



## **2023 SDRAN RAC Preparatory Sessions FAQs**

### **What is RAPS?**

The [Regulatory Affairs Professionals Society \(RAPS\)](#) is a global membership organization of regulatory professionals in the rapidly growing medical device, pharmaceutical, and biotechnology sectors. RAPS launched the Regulatory Affairs Certification (RAC) program in 1990, and this program is guided by the Regulatory Affairs Certification Board (RACB). The RAC certification is granted by RAPS and RACB.

### **What is RAC?**

The RAC is the only certification offered specifically for regulatory professionals in the healthcare product sector. The RAC credential is a professional distinction that denotes commitment to excellence, pursuit of knowledge, and career advancement. RAC-credentialed professionals are among the current and rising leaders in the regulatory profession. Two different RAC certifications are available:

- RAC (Devices): the exam will test knowledge of the full product development and lifecycle requirements for medical devices and IVDs under US and European regulations and guidances, as well as globally applicable regulatory practices.
- RAC (Drugs): the exam will cover the equivalent scope for pharmaceutical, medicinal and related products, APIs, biologics, and biotechnology products

### **Note(s):**

- *Canadian regulations are not currently part of the scope of either RAC exam.*
- To be eligible for the RAC exam, at a minimum you must hold a bachelor degree, have at least 1 to 3 years of regulatory-related experience (depending on your highest degree obtained). Regulatory-related experience may include quality assurance, quality control, clinical research related to the approval of health products, or health product project management. Click [here](#) for detailed information regarding the application for the RAC examination, and to read the RAC Policies and Procedures, and Candidate Guide.

### **What is SDRAN?**

The [San Diego Regulatory Affairs Network \(SDRAN\)](#) is a nonprofit organization dedicated to educating and supporting its members through various educational and professional development programs. SDRAN offers the RAC Devices and Drugs Preparatory Sessions program each spring/summer for those individuals interested in the RAC examination, or in the regulations of healthcare products.

### **Why should I participate in the RAC Preparatory Sessions promoted by SDRAN? How would it benefit me?**

As stated in the RAPS website, "RAC is the only globally recognized certification in the regulatory profession." Obtaining such a certificate can facilitate your career growth in the regulatory affairs field. Click [here](#) for additional information on the benefits of RAC.

In addition to helping you prepare for the RAC certification exam, the SDRAN RAC Preparatory Sessions review laws, regulations, guidelines, and regulatory policies that apply to regulated pharmaceuticals, biologics, and/or medical devices. By the end of the Sessions, you will have a basic understanding of the responsibilities of a regulatory professional that will help you draft a targeted study plan in preparation for the RAC examination. Through the SDRAN RAC Preparatory Sessions program, you can enrich your

professional network and form study groups with peers who share similar interests in taking the RAC exam.

### **What will enrollment in the SDRAN RAC Preparatory Sessions do and not do?**

The materials offered through the SDRAN RAC Preparatory Sessions are an overview from which participants can develop study plans to address their personal areas that need further study. Participants cannot rely on attending the SDRAN RAC Preparatory Sessions alone to prepare them for the RAC exam.

### **Are the SDRAN RAC Preparatory Sessions only for those interested in taking the RAC examination?**

No. A significant number of individuals participate in the SDRAN RAC Preparatory Sessions to strengthen and freshen up their regulatory knowledge. Also, participating in the class can count toward RAC recertification credits.

### **I am already US, EU, or CAN RAC certified; will I get recertification credit for attending Drugs or Devices classes?**

According to RAPS, any regulatory related activity can be submitted for RAC recertification. For additional information on Regulatory Affairs recertification, please see the [Recertification Guide](#).

### **Who is eligible to register for the SDRAN RAC Preparatory Sessions?**

The SDRAN RAC Preparatory Sessions are open to SDRAN members only. You must become a SDRAN member before registering for the SDRAN RAC Preparatory Sessions.

### **Do I have to become a RAPS member to participate in the SDRAN RAC Preparatory Sessions or to shop at the RAPS Store?**

To participate in the SDRAN RAC Preparatory Sessions, you are required to join SDRAN, but not RAPS. By signing up for the SDRAN RAC Preparatory Sessions, you will be eligible to receive a discount off of currently available RAPS drug or device Fundamentals books.

- Fundamentals of Medical Device Regulation (Fifth Edition), Fundamentals of Pharmaceutical and Biologics Regulations: A Global Perspective, RAPS practice exams
- RAPS members and non-members are eligible to receive the following discounts when registered in the SDRAN RAC Preparatory Sessions: 10% discount hardcover textbook, 30% discount e-book and 5% discount practice exams.
- For current pricing information, please visit [RAPS](#).

### **How do I register for the SDRAN RAC Preparatory Sessions?**

SDRAN will email an announcement to all SDRAN members and post an announcement on the [SDRAN website](#) and LinkedIn when registration opens. SDRAN members can register for the SDRAN RAC Preparatory Sessions online through the SDRAN website or through the signup link in the email announcement. **Registration for the SDRAN RAC Devices and Drugs Preparatory Sessions are separate,** and are available in the Education Programs section of the SDRAN website under 2023 RAC Preparatory Sessions Announcement & Registration. **Space is NOT limited since we are using Zoom, but registrations will not be processed after the registration close date.** Please visit [SDRAN](#) for more details and to register.

**Registration is open August 1-28, 2023. Session access starts September 1, 2023 and ends December 29, 2023.**

*OCRA members are also eligible to register for these sessions at the SDRAN member rate. Please contact the [VP of Education](#) to access registration.*

### **Where and when will the SDRAN RAC Preparatory Sessions be held?**

The SDRAN RAC Devices and Drugs Preparatory Sessions will be held as pre-recorded sessions via Zoom. Zoom connection instructions will be provided along with the class schedule and Google drive link to lecture slides after your registration for the study sessions is confirmed.

### **What is the cancellation/refund policy for the SDRAN RAC Preparatory Session registration?**

**REGISTRATION IS NON-REFUNDABLE;** You will not be able to cancel the registration once you have registered. SDRAN reserves the right to cancel the classes should we not meet a quorum of registrants (refunds will be sent if the classes are canceled by SDRAN).

### **What are the reference materials that I will use for the SDRAN RAC Preparatory Sessions and what should I prepare before attending the class?**

The recommended reference for the RAC Devices Preparatory Sessions is the RAPS *Fundamentals of Medical Device Regulations, Fifth Edition*; and the recommended reference for the RAC Drugs Preparatory Sessions is the RAPS *Fundamentals of Pharmaceutical and Biologics Regulations, Fourth Edition (for 2023)*.

Please note that the drugs textbook has been updated by RAPS mid-2023 and the following can be used as reference *Fundamentals of Pharmaceutical and Biologics Regulations: A Global Perspective (for 2024)*. The current SDRAN sessions are aligned with the Fourth Edition Chapters.

Click [here](#) for RAC preparation resources.

Classes cover topics from selected chapters; *it is highly recommended that students use the books as supporting reference material.* You will also receive a PDF of the instructors' slides for every class.

### **I have the previous edition of the RAPS Fundamentals Book. Can I still use it for the class?**

The older editions of the Fundamentals Books may still be used as the majority of information related to US and EU regulations remains relevant. Investing in the newest edition ensures the most current reference information available.

### **Where do I purchase the RAPS Fundamentals textbooks and RAC Preparation Tools? Can I acquire them through SDRAN?**

These books can be purchased from the [RAPS Marketplace](#). The [RAC preparation tools](#) can be purchased through RAPS.

### **Can I borrow the book “Fundamentals of Medical Device Regulations, Fifth Edition” and/or “Fundamentals of Pharmaceutical and Biologics Regulations, Fourth Edition” from the SDRAN Education Committee?**

SDRAN does not buy or sell these textbooks, nor have available copies for lending. We recommend that you procure your own book(s) and believe these are a valuable professional resource.

### **What is the timeframe for taking the RAC exam after completing the SDRAN RAC Preparatory Sessions?**

RAPS is offering the RAC exams three times in 2023: Spring (March/April), Summer (July/August), and Autumn (October/November/December). For exam schedules and locations, please visit [RAPS](#).

### **How many times can I take the RAC exam?**

The RAC exams can be taken as many times as needed to obtain a passing grade; however, there is a fee for every attempt.

### **What is the “SDRAN RAC Exam Expenses Reimbursement” and how do I apply for the reimbursement?**

SDRAN offers an RAC Exam Expenses Reimbursement to a limited number of 2023 RAC Preparatory Sessions registrants who pass the Summer 2023, Autumn 2023, or Spring 2024 Devices or Drugs RAC

exam. You must be an SDRAN member at the time you submit the Reimbursement Application Form to be eligible to receive the SDRAN RAC Exam Reimbursement. Detailed conditions, eligibility, and application is available on the SDRAN website under [educational programs](#).