



REGULATORY AFFAIRS CERTIFICATION



CANDIDATE GUIDE



REGULATORY AFFAIRS  
PROFESSIONALS SOCIETY

*Making better healthcare products possible<sup>sm</sup>*



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## EXAM OVERVIEW

- 100 multiple-choice questions for the RAC exams.
- Two hours to complete each exam.
- Administered by computer.
- Administered only in English.

## WHAT THE EXAMS ASSESS

The three regional RAC Examinations (US, EU & CAN) are knowledge-based examinations addressing laws, regulations, policies and guidelines affecting regulated health products, including medical devices, pharmaceuticals, biologics and biotechnology in their respective regions. The RAC General Scope (GS) also is a knowledge-based exam. It tests general knowledge of the full product lifecycles for medical devices, IVDs, pharmaceutical and medicinal products and biologics as well as ICH, GHTF, WHO and ISO guidelines and standards. The examinations each consist of 100 items, presented in multiple-choice formats. Each examination is reviewed and revised annually and content is updated for the October/November exam window. Examination content is based on information effective 31 December of the prior year. For example, material included on both the October/November 2009 and the April/May 2010 examinations were based on regulations in effect 31 December 2008.

## RAC EXAM TESTING WINDOWS AND DEADLINES

<b>Testing Window</b>	<b>Registration Deadline</b>	<b>Late Deadline</b>
1 April–31 May 2010	15 February 2010	8 March 2010
1 October–30 November 2010	15 August 2010	8 September 2010

### EXAM FEES

	<b>Registration Deadline</b>	<b>Late Deadline</b>
<b>Application Fees</b>		
RAPS Member	\$325 (US)	\$375 (US)
Nonmember	\$510 (US)*	\$560 (US)*
<b>Reapplication Fees</b>		
RAPS Member	\$225 (US)	\$275 (US)
Nonmember	\$410 (US)*	\$460 (US)*

\*Includes one year of RAPS membership (membership may be waived however fee remains the same)

A cancellation fee of \$100 will be assessed on any cancelled application. No cancellations will be accepted after 8 March for the April/May exam or after 8 September for the October/November exam.

## THE FOUR RAC CREDENTIALS – AN OVERVIEW

	RAC (US)	RAC (EU)	RAC (CAN)	RAC (GS)
Knowledge required and regulatory basis	<ul style="list-style-type: none"> <li>▪ Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceutical, and biologics</li> <li>▪ FDA regulations</li> <li>▪ Critical thinking and analytical skills</li> </ul>	<ul style="list-style-type: none"> <li>▪ Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, medicinal products (e.g., pharmaceuticals, biologics)</li> <li>▪ European regulations and guidances from the European Commission, EMEA, competent authorities</li> <li>▪ Critical thinking and analytical skills</li> </ul>	<ul style="list-style-type: none"> <li>▪ Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceuticals, medicinal products and biologics</li> <li>▪ Health Canada regulations</li> <li>▪ Critical thinking and analytical skills</li> </ul>	<ul style="list-style-type: none"> <li>▪ Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceuticals, medicinal products and biologics</li> <li>▪ ICH, GHTF, WHO and ISO guidelines and standards</li> <li>▪ Critical thinking and analytical skills</li> </ul>
Best suited for	Regulatory professionals submitting to, or involved with, regulatory authorities in the US	Regulatory professionals submitting to, or involved with, regulatory authorities in the European Union	Regulatory professionals submitting to, or involved with, regulatory authorities in Canada	Regulatory professionals without an RAC credential, not currently involved with regulatory authorities in the US, EU or Canada
Eligibility	Baccalaureate degree (or equivalent) or 3–5 years regulatory experience			
The exams	Two hours to complete; 100 multiple-choice questions; administered at locations worldwide			
Application fee (In US\$)	<p><b>RAPS members:</b> \$325; late registration: \$375  <b>Nonmembers*:</b> \$510; late registration: \$560  <i>* Includes one year RAPS membership</i></p> <p><b>Reapplication fee</b>  <i>Candidates who do not pass or are deemed no-shows may take a future exam by completing and submitting a new application, within three years.</i>  <b>RAPS members:</b> \$225; late registration: \$275  <b>Nonmembers*:</b> \$410; late registration: \$460  <i>* Includes one year RAPS membership</i></p>			
Credential maintenance	RAC-credentialed professionals must accumulate 60 recertification credits every three years after initial certification to maintain RAC status.			

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# INTRODUCTION

## About the RAC Credential

Regulatory Affairs Certification, known as the RAC, is the only certification 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. They work in all parts of the world and in many settings, including industry, government and academic organizations. To date, more than 5,000 individuals have earned the RAC.

Four different certifications are available:

- RAC (US): knowledge of US regulations
- RAC (EU): knowledge of European Union regulations
- RAC (CAN): knowledge of Canadian regulations
- RAC General Scope (GS): knowledge and critical thinking skills related to the general scope of practice of regulatory professionals throughout the product lifecycle, with reference to global standards from ICH, GHTF, WHO and ISO.

The RAC credential initially is earned by passing one of the four examinations, US, EU, CAN or GS. Candidates may take multiple RAC examinations. The RAC is maintained through continuing professional development.

## RAC Exam Content

Each of the four RAC examinations are based on extensive study of the scope of practice and specific roles and responsibilities of regulatory professionals with at least three years of regulatory experience. The examinations address all regulated health care products (e.g. pharmaceuticals, medical devices, biologics, etc) and regulatory professional functions throughout the lifecycle of a product. The exams are balanced with respect to product types and general critical thinking skills of regulatory professionals. Generally, the exams are organized by Domains which address strategic planning, interfacing, pre-market and post-market regulatory functions. Detailed outlines of each examination are available in the accompanying examination guides. These guides also provide useful suggestions for study planning and how to access study materials. These guides are available at [RAPS.org/rac](http://RAPS.org/rac).

## RAC Recognition

Candidates who pass the RAC (US), (EU), (CAN) or (GS) examination may use the RAC designation after their name. All RAC credentialed professionals on the RAPS/RAC website at [RAPS.org/rac](http://RAPS.org/rac), and a listing of newly-certified RACs is published annually in an issue of *Regulatory Focus*, the monthly, flagship magazine of RAPS.

## Why Get RAC-Certified?

Certification sets RAC-certified regulatory professionals apart, increases their value to employers and attests to their expertise and credibility. Attaining the RAC is a public recognition of professional achievement—to those both within and outside the profession. The RAC is recognized and appreciated among leaders in industry, government and academia. Certification reflects a personal commitment to career growth and continual continuing learning. The RAC provides a means to measure and validate regulatory knowledge. It also can serve as step toward further career advancement, and in some cases, increased compensation. RAPS research has shown RAC certification correlates to higher compensation for professionals in entry- to mid-level positions and the proportion of RAC-credentialed professionals increases steadily at higher levels.

The RAC Credential:

- Establishes professional standards for the regulatory profession
- Identifies individuals who meet these standards and demonstrate essential regulatory knowledge
- Encourages professional growth and continuing learning, which are critical to the profession and the healthcare product sector

## Maintaining the RAC Credential

Once certified, the RAC designation is maintained through continued learning and involvement in professional activities. It is the responsibility of the RAC-certified individual to recertify on time. RAPS will send reminders via email to those who have maintained current, up-to-date contact information with RAPS. Please see the RAC Recertification Guide for more information.

## Certification Program Administration

The Regulatory Affairs Certification Board (RACB) and its examination committees are responsible for the content, policies, standards and administration of the RAC Program. The RACB and the examination committees for each of the four exams are composed of regulatory professionals who have achieved RAC certification. A professional testing firm is used in the technical areas of occupational research, test construction and validation, statistical analyses, and test administration and scoring. The RAC Program is managed by professional staff working closely with the RACB, examination committees and the testing services contractor. The RAC (US), RAC (EU), RAC (CAN) and RAC (GS) examination committees use job analysis studies of regulatory professionals, published policies and other technical resources to develop examinations that reflect the demands and knowledge requirements of the workplace. Each examination is revised annually and carefully reviewed based on content analyses of the test design, topic/subject mix and accuracy of questions. These procedures assure the quality, reliability and validity of the RAC examinations.

### **Release of Information**

The RAC Program maintains strict procedures for ensuring the confidentiality of candidates' records. Information on prospective candidates is not released to anyone other than the candidates themselves. Candidates' scores are only released to the candidate and are not released by telephone or fax. The RAC Program reserves the right to publish a listing of individuals who successfully earn the RAC designation. However, under no circumstances will information be released on individuals who have not earned the RAC credential.

### **Nondiscrimination**

The RAC Program does not discriminate among candidates on the basis of age, gender, race, religion, national origin, disability, sexual orientation or marital status.

### **Due Process Appeals**

Concerns or complaints about the certification process, an applicant or an RAC designation will be addressed by the RACB. Concerns must be expressed in writing and sent to the RAC Program Office at RAPS. The RACB will review all complaints and will respond directly to the individual. If warranted, the RACB may appoint a special committee to review and/or respond to concerns.

# APPLYING FOR THE EXAM

## Eligibility Requirements

To be eligible for the RAC Examination you must demonstrate one of two basic requirements:

- Bachelor's (Baccalaureate) degree or its equivalent  
or
- at least three years of regulatory experience

Applications from individuals who do not meet these basic requirements will not be accepted.

## RAC Application Deadlines

Testing Window	Application Deadline	Final Application Deadline <sup>1</sup>
1 April–30 May	15 February	8 March
1 October–30 November	15 August	8 September

Additional later registration fees apply

## Applying For The Exam

The RAC exam application is available online at [RAPS.org/rac](https://RAPS.org/rac). Candidates may apply online, and submit registration fees by credit card, or may print a copy of the application form for submission by fax or mailing. It is the responsibility of the candidate to contact RAPS to confirm receipt of applications submitted via fax or mail. No applications will be accepted after the final deadline.

The RAC exam application must be fully completed by the applicant. Applicants must acknowledge that they meet the application and have read the Code of Ethics for Regulatory Professionals.

Applications must be received by the deadlines listed above. . All deadlines are postmark dates. For purposes of clarity, the term “postmark date” includes system date/time stamps for online, email and fax applicants. Applications will not be accepted after 11:59 pm (US Eastern Time) on the late deadline date.

Applicants will receive email or written notification that their application has been accepted/not accepted within 10 business days of receipt of application by the RAC Program office. Questions regarding application receipt should be directed to the RAC Program office.

## Special Accommodations for the Examination

Candidates who require special accommodations to take the exam due to disability, handicap or other conditions must notify the RAC Program Office at the time of application or no later than the late registration deadline. You must submit supporting medical or other appropriate documentation to complete your request.

## Exam Fees & Cancellation/Refund Policy

	First Time Application		Re-Examination	
	Initial Deadline	Late Deadline	Initial Deadline	Late Deadline
<b>RAPS Member</b>	\$325 (US)	\$375 (US)	\$225 (US)	\$275 (US)
<b>Nonmember*</b>	\$510 (US)	\$560 (US)	\$410 (US)	\$460 (US)

\*Includes one year of RAPS membership (membership may be waived however, the fee remains the same)

### Cancellation/Refunds

A cancellation fee of \$100 will be assessed on any cancelled application. No cancellations will be accepted after the late application deadline for the exam cycle (e.g., 8 March or 8 September).

### Payment Methods

Exam fees are due at the time of application submission. Applicants may pay by credit card (VISA, MasterCard or American Express), by check or Money Order. Checks and Money Orders should be made payable to RAPS. Candidates' names must appear on all payments made by money order, certified or cashier's check, personal check or organizational check. If fees for more than one candidate are paid by a single check or money order, a list of all candidates' names and primary contact telephone numbers (including area codes) must be included with the check and the application materials. Checks and money orders received without proper candidate identification may be returned to the sender unprocessed.

### Checking Application Status

Eligible candidates will receive confirmation via email within 10 business days after application receipt by the RAC Program Office. If ineligible, candidates will receive an email notice of ineligibility.

Candidates who have questions about the receipt of their application should contact the RAC Program office directly at [certification@raps.org](mailto:certification@raps.org). It is the responsibility of candidates applying via mail or fax to confirm receipt of their application by RAPS.

### Incomplete Applications

Candidates submitting incomplete applications receive email notification from the RAC Program office detailing the additional information needed to complete the application. To become eligible to take the exam, candidates must submit the required information by the late application deadline and pay a US \$20 resubmission fee. Payment instructions will be provided in the incomplete notification communication. Candidates who do not rectify the application deficiencies by the date indicated on the incomplete letter will be deemed ineligible and issued a refund of their examination fees.

## **Application Refusal**

Applications for the Regulatory Affairs Certification exams may be refused due to one or more of the following:

- Failure to meet eligibility requirements or deadlines, or submit a complete application
- Falsification of application information
- Use of fraud or deception in an attempt to obtain certification and/or knowingly assisting another person in obtaining or attempting to obtain certification by fraud or deception
- Illegal use of the credential certificate or falsification of credentials
- Unauthorized possession or distribution of any official RAC examination materials, including copying or reproduction of any part of the exam
- Exhibiting unethical or inappropriate behavior during prior examinations
- Conviction of a felony or a crime of moral turpitude in a court of law
- Revocation of a professional license
- Debarment under state, federal or territorial laws

There is no appeal process for candidates who do not meet the minimum eligibility requirements.

Candidates who are ineligible because they do not meet the eligibility requirements will be refunded exam fees, less a nonrefundable \$100 (US) application fee.

Applications postmarked after the late deadline will be returned unprocessed.

## **Transferring to Another Testing Cycle**

Candidates may transfer to the testing cycle immediately following the window applied for (i.e., April/May 2010 may transfer to October/November 2010). One transfer is permitted and the request must be received in writing by the final application deadline date. Refunds and transfers are not permitted after the final deadline date.

## **Application Withdrawal**

Candidates must submit written request for withdrawal of their application by the final registration deadline date to receive a refund less a \$100 nonrefundable processing fee.

Candidates who do not submit a written notification of withdrawal by the final registration deadline date will not receive a refund but may submit a new application for a future testing window and pay the reapplication fee.

## EXAMINATION SCHEDULING

Eligible candidates will receive a confirmation of acceptance via email within 10 business days after receipt of a completed application by the RAC Program office.

Candidates should review the information in the confirmation email to ensure accuracy of name and key contact information as this information will be used to access examination scheduling websites and for testing site confirmation. Candidates should immediately notify the RAC Program office to correct any information (+1 301 770 2920, ext. 200 or email [certification@raps.org](mailto:certification@raps.org)).

### Test Site, Date, Time Selection

Eligible candidates will receive instructions via email from the testing service, **CASTLE Worldwide** with a web site link, login ID and password unique to each candidate. This email is sent within seven days after the late application deadline (close of the application window). Candidates must use this site to select the testing center location and to request a test date and time. Scheduling requests must be submitted **at least** 15 days prior to your desired examination date.

Applicants must select a testing site from the list provided. In most cases, applicants will be assigned to the requested site. Applicants will be notified if the requested site is not available and will be advised of the nearest open testing location.

Candidates may submit a request for a testing center in a city not included in the available listing. This request must be made to **CASTLE Worldwide** at the opening of the notification to schedule. It may not be possible to establish a satisfactory testing facility at new locations during an active testing cycle. Further, candidates may be charged additional fees incurred to establish a site. Candidates will be notified in advance of any additional charge for these sites.

### Changing Your Exam Appointment

Applicants must contact **CASTLE Worldwide** to make changes in the date, time or location of a scheduled examination. There is a fee of US \$35 for each change, payable to **CASTLE Worldwide** for changes to location, time or date. Changes may not be made less than five business days before the candidate is scheduled to take the exam. Candidates may only reschedule to another date within the current testing window.

### Emergency Situations

Candidates who experience a documented severe medical emergency or have a death in their immediate family may request to transfer to the next testing window. Appropriate documentation must be received at the RAC Program office within 60 days of the original RAC examination date. Candidates may reschedule the exam once due to emergency situations. A \$79 rescheduling fee applies.

### **No-Show Candidates**

Candidates who fail to schedule an exam appointment within the testing cycle for which they applied, who do not appear for their scheduled exam appointment, who arrive more than 15 minutes late for their appointment, who appear with improper ID or who cancel their appointment later than 12:00 pm (US Eastern Time) five business days before the scheduled exam without a documented personal or medical emergency will be considered no-shows and will forfeit all fees. No-show candidates may submit a new application for a future testing window and pay the reapplication fee.

### **Testing Site Cancellations**

**CASTLE Worldwide** reserves the right to cancel any testing site. In the event of a cancelled site, candidates will be notified by **CASTLE Worldwide**.

## PREPARING FOR THE RAC EXAM

Candidates can access the detailed content outline for the RAC examination at [RAPS.org/rac](https://RAPS.org/rac). These guides provide additional information about the examination content, types of questions and distribution of questions.

For additional information and useful resources to help prepare to take one or more of the RAC exams, visit [RAPS.org/rac](https://RAPS.org/rac) and click on the RAC Exam Preparation section.

## EXAM DAY

Candidates should arrive at the testing location at least 30 minutes before their scheduled appointment and must adhere to the requirements listed below.

### **Proof Of Identity**

All candidates must present proof of identity by providing an unexpired government-issued photo ID with a signature, such as a driver's license which includes a photograph, a military photo ID, a passport or valid national identification card. Credit cards with photos and Social Security cards are not acceptable forms of identification.

Candidates who cannot present an unexpired government-issued photo ID should contact the RAC Program Office at least 10 business days before the exam.

The candidate's name on the identification must match the name appearing on the exam scheduling notification. Candidates with hyphenated last names whose photo IDs show only one of the last names may be admitted if the single name matches part of the hyphenated name and the signature and photograph clearly match. Candidates whose middle names are spelled out on their ID but are listed with an initial on the application may be admitted as long as the initial matches the first letter of the middle name and the signature and photograph match. This also applies to candidates who use their middle name instead of their first name on their application but their ID displays their first, middle and last name.

### **Test Center Rules**

The following rules are enforced at all test centers to ensure a fair and consistent test experience for all test takers:

- Arrive at the test center at least 30 minutes before scheduled reporting time.
- Present an unexpired government-issued ID bearing their photo and signature to be admitted to the test center.
- Bring a copy of the exam appointment confirmation email.
- Admittance to the test center is by appointment only. Candidates must be present at the time and location of their appointment to be admitted.
- No test materials, documents or memoranda of any sort may be taken into or from the test room.
- Smoking is prohibited.
- Candidates may not ask questions about exam content.
- All exams are monitored and may be recorded in both audio and video format.
- No breaks are scheduled during the exam. Candidates who have to leave the testing room to take a break will not be given extra time on the exam and must present ID as they sign out and back into the testing room.

- Food, drinks, purses, briefcases, notebooks, calculators, pagers, cellular telephones, recording devices and photography equipment are not allowed into the testing room.
- It is expressly prohibited to disclose, publish, reproduce or transmit any part of the exam, in any form, by any means, verbal or written, for any purpose, without the express written permission of RAPS. Violation may result in civil or criminal prosecution.
- Religious headwear may be worn into the testing room; however, it may be subject to inspection by a test center administrator before entry into the testing room is permitted.
- RACB reserves the right to cancel any test score believed to be obtained in a questionable manner.

## AFTER THE EXAM

### **Test Scoring, Passing Standards**

RAC examinations are scored by an independent testing agency. RAC examinations are scored after the close of the testing cycle and are not scored at testing center. A statistical report of scoring is reviewed by the testing contractor and the examination committee to assure ongoing quality of the RAC exams.

The pass point of cut score for each RAC examination is based on a criterion-referenced approach, considered by experts to be the best method for use with professional credential testing. Since the certification examinations are revised annually, the content and difficulty levels of the examination may change slightly. Test developers use an equating procedure which equates new versions of the examinations to the initial or anchor version. This method of linear equating ensures that candidates are not rewarded or penalized for taking different versions of the examination.

### **Candidate Notification**

RAC examination results typically are available four weeks after the end of the testing cycle (i.e. 31 May or 30 November). Candidates will receive an email message when RAC examination results are processed and available. Candidates will be notified of any special electronic distribution of examination results and the scheduled date for mailing of reports. Candidates will receive a notice presenting their pass/fail status and a summary report of their performance. Results, including scores are released only to candidates. No results will be reported over the telephone or by fax.

No information is released or accessible on candidates who do not pass the examination except to the candidate.

### **Listing of RAC professionals**

A listing of all RAC credentialed professionals is available on the RAPS and RAC website. Newly credentialed professionals are added after all candidates are notified about their status. A listing is also published in *Focus* magazine. These listings only contain the names of candidates who pass the examination.

### **Reexamination**

Candidates who do not pass the RAC examination are eligible to retake the examination. To apply for reexamination, candidates must submit an application and pay the re-examination fee. The reapplication fee will be extended for three years from the exam cycle in which the candidate does not pass the exam. Candidates who apply after this three year period must pay the full application fee. There is no limit on the number of times a candidate can take an examination.

### **Use of the RAC Credential**

Once candidates pass an RAC examination they are granted the RAC credential. They may use the RAC after their names as a professional credential. The RAC may also be used on resumes, CVs and other professional records. RAC-credentialed professionals may also provide additional information on the specific RAC credential(s) they have received (e.g. US, EU, CAN or GS).

The RAC credential cannot be used by individuals who fail to maintain the required recertification requirements noted below. Please see the RAC Recertification Guide for details.

## MAINTAINING PROFESSIONAL CERTIFICATION

Continual learning, knowledge enhancement and professional development are vital to regulatory professionals. Thus, to maintain the RAC credential, an RAC-certified regulatory professional must accumulate 60 professional credits and submit a recertification report every three years. Credits may be accumulated in many ways, including participation in continuing education and/or self-study courses, speaking on regulatory topics, professional writing and involvement with professional organizations.

RACs who hold more than one of the four designations (US, EU, CAN, GS) only need to recertify once every three years for all certifications, maintaining the recertification date of the first designation earned, with a total of 60 credits.

For detailed information on earning credits, recertification instructions, including fees, and mailing information, the Recertification Guide is available on [RAPS.org](https://RAPS.org) at [RAPS.org/rac](https://RAPS.org/rac) or contact RAPS.

<sup>1</sup> Additional later registration fees apply



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