RAPS ONLINE UNIVERSITY

Practical education and training for business success.

For regulatory professionals, there is only one name to know and trust for online education and training–RAPS Online University.

RAPS ONLINE UNIVERSITY
Essential knowledge. Well earned.

RAPS Online University was developed to deliver comprehensive learning to busy regulatory professionals like you. The immersive format puts you inside real-world scenarios that build your knowledge and establish best practices for better decision making.

Top 3 Reasons to Choose e-Learning with RAPS Online University

- Unique regulatory-focused education that serves as a cost-effective alternative to traditional, in-person training
- 24/7 access to programs and courses, available from your laptop, iPad or Android
- Relevant and timely course curricula continually adapted to address today's regulatory requirements

94% of customers surveyed would recommend RAPS Online University courses and certificate programs to a colleague.

REGULATORY AFFAIRS CERTIFICATE PROGRAMS

This unique series of courses gives you the knowledge and expertise you need to advance your career. Build your customizable curricula of online courses around medical devices, pharmaceuticals or both.

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.

Member: $2,100
Enterprise Member: $1,890
List price: $2,625

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.

Member: $2,100
Enterprise Member: $1,890
List price: $2,625

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.

Member: $3,300
Enterprise Member: $2,970
List price: $4,125

GROUP RATES

Email **jharoon@raps.org** and let us help you create a package that meets the training needs of your team or organization.

CERTIFICATES AND CERTIFICATIONS

Certificate program. Certification program. The names sound similar, but the features of these programs and the benefits they provide are quite different. Understanding the differences between certificate and certification programs, such as the RAPS' Regulatory Affairs Certification (RAC), will help you make an informed decision about which program will best meet your professional development needs.

Certificate

- Results from an educational process
- For both newcomers and experienced professionals alike
- Awarded by educational programs or institutions
- Indicates completion of a course or series of courses with a specific focus
- Demonstrates knowledge of course content at the end of a set time period

Certification

- Results from an assessment process
- Typically requires some amount of professional experience
- Awarded by a third-party, standard-setting organization
- Indicates mastery/competency as measured against a set of standards, usually by application and/or exam
- Standards set through an industry-wide process
- Typically results in a designation to use after one's name, e.g., RAC
- Has ongoing requirements in order to maintain; holder must demonstrate s/he continues to meet requirements

> 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 BUNDLES

RAPS course bundles consist of relational topics that intersect in practice. These important and relevant compilations deliver reliable and focused content, at an affordable rate.

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.

Bundle Courses

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

Member: $795
List price: $1,115

Medical Devices Postapproval Bundle

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

Bundle Courses

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

Member: $1,120
List price: $1,560

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.

Complete	US/CAN	EU
Member: $500	**Member:** $400	**Member**: $320
List price: $700	**List price:** $560	**List price:** $440

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.

Bundle Courses

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

Member: $924
List Price: $1,296

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.

	Complete	Package 1	Package 2	Package 3	Package 4
Introductory Medical Writing	●	●	●		●
Intermediate Medical Writing: Investigational Applications	●	●	●	●	
Intermediate Medical Writing: Pharmaceuticals and Biologics	●	●		●	●
Intermediate Medical Writing: Medical Devices	●		●	●	●
Member Price	$1,164	$976	$896	$896	$724
List Price	$1,632	$1,368	$1,256	$1,256	$1,016

COMPLETE COURSE DIRECTORY

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 and quality were all developed to challenge your knowledge and provide the information you need to do your job better.

MD Purchase individually or as part of the Regulatory Affairs Certificate: Medical Devices
P Purchase individually or as part of the Regulatory Affairs Certificate: Pharmaceuticals

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.

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.

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.

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.

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.

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.

Introduction to Regulatory Affairs in the EU MD P

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.

Introduction to Regulatory Affairs in the US and Canada MD P

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.

Introductory Medical Writing MD P

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.

Project Management for Regulatory Professionals MD P

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.

Regulatory Due Diligence for Product Development MD P

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.

The Role of the Regulatory Professional MD P

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.

Supplier Management MD P

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.

Supply Chain Controls MD P

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.

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.

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.

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.

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.

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.

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.

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.

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*.

Medical Devices: Postmarket Surveillance MD

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.

Medical Devices: Risk Management MD

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.

Medical Devices: US Regulations MD

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.

Regulation of Combination Products in the US MD

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.

Regulation of IVDs for Key International Markets MD

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.

Regulation of IVDs in the US MD

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.

> 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) P

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).

Global Regulatory Strategy for Pharmaceuticals P

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.

Pharmaceuticals: Advertising and Promotional Labeling in the US P

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.

Pharmaceuticals: Canada Regulations P

During this course, participants learn about the Canadian regulatory framework and applicable legislation for prescription drugs, nonprescription drugs and natural health products (NHPs).

Pharmaceuticals: Compliance and Audits P

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.

Pharmaceuticals: Definition and Lifecycle P

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.

Pharmaceuticals: EU Regulations P

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.

Pharmaceuticals: US Regulations P

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.

Pharmacovigilance P

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.

Regulation of Biosimilars P

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.

Regulation of Combination Products in the US MD P

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.

Regulation of Dietary Supplements and NHPs P

This course provides an explanation of the regulatory requirements for dietary supplements in the US and natural health products (NHPs) in Canada.

Regulation of Generic Drugs in the US P

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.

Regulation of US and EU Biologics P

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).

Risk Evaluation and Mitigation Strategies (REMS) and Risk Management Plans (RMPs) P

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.

QUALITY

Good Laboratory Practice (GLP) MD P

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.

Good Manufacturing Practice (GMP) P

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.

Quality System Regulation (QSR) MD

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.

CLINICAL

Globalization of Clinical Research Trials and Investigations MD P

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.

Good Clinical Practice (GCP) MD P

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.

Understanding and Managing the US Clinical Trial Process MD P

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.

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- FDA Hot Topics: Update on Medical Device Guidances **VIRTUAL PROGRAM**

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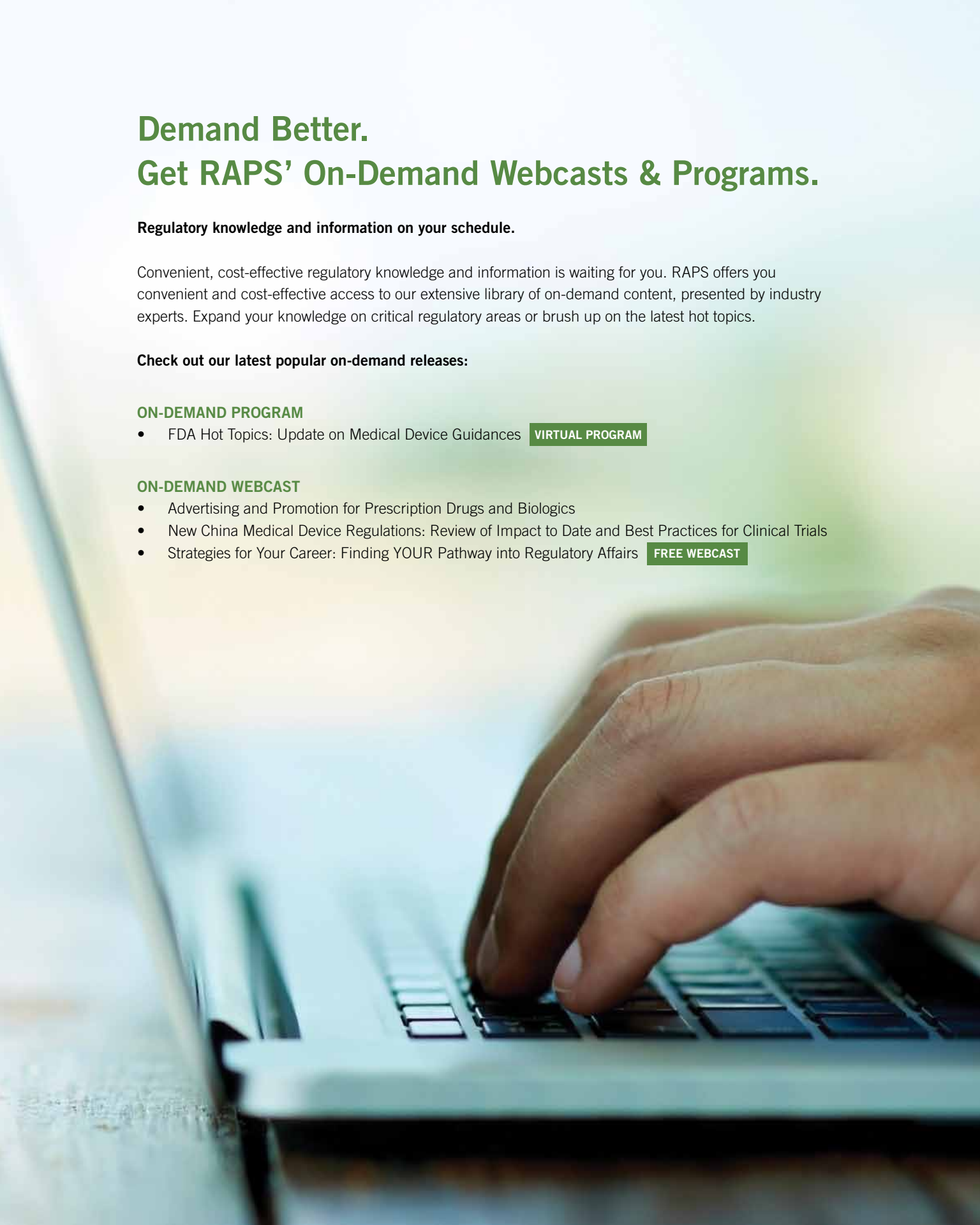
- Advertising and Promotion for Prescription Drugs and Biologics
- New China Medical Device Regulations: Review of Impact to Date and Best Practices for Clinical Trials
- Strategies for Your Career: Finding YOUR Pathway into Regulatory Affairs **FREE WEBCAST**



Corporate Solutions

Give your organization access to global regulatory education and information developed by leading regulatory experts.

RAPS offers corporate/group rates for:

- RAPS Online University courses
- Regulatory Affairs Certificates

Advantages & Benefits

- Subscription options for small teams or enterprise-wide
- SCORM compliant (online courses)
- Course integration with corporate LMS (conditions apply)

Need More Information?

For more information or to speak with a RAPS representative about your organization's needs, contact our Business Development Team at +1 301 770 2920, ext. 228 or visit **RAPS.org/smartorgs**

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Driving Regulatory Excellence™

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Essential knowledge. Well earned.