regulations and make improvements to quality management systems. Regardless of the nature and scope of an audit, any finding should be addressed with corrective and preventive actions (CAPAs) to help drive compliance to standards and continuous improvement(s). Audits often identify areas that need improvement and offer valuable insight into the proper functioning of a compliant QMS.

Pricing Member: $545 Nonmember: $745

SIGNUP NOW

Medical Devices: Corrections, Removals and Directed Recalls

6 RAC Credits

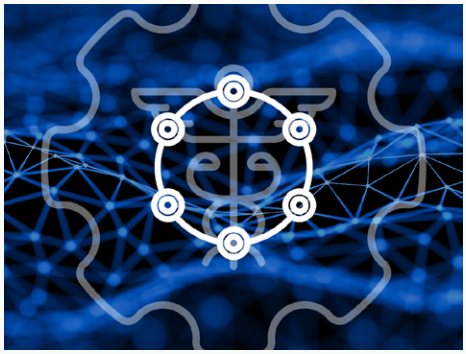
Medical device recalls are disruptive to medical device manufacturers and distributors, and most importantly, the end users of these devices. Balancing the needs of the users along with the various regulatory requirements creates challenges for those responsible for deciding on and executing recalls. A medical device recall does not always mean that users must stop using the product or return it to the company. It sometimes means that the medical device needs to be checked, adjusted, fixed or provided with additional labeling to ensure the safe and effective use of the product. This course examines compliance with the US Food and Drug Administration (FDA), Health Canada, and EU requirements and regulations.

Pricing Member: $570 Nonmember: $790

SIGNUP NOW

Medical Devices: Definition and Lifecycle

1 RAC Credit



Medical devices go through a long and complex process of development before being made available for therapeutic or diagnostic use. This process involves professionals from varied backgrounds such as scientists, clinicians, regulatory specialists, legal experts and business specialists. Whether you are considering a career in medical device development or simply seeking a better understanding of the medical device business, this course acts as a primer—a basic introduction to medical devices and general aspects of product and regulatory lifecycles. It also provides a brief history of medical device regulation and information on basic regulatory principles and concepts as they apply to medical devices.

Pricing Member: $135 Nonmember: $185

SIGNUP NOW

Medical Devices: EU Regulations

5 RAC Credits

This course provides a solid understanding of medical device regulation in the EU. It covers the history of medical device regulation in Europe and follows the regulatory requirements throughout the product lifecycle. You will gain a strong foundation of the key elements of the EU directives and regulations governing medical devices. This course examines how devices are classified and the effect classification has on labeling, registration, marketing and postmarketing requirements.

Pricing Member: $545 Nonmember: $745

SIGNUP NOW

Medical Devices: Postmarket Surveillance

4 RAC Credits

Regulatory authorities allow medical devices to be placed on the market based on data supporting the reasonable assurance that the proposed device is both safe and effective. Retrospective postmarket data derived from devices and conditions may differ from the premarket testing in ways both obvious and subtle. An effective postmarket surveillance program monitors the performance of the full range of actual devices under all actual usage conditions to ensure that the assumptions and estimates applied during the product development process were accurate and remain so throughout the total product lifecycle. This course highlights the requirements and importance of an effective postmarket surveillance program that satisfies the regulatory and quality system requirements in the US, Canada and Europe.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW

Medical Devices: Risk Management

4 RAC Credits

Risk management is a process for identifying, evaluating and mitigating risk. For medical devices, this means product safety, including risks associated with harm to people and damage to property or the environment. Risk management has become an integral part of medical device design and development, production processes and evaluation of field experience. Risk management is applicable to all types of medical devices and evidence of its application is required by most regulatory bodies. This course is not intended for implementing enterprise risk management, but is oriented to product safety risk management, a completely separate process. It is important to remember throughout the course that the focus is on product safety for people (not just the patient), property and the environment.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW

Medical Devices: US Regulations

5 RAC Credits

This course provides a basic overview of US medical device regulation. It covers a wide range of topics and issues, from the history of medical device regulation to the steps required to submit an application to the US Food and Drug Administration (FDA) for approval or clearance, and to adhere to postmarket requirements. This course also discusses device classification as well as how to select the appropriate FDA application for the device and other general device controls, including labeling, establishment registration and device listing, quality system regulation, and adverse event reporting, as well as device corrections and removals reporting.

Pricing Member: $545 Nonmember: $745

SIGNUP NOW

Regulation of Combination Products

3 RAC Credits

Combination products have the potential to offer novel alternatives for patient care because the unique combination of drugs, medical devices and/or biologic products produces therapeutic or diagnostic results not seen when such products are used independently. However, development of combination products creates several challenges in defining specific regulatory requirements because the constituent parts are regulated using different regulatory standards by different US Food and Drug Administration (FDA) centers. This course provides a historical perspective on combination product regulation in the US and examines the current regulations and policies covering the identification, jurisdiction and review of combination products. It covers premarket activities, applicability of Good Manufacturing Practice (GMP) and postmarket requirements, such as adverse event reporting, inspection and enforcement.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Regulation of IVDs in the US and Major Markets Outside the US

5 RAC Credits

In vitro diagnostic devices (IVDs) drive a significant portion of clinical decision making today. IVDs assist in the identification, diagnosis and monitoring of disease or other conditions and aid in the determination of states of health. These products are also intended for use in the collection, preparation and examination of specimens taken from the human body. This course provides a basic overview of IVDs, explains the key regulations and guidelines necessary for effective product development and details the regulatory aspects related to IVDs' performance evaluation and testing, submission requirements for marketing authorization and postmarket considerations, such as adverse event and malfunction reporting.

Pricing Member: $545 Nonmember: $745

SIGNUP NOW

Chemistry, Manufacturing and Controls (CMC)

5 RAC Credits

Information regarding chemistry, manufacturing and controls (CMC) for drugs is an important and detailed section in a dossier to support clinical studies and marketing applications. This information must be updated as more is learned throughout a drug's lifecycle. This course provides an overview of the CMC section of dossiers. It discusses the CMC information necessary to support original investigational applications, identifies CMC changes that require investigational application amendments, and provides an understanding of the CMC information needed to support marketing applications and postapproval submissions, including the use of Drug Master Files (DMFs) and CMC-specific guidances.

Pricing Member: $545 Nonmember: $745

SIGNUP NOW

Global Regulatory Strategy for Pharmaceuticals

4 RAC Credits

Understanding global demands from the perspective of regulators, patients, healthcare providers and payers is a necessity when creating a global regulatory strategy to support the development and marketing of a drug product. The concept of global, simultaneous marketing applications has moved from a wish to an ethical and business reality. This course provides a basic understanding of the challenges and goals confronting a regulatory professional when defining a global regulatory strategy. It provides an examination of the regulatory considerations in the major regions of the world where marketing applications are pursued and compares the application requirements in these regions. It describes regulatory tools and discusses reimbursement considerations and how they may affect strategy development, from both a global and regulatory perspective.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW

Pharmaceuticals: Advertising and Promotional Labeling in the US

4 RAC Credits

This course outlines the regulatory framework for prescription drug and biologic promotional materials by examining US Food and Drug Administration (FDA) regulations and issues involved in producing compliant promotional materials. Practical aspects of the review of promotional materials will be discussed, along with key evidentiary standards required to substantiate claims. Emerging trends in promotion, incldluing use of social media, will also be discussed.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Pharmaceuticals: Canadian Regulations

6 RAC Credits

The Canadian regulatory landscape is subject to many of the same types of pressures and trends as other jurisdictions and is continuously evolving. Both regulators and industry must adapt to new technologies, address consumers' desire for greater involvement and transparency in healthcare decisions, accommodate the interest in harmonization and electronic requirements, and respond to increasing scrutiny of drug safety. This course will introduce you to essential areas of regulatory knowledge for a broad range of pharmaceutical, radiopharmaceutical and biologic products in Canada.

Pricing Member: $570 Nonmember: $790

SIGNUP NOW

Pharmaceuticals: Compliance and Audits

5 RAC Credits

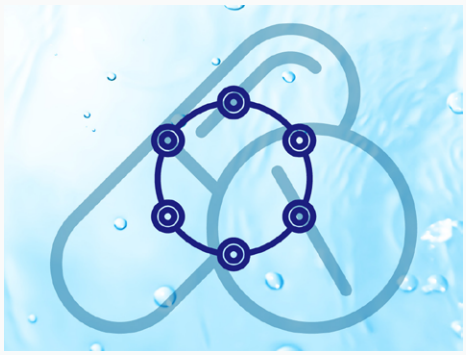
Agencies around the world are tasked with regulating the healthcare product industry within their respective countries. These agencies and organizations require manufacturers to conduct internal audits of their Quality Management Systems (QMS) on a regular basis to ensure compliance with the appropriate standards and regulations. In addition, critical suppliers must be audited to ensure their systems and processes meet the appropriate standards and regulations. This course provides knowledge of fundamental, high-quality auditing practices and skills. It is intended to provide background information on auditing practice and the evolution of the requirements from a regulatory point of view, with an overview of the applicable regulations.

SIGNUP NOW

Pricing Member: $545 Nonmember: $745

Pharmaceuticals: Definition and Lifecycle

1 RAC Credit



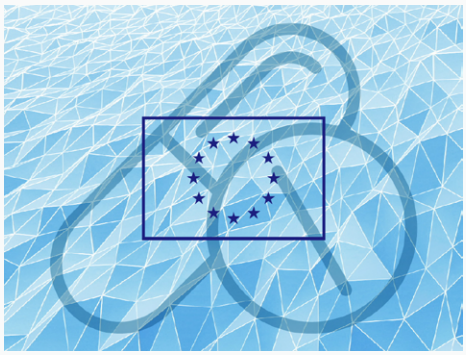
Drugs and biologics go through a long and complex process of development before being made available for the treatment or prevention of diseases. This process involves a wide range of experts, including chemists, pharmacists, medical doctors and clinicians, as well as professionals in areas such as regulatory affairs, legal and marketing. Whether you are considering a career in one of the many functional areas involved in pharmaceutical development, or simply seeking a better understanding of the pharmaceutical business, this course will provide an introduction to the pharmaceutical industry, the drug development process, and regulatory requirements governing the pharmaceutical industry. This course also provides an introduction to the lifecycle of drug products, from discovery to on-market support. You will learn the basic terminology used in the pharmaceutical industry as well as key regulatory principles and processes governing the stages in the development of a pharmaceutical product.

SIGNUP NOW

Pricing Member: $135 Nonmember: $185

Pharmaceuticals: EU Regulations

6 RAC Credits



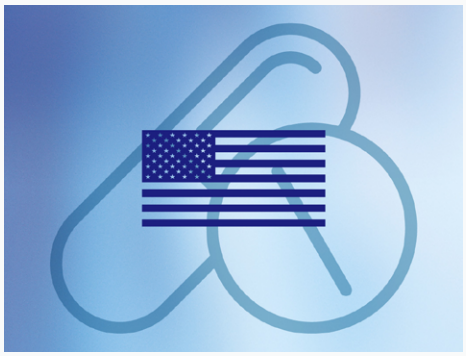
Directives and regulations from the European Union (EU) outline the requirements for the development, manufacture and marketing of medicinal products for human and veterinary use. The European Medicines Agency (EMA) is a decentralized organization responsible for the scientific evaluation of EU Marketing Authorisation Applications for human and veterinary medicines through the centralized procedure. This course provides an overview of the regulations and legislative framework, as well as the EMA entities responsible for medicinal product reviews.

Pricing Member: $570 Nonmember: $790

SIGNUP NOW

Pharmaceuticals: US Regulations

5 RAC Credits



Whether you are new to US pharmaceutical regulations or have been working in this field for some time, having the right tools and abilities to overcome challenges and meet professional expectations can be a never-ending struggle. Get an in-depth understanding of pharmaceuticals in the US, beginning with historical justifications for why some pharmaceutical regulations exist today, and then take the plunge into the current state of US pharmaceuticals. This course covers the requirements to obtain prescription (Rx) and over-the-counter (OTC) drug approvals and other requirements that are in place to ensure compliance with US Food and Drug Administration (FDA) regulations, such as pharmacovigilance reporting, labeling updates and proper product promotion.

Pricing Member: $545 Nonmember: $745

SIGNUP NOW

Pharmacovigilance

4 RAC Credits

Pharmacovigilance (PV)—the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems—is a dynamic and rapidly changing area of the pharmaceutical industry. As a critical component of ensuring consumer safety, the role of pharmacovigilance has been shaped by several historic events, as well as an increased understanding of the factors that affect drug safety. While there are differences in adverse event reporting obligations among agencies worldwide, recent initiatives have harmonized standards and practices within the industry. Despite these efforts at harmonization, there still remain many regional differences. This introductory course provides an overview of pharmacovigilance across a spectrum of topics, presenting both US and global perspectives.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW

Regulation of Biosimilars

2 RAC Credits

Biologic products are proteins that are derived from cells or tissues. Biosimilars are biologic products that have been demonstrated to have sufficient similarities to a previously approved biologic drug, and therefore can gain approval with a reduced clinical and nonclinical data package. Unlike small molecule generics, the complexity of a biologic does not permit the production of an exact copy of the approved product. The first part of the course will examine the sources of complexity in biologics and their production processes. The second part will provide an overview of the current guidance documents available to address the regulatory approval pathways for biosimilars, and compare the quality, nonclinical and clinical aspects of biosimilar development in three major regulatory jurisdictions, the EU, US and Canada.

Pricing Member: $255 Nonmember: $350

SIGNUP NOW

Regulation of Dietary Supplements and NHPs

3 RAC Credits

Dietary supplements are trusted by millions in the US to enhance their diets with a wide variety of nutrients, botanicals and other dietary ingredients. Similarly, many Canadians rely on natural health products (NHPs) like vitamins and minerals, herbal products and homeopathic medicines. As over-the-counter products, they must be safe, and all claims made regarding these products must meet appropriate evidentiary requirements. This course provides an overview of the regulatory requirements for dietary supplements in the US and for NHPs in Canada. Lesson one will consider dietary supplements in the US. Lesson two will consider NHPs in Canada.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Regulation of Generic Drugs in the US

3 RAC Credits

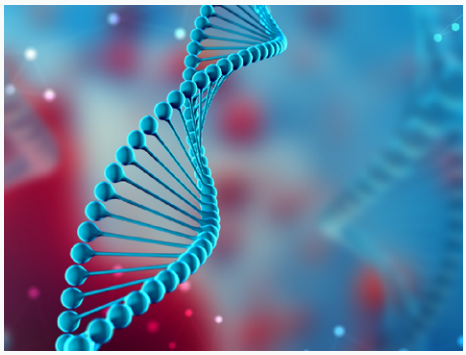
This course provides a basic understanding of the legal and regulatory structure of generic drugs in the US. It covers myriad topics, including the concepts of bioequivalence and therapeutic equivalence, the role and mechanics of patents and nonpatent marketing exclusivity, application components, postapproval maintenance of approval, and generic drug user fee requirements.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Regulation of US and EU Biologics

5 RAC Credits



This course examines the special characteristics of biologic products and the challenges associated with their development in the US and EU. It also introduces various aspects specific to their manufacturing, nonclinical and clinical development, and some global regulatory considerations that add further complexity (e.g., electronic submission). Each lesson includes references to regulatory source documents, as well as to international guidance documents that will provide further knowledge and understanding of biologic products.

Pricing Member: $545 Nonmember: $745

SIGNUP NOW

REMS and RMPs

3 RAC Credits

Over the past decade, risk management has gained increased global visibility due to several high-profile drug safety issues. However, risk management tools have been used since the beginning of modern drug development. More-stringent risk management tools have been implemented since 1989 to maintain product availability and provide beneficial drugs to patients while minimizing risks. Risk management and the associated guidance and regulations have continued to evolve. This course provides an overview of the history of risk management, reviews risk management philosophies and examines regulatory requirements and interactions between industry and regulators in the US, EU and Canada. It discusses methods for conducting successful risk management programs and developing an organization to support lifecycle safety and explores the future of risk management.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Good Clinical Practice (GCP)

2 RAC Credits

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials or studies involving human subjects. This course identifies the regulations on the proper conduct of clinical research with human subjects that were put in place due to ethical issues in human research, explains the role of the informed consent process in protecting human subjects, and describes the roles and responsibilities of the clinical review team. In discussing the factors that led to the development of GCPs, the course will provide an understanding of the overall goals of GCPs.

Pricing Member: $255 Nonmember: $350

SIGNUP NOW

Good Laboratory Practice (GLP)

3 RAC Credits

Good Laboratory Practices (GLPs) are the minimum standards for the proper conduct of safety testing in a nonclinical environment. They include principles for managing and operating laboratory testing facilities involved in the early development of new chemicals and substances that are pharmacologically active, or have an impact on living organisms' physiology or the environment. This course provides an overview of GLP regulations as they are applied and interpreted by the US Food and Drug Administration (FDA), US Environmental Protection Agency (EPA) and the Organization for Economic Cooperation and Development (OECD).

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Good Manufacturing Practice (GMP)

4 RAC Credits

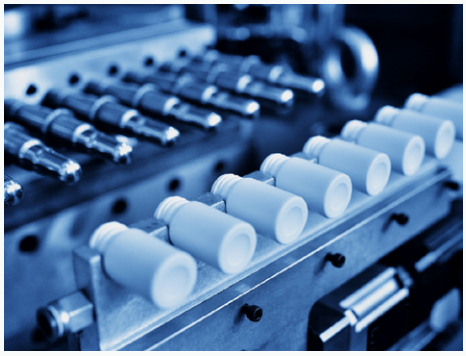
Good Manufacturing Practice (GMP) is a term that is recognized worldwide for the control and management of manufacturing and quality control of active pharmaceutical ingredients, foods, pharmaceutical products and medical devices. GMP regulations and guidance are designed to ensure that products are consistently produced and controlled to quality standards. This course provides a basic understanding of current regulations and their impact on product quality and patient safety. It covers a wide range of issues, including why regulations were created and are enforced worldwide, how pharmaceutical companies ensure compliance with the regulations, reasons for making quality products, US and EU regulations, the consequences for failing to comply and associated regulatory actions.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW

Quality System Regulation (QSR)

5 RAC Credits



This course is organized to align with the organization of the subparts and paragraphs as presented in the Quality Systems Regulation (QSR). It is advisable to have a copy of the QSR in hand to follow along as the course progresses. This course reviews the background and history of the QSR and the essential elements of an acceptable quality system. Other important topics covered include the applicability and/or exemption of QSR paragraphs to certain cases and the minimum regulatory requirements for manufacturing and marketing medical devices in the US.

Pricing Member: $545 Nonmember: $745

SIGNUP NOW

Globalization of Clinical Research Trials and Investigations

5 RAC Credits

This course will cover regulatory requirements for conducting pivotal clinical trials in three countries that are often discussed as critical for global registration—China, India and Japan. The key challenges for the creation of global regulatory and clinical development plans are reviewed, along with a discussion of the essential components required to meet Good Clinical Practice (GCP) and regulatory expectations for the conduct of a global trial.

Pricing Member: $365 Nonmember: $500

SIGNUP NOW

Understanding and Managing the US Clinical Trial Process

5 RAC Credits

Clinical trials are an essential part of the evaluation of safety and efficacy for new drugs, biologics and medical devices, and are critical to obtaining regulatory approval as the final milestone in product development. As a regulatory professional, you have a significant role in clinical trial management, so it is imperative that you understand the clinical research process and basic issues associated with the infrastructure elements required for the successful management of clinical trials. This course provides an overview of the foundation for clinical trials in the US, including their historical evolution, ethical conduct and regulations, and the responsibilities of the parties involved in clinical research. The types and phases of clinical trials and protocol development, as well as key issues related to clinical trial management and monitoring, are reviewed from a regulatory perspective.

Pricing Member: $465 Nonmember: $640

SIGNUP NOW