Regulatory Affairs Certification: RAC-Drugs

Candidate Guide 2023

January 2023

Contents

Welcome and Overview

Introduction

Congratulations on pursuing Regulatory Affairs Certification (RAC-Drugs). RAPS commends this demonstrated commitment to your career and the regulatory profession.

This guide contains information about:

- Eligibility requirements
- Submitting an exam application
- Preparing for the exam
- Scheduling the exam
- What to expect at the testing center
- What to expect after the exam

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

The 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 and the pursuit of knowledge and career advancement. Success on the RAC exam 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 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. 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 successful performance of a professional role. This assessment is typically accomplished by the successful completion of an exam.[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, with some holding multiple credentials.

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

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

RAC Exam 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 Content is updated for the summer cycle. Updated exam content is based on regulations and guidelines in effect on 31 December of the prior year. Example: exams taken in the summer are based on regulations 'on the books' as of 31 December the prior year.**

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 Exam

The RAC exams are challenging, so it is important to develop a study plan. Here are some things to consider:

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

Question Types

The exam consists of 100 multiple-choice questions that must be answered within two hours. 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 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 exams are computer-based. Testing can take place at selected testing centers 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 when applying. Modality is chosen when scheduling.

Your Journey

Check the RAPS website at RAPS.org for additional resources. Some are free of charge; others are available for purchase. RAPS' resources are not required.

PREPARE

APPLY

SCHEDULE

TAKE EXAM

RECERTIFY

Key Exam Facts

- US, EU and global content
- **Exam content is updated every summer**
- 100 questions
- 120 minutes
- Computer-based
- Three question formats — recall, application, analysis
- Can be taken at a testing facility or online

Applying for the Examination

RAC Application Process

Apply for the RAC online or submit the printable application form.

Testing windows, application deadlines and fees are listed in Appendix F.

Eligibility Requirements

One of the following educational and professional experience requirement combinations is required to apply:

- 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*

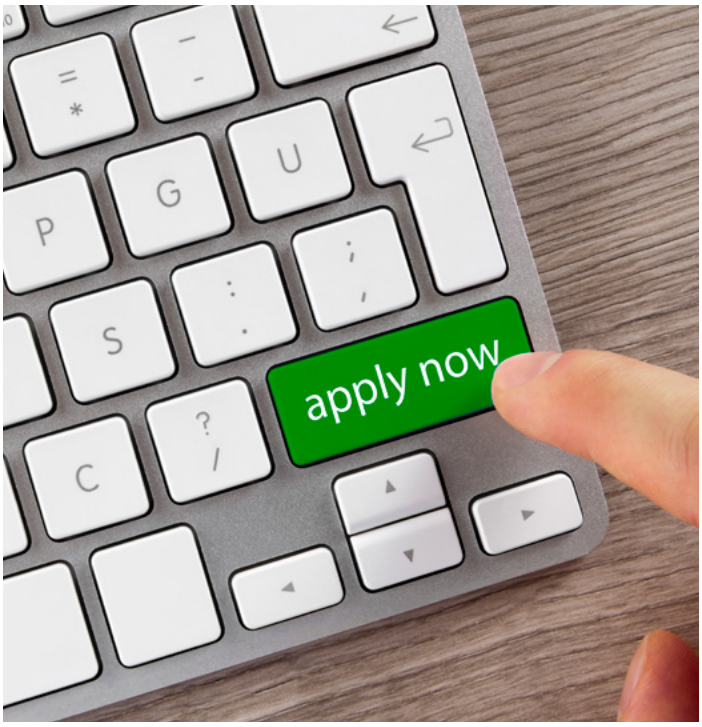
*Regulatory-related experience may include quality assurance, quality control, clinical research related to the approval of health products or health product project management.

General Application Instructions

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

Provide a valid e-mail address that will be maintained throughout the RAC application period. If using a work e-mail address, please keep in mind that any change in employment during the application process could affect access to that e-mail account. All communications about the RAC exam, including scheduling and results information, are electronic. Please contact the RAC Program Office with e-mail address changes.

Complete the RAC exam 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 could lead to rejection if not completed by the application deadline.

Key Application Facts

- Make sure application name matches the provided government-issued ID
- Use an e-mail with long-term access; personal e-mails are often more effective than work e-mails
- Read the Candidate Guide
- Read and agree to abide by the RAPS Code of Ethics
- Review eligibility rules and ensure adherence before applying

Submitting Payment

The correct payment must accompany applications.

Application Receipt Confirmation

Receipt of a "thank you" e-mail signifies application receipt. The RAC Program Office will contact candidates with application questions or if an application is selected for audit.

Application Audit

RAPS may audit a percentage of applications for completeness and accuracy. If selected for audit, the candidate will receive an e-mail detailing additional documentation requirements. Noncompliance by the stated deadline will result in the candidate not being allowed to test. The candidate will be issued an exam refund minus the administration fee.

Incomplete Applications

Any application deficiency must be corrected by the application deadline. Noncompliance by the stated deadline is grounds for application rejection. Candidates will be issued an exam refund minus the administration fee.

Application Rejection

Applications will be rejected for failure to meet eligibility requirements or falsification of application information. Applicants rejected on these grounds will be issued an exam refund minus the administration fee. Penalties and sanctions may also apply.

Application Withdrawal/Cancellation and Refunds

To withdraw or cancel an application, submit a written request to the RAC Program Office at certification@ raps.org by the application deadline (prior to any transfer). There is an administrative fee for withdrawn or cancelled applications. Candidates are ineligible for refunds following a transfer. Requests to withdraw or cancel after the deadline will be rejected.

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. Only two transfers are permitted. Additional transfers require re-applying to the program at full price.

For candidates seeking transfers because of an unavoidable emergency, consult the "Emergency Situations" section.

Requests to transfer to the next testing cycle are free if they are done before the application deadline. Transfer fees apply if the transfer is made after the application deadline and until the end of the exam window. Transfers will be allowed until the last day of the testing window. After this period, transfers will not be permitted and applicants will be required to pay the full application fee.

Appeals Process

Candidates have the right to appeal any adverse decision made by the RAC Program Office. An appeal must be submitted in writing within 30 days after adverse decision notification using the form provided in Appendix E. Send appeals to certification@raps.org. RAPS will acknowledge appeals in writing within 10 days. The Regulatory Affairs Certification Board (RACB) addresses appeals. Appeals notifications are provided within 90 days. RACB decisions 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.

Exam Scheduling

Notice to Schedule E-mail

Exams are scheduled directly with the contracted testing vendor, Meazure Learning, which will send "Notice to Schedule" e-mails 10 to 14 days before the testing cycle starts. It provides exam scheduling instructions. Applicants should add "candidatesupport@meazurelearning.com" to their e-mail safe list to ensure receipt.

The e-mail will contain a website link, unique login ID, and password. Use the link to choose the test date, time, and between Live Remote Proctoring (LRP)—also referred to as online testing—and in-person testing.

Exam Scheduling

Log into the Meazure Learning scheduling site and choose between in-person and online testing.

Candidates should schedule their exam as soon as possible to receive the most date, time and location options. Scheduling requests must be submitted at least two days before the preferred testing date. All exams must be scheduled two days before the testing cycle closes.

Meazure Learning will e-mail exam scheduling confirmation, a copy of which candidates must present at the testing center on test day.

Meazure Learning reserves the right to cancel any testing site. Meazure Learning will send notification and instructions for fee-free rescheduling if it cancels a site.

Scheduling a Live Remote Proctored Exam (LRP)

When choosing LRP, candidates must confirm their demographic information, attest to Meazure Learning's privacy policy, and test their computers for both exam delivery and LRP system requirements. **Meazure Learning strongly encourages that systems' performance checks are conducted during testing-appointment scheduling. Candidates whose computers fail the check will 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 systems' check information is included in the confirmation e-mail. Candidates are reminded to perform the check prior to testing. Following these administrative tasks, the candidate selects "schedule" to proceed.

The candidate's computer must have webcam capability as well as a microphone and speakers. Candidates must have an adequate internet connection to ensure that the proctor can access the candidate's computer and that the session can proceed without internet disruption on exam day.

See the "Computer Requirements" section for full details on specifications needed for LRP testing. Basic system available at https://go.proctoru.com/students/system-metrics/new .

International Testing

Applicants looking to schedule an exam outside of the US or Canada should follow the instructions to schedule through the Meazure Learning scheduling site.

Candidates should consider locations they may visit for business or pleasure if they cannot find a location near their homes or offices. Meazure Learning cannot guarantee availability of any particular international site/date during the designated testing period.

Within five business days, Meazure Learning will issue a confirmation notice for one of the preferred sites/dates. If the preferred site or dates are not available, Meazure Learning will offer candidates alternatives. Upon candidate approval, Meazure Learning will issue a confirmation notice.

Changing Appointments (Onsite Testing)

Candidates should use the link provided in their appointment confirmation e-mails if they wish to change the date, time or location of the appointment within the same exam window.

Tests may be rescheduled with the same testing window up to two days before the scheduled appointment. To move to a different testing window, consult the "Transferring to Another Testing Cycle" section.

Meazure Learning charges a rescheduling fee for each request. Meazure Learning's e-mail is: candidatesupport@MeazureLearning.com. Contact Meazure Learning by telephone at +1 919 572 6880 if online rescheduling is problematic.

Changing an LRP Appointment

Access the LRP system via the scheduling link provided in the "Notice to Schedule" e-mail to change appointments.

The rescheduling fee does not apply to LRP candidates rescheduling to another LRP slot or switching from LRP to in-person testing. The fee does apply to candidates rescheduling from in-person testing to another in-person time, location or LRP.

Changing the Exam Type or Method

A candidate requesting to change exam type (e.g., from Drugs to Devices or vice versa) or change testing method (e.g., from online testing to on-site testing, or vice versa) must submit the request by the application deadline. Changes to the exam type should be directed to the RAC Program Office at certification@raps.org. A change fee will apply.

Emergency Situations

Under certain circumstances, as outlined, the RAC Program Office 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
- Geopolitical event (e.g. breakout of war)

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 window close.

To apply for a transfer waiver, the appropriate documentation must be submitted to the RAC Program Office at certification@raps.org. Work-related emergencies do not qualify for this exception.

Failure to Schedule or Keep an Appointment

Such failures are considered a "no-show" and forfeit all exam fees. The following are no-show situations:

- Failure to schedule an exam appointment during the testing cycle
- Failure to fulfill a scheduled appointment
- Arriving at the testing site more than 15 minutes late
- Failure to produce appropriate government-issued ID at the exam appointment

No-shows must pay the full application fee and reapply take the exam.

Special Accommodations for the Exam

Candidates who require special accommodations under the Americans with Disabilities Act (ADA) must send the completed "Special Accommodations Request" and "Disability-Related Needs" forms 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 specify the accommodation requested. Candidates will be notified in writing if their request is approved. Consult appendices B and C for more information.

On Exam Day (Onsite Testing)

What to Bring to the Testing Center

Arrive at the testing center at least 15 minutes early with a copy of the exam confirmation e-mail and a valid government-issued ID. IDs must include name (in English characters or translation to compare with RAC application information) photograph and signature. Make sure that the name on the ID EXACTLY match that on the scheduling screen. If the ID lists more than one last name, the same last name must be reflected in the confirmation e-mail.

In case of a mismatch or incorrect name, contact RAPS immediately at +1 301 770 2920, ext. 200.

Candidates who cannot produce ID or exact matching ID forfeit their exam fees and will not be permitted to take the exam.

The following are acceptable ID forms:

- driver's licenses
- military IDs
- passports
- national identification cards

Items Prohibited at the Testing Center

Candidates are prohibited from bringing the following into 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 exam 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)

Provided onsite:

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

Meazure Learning testing centers administer exams for multiple organizations. Others in the testing room may be taking different exams and have different rules for their exam, including time allocation and permitted items.

Other Considerations

- Smoking is prohibited
- No questions about exam content are allowed
- Exams are monitored and may be recorded in both audio and video format
- **Breaks are allowed, but the clock keeps running**

Inclement-Weather Cancellations

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

Exam Security and Confidentiality

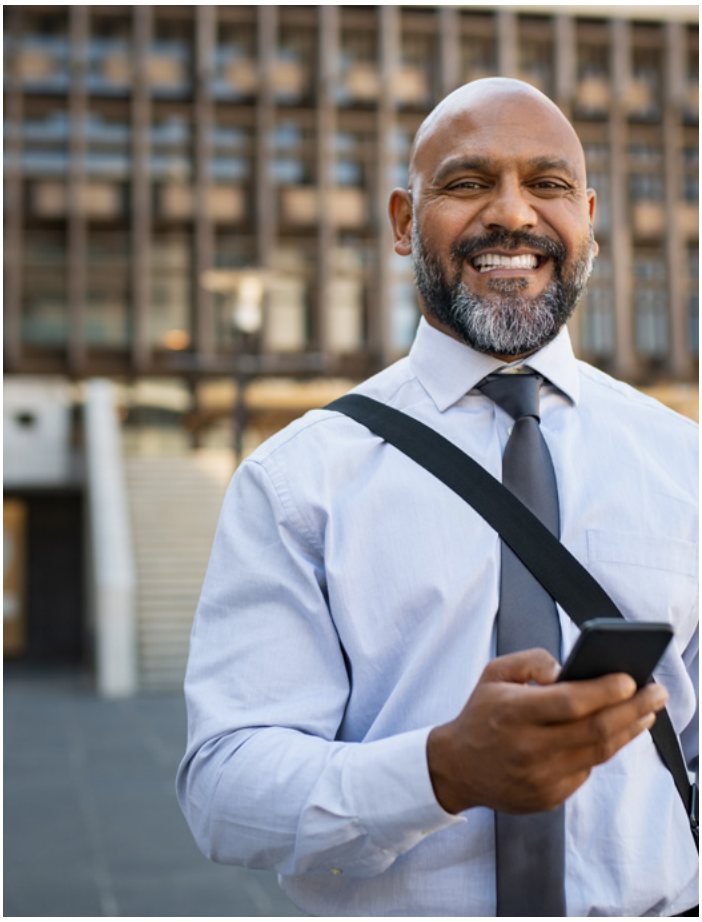
The RAC exams are the sole and exclusive property of the RAC Program Office. These materials are confidential and not available for review by any person or organization other than the RACB and the exam committees.

Copying, publishing or disclosing exam content in any form is considered a violation of the RAC security and confidentiality policy, and subject to disciplinary action, which may include termination of a testing session, invalidation of test results and/or revocation of RAC credentials.

Termination of Exam Administration/ Dismissal from the Testing Center

Candidates are expected to always conduct themselves in a professional manner at the testing center. The test center administrator or proctor is authorized to dismiss anyone and/ or request that a test score be nullified under the following circumstances:

- Using or attempting to use someone else to take the exam
- Using notes or other study materials during the testing process
- Creating a disturbance—any disruptive behavior will not be 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 exam policies or requirement explained in this Candidate Guide



Problems at the Testing Center

The RAC Program Office and Meazure Learning take steps to assure that the RAC exam process is effective. However, sometimes there are irregularities. Contact the proctor immediately about any technical difficulties during the exam. Candidates may reschedule their exam appointment if a delay lasts longer than 30 minutes.

On Exam Day (LRP)

Authentication

- Show government-issued photo ID with a signature exactly matching the name used for registration
- Username, password, and exam password from "Notice to Schedule" e-mail

Before Beginning

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 clipboards.

Candidates are required to pass the systems' requirements check prior to testing. After the systems' 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 LRP launch site.

If a computer fails the check of systems' requirements, candidates must correct the issue or obtain another computer to complete the testing appointment.

If directed by the proctor, or in case of technical difficulties, the candidate may contact the proctor by telephone.

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 exam login process.

During the Exam

The environment should be quiet to avoid distractions and to ensure that the online proctor can hear everything at the candidate's location.

The proctor has complete access to the candidate's computer to monitor for unauthorized activities, such as accessing other software applications, using multiple monitors, letting someone else take the exam and allowing anyone other than the proctor remote access to the computer.

The proctor can terminate the testing appointment for integrity reasons at any time.

During the exam login process, the proctor and candidate complete a dual login, in which candidates verify their information, complete the candidate-attestation statement and review the testing rules and policies. In addition, prior to launching the exam, the candidate can review the online tutorial of ProctorU.

Testing time for candidates begins when the exam is launched. When a candidate completes the exam, click "submit exam" and confirm readiness to submit the exam. 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

- Quiet location
- Only candidates in the room
- Working, powered and connected computer matching required specifications
- No cell phones, headphones or other electronic devices in the vicinity
- Clear desk/test-taking surface except for two pieces of scratch paper and a writing implement
- Proctor can ask to see the scratch paper
- Destroy scratch paper after the exam is completed
- Remain seated
- Speak only to the proctor
- No food or drink
- No hats, hoods or other headgear, other than for religious purposes
- No coats or jackets

Other Considerations

- All exams are monitored and may be recorded in both audio and video format
- **Breaks are not permitted for LRP exams**
- No noteboard or scratch paper is permitted.

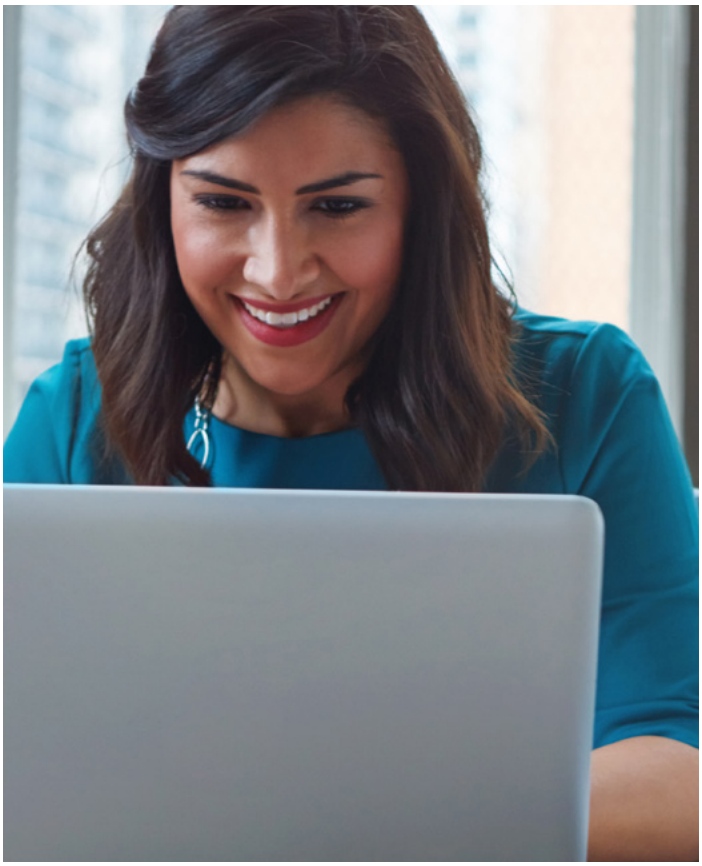
LRP Log-In Issues

Log-in issues for online tests occur very rarely. However, 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 to another date within the same exam window. In such an event, candidates must call Meazure Learning to reschedule, no later than close of business of the next available business day. If a candidate can log into the exam but is unable to complete the exam because of technical issues, the candidate will be permitted to re-test during the next testing window.

LRP Privacy Statement

By taking the exam by LRP, candidates attest that they understand the exam 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 LRP, the candidate agrees to exam-session recording and review by the testing agency and testing program owners.

After the Exam



Exam Scoring

RAC exams are scored by Meazure Learning after the close of the testing cycle. Exams are not scored at testing centers. A statistical report of scoring is reviewed by a statistician and the exam committee to assure ongoing quality of the exams.

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

Notification of Exam Results

Exam results are typically available six weeks after the close of the testing cycle. Results will be sent via e-mail. No results will be reported over the telephone. Results are released only to candidates.

RAC Recognition

A list of all active RAC-credentialed professionals is available online at RAPS.org. Newly credentialed professionals are added after all candidates are notified of their status. Anyone not wishing to be included in the online listing should contact the RAC Program Office at certification@raps.org.

Use of the RAC Designation

After passing, candidates can use the "RAC-Drugs" designation as a professional credential after their names, as well as on resumes, curriculum vitae, employment and other professional records. The RAC designation cannot be used by anyone who does not recertify. See raps.org for more specific information on proper use of the RAC designation.

Retaking the Exam

Candidates who fail the RAC exam are eligible to retake the exam during the following window. Candidates cannot retake the exam during the same window. To apply to retake the exam, candidates must submit a new application. There is no limit on the number of times a candidate may retake the exam.

Release of Information

The RAC Program Office maintains strict procedures for ensuring the confidentiality of all candidate records. Information about candidates is released only to the candidate.

Recertification

Maintaining RAC Credentials

Continual learning, knowledge enhancement and professional development are vital to regulatory professionals. Once certified, holders maintain their credentials through continued learning and involvement in professional activities. Holders must renew their RAC every three years by earning 36 RAC recertification credits. Credits may be accumulated in many ways, including participating in continuing education, publicly 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. Detailed information about maintaining and renewing in the RAC Recertification Guide.

Contact Information

Regulatory Affairs Professionals Society
RAC Program Office
Tel: +1 301 770 2920, ext. 200
Email: certification@raps.org

Meazure Learning
Tel: +1 855 772 8678
Chat: https://auto.proctoru.com/chat
Email: candidatesupport@meazurelearning.com

Appendix A

RAC-Drugs Exam Content Outline

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; content is updated before the summer -exam cycle. Domains are weighting percentages approximate and may be +/-2%. Exam content for the RAC -Drugs exam is based on regulations and guidelines in the following areas:

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: Maintain authorization for ongoing clinical trials/ investigations (e.g., amendments, annual reports, updates) and monitor the progress of the regulatory authority review process.

Task 18: Evaluate proposed manufacturing changes on nonclinical and clinical development and regulatory submission strategies.

Task 19: Facilitate the development of appropriate and timely responses to regulatory authority queries and actions to ensure compliance with company procedures.

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, application, 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 accommodation.

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

For which exam is accommodation requested?

○ RAC-Devices) ○ RAC-Drugs

Type of accommodation requested

Have you previously received accommodation in any educational or testing situation? ○ Yes ○ No

If yes, please describe the accommodations received

I certify that the above information is true and accurate.

Signature | Date

Appendix C

Documentation of Disability-Related Needs

To the Professional: The individual identified below is requesting accommodations for the Regulatory Affairs Certification (RAC) exam. 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 exam.

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 conducted 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 increasingly 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 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 ever-changing 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. 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. The Regulatory Affairs Certification Board (RACB) will address appeals. Appeals notifications will be provided within 90 days of receipt. All 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

Appendix F 2023 Application Deadlines and Testing Windows

Application Deadlines and Testing Windows

Application Deadline	Testing Window
23 Feb 2023	20 Mar – 28 Apr 2023
15 Jun 2023	10 Jul – 18 Aug 2023
05 Oct 2023	30 Oct – 08 Dec 2023

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.

Appendix G 2023 Application, Transfer, and Other Fees

Application Fees

2023 Pricing	RAPS Member	$495 (US)
	List	$625 (US)

Candidates must be a RAPS member at the time of application submission to receive the members' rate. If applying for RAPS membership prior to submitting a RAC application, ensure RAPS membership confirmation receipt before submitting the RAC application. RAPS membership information at raps.org.

Other Fees

Category	Amount
Administrative Fee	$100
Transfer Fee	$250
Rescheduling Fee	$50
Form Change Fee	$50

Appendix H Important Contact Information

Important Contact Information

Meazure Learning:

+1 919 572 6880
candidatesupport@MeazureLearning.com

RAPS Customer Support:

RAPS immediately at +1 301 770 2920, ext. 200
certification@raps.org