Take a Course of Action.

RAPS ONLINE UNIVERSITY
Essential knowledge. Well earned.

RAPS.org/OnlineU
When you choose RAPS Online University, you’ll be on track to expand your regulatory knowledge and advance your career. Our comprehensive learning provides an immersive experience that puts you inside real-world scenarios where the decisions you make have an impact on you, your team and your organization.

Learn in a 100% asynchronous, mobile capable environment; meaning you learn when it is most convenient for you. Invest as much time as you need to truly understand the material. Our extensive catalog offers flexibility for you to select a program of study that aligns with your interests and skill level.

Make a game plan today for your career and continuing your regulatory education. Execute it through RAPS Online University.

RAPS ONLINE UNIVERSITY
Essential knowledge. Well earned.

RAPS.org/OnlineU
REGULATORY AFFAIRS CERTIFICATE PROGRAMS

This unique series of courses gives you the knowledge and expertise you need to advance your career in just 6–12 months. Choose from a sector specific certificate or a dual certificate for a comprehensive program. Select courses specific to your educational level. Learn on your own schedule, with access to program experts as needed. Regulatory Affairs certificate programs earn from 10–30 credits, depending on your full certificate course selections.

**Regulatory Affairs Certificate: Medical Devices**

Gain a better understanding of the medical devices industry, enhance your resume or train your whole team. The Medical Devices certificate includes nine interactive courses that cover the essentials of medical device regulation.

Start with the required core courses:
- Ethics
- Global Regulatory Strategy for Medical Devices
- Medical Devices: Definition & Lifecycle
- Role of the Regulatory Professional

Then add five more courses from our extensive list of electives that meet your specific needs and goals.

**Regulatory Affairs Certificate: Pharmaceuticals**

Cost-effective and convenient, the Pharmaceuticals certificate equips you or your organization’s team with the tools and knowledge needed to progress as a regulatory professional and stay ahead of the competition. Whether you’re new to pharmaceuticals, transferring from a related area or just brushing up, gain the skills you need in just nine courses.

Start with the required core courses:
- Ethics
- Global Regulatory Strategy for Pharmaceuticals
- Pharmaceuticals: Definition & Lifecycle
- Role of the Regulatory Professional

Then add five more courses from our extensive list of electives to meet your specific needs and goals.*

**Regulatory Affairs Certificate: Medical Devices and Pharmaceuticals (Dual)**

This comprehensive program combines key components of both the Medical Devices and Pharmaceuticals certificate programs. Six core and eight elective courses capture the essentials of both fields in a single flexible program. Any course in the catalog qualifies as an elective.*

*Elective courses can be selected from our course directory on page 7.
RAC Prep Toolbox for US and EU Exams

Prepare for your RAC with all the right stuff

You’re ready to demonstrate your mastery of regulatory by earning the RAC. Now you need a plan and the right resources to make sure you’re well-prepared on exam day. The Toolbox brings together a full range of valuable resources to help you identify your strengths and gap areas, gives you a sense for the kinds of questions you will be tested on and clarifies how the exam is structured.

Your US Toolbox includes anytime access for an entire year to:
- 25+ hours of in-depth elearning review material, including extensive content from the Fundamentals of US Regulatory Affairs, 10th Edition
- RAC (US) Practice Exam
- Interactive Study Checklist
- US Exam Content Outline
- Hands-on activities to help improve your test taking skills

Your EU Toolbox will include:
- 25+ hours of in-depth elearning review material, including extensive content from the Fundamentals of EU Regulatory Affairs, 8th Edition
- RAC (EU) Practice Exam
- Interactive Study Checklist
- EU Exam Content Outline
- Hands-on activities to help improve your test taking skills

RAPS.org/rac/prepare
RAPS course bundles consist of relational topics that intersect in practice. Bundles offer a quick and cost-effective option to build expertise in a defined area. Bundles are an excellent way to add a focused area of study for a learn today, use tomorrow solution.

**GxP Bundle**

The topics included in this bundle provide the foundation for product quality–critical knowledge for new professionals in regulatory, quality assurance, compliance or related departments such as laboratory management or clinical operations. **9 RAC Credits**

Bundle Courses
- Good Clinical Practice (GCP)
- Good Laboratory Practice (GLP)
- Good Manufacturing Practice (GMP)

**Medical Devices Postapproval Bundle**

Intended for experienced regulatory, quality systems, medical affairs, legal, compliance management and product development engineering personnel, this set of courses provides an examination of the applicable regulations, requirements and health authority reporting criteria across the US, Canada and EU. **14 RAC Credits**

Bundle Courses
- Medical Devices: Corrections, Removals and Directed Recalls
- Medical Devices: Postmarket Surveillance
- Medical Devices: Risk Management

**Regulatory Basics Bundle**

This bundle provides fundamental information on product lifecycles, gives insight into professional roles and responsibilities and discusses regulatory mechanisms, processes and agencies within key markets. Combined, these courses serve as an excellent foundation for regulatory affairs knowledge.

Bundle Courses
- Pharmaceuticals: Definition and Lifecycle
- Medical Devices: Definition and Lifecycle
- Role of the Regulatory Professional
- Introduction to Regulatory Affairs in the EU
- Introduction to Regulatory Affairs in the US and Canada

This bundle is available in three options, based on regions.

<table>
<thead>
<tr>
<th>Complete</th>
<th>US/CAN</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 RAC Credits</td>
<td>6 RAC Credits</td>
<td>5 RAC Credits</td>
</tr>
</tbody>
</table>
Clinical Trial Foundations Bundle

Improve your knowledge concerning the proper conduct of clinical research with human subjects. Learn more about the fundamental requirements for major markets, the role of the informed consent process, types and phases of clinical trials and protocol development, roles and responsibilities of parties involved in clinical research and issues related to trial management and safety monitoring. **10.5 RAC Credits**

**Bundle Courses**
- Good Clinical Practice (GCP)
- Understanding and Managing the US Clinical Trial Process
- Clinical Trials Primer for Regulated Pharmaceuticals (On-demand Webcast)

Regulatory Medical Writing Bundle

Regulatory and medical writing is an integral part of the product development and approval process. It is a skill that must be honed and refined as you gain regulatory knowledge and experience. Learn more about the components of various application types and techniques for improving document quality.

This bundle is offered in five different packages. Review the options below and select which one is right for you.

<table>
<thead>
<tr>
<th></th>
<th>Complete</th>
<th>Package 1</th>
<th>Package 2</th>
<th>Package 3</th>
<th>Package 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introductory Medical Writing</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Intermediate Medical Writing: Investigational Applications</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Intermediate Medical Writing: Pharmaceuticals and Biologics</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Intermediate Medical Writing: Medical Devices</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>RAC Credits</td>
<td>14</td>
<td>12</td>
<td>11</td>
<td>11</td>
<td>8</td>
</tr>
</tbody>
</table>

The flexibility of choosing electives modules to fit my own interests and the basic module helps to strengthen the foundation basics required to perform my job duties. It has been an enriching experience as it broadens my expertise and deepens my knowledge in the regulatory world.

-Audrey Lee, Regulatory Affairs Specialist, Singapore
RAPS Online University provides you with education options to hone your skills in your area of expertise. Individual courses on a variety of regulatory topics, from the basics to product- and region-specific subjects, including:

- regulatory essentials
- clinical
- medical devices
- pharmaceuticals
- quality

There courses were all developed to challenge your knowledge and provide the information you need to do your job better. Any course can be taken alacarte.

MD Denotes Medical Device Certificate Elective
P Denotes Pharmaceutical Elective

**ESSENTIALS**

**Effective Regulatory Communication (MD P)**
Gain a perspective on the critical elements in effective communication from the regulatory professional’s point of view, from influencing teams to managing meetings, as well as everyday activities within and across the company. **3 RAC Credits**

**Ethics (MD P)**
Identify and analyze ethical issues as they relate to complex concepts and theories, including bioethics and legal principles. Ethical issues in areas of product development, compliance and clinical testing are highlighted. **4 RAC Credits**

**FDA Law and Regulation (MD P)**
This course provides insight into FDA regulatory reform and the initiatives FDA is undertaking to create a globally harmonized regulatory scheme for food, drug, device and cosmetic products. **4 RAC Credits**

**Intermediate Medical Writing: Biologics and Pharmaceuticals (P)**
This course focuses on the Common Technical Document (CTD) and includes a breakdown of region-specific considerations for clinical sections of the NDA, BLA and MAA. **3 RAC Credits**

**Intermediate Medical Writing: Investigational Applications (MD P)**
Learn a variety of investigational applications prepared by regulatory and medical writers for both drugs/biologics and medical devices, including IND, CTA, IDE, ITA and IMPD. **6 RAC Credits**

**Intermediate Medical Writing: Medical Devices (MD)**
This course looks at key sections of the Premarket Approval (PMA) and 510(k) Premarket Notification applications for medical devices in the US. **2 RAC Credits**
Introduction to Regulatory Affairs in the EU

Focus on the development of healthcare product regulation in the EU and the responsibilities of agencies involved, processes employed and interactions among agencies. Gain a basic understanding of the regulatory requirements for obtaining marketing approval for healthcare products. **1 RAC Credit**

Introduction to Regulatory Affairs in the US and Canada

This course examines 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—FDA and Health Canada. The course reviews the applicable legislation that drives the regulatory processes. **2 RAC Credits**

Introductory Medical Writing

Take a look at the medical writing profession from a regulatory perspective, including an introduction to the basic skills important for medical writing in regulatory. **3 RAC Credits**

Project Management for Regulatory Professionals

Learn how to effectively establish a regulatory development project plan, including identifying resources and determining the effort and time required to create projects and budget reports. **4 RAC Credits**

Regulatory Due Diligence for Product Development

Gain a basic understanding of the principles and practices of due diligence within the medical product environment. The processes and checklists commonly used in due diligence also are discussed and put into practice using a hypothetical case study. **3 RAC Credits**

The Role of the Regulatory Professional

Discuss the evolution of the regulatory profession and the professional’s roles and responsibilities. The course also outlines critical events and their impact for each product lifecycle stage for drugs, biologics and medical devices. **1 RAC Credit**

Supplier Management

Get a basic understanding of supplier management practices and their impact on product quality and patient safety. Upon completion, you will understand the key risks associated with suppliers and the best way to help your organization as a regulatory professional. **3 RAC Credits**

Supply Chain Controls

Review common supply chain issues, key steps in supply chain control and ways FDA encourages organizations to improve their supply chain controls through guidance documents and regulatory harmonization activities. It is recommended that you have a working knowledge of supplier qualification and management before taking this course. **3 RAC Credits**
MEDICAL DEVICES

Global Regulatory Strategy for Medical Devices MD
Become familiar with guidelines for developing successful global strategies for medical devices, including definitions and classifications worldwide, elements of regulatory strategy, sources of competitive and regulatory intelligence, selection of development and product approval pathways and suggestions for professional development. 4 RAC Credits

Medical Devices: Advertising and Promotions in the US MD
This course provides information on the US agencies that regulate medical devices, their enforcement tools, as well as strategies to avoid enforcement actions. Included are guidelines for a regulatory review of medical device advertising, methods used to identify claims in promotional materials and evaluating evidence to substantiate various types of claims. 3 RAC Credits

Medical Devices: Canadian Regulations MD
This course addresses a wide range of issues, from the regulatory framework provided by Health Canada and the steps to submit an investigational testing application (ITA) or a medical device license application to postmarket activities. 3 RAC Credits

Medical Devices: China, Japan, Singapore and South Korea Regulation Overview MD
Examine medical device regulations and registration in China, South Korea, Japan and Singapore. You will learn how to effectively plan a submission, and actively manage potential registration or compliance issues. 4 RAC Credits

Medical Devices: Compliance and Audits MD
Review the background on auditing practice and the evolution of the requirements for medical devices, from a regulatory point of view, and look at applicable medical device regulations. 5 RAC Credits

Medical Devices: Corrections, Removals and Directed Recalls MD
Examines the definitions of recall classifications and types, and explains them, with emphasis on the importance of the recall strategy, planning, communication, reporting and recordkeeping. 6 RAC Credits

Medical Devices: Definition and Lifecycle MD
This course is 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. 1 RAC Credit

Medical Devices: EU Regulations MD
Gain a strong foundation of the key elements of the EU directives governing medical devices, including the Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC, Medical Devices Directive (MDD) 93/42/EEC and In Vitro Diagnostic Devices Directive (IVDD) 98/79/EC in their latest revision, including the 2007/47/EC amendments to AIMDD and MDD. 5 RAC Credits
Medical Devices: Postmarket Surveillance

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 EU. 4 RAC Credits

Medical Devices: Risk Management

This course is not intended for implementing Enterprise Risk Management, but is oriented to product safety risk management. Throughout the course, the focus is on product safety for people (not just the patient), property and the environment. 4 RAC Credits

Medical Devices: US Regulations

Examine a wide range of medical device regulation issues, from the history of medical device regulation, through the steps required to submit an application to FDA for approval (or clearance) to market a device and address postmarket requirements. 5 RAC Credits

Regulation of Combination Products in the US

See an historic perspective on combination product regulation in the US. Examine the current regulations and policies covering the identification, jurisdiction and review of combination products including, premarket activities, applicability of Good Manufacturing Practices and postmarket requirements, such as adverse event reporting, inspection and enforcement. 3 RAC Credits

Regulation of IVDs for Key International Markets

This course will cover IVD regulatory requirements in three key markets— Europe, Canada and Japan. Topics within each market include IVD risk classifications, manufacturer's premarket responsibilities, labeling requirements and postmarket surveillance requirements. The unique regulatory structure in each market will be examined, with clear directions regarding the process for obtaining market clearance. 4 RAC Credits

Regulation of IVDs in the US

Review in vitro diagnostic medical devices with a focus on FDA's regulatory requirements. This course introduces key regulations and guidelines necessary for effective product development, explains what IVDs are and describes development and testing, getting a product to market, product review and FDA submission requirements. 3 RAC Credits

"I was able to learn many things about the regulated industries that I couldn’t otherwise. The self-paced and interactive courses made the information much more appealing. This was a great learning experience for me.

-Juan Figueroa,
Process Transfer
Senior Manager, USA"
## PHARMACEUTICALS

### Chemistry, Manufacturing and Controls (CMC)
Review the CMC section of dossiers and discuss the CMC information necessary to support investigational applications and information on CMC specific guidances—including Drug Master Files (DMFs). 5 RAC Credits

### Global Regulatory Strategy for Pharmaceuticals
This course provides a look at regulatory considerations in pursuing marketing approval in the major regions of the world and compares the application requirements in these regions. 4 RAC Credits

### Pharmaceuticals: Advertising and Promotional Labeling in the US
This course outlines the regulatory framework for prescription drug and biologic promotional materials by examining FDA regulations and issues involved in producing compliant promotional materials. Practical aspects for the review of promotional materials will be provided, along with key evidentiary standards required to substantiate claims. Emerging trends in promotion (i.e., use of social media) will also be discussed. 3 RAC Credits

### Pharmaceuticals: Canada Regulations
During this course, participants learn about the Canadian regulatory framework and applicable legislation for prescription drugs, nonprescription drugs and natural health products (NHPs). 6 RAC Credits

### Pharmaceuticals: Compliance and Audits
Gain knowledge of fundamental good quality auditing practices and skills. This course is intended to provide background information on auditing practice and the evolution of the requirements from a regulatory point of view, with a review of the applicable regulations. 5 RAC Credits

### Pharmaceuticals: Definition and Lifecycle
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, including early-stage research, nonclinical and clinical trials, manufacturing, marketing and postmarketing. 1 RAC Credit

### Pharmaceuticals: EU Regulations
This course describes the different EU application and registration procedures, followed by an explanation of the regulatory requirements for a product’s lifecycle, including marketing and postmarketing requirements and the switch to over-the-counter status. The enforcement of regulations through inspections and other compliance activities is also addressed. 5 RAC Credits

### Pharmaceuticals: US Regulations
Examine the history of pharmaceuticals in the US, the requirements to obtain prescription and over-the-counter drug approvals, and other requirements that are in place to ensure compliance with FDA regulations, such as pharmacovigilance reporting. 5 RAC Credits
Pharmacovigilance
This introductory course looks at pharmacovigilance across a spectrum of topics, presenting both US and global perspectives. Participants learn the basic concepts, regulatory requirements and recent trends and approaches, to understanding and communicating a safety profile. 4 RAC Credits

Regulation of Biosimilars
The major part of this course compares the current 2013 guidances discussing the quality, nonclinical and clinical aspects of biosimilar development from three major regulatory jurisdictions: the EU, US and Canada. 2 RAC Credits

Regulation of Combination Products in the US
Examine the historic perspective on combination product regulation in the US. This course reviews the current regulations and policies covering the identification, jurisdiction and review of combination products. It also covers premarket activities, applicability of Good Manufacturing Practices and postmarket requirements, such as adverse event reporting, inspection and enforcement. 3 RAC Credits

Regulation of Dietary Supplements and NHPs
This course provides an explanation of the regulatory requirements for dietary supplements in the US and natural health products (NHPs) in Canada. 3 RAC Credits

Regulation of Generic Drugs in the US
Cover a broad range of topics, including the concepts of bioequivalence and therapeutic equivalence, the role and mechanics of patents and nonpatent marketing exclusivity, application components, postapproval maintenance and the new generic drug user fee requirements. 3 RAC Credits

Regulation of US and EU Biologics
This course introduces various aspects specific to biologics manufacturing, nonclinical and clinical development and some global regulatory considerations that add further complexity (e.g., e-Submission). 5 RAC Credits

Risk Evaluation and Mitigation Strategies (REMS) and Risk Management Plans (RMPs)
This course looks at 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. 3 RAC Credits
QUALITY

**Good Laboratory Practice (GLP)**
This course outlines the role of regulatory bodies involved in creating and improving GLPs with the goal of achieving human safety. It also provides an understanding of how GLPs fit into a quality system, what types of studies are covered and how GLPs in the US and international market align. **3 RAC Credits**

**Good Manufacturing Practice (GMP)**
Review 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 with any regulations and associated regulatory actions. **4 RAC Credits**

**Quality System Regulation (QSR)**
This course is designed to align with the organization of the subparts and paragraphs as presented in the Quality System Regulation (QSR). You’ll take a look at the background and history of the QSR, essential elements of an acceptable quality system, applicability and/or exemption of QSR paragraphs to certain cases and the minimum regulatory requirements for manufacturing and marketing medical devices in the US. **5 RAC Credits**
CLINICAL

Globalization of Clinical Research Trials and Investigations

During this course you will be introduced to the historical background and current regulatory requirements for conducting pivotal clinical trials in three countries that are often discussed as critical for global registration—China, India and Japan. 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. The logistics that are central to the conduct of multinational trials will also be discussed. 3 RAC Credits

Good Clinical Practice (GCP)

During this course, you learn what led to the need for GCPs and gain an understanding of the overall goals of GCPs. Because GCPs are international guidelines, the cooperation and collaboration between FDA and other regulatory agencies also are explored. 2 RAC Credits

Understanding and Managing the US Clinical Trial Process

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. 4 RAC Credits
Is your regulatory team plugged in?

When you tap into RAPS resources, you get the tools to empower your team to drive toward regulatory excellence. Our three-tiered approach enhances your team development with online learning, onsite training and the advantages of Enterprise membership.

Train together. Grow together. Strengthen your regulatory connection with RAPS. For more information, email inquiry@raps.org.

ONLINE LEARNING • ONSITE TRAINING • ENTERPRISE MEMBERSHIP
Regulatory Expertise On-Demand.

Convenient, cost-effective regulatory knowledge and information is waiting for you with RAPS’ extensive on-demand webcasts, presented by industry experts. Expand your knowledge on critical regulatory areas or brush up on the latest hot topics.

Trending now in on-demand releases:
• Understand the New EU Medical Device/IVD Regulations
• Argumentation & Persuasion for Regulatory Professionals
• Writing Effective Test Reports and Persuasive Test Summaries

learningportal.raps.org/webcasts