



Regulatory Affairs Certification: RAC-Drugs

Candidate Guide 2022

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Welcome and Overview

Introduction

Congratulations on your decision to pursue Regulatory Affairs Certification (RAC-Drugs). We commend your commitment to your career and the regulatory profession.

This guide contains information about:

- RAC-Drugs exam eligibility requirements
- Guidelines for submitting an exam application
- Preparing for the examination
- How to schedule your examination
- What to expect at the testing center
- What to expect after the examination

This Candidate Guide pertains to the RAC-Drugs certification only. For information about RAC-Devices certification, see the RAC-Devices Candidate Guide.

Regulatory Affairs Certification (RAC) is the leading credential for regulatory professionals in the healthcare product sector. It is intended for individuals employed in regulatory agencies, industry, consultancies and other settings involved with the regulation of healthcare products. The RAC denotes commitment to excellence, pursuit of knowledge and career advancement. Success on the RAC exams requires knowledge of the appropriate regulations and the ability to think critically about the regulatory issues and challenges that occur throughout the healthcare product lifecycle.

Value of the RAC

The RAC demonstrates to employers, clients and colleagues that a regulatory professional has the essential knowledge, skills, critical thinking abilities and a commitment to advancing professional knowledge and abilities. As the demand for competent regulatory professionals increases globally, RAC-credentialed professionals are well positioned to be effective team members and contributors in every work setting.

Recognition of the RAC continues to grow around the world and RAC-credentialed professionals earn higher salaries than those who do not hold the credential.*

*RAC holders in North America reported earning an average of 9% more than their counterparts who do not hold the credential.**

About Certification

The primary purpose of any professional certification program is to provide an independent assessment of the knowledge, skills and/or competencies required for competent performance of a professional role. This assessment is typically accomplished by the successful completion of an examination.¹

RAC-credentialed professionals are among the current and rising leaders in the regulatory profession. To date, more than 15,000 individuals have earned the RAC, some holding multiple credentials.



*Based on data from the RAPS' 2020 Scope of Practice & Compensation Survey of the regulatory profession

¹Defining Features of Quality Certification and Assessment-Based Certificate Programs. (2010) The Institute for Credentialing Excellence.

RAC Examination Overview

Each exam is based on a survey of the scope of practice and specific roles and responsibilities of regulatory professionals in the workplace with at least three years of regulatory experience. **Each exam is reviewed and revised annually, and content is updated in the summer exam cycle. Exam content is based on regulations and guidelines in effect on 31 December of the year prior. So, exams taken in Summer 2022 will be based on regulations 'on the books' on 31 December 2021. Exams taken before summer will be based on regulations on the books as of 31 December 2020.**

Knowledge Required and Regulatory Basis

- Knowledge of the full product development and lifecycle for pharmaceutical, medicinal and related products, APIs, biologics and biotechnology products.
- 30% US FDA requirements
- 30% European regulations and guidance from the European Commission, EMA, and competent authorities
- 30% globally applicable regulatory practices - ICH and WHO guidelines and standards
- Critical thinking and analytical skills

Preparing for the Examination

The RAC exams are challenging, so it is important to develop a study plan. Your plan should be based on your knowledge, experience and preferred approach to learning. Here are some things to consider:

- **Review the exam content outline.** The content outline contains the domains, competency statements and number of questions in each domain.
- **Assess the scope and depth of your knowledge and experience.** Use the content outline as a checklist to evaluate your areas of strength and weakness. This will help focus your study on the areas you need most.
- **Build and implement your plan.** Allow sufficient time to build your knowledge base in areas where you have limited experience and to expand your knowledge in areas more familiar to you. Use reference materials to supplement your knowledge.

Question Types

The exam consist of 100 multiple-choice questions, answered within a two-hour time limit. There are three question formats used in the RAC exams.

- **Recall** questions ask for specific information, typically about regulations and guidance that are important aspects of the regulatory process. These questions may relate to any stage of product development and may relate to regulations for specific product types.
- **Application** questions require relating specific knowledge to a situation that may be encountered in the scope of practice of a regulatory professional.
- **Analysis** questions may be described as a small case or example requiring the candidate to read and assemble information in order to identify and evaluate various solutions.



Preparing for the Exam

Computer-Based Testing and Testing Modality

All RAC examinations are computer-based. Testing can take place at testing centers selected and confirmed by the testing vendor, or online at a suitable location of the candidate's choosing. Candidates **do not** need to choose their preferred testing modality at application. Modality is chosen when scheduling the exam. See the Examination Scheduling section of this Candidate Guide.

Your Journey

Check the RAPS website at RAPS.org/RAC for additional resources that may be helpful to you. Some resources are free of charge, and others are available for purchase. RAPS-produced resources are not required.

PREPARE

APPLY

SCHEDULE

TAKE EXAM

RECERTIFY

Key Exam Facts

- US, EU and global content
- **Each exam is reviewed and revised**
- **Exam content will be updated each summer**
- 100 questions
- 120 minutes
- Exam is computer-based
- Three question formats — recall, application, analysis
- Exam can be taken at testing facility or online



Applying for the Examination

RAC Application Process

You may apply for the [RAC online](#) or submit the printable application form.

Testing Windows and Application Deadlines

Application Deadline	Testing Window
24 Feb 2022	21 Mar – 29 Apr 2022
16 Jun 2022	11 Jul – 19 Aug 2022
06 Oct 2022	31 Oct – 09 Dec 2022

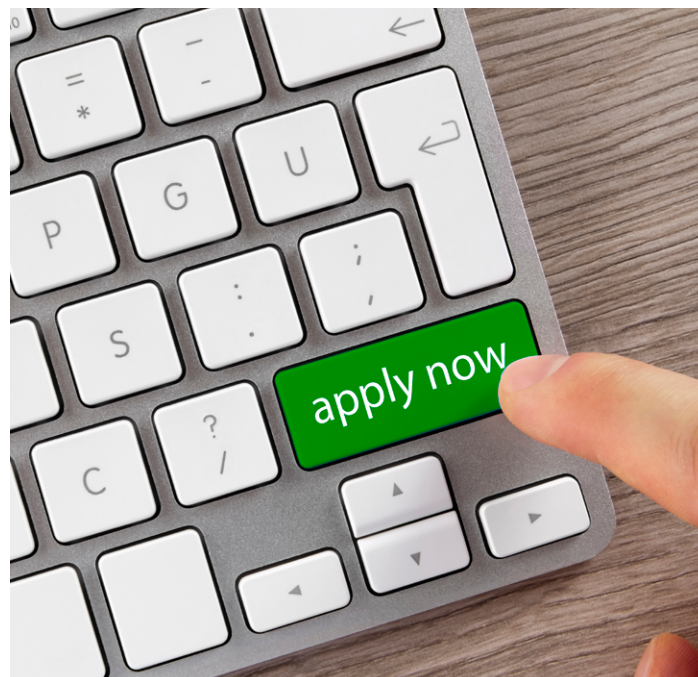
Applications and payment must be received by 11:59 pm (US Eastern Time) on the application deadline dates listed above. Applications received after the deadline will not be processed.

Examination Fees

2022 Pricing	RAPS Member	\$490 (US)
	List	\$615 (US)

The RAPS member rate applies only if you are a member at the time you submit your application. If you apply for RAPS membership prior to submitting an RAC application, please be sure you receive confirmation of your RAPS membership before you submit your RAC application. If you apply for RAPS membership after you submit an RAC application, RAPS will not refund the difference.

Get information about RAPS membership online at www.raps.org/join-raps.



Eligibility Requirements

To be eligible for the RAC examination, you need to meet one of the following educational and professional experience requirement combinations:

- Baccalaureate or equivalent first university degree, and a minimum of three years of regulatory or regulatory-related work experience*
- Master's degree and a minimum of two years of regulatory or regulatory-related work experience*
- Doctorate degree and a minimum of one year of regulatory or regulatory-related work experience*

*Regulatory-related experience may include quality assurance, quality control, clinical research related to the approval of health products or health product project management.

General Application Instructions

Include your name on the application as it appears on your government-issued photo identification (ID). If your name on your application does not match the government ID, you will not be allowed to sit for the exam.

Provide a valid e-mail address that will be maintained throughout your RAC application period. If you choose to provide a work e-mail address, please keep in mind that any change in your employment during your application may mean you no longer have access to that e-mail account. All communications about your RAC examination, including information about scheduling your examination and examination results, are electronic. Please contact the RAC program office at certification@raps.org if there is any change in your email address after you have submitted your application.

Complete the RAC examination application fully. As part of the application process, you must attest to the following:

- I have read, understood and agree to comply with all policies outlined in the RAC Candidate Guide.
- The information in my RAPS account is complete and accurate.
- I meet all eligibility requirements for the RAC exam, and I authorize RAPS to make any inquiries deemed necessary to verify my credentials. I understand that false information may be cause for denial of this application or loss of the RAC credential.
- I allow RAPS to use information from my application and from the examination for the purpose of aggregate statistical analysis, provided that any personal information or identifiers are removed.
- I understand and agree to the policies related to withdrawing from the examination, presented in the Candidate Guide.
- I acknowledge that I have read and understand the tenets outlined in the RAPS Code of Ethics

Please see Appendix D for the Code of Ethics for Regulatory Professionals.

Incomplete applications will delay processing and may cause your application to be rejected if not completed by the application deadline.

Key Application Facts

- Make sure name on application matches the name on your Government-issued ID
- Please use an email that you will have long-term access to; personal emails are often more effective than work emails for this purpose
- Candidates must read the Candidate Guide
- Candidates must read and agree to abide by the RAPS Code of Ethics
- Candidates must review the eligibility rules and make sure they meet them before applying

Submitting Payment

The correct payment must accompany your application. You may submit your application and payment in the following ways:

Credit Card, Check or Money Order

Apply online, by fax or postal mail to:
Regulatory Affairs Professionals Society
Attn: RAC Program Office
5635 Fishers Lane, Suite 400
Rockville, MD 20852, USA

International Wire Transfer

Fax a completed application form and copy of bank wire confirmation to confirm your application to:
RAPS Account: #1000043228997
ABA: #061000104
Swift Code: SNTRUS3A SunTrust Bank
303 Peachtree St. NE Atlanta, GA 30308, USA

Must reference candidate name. All bank charges are the responsibility of the payer. For all wire payments: fax +1-301-770-2924 or email certification@raps.org a completed form and a copy of the bank wire confirmation to confirm your registration.

Application Receipt Confirmation

You will receive an email notification thanking you for your order, which signifies that your application has been received. If there are any questions about your application or your application is selected for audit, you will be contacted by the RAC program office.

Application Audit

RAPS may audit a percentage of applications for completeness and accuracy. If your application is selected for audit, you will receive email notification of the audit, information on the types of documentation that must be submitted and the deadline for submission of requested documentation. If you do not comply with the terms of the audit by the stated deadline, you will not be allowed to test, and your examination fee will be refunded minus a \$100 processing fee.

Incomplete Applications

If your application is incomplete, you will be notified by the RAC program office, and the application deficiencies must be corrected by the application deadline. Failure to submit required information prior to the deadline will lead to rejection of your application and you will be issued a refund of the examination fee, minus a \$100 processing fee.

Application Rejection

Applications for RAC examinations will be rejected for failure to meet eligibility requirements or falsification of application information. Rejected applicants will be refunded the examination fee, minus a \$100 processing fee.

Application Withdrawal/Cancellation and Refunds

An application may only be withdrawn or cancelled before the application deadline. Requests to withdraw or cancel an application will not be accepted after this deadline. To withdraw or cancel an RAC application, you must submit a written request to the RAC program office at certification@raps.org. There is a \$100 processing fee for withdrawn or cancelled applications.

Transferring to Another Testing Cycle

A request to transfer to the next testing cycle may be made without charge before the application deadline by contacting RAPS at certification@raps.org.

Requests to transfer to the next testing cycle after the application deadline but before the end of the testing window will incur a transfer fee of \$250. Transfers will be allowed until the last day of the testing window. After this period, transfers will not be allowed, and applicants will be required to pay a new application fee at full price.

For individuals who require a transfer due to an unavoidable emergency please see the Emergency Situations section of this guide.

Appeals Process

Candidates have the right to appeal any adverse decision made by the RAC program office. An appeal must be submitted in writing not more than 30 days following the date of notification of the adverse decision using the form provided in Appendix E. Appeals should be sent to RAPS at certification@raps.org. All appeals will be acknowledged by RAPS within 10 days in writing. Appeals will be addressed by the Regulatory Affairs Certification Board (RACB). Appeals notifications will be provided within 90 days. Decisions made by the RACB are final.

Nondiscrimination Policy

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

Examination Scheduling

Notice to Schedule Email

You will schedule your examination online directly with the RAC program's contracted testing vendor, Scantron.

You will receive a "Notice to Schedule" email from Scantron 10–14 days prior to the start of the testing cycle, with instructions on how to schedule your examination. Be sure that your email address can accept emails from candidatesupport@scantron.com by adding the email to your safe list.

This email will contain a website link, unique login ID, and password. You will use this link to choose between Live Online Proctoring (LOP)—also referred to as online testing—or taking your exam at a testing center. You will also choose your test date and time.

Scheduling a Live Online Proctored Exam

When choosing the Live Online Proctoring (LOP) option, also called Live Remote Proctoring, you will confirm your demographic information, attest to Scantron's privacy policy, and test your computer for both examination delivery and live proctoring system requirements. Scantron strongly encourages that you perform the system checks during testing appointment scheduling. Candidates whose computers fail the check of system requirements receive feedback on the hardware or software issues. Candidates must correct the issue, update the computer, or obtain another computer to complete the testing appointment.

The same system requirements check is included in the confirmation email, and candidates are reminded to perform the check prior to testing. Following these administrative tasks, the candidate selects "Schedule" to proceed to testing appointment scheduling.

See the Computer Requirements, for full details on specifications needed for LOP testing.

Scheduling Your Exam

To schedule your examination, log into the Scantron scheduling site. At this stage, you will need to decide whether you wish to take the exam at a testing center or if you would prefer to take the exam only through Live Online Proctoring (LOP). Please make certain you review the technological requirements if you wish to take the exam using LOP.

Once you have chosen your exam location/modality, you will then be shown the available dates and times. Once you submit your selection, you will receive a confirmation email.

You should schedule your examination as soon as possible for the best chance of receiving your preferred testing date and location. You must submit your test scheduling request at least two days prior to your preferred testing date. All examinations must be scheduled two days prior to the close of the testing cycle.

Once you have scheduled your examination, you will receive a confirmation email from Scantron. You must bring a copy of the confirmation email with you to the testing center on test day.

Scantron reserves the right to cancel any testing site. In the event of a cancelled site, you will be notified by Scantron and instructed how to reschedule your testing location and appointment without additional fees.

International Testing

Applicants looking to schedule an examination outside of the US or Canada should follow the instructions to schedule through the Scantron scheduling site. However, should international sites or dates be unavailable at your preferred international location, you may click on the "More International Sites" button to see a full list of sites in our network.

Consider locations that you may be traveling to for business or pleasure if you cannot find a location near your home or office. You may then submit three preferred international site/date options. Scantron cannot guarantee availability of any international site/date during the designated testing period. Within five business days, Scantron will issue a confirmation notice for one of the preferred sites/ dates. If none of the preferred site or dates are available, Scantron will offer an alternate site or date for your approval. Upon approval, Scantron will issue a confirmation notice.

Changing Your Examination Appointment After It Has Been Scheduled (Onsite Testing)

If you wish to change the date, time or location of an examination that has already been scheduled, and that you wish to take in the same examination window, you will need to go to the link on your appointment confirmation email.

You may reschedule a testing appointment up to two days in advance of your existing appointment. Reschedule requests are not accepted within two days of your scheduled testing appointment. If you have difficulty rescheduling online, you can contact Scantron by telephone at +1 919 572 6880.

A fee of \$50 for each change is required, payable to Scantron. You may only reschedule to another date within the current testing cycle. If you wish to reschedule to another testing window, please see 'Transferring to Another Testing Cycle'. Scantron email: candidatesupport@scantron.com.

Changing Your Exam Appointment After It Has Been Scheduled (Live Online Proctoring)

If you are testing via Live Online Proctoring (LOP), you may reschedule your online appointment via Scantron's scheduling system within the exam window. To access the LOP system, please click on the scheduling link in the Notice to Schedule email to log into the scheduling system.

The \$50 fee does not apply to LOP candidates rescheduling to another LOP slot or switching from LOP to an in-person test. The \$50 fee does apply to candidates rescheduling from in-person testing to another in-person time or location, or to LOP.

Changing the Examination Type or Method

A candidate requesting to change the type of examination they wish to take (e.g., from Drugs to Devices or vice versa), or changing testing method (e.g., from online testing to onsite testing, or vice versa) must submit the request no later than seven business days prior to the scheduled testing appointment. Changes to the exam type should be directed to the RAC program office at certification@raps.org. The RAC program staff will notify the testing vendor no later than two business days prior to the candidate's scheduled examination appointment. Changes to the testing method should be directed to Scantron at candidatesupport@scantron.com. A fee of \$50 will apply.

Emergency Situations

Under certain circumstances, as outlined, the RAC program may, at its discretion, transfer an applicant's test to the next testing window and waive the transfer fee.

If an applicant cannot take the RAC exam for one of the following reasons the applicant may request to transfer to the next testing cycle:

- Serious illness (either the candidate or an immediate family member)
- Death in the immediate family

- Disabling accident
- Court appearance or jury duty
- Unexpected military deployment
- Mandatory quarantines

The applicant may request to transfer to the next testing cycle. In such circumstances the applicant must contact the RAC program office at certification@raps.org no more than three days after the scheduled examination date (if a date has already been scheduled through the testing vendor).

To apply for a transfer waiver, the appropriate documentation must be submitted to the RAC program office at certification@raps.org. Candidates will not be eligible for a refund following a transfer. Work-related emergencies do not qualify for this exception.

Failure to Schedule An Appointment or Appear for Your Scheduled Exam Appointment

If you do not schedule an exam appointment, or fail to appear for your scheduled exam appointment, you will be considered a 'no-show' and will forfeit all exam fees. The following are situations in which you will be considered a 'no-show':

- Failure to schedule an examination appointment during the testing cycle
- Failure to appear at your scheduled appointment
- Arriving at the testing site more than 15 minutes after your scheduled appointment time
- Failure to have appropriate photo identification at the examination appointment

If you fail to schedule or appear, you may reapply to take an RAC exam in the future and will be required to pay full application fees.

Special Accommodations for the Exam

Candidates who require special accommodations under the Americans with Disabilities Act (ADA) and ADA Amendments Act (ADAAA) should send the completed Special Accommodations Request Form with the Documentation of Disability-Related Needs form (see Appendices B and C) completed by a qualified professional, to the RAC program office at certification@raps.org at the time of application. The request must indicate the nature of the disability and specific testing accommodations requested. Candidates will be notified in writing if their request is approved.

On Examination Day (Onsite Testing)

What to Bring to the Testing Center

You should arrive at the testing center at least 15 minutes before your scheduled appointment for check in. You must bring a copy of the examination appointment confirmation email with you.

To be admitted to the testing center you must bring current, valid government-issued identification (ID). Your identification must include your name (in English characters or translation to compare with your RAC application information), photograph and signature.

You are required to present a valid, government-issued photo ID (e.g., driver's license, passport, state-issued ID card) on exam day. Please ensure that your first and last name on the valid, government-issued photo ID match your first and last name EXACTLY as they appear on the scheduling screens. If your first and last names are incorrect, please contact Scantron immediately at +1 301 770 2920, ext. 200. If you have more than one last name listed on your government-issued ID, the same last names must be reflected on your confirmation email. If you do not provide appropriate and/or matching identification, you will not be permitted to take the examination and will forfeit all examination fees.

The following are acceptable forms of government-issued identification:

- driver's license
- military ID
- passport
- national identification card

Items Prohibited at the Testing Center

Candidates are expressly prohibited from bringing the following items to the test center:

- cameras, cell phones, optical readers or other electronic devices that include the ability to photograph, photocopy or otherwise copy test materials
- notes, books, dictionaries or language dictionaries
- book bags, luggage, purses or handbags
- iPods, mp3 players, tablets, headphones or pagers
- calculators, computers, PDAs or other electronic devices with one or more memories
- personal writing utensils (i.e., pencils, pens and highlighters)
- watches and other jewelry except wedding or engagement rings
- food and beverages
- coats and jackets
- weapons
- hats, hoods or other headwear are not permitted in the examination room unless required for religious purposes; all items are subject to inspection by the proctor if suspicious behavior is detected
- sweaters and sweatshirts without pockets or hoods are permitted
- Google and smart glasses (any glasses with electronics)
- medicine (except as expressly permitted in advance)

You will be provided with:

1. paper and pencil or erasable note boards and markers at the test center
2. abbreviations table

Please note that Scantron testing centers administer examinations for multiple organizations. Individuals in the testing room with you may be taking different examinations and have different rules for their examination including time and what is allowed at their testing station.

Other Considerations

- Smoking is prohibited.
- You may not ask questions about examination content.
- All examinations are monitored and may be recorded in both audio and video format.
- No breaks are scheduled during the examination. If you need to leave the testing room to take a break, you will not be given extra time to finish the examination. You may be required to present your ID when returning to the testing room.

Cancellation Due to Inclement Weather

In the event of dangerous weather, a natural disaster or other emergency, Scantron will post the information on its website. Candidates scheduled at a site operating on a delay will receive an email from Scantron. Should the site be closed entirely, Scantron will contact the candidates to reschedule.

Examination Security and Confidentiality

The RAC examinations are the sole and exclusive property of the RAC program. These materials are confidential and not available for review by any person or organization other than the RACB and the examination committees. Copying, publishing or disclosing examination content in any form is considered a violation of the RAC security and confidentiality policy, and will be subjected to disciplinary action, which may include termination of a testing session, invalidation of test results and/or revocation of an RAC credential.



Termination of Exam Administration/Dismissal from the Testing Center

You are expected to conduct yourself in a professional manner at all times at the testing center. The test center administrator or proctor is authorized to dismiss you from an examination and/or request that a test score be cancelled if you engage in any of the following:

- Using or attempting to use someone else to take the examination
- Using notes or other study materials during the testing process
- Creating a disturbance. Disruptive behavior in any form is not tolerated. The test administrator has sole discretion to determine what constitutes disruptive behavior.
- Communicating in any manner with anyone other than the administrator or proctor during the testing process
- Leaving the testing room without permission
- Tampering with a computer
- Removing or attempting to remove any material from the testing room
- Failing to follow any examination policies or requirement explained in this Candidate Guide

Problems at the Testing Center

The RAC program and Scantron take steps to assure that the RAC examination process is effective. However, irregularities may sometimes occur. If you encounter technical difficulties during the examination, please contact the proctor immediately. If a delay exceeds 30 minutes, you may request to reschedule your examination to another date if you are unable to wait any longer.

On Examination Day (Live Online Proctoring)

To increase flexibility and exam availability for candidates taking the RAC, the RAC program is pleased to offer Live Online Proctoring (LOP) as an additional method of testing. This will allow candidates the possibility of taking the RAC exam from their homes or offices and is in addition to regularly available testing that takes place at our testing centers around the globe.

LOP test administration allows candidates to complete their examinations from their own computers via an internet connection at a time and place of their choosing (during the exam window). Testing sessions are available 24/7/365, based on seating availability. The RAC program's testing vendor, Scantron, uses its proprietary software, Scantron PASS™, to deliver examinations to candidates. Scantron partners with Examity for online, real-time monitoring of testing candidates. The candidate's computer must have webcam capability as well as a microphone and speakers, and the environment should be quiet to avoid distractions and to ensure that the online proctor can hear everything at the candidate's location. There are technical requirements, such as an adequate internet connection, to ensure that the proctor can access the candidate's computer and that the session can proceed without internet disruption. Candidates are informed of the computer specifications in advance of the testing session.

On Exam Day for Candidates Who Choose LOP

On the date and time of the candidate's scheduled testing appointment, the candidate clicks on the link provided in the confirmation notice email, entering their username and password from the Notice to Schedule email to return to the LOP dashboard.

From the dashboard, the candidate selects "Start Exam" to begin the testing appointment.

Please remember: if a candidate's computer fails the check of system requirements, they must correct or update the issue or obtain another computer to complete the testing appointment.



Candidates are required to pass the system requirements check prior to testing.

After the system requirements check, the proctor verifies the identity of the candidate by examining the candidate's government-issued ID. The candidate may communicate with the proctor via chat features available within the LOP launch site.

If directed by the proctor, or in case of technical difficulties, the candidate may contact the proctor by telephone. The proctor has complete access to the candidate's computer to monitor for unauthorized activities, such as accessing other software applications, using multiple monitors, or having someone else take the examination remotely. The proctor can terminate the testing appointment for integrity reasons at any time.

As part of the login process, the candidate shows the proctor a 360-degree view of his or her environment, including the desk, by holding and moving the webcam or laptop with a webcam as directed by the proctor. After the environment check, the proctor enables the monitoring software, which allows the proctor to watch the candidate via the candidate's webcam and record video and audio during the testing appointment.

When the proctor has completed the necessary steps to ensure monitoring, the candidate clicks a link to launch the examination login process.

During the examination login process, the proctor and candidate complete a dual login, in which the candidate verifies their information, completes the candidate attestation statement, and reviews the testing rules and policies. In addition, prior to launching the examination, the candidate can review the online tutorial of Scantron PASS™.

Testing time for candidates begins when the examination is launched. When a candidate completes their examination, they click the “Submit Exam” button and confirm that they are ready to submit the examination. If a candidate does not submit the exam before the conclusion of the two-hour time limit, the exam will be automatically submitted at that time. A thank you message will be presented to candidates after the submission.

Room Environment

- You must be alone in a quiet room.
- Your computer must be in working order, match the provided specifications, and be powered on and connected to a power source.
- Cell phones, headphones and other electronic devices are not permitted.
- Your desk must be clear except for two pieces of scratch paper and a writing implement. You may be asked to show the paper to the proctor and the scratch paper will be destroyed after the exam is completed.
- There are no breaks during the exam, and you are not permitted to leave your seat.
- No talking is permitted except to the proctor.
- No food or drink
- No hats, hoods, or other headgear, other than for religious use
- No coats or jackets

Authentication

- You will need a government-issued photo ID with signature that matches your name as registered.
- Username, password, and exam password from your scheduling confirmation email to start the exam.

What Candidates Will Need to Take an LOP Exam

The candidate's computer must have webcam capability as well as a microphone and speakers, and the environment should be quiet to avoid distractions and to ensure that the online proctor can hear everything at the candidate's location.

You can run a basic test on your system at <https://prod.examity.com/systemcheck/check.aspx>.

Basic List of Candidate Requirements for LOP

Computer Requirements:

- You are required to have a webcam installed on your exam workstation and reliable access to the Internet. An Internet connection disruption will suspend the test session.
- A well-working computer with 1 GB of RAM or higher
- A high-speed Internet connection (5 mbps). Wireless is acceptable; however, a wired connection is preferred.
- A webcam with 640×480 video pixel resolution (a laptop camera is acceptable)
- Working speakers connected to the computer
- Microphone connected to the computer (consider a webcam with a built-in microphone)
- Browser compatibility: **Google Chrome** and **Firefox** are the only internet browsers permitted for use
- You must use a computer with admin access
- You must download GoToMeeting in advance, [click here](#)
- Pop-up blockers must be disabled to connect to the exam
- For information on how to disable pop-up blockers for specific browsers, [click here](#)

*See full specifications section for detailed list of technology requirements. Check your computer configuration before your scheduled examination at <https://prod.examity.com/systemcheck/check.aspx>.



Full Specifications

System requirements to run Scantron PASS™ for LOP test administration:

Hardware:

- 2 GHz or faster 32-bit (x86) or 64-bit (x64) processor
- 2 GB RAM (32-bit) or 2 GB RAM (64-bit)
- 16 GB available disk space (32-bit) or 20 GB (64-bit) – just for the OS, not applications or data files
- Audio output capability
- Webcam and microphone
- Screen resolution:
 - For best experience, use 1920 x 1080 or higher
 - Minimum acceptable is 1024 x 768

Software:

- Minimum Windows 7 or Mac OSX v10.6
- Latest version of Google Chrome or Firefox are the only internet browsers permitted for use.
- You must use a computer with admin access.
- Latest version of Zoom
- Telecommunications:
 - High-speed internet connection (approximately 5 mbps upload and download per candidate)
 - Minimum: ISDN connection
 - Preferred: T-1 connection (or greater)
 - Browser must:
 - accept cookies from Scantron's site
 - allow popup windows
 - support JavaScript and have it enabled
 - Browser must be able to load the following:
 - jQuery, a JavaScript library (ajax.googleapis.com)
 - AJAX Content (ajax.aspnetcdn.com)
 - MathJax (cdn.mathjax.org)
 - CDN (castlecdn.blob.core.windows.net)

LOP Log-In Issues

Log-in issues for online tests occur very rarely, but when they do, they can make for a difficult testing experience. As such, the following policy is in place: If a candidate is unable to begin the exam within 30 minutes of the scheduled exam start time, the candidate shall be provided the opportunity to choose to reschedule their exam to a later date within the exam window if they wish. In such an event, candidates must call Scantron to reschedule, no later than close of business of the

next available business day. If a candidate is able to log into the exam but not able to complete the exam due to technical issues, the candidate will be permitted to re-test during the next testing window.

Should you feel that you cannot meet the technical requirements or that any part of the LOP testing process could cause you to experience difficulties, please consider onsite testing and taking the exam at one of our testing centers.

LOP Privacy Statement

When candidates take the RAC via Live Online Proctoring (LOP), they must be aware of the following: by taking the exam by LOP, the candidate attests that they understand the examination session, including video, is recorded and may be saved for up to one year. The recordings will be deleted no later than one year after the exam date. By agreeing to take the exam via LOP, the candidate agrees to have their examination session recorded and reviewed by the testing agency and testing program owners.

Both before and after the exam, candidates will be asked to open their task manager (PC) or activity monitor (Mac) and ensure that all programs not needed for the exam are shut down. Candidates will also be asked to open and clear their clipboard.



After the Examination



Examination Scoring

RAC examinations are scored by Scantron after the close of the testing cycle. Examinations are not scored at testing centers. A statistical report of scoring is reviewed by a statistician and the examination committee to assure ongoing quality of the examinations.

All scores are reported on a scale of 0 to 99, with 75 being the passing score. The scaled score is neither the number of questions answered correctly, nor the percent of questions answered incorrectly. You cannot look at the scaled score and determine the number of correctly answered questions needed to pass the examination.

Notification of Exam Results

Examination results are typically available six weeks after the close of the testing cycle. You will receive an email notification with your results. Results are released only to candidates. No results will be reported over the telephone or by fax.

RAC Recognition

A list of all active RAC-credentialed professionals is available online at RAPS.org/RAC. Newly credentialed professionals are added after all candidates are notified of their status. If you do not wish to be included in the online listing, please contact the RAC program office.

Use of the RAC Designation

When you pass a RAC examination you may use the RAC designation after your name as a professional credential. You should list your RAC and specific RAC credentials on your resume, curriculum vitae, employment or other professional records. The RAC designation cannot be used by individuals who fail to maintain the RAC credential by meeting recertification requirements.

Retaking the Examination

Candidates who do not pass the RAC examination are eligible to retake the examination in the next window. To apply for re-examination, candidates must submit a new application. Candidates are limited to taking only one exam per window. There is no limit on the number of times a candidate can take an examination across windows. Candidates can retake the exam as soon as the next testing window begins.

Release of Information

The RAC program maintains strict procedures for ensuring the confidentiality of all candidate records. Information about candidates is released only to the candidates themselves. Scores are only released to the candidate and are not released by telephone or fax even to the candidate.

Recertifying

Maintaining Your RAC Credential

Continual learning, knowledge enhancement and professional development are vital to regulatory professionals. Once certified, you maintain your RAC through continued learning and involvement in professional activities. You are required to renew your RAC every three years by earning 36 RAC recertification credits. Credits may be accumulated in many ways, including participation in continuing education, public speaking on regulatory topics, professional writing and involvement with professional organizations.

Individuals who hold more than one RAC designation are only required to submit a single recertification application with a total of 36 credits. The recertification cycle is based on the initial RAC certification and the related recertification cycle. You can find detailed information about maintaining and renewing your RAC in the [RAC Recertification Guide](#).

Contact Information

Regulatory Affairs Professionals Society

Attention: RAC Program Office
5635 Fishers Lane, Suite 400
Rockville, MD 20852
USA

Tel: +1 301 770 2920, ext. 200

Fax: +1 301 770 2924

Email: certification@raps.org

Scantron

6001 Hospitality Court, #100
Morrisville, NC 27560
USA

Tel: +1 919 572 6880

Email: candidatesupport@scantron.com



Appendix A

RAC-Drugs Detailed Examination Content Outline

Each examination is based on a survey of the scope of practice and specific roles and responsibilities of regulatory professionals in the workplace with at least three years of regulatory experience. Each examination is reviewed and revised annually, and content is updated for the October/November exam cycle. Domain weighting percentages approximate and may be +/-2%. Examination content for the RAC (Drugs) exam is based on regulations and guidelines in:

Domain I: Strategic Planning—Exam Weighting approximately 24%

- Task 1:** Evaluate the regulatory environment and provide internal advice throughout the life cycle of the product (e.g., concept, development, manufacturing, marketing) to ensure compliance.
- Task 2:** Perform risk/benefit analysis on product development concept for initial product viability.
- Task 3:** Determine endpoints for safety and efficacy testing at the feasibility phase to determine the ability to comply with regulatory standards.
- Task 4:** Advise research and development programs to ensure regulatory compliance.
- Task 5:** Provide regulatory intelligence to develop local, regional, and global regulatory strategies that include determination of regulatory classification, submission type (e.g., eCTD, electronic, paper) for regulatory applications, due diligence, and internal/external license opportunities.
- Task 6:** Evaluate the regulatory outcomes of initial product concepts and make recommendations for future actions.
- Task 7:** Evaluate and interpret regulatory decisions in a similar product category to assess regulatory implications for approval.
- Task 8:** Identify and engage appropriate regulatory authorities for submission of data concerning the product being developed.
- Task 9:** Assess impact of local, regional, and global requirements and considerations on the regulatory dossiers.
- Task 10:** Consult with multidisciplinary teams to develop indications for use, intended use, and product claims (e.g., target product profile, product requirements).
- Task 11:** Evaluate the regulatory merits of domestic versus regional or global submission strategies (e.g., simultaneous filings, joint reviews, mutual recognition agreements, assessment of similarity or dissimilarity of requirements) to define market feasibility.

Task 12: Anticipate regulatory issues arising from trade-related matters (e.g., applicable treaty law, international conventions, “for export only” status).

Task 13: Develop strategies for regulatory authority interactions (e.g., FDA/CA meetings, correspondence, documenting verbal communication or commitments) to guide product development life cycle management.

Task 14: Ensure regulatory compliance of company standard operating procedures impacting internal stakeholders.

Task 15: Provide internal trainers with information on regulatory requirements to incorporate in ongoing training programs.

Domain II: Pre-marketing—Exam Weighting approximately 37%

Manufacturing Section

Task 1: Determine applicable regulatory requirements for manufacturing and/or development of drug products.

Task 2: Review documentation of raw materials to ensure compliance with regulatory requirements (e.g., API/drug substance, novel excipients, animal-derived materials).

Task 3: Review documentation (e.g., stability data, specifications, investigational labeling) for adequacy to support IND/CTA submission.

Task 4: Ensure regulatory compliance of manufacturing and release of investigational products for clinical use.

Nonclinical Section

Task 5: Determine nonclinical test requirements (e.g., GLP, toxicology studies) and ensure compliance with applicable guidance, standards, and regulations for product-specific requirements.

Task 6: Evaluate adequacy of nonclinical data and risk management activities to support initiation of clinical trials.

Clinical Section

Task 7: Determine requirements for clinical development and ensure compliance with applicable guidance, standards, and regulations for product-specific requirements (e.g., ICH, GCPs, monitoring, auditing, ethics committee, safety reporting, informed consent, financial disclosure).

Task 8: Ensure that reporting procedures are in place to report adverse events that occur during clinical trials/investigations to appropriate regulatory bodies.

Task 9: Generate and ensure regulatory compliance of product labeling.

Task 10: Inform stakeholders of regulatory implications regarding ongoing clinical trials/ investigations (e.g., protocol amendments, ICF amendments).

General Section

Task 11: Advise stakeholders of regulatory requirements for quality, nonclinical, and clinical data to meet applicable regulations.

Task 12: Assess the acceptability and completeness of quality, nonclinical, and clinical documentation for submission filing to comply with applicable regulations (e.g., IND/CTA, NDA/ BLA/MAA submission, manufacturing transfer).

Task 13: Initiate and monitor the process to obtain nonproprietary (e.g., USAN, INN) and proprietary names.

Task 14: Manage outsourcing strategy (e.g., contract research organizations, subcontractors, test facilities, consultants) using appropriate communication tools throughout the product development life cycle.

Task 15: Compile and review regulatory submission packages in accordance with applicable regulations.

Task 16: Prepare or review study data and manufacturing information to ensure compliance with local, regional, national, and international regulatory requirements.

Task 17: Prepare or review study data and manufacturing information to ensure compliance with local, regional, national, and international regulatory requirements.

Task 18: Prepare or review study data and manufacturing information to ensure compliance with local, regional, national, and international regulatory requirements.

Task 19: Prepare or review study data and manufacturing information to ensure compliance with local, regional, national, and international regulatory requirements.

Task 20: Participate in developing a risk management system (e.g., vigilance) to ensure that local, regional, and global regulatory requirements as applicable are met for the development program.

Task 21: Identify, monitor, and submit applicable reports (e.g., serious adverse events) or notifications (e.g., changes in manufacturing) to regulatory authorities to comply with regulations.

Task 22: Participate in audits/inspections by regulatory authorities and contribute to responses to audit findings as required.

Domain III: Post-marketing—Exam Weighting approximately 28%

Task 1: Evaluate advertising and promotional materials for adherence to regulations, guidelines, and standard operating procedures to ensure compliance.

Task 2: Generate and evaluate product labeling (e.g., package insert, instructions for use) for adherence to regulations, guidelines, and standard operating procedures to ensure compliance.

Task 3: Submit notifiable changes and supplemental dossiers and follow up with the appropriate regulatory authorities to achieve compliance.

Task 4: Ensure that appropriate standard operating procedures are in place to manage product-associated events, complaints, adverse drug reports, recalls, market withdrawals, and vigilance reports in accordance with regulatory requirements.

Task 5: Provide regulatory input for risk management strategy to be presented to stakeholders and implement appropriate regulatory steps for selected options (e.g., consumer information, advertising, or labeling changes, warnings or alerts, product changes, recalls, withdrawals).

Task 6: Implement regulatory strategy for handling communication to stakeholders for notifiable product-associated events, complaints, adverse drug reports, and recalls (e.g., dear healthcare provider letters, patient letters, distributor letters, health authorities).

Task 7: Report notifiable manufacturing product-associated events (e.g., failures, recalls, corrective actions resulting from inspections) to regulatory authorities to maintain compliance.

Task 8: Report product safety issues/failures to regulatory authorities to comply with local, regional, and global regulations.

Task 9: Engage regulatory authorities and comply with product post-marketing commitments and requirements to meet conditions of approval.

Task 10: Participate in crisis/issue management team (e.g., product recall, counterfeiting) and assess the regulatory impact and resolution of product-related events.

Task 11: Review regulatory aspects (e.g., quality, product complaints, recalls, vigilance) of contracts for product manufacturing and distribution to ensure compliance.

Task 12: Control access to regulatory documentation to ensure confidentiality and protection of proprietary information.

Task 13: Maintain licenses (e.g., registration and listings, narcotics, controlled substances) and submit renewals as required.

Task 14: File new and amended patent/trademark forms to update information with applicable regulatory authorities to meet regulations.

Task 15: Provide required information (e.g., clinical data) in support of product reimbursement requests.

Task 16: Ensure compliance with regulatory requirements for lot distribution and release.

Task 17: Provide regulatory oversight of quality system compliance (e.g., ISO, GxPs, SOPs).

Task 18: Comply with import and export requirements.

Task 19: Ensure compliance with applicable market controls and requirements (e.g., controlled substances, veterinary use only).

Task 20: Ensure adequacy of product traceability systems.

Domain IV: Interfacing—Exam Weighting approximately 11%

- Task 1:** Advise on regulatory strategy for risk management process to mitigate impact to company.
- Task 2:** Coordinate company presentations and development of briefing documentation for regulatory advisory committee, agency representatives, and other government agencies to facilitate regulatory compliance.
- Task 3:** Provide input on proposed legislation, regulations, guidelines, and/or standards to be followed by industry and regulatory authorities to ensure consistent and clear application of requirements.
- Task 4:** Manage regulatory authority inspections to ensure company personnel are well-prepared and understand inspection processes.
- Task 5:** Evaluate legislation, regulations, guidelines, standards, and related issues to facilitate compliance on regulated products and to support strategic planning.

- Task 6:** Advise stakeholders on the impact of current and proposed legislation, regulations, guidelines, and standards and provide training when necessary to facilitate regulatory compliance.
- Task 7:** Communicate with legal counsel and company officials when appropriate to minimize exposure to legal liability.
- Task 8:** Participate on cross-functional product development teams (e.g., individuals from CMC, quality, labeling, research and development, clinical, nonclinical, marketing, legal) to provide regulatory affairs expertise.

All Tasks may be examined under the following knowledge or skill areas:

- a. Regulatory intelligence
- b. Product development
- c. Risk management
- d. Licensing, registration, and maintenance
- e. Post-market activities

Appendix B

Special Accommodations Request Form

The Regulatory Affairs Certification Board (RACB) may provide accommodations to candidates with a disability as defined by the *Americans with Disabilities Act (ADA)*. Please review the RAC Candidate Guide before submitting this form to be sure a candidate qualifies for special accommodations.

Please Type or Print

Name	First		Last		MI
Address	Street				Mail Stop/Suite/Apt
	City	State/Province	Zip/Postal Code	Country	

Phone	Country & Area Code	Email	
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For which of the following examinations are you requesting accommodations?

○ RAC (Devices) ○ RAC (Drugs)

Type of accommodation you are requesting

Have you previously received accommodations in any educational or testing situation? ☐ Yes ☐ No

If yes, please describe the accommodations received

If yes, please describe the accommodations received

I certify that the above information is true and accurate.

Signature	Date
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Appendix C

Documentation of Disability-Related Needs

To the Professional: The individual identified below is requesting accommodations for the Regulatory Affairs Certification (RAC) examination. The Regulatory Affairs Professionals Society (RAPS) requires that candidates requesting testing accommodations provide documentation of the disability from a person qualified to assess the disability.

By completing and signing this form, you are verifying that the individual named below has been diagnosed with the stated disability, and the recommended accommodation is required to fairly demonstrate the candidate's ability on the examination.

Candidate Name	First	Last	MI
Phone	Country & Area Code	Email	

Please include the following:

1. Diagnosis (note: mental and emotional disabilities must include a diagnosis from the DSM-IV)

2. Description of the candidate's disability and how the disability affects the candidate's major life activities (e.g., hearing, seeing, walking, talking, performing manual tasks)

3. Recommended Accommodations:

Signature	Date

Appendix D

Code of Ethics

As the international leader for the healthcare regulatory profession, RAPS has initiated and supported the development of this code of ethics for the profession. Following a series of surveys and focus groups held over two years, a task force of volunteers was convened in February 2003. Their work, reviewed and shaped by many regulatory professionals, forms this code.

The task force identified eight core values that regulatory professionals embrace. The principles embodied by these core values are outlined in the section (below) entitled “Fundamental Principles.” Following that, each core value is presented with suggested behaviors that should be encouraged or discouraged.

RAPS believes that this is a living document and encourages your feedback. Use this code of conduct in your work and share it with your colleagues and employer.

Statement of Personal Responsibility

Regulatory professionals have the professional and ethical responsibility to maintain the highest standards of professional conduct as they exercise their professional duties of upholding and clarifying the laws and regulations of the authorities under which we operate.

As individual regulatory professionals, we are making a positive contribution to public health, and we aspire to embody this code of ethics in our words, actions and deeds.

As regulatory professionals, we play a pivotal role in ensuring compliance with applicable laws and regulations in the development and commercialization of healthcare products. We are a diverse profession: we work in healthcare companies, for government regulatory agencies, for contract research organizations and as independent consultants around the world. Our profession includes attorneys, engineers, managers, nurses, pharmacists, physicians and scientists, among others. We are a growing profession, and we are developing and continually exploring our core values in an increasing complex global regulatory environment. We do this in the hope that everyone who practices in this field will aspire to these principles. We do this also in the hope that those whom we serve will hold these principles as inviolable.

The following eight core values defined below are maintained from the original code:

- Regulatory Compliance
- Competency
- Objectivity
- Integrity
- Honesty/Credibility
- Accountability
- Equitability
- Dignity and Respect

Fundamental Principles

As a regulatory professional I aspire to:

- To ensure my employer's activities are conducted in compliance with the laws and regulations of the authorities under which we operate, consistent with advancing, preserving and protecting public health.
- Be competent to perform the services I have been hired or retained to perform. As a regulatory professional, I hereby commit myself to continual learning while being able to acknowledge areas outside my expertise.
- Act in an objective manner. As a regulatory professional, I will base decisions on factual information. I will not be unduly influenced by competing or conflicting interests, and I will clearly communicate competing or conflicting interests when appropriate.
- Have integrity. As a regulatory professional, I must be principled and consistent in applying my views. I must live up to my commitments and be trustworthy and scrupulous at all times.
- Be honest in all dealings with my employers and others with whom I interact. As a regulatory professional, I must ensure all information and communications, whether oral or written, are accurate and complete. I acknowledge and affirm personal and institutional credibility is crucial to my success.
- Have the courage to make difficult decisions. As a regulatory professional, I will present all relevant information to my organization to promote wise decisions. I must be able to withstand challenges to my views, while at the same time being accountable for my mistakes.
- Be fair in my dealings with all parties. As a regulatory professional, I must apply legal and regulatory standards equitably. I must be just in considering the interests of all parties in decision processes.
- Be respectful of others. I must treat all individuals with dignity and courtesy.

Duty

Our role as regulatory professionals is defined by our duty to advise individuals and organizations regarding the appropriate regulatory context for actions they may want to take.

Our role is further defined by our obligations as employees of companies making important medical products for patients, as members of teams conducting nonclinical and clinical studies, as regulators and as members of our profession.

Regulatory professionals have a duty to:

- Disseminate and interpret relevant governmental regulations, industry standards and good practice guidelines without bias.
- Ensure products are safe and beneficial to patients, while maintaining the long-term interests of our employers.
- Ensure, to the extent possible, the benefits justify the risks for those who participate in clinical studies and who use regulated products.
- Provide physicians and other healthcare professionals with accurate and complete information about the safety and effectiveness of products.
- Maintain the long-term integrity of our profession and strive to deserve the public's confidence and respect.

Competence

Competence means a regulatory professional has the knowledge, experience, ability and skill necessary to effectively identify, analyze and solve or recommend solutions to regulatory challenges. Regulatory professionals must be dedicated and flexible enough to adapt to the everchanging realm of the regulatory profession.

The diversity of individuals and organizational contexts within the regulatory profession necessitates commitment to continually develop competence by a variety of means: seeking continuing education, work experience, professional training and certification.

Just as the regulatory profession continues to evolve, maintaining competence within the field is a continual learning process.

Regulatory professionals develop competence by:

- Being informed and knowledgeable about current and future trends.
- Claiming competence only in areas where they have a thorough understanding.
- Encouraging and supporting professional growth and development among peers and subordinates so all who work in the field can gain and demonstrate competence in the profession.

Objectivity

Regulatory professionals must be objective and must display their objectivity by representing facts without distortion by personal feelings or biases. The regulatory professional must understand the facts and must evaluate information from several points of view.

Regulatory professionals must understand their decisions may affect the interests of many parties including companies, regulators, healthcare professionals, patients and shareholders. Regulatory professionals must be aware of these differing interests without letting them influence their final regulatory interpretations and actions.

Regulatory professionals develop objectivity by:

- Responding carefully to opinions and issues and recognizing a single right or wrong answer is rare. Opinions can often take on a partisan perspective. The regulatory professional should always strive to offer an unbiased expression of facts.
- Presenting reasonable regulatory opinions, options and associated risks when developing regulatory strategies.
- Clearly differentiating among regulatory requirements, internal requirements and personal preferences.
- Disclosing new information appropriately within the proper context.

Integrity

Regulatory professionals with integrity will not compromise their values or trustworthiness for personal gain or professional enhancement. Individuals with integrity are principled, scrupulous and trustworthy. Having integrity suggests that one is "whole," and one's beliefs, words and actions are congruent and consistent.

Regulatory professionals develop and maintain integrity by:

- Keeping commitments.
- Giving credit for the work of others.
- Maintaining confidentiality of information and never disclosing information concerning the business or technical affairs of others without their consent.
- Seeking advice from others when uncertain.
- Considering their obligations and the long-term consequences of their actions when asked to compromise integrity for the sake of one party over another.
- Avoiding situations that put their integrity at risk.
- Recognizing the best course of action may not be in the short-term interest of their employer.
- Accepting compensation only when earned.
- Avoiding conflicts of interest or making conflicts known when they are unavoidable.

Honesty

Regulatory professionals must exhibit honesty in all of their activities. Honesty is truthfulness, candor and sincerity. Honesty requires a regulatory professional to act in ways free from deceit or deception, including dishonesty by omission or failing to say something when comment is ethically required. Honesty requires candid and forthcoming actions, not simply refraining from false statements.

Regulatory professionals build honesty and trust, which is absolutely essential to fostering effective working relationships, by:

- Ensuring information is accurate and complete.
- Protecting against the omission of information or the creation of false impressions.
- Resisting pressures to relax standards of honesty, for example, to achieve expediency.
- Representing a complete profile of the product under review in all regulatory submissions.

Courage

Regulatory professionals demonstrate courage by choosing the right thing even when doing so is difficult. Regulatory professionals must have the courage to evaluate, conclude and provide consistent and accurate regulatory advice while accepting the consequences of their actions. They must gain access to information required to do their jobs as completely as possible.

Regulatory professionals develop courage by:

- Reviewing and reiterating their advice and strategy when necessary or when challenged and changing their advice when appropriate.
- Asking for help when needed.
- Encouraging an open exchange of views even if those views challenge their regulatory advice.
- Admitting mistakes, accepting accountability and taking appropriate measures to promptly correct any errors, miscommunications or misperceptions.
- Delivering bad news quickly to management when necessary.
- Providing information to stakeholders about regulatory risks and describing consequences if regulatory advice is overruled or ignored.

Fairness

Regulatory professionals strive to treat all persons fairly, equitably and equally in accordance with the law by holding all those with common responsibilities to a common standard. Regulatory professionals should consider the rights and needs of all parties in the context of all applicable laws, regulations and scientific and societal norms.

Regulatory professionals demonstrate fairness by:

- Respecting the letter and spirit of laws and regulations.
- Applying the appropriate legal and regulatory standards to all cases.
- Considering cultural and regional differences and local requirements.
- Presenting the facts and objective analysis of scientific information using sound statistical interpretation to minimize bias while clarifying uncertainty.
- Ensuring all interests, public and private, are appropriately considered in the regulatory decision processes.

Respect

Regulatory professionals demonstrate respect by appreciating the worth or value of people and things. Regulatory professionals must respect the roles of their colleagues and should recognize and acknowledge the worth of all parties.

Regulatory professionals develop respect by:

- Listening to what others have to say.
- Treating all parties, regardless of level or position, with dignity, civility and courtesy.
- Accepting personal differences but working diligently toward accommodating those differences wherever possible.
- Creating a positive environment encouraging participation of all parties without embarrassment, ridicule or hurtful actions or inactions.
- Sharing what they know in a nonintimidating way.
- Tolerating and encouraging those who do not initially understand.
- Avoiding conflict where possible and finding creative ways to resolve conflict quickly.
- Being patient and forgiving when others make mistakes and working to prevent mistakes from recurring rather than assigning blame.

Appendix E

Appeals Request Form

Candidates have the right to appeal any adverse decision made by the RAC program office. An appeal must be submitted in writing not more than 30 days following the date of notification of the adverse decision using the form provided in Appendix E. Appeals should be sent to the RAC program office at certification@raps.org. All appeals will be acknowledged by RAPS within 10 days in writing. Appeals will be addressed by the Regulatory Affairs Certification Board (RACB). Appeals notifications will be provided within 90 days. Decisions made by the RACB are final.

Candidate Name	First	Last	MI
Phone	Country & Area Code	Email	

Mark the Pertinent Exam Window and Exam Type:

☐ Spring
 ☐ Summer
 ☐ Fall
 ☐ N/A

☐ RAC (Devices)
 ☐ RAC (Drugs)

1. Mark the reason for the appeal:

- ☐ Eligibility
☐ Testing Conditions
☐ Exam Scoring
☐ Other (please specify):

--

2. Provide a concise description of the situation or issue and your desired outcome.

--

Signature	Date