



Updated FAQs for RAC Study Groups 2019

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 RAC certification program in 1990, and this program is guided by the Regulatory Affairs Certification Board (RACB). The RAC certification is granted by RAPS and RACB. The RAPS website is www.RAPS.org

What is RAC?

Regulatory Affairs Certification, known as 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. Six different RAC certifications are available:

- RAC (US): knowledge of US regulations
- RAC (EU): knowledge of European Union regulations
- RAC (CAN): knowledge of Canadian regulations
- RAC (Global): knowledge and critical thinking skills related to the international practice of regulatory affairs, with special attention to global standards from ICH, GHTF (through IMDRF), WHO, and ISO
- RAC (Devices): knowledge of Global regulations for Medical Devices.
- RAC (Drugs): knowledge of Global regulations for Medical Pharmaceuticals.

Important Note: The eligibility requirements for the exams changed in early 2014. At a minimum, you must hold a bachelor degree. Additionally, you must have at least 1 to 3 years of regulatory-related experience, depending on your highest degree. Regulatory-related experience may include quality assurance, quality control, clinical research, or health product project management. For detailed information regarding the application for the RAC examination, please read the RAC Policies and Procedures, and the RAC Candidate Guide at:

http://www.raps.org/uploadedFiles/PDF_Assets/RAC_docs/RAC%20Policies%20and%20Procedures.pdf
http://www.raps.org/uploadedFiles/PDF_Assets/RAC_docs/RAC-Candidate%20Guide%20Autumn.pdf

What is SDRAN?

SDRAN, San Diego Regulatory Affairs Network, is a nonprofit organization dedicated to educating and supporting its members through various educational and professional development programs. SDRAN offers the Can, EU, & US RAC Study Group programs each summer for those individuals interested in the RAC examination, or in the regulations of healthcare products. For more information, please go to www.sdran.org

Why should I participate in the RAC Study group 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. For additional information on the benefits of RAC, please go to <http://www.raps.org/rac/earn/>

In addition to helping you prepare for the RAC certification exam, the RAC study group classes review laws, regulations, guidelines, and regulatory policies that apply to any regulated pharmaceuticals, biologics, and medical devices. By the end of the Study Group, 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 RAC study group program, you can enrich your professional network and form study groups with peers who share similar interest in taking the RAC exam.

What the RAC classes will and will not do?

The materials offered through the RAC classes are an overview from which participants can develop a study plan addressing their personal areas that need further study. Participants cannot rely on taking the RAC classes alone to prepare them for the RAC exam.

Is the RAC Study Group only for those interested in taking the RAC examination?

No. As a matter of fact, a significant number of individuals participate in the Study Group solely to strengthen and freshen up their regulatory knowledge. Also, participating in the class can count toward RAC recertification credits.

I am already US RAC certified; will I get recertification credit for attending EU or CAN 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 (PDF) at http://www.raps.org/uploadedFiles/PDF_Assets/RAC_docs/RAC%20Recertification%20Guide.pdf

Who is eligible to register for the RAC study group?

The RAC study group is open to SDRAN members only. You must become a SDRAN member before registering for the RAC study group.

Do I have to become a RAPS member to participate in the SDRAN RAC Study Group or to shop at the RAPS Store?

To participate in the SDRAN RAC Study Group, you are required to join SDRAN but not RAPS. However, a RAPS membership will qualify you for discounts when shopping at the RAPS Store for the RAC exam and reference materials. It is something to consider if you are preparing for the RAC examination.

How do I register for the RAC study group?

SDRAN will send out and also post an announcement when registration is open. SDRAN members can register for the RAC study group online through the SDRAN website or through the email announcement. **EU, US, and CAN study group registrations are separate** and are available in the Education Programs section of the SDRAN website under RAC study group. **Space is NOT limited now that we are using WebEx but registrations will not be processed after the registration close date.** Please visit www.sdran.org

Where and when will the RAC study groups be held?

EU, US and CAN study sessions meet on line with WebEx or by phone from 6:30 to 8:30 PM. The US and EU sessions start in mid-May and end in late July or early August. The CAN session starts in late May and lasts through early August. The schedule is primarily determined on the basis of instructor availability.

Directions will be provided along with the class schedule after your registration for the study group is confirmed.

What is the cancellation/refund policy for the RAC study group registration?

The registration fee is not 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 cancelled by SDRAN).

Do I have to attend the RAC class sections on-site or is remote access available for registered students who cannot come to the on-site class?

Classes are on WebEx only. Classes will not be recorded for students and must be attended during the hours offered.

What are the reference materials that I will use for the RAC study group and what should I prepare before attending the class?

The recommended reference for the US Study Group is *Fundamentals of US Regulatory Affairs, tenth Edition*; the recommended reference for the EU Study Group is *Fundamentals of EU Regulatory Affairs, Eighth Edition*; and the recommended reference for the Canadian Study Group is *Fundamentals of Canadian Regulatory Affairs, Fourth Edition*. Once you enroll in the class, you may purchase the text book or an electronic copy. The electronic copy is stored on an E-cloud by RAPS and may be accessed for up to five years from the date of purchase. You may buy the book for 50% of the market price by being enrolled in our classes. The purchase of the Self-Assessment Practice Exam that helps you experience a real-time exam is also recommended. For the RAC preparation resources, please visit <http://www.raps.org/store/rac-prep/>. Each class covers selected chapters in the Fundamentals book; **it is highly recommended that students complete the reading assignment before each class.** You will also receive a PDF of the instructors' slides in advance for every class.

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

The older edition of the Fundamentals Book may still be used as the majority of the information remains relevant. Instructors typically update their presentations when a new edition comes out or alert the class of potential changes. However, investing in the newest edition will ensure that you have the most current information available.

Where do I purchase the book "Fundamentals of US Regulatory Affairs, 10th Edition," "Fundamentals of EU Regulatory Affairs, 8th Edition," "Fundamentals of Canadian Regulatory Affairs, 4th Edition" and RAC Reference Tools? Can I acquire them through SDRAN?

These books and RAC reference tools can be purchased from the RAPS Store at www.raps.org/publications-amp-resources/raps-store.aspx. SDRAN will issue codes to purchase the materials at 50% once you have enrolled. SDRAN emails handouts of the lectures before every class. SDRAN does not provide or sell any class materials.

When should I purchase the book “*Fundamentals of US Regulatory Affairs, 10th Edition,*” “*Fundamentals of EU Regulatory Affairs, 8th Edition,*” or “*Fundamentals of Canadian Regulatory Affairs, 4th Edition*”?

You should purchase the book from the RAPS Store at your earliest convenience. As mentioned above, students are advised to read the class topic material in the Fundamentals Book before attending each class.

Can I borrow the book “*Fundamentals of US Regulatory Affairs, 10th Edition,*” “*Fundamentals of EU Regulatory Affairs 8th Edition,*” or “*Fundamentals of Canadian Regulatory Affairs, 4th Edition*” from the SDRAN Education Committee?

We recommend that you procure your own book(s). We believe these books are valuable professional resources and should be purchased as an investment in yourself and for your career. Also, it is difficult for the SDRAN Education Committee to act as intermediate agents for book borrowing activities.

What is the timeframe for taking the RAC exam after completing the RAC Study group?

Generally, the RAC exams are offered twice a year during the fall (October/November) and spring (April/May). For exam schedules and locations, please visit <http://www.raps.org/rac/exam-schedules-locations/>

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 Expense Education Award” and how do I apply for the award?

SDRAN offers a 2018 RAC Educational Award to a limited number of 2018 RAC Study Group registrants who pass the Fall 2018 or Spring 2019 EU, US, or CAN RAC exam. You must be a SDRAN member at the time you submit the Reimbursement Application Form to be eligible to receive the Education Award. Detailed award conditions, eligibility, and application information will soon be available under “Education Program” -->RAC study group on the SDRAN website.