Regulatory Affairs Certification: Medical Devices

RAC-Devices

2027 Candidate Guide



RAPS
REGULATORY AFFAIRS PROFESSIONALS SOCIETY

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Welcome and Overview

Introduction

Congratulations on pursuing the Regulatory Affairs Certification (RAC-Devices). RAPS commends this 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-Devices certification only. For information about RAC-Drugs certification, see the RAC-Drugs 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 signals a 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 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. RAC-credentialed professionals earn higher salaries than those who do not hold the credential.[1]

RAC holders in North America reported earning an average of 12% more than their counterparts who do not hold the credential[1]

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.[2]

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.

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 spring exam window. The updated exam content is based on regulations and guidelines in effect on 1 September of the prior year.

[1] Based on data from the RAPS' 2024 Scope of Practice & Compensation Survey of the regulatory profession

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

Prepare for the Exam

Knowledge Required and Regulatory Basis

- Knowledge of the full product development and lifecycle for medical devices and IVDs
- 30% US FDA requirements
- 30% European regulations and guidance from the European Commission and competent authorities
- 40% globally applicable regulatory practices—IMDRF, WHO and ISO guidelines and standards
- Critical thinking and analytical skills

Prepare 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 content domains, competency statements and number of questions in each domain.

Assess knowledge and experience of scope and depth— Use the content outline as a checklist to evaluate areas of strength and weakness; it will help to focus your studying.

Build and implement a plan—Allow sufficient time to build a knowledge base in areas of limited experience to expand knowledge in more familiar areas. Use reference materials to supplement your knowledge.

Question Types

The exam consists of 120 multiple-choice questions that must be answered within a two and a half-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 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.



Computer-Based Testing and Testing Modality

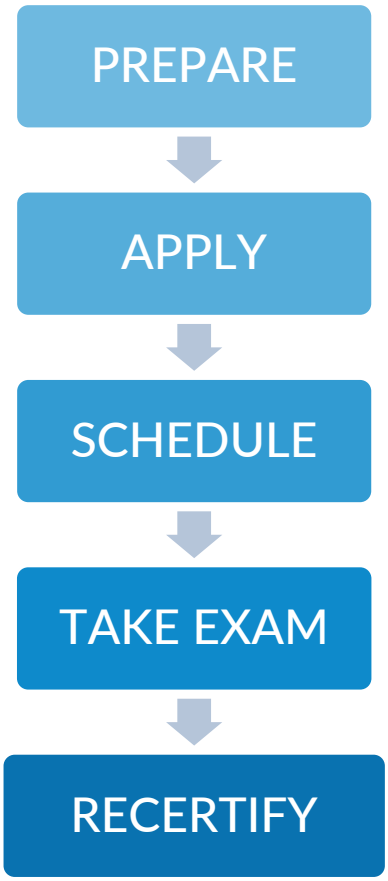
All exams are computer-based. Testing can occur at selected testing centers, confirmed by the testing vendor, or online at a suitable location of your choosing. You do not need to choose your preferred testing modality when applying. Modality is selected when scheduling the exam.

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.

Key Exam Facts

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





Apply for the Exam

RAC Application Process

Apply online at raps.org/rac. Testing windows, application deadlines, and fees are listed in the Appendix.

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
- Minimum ten years of regulatory-related work experience*, regardless of a formal degree*

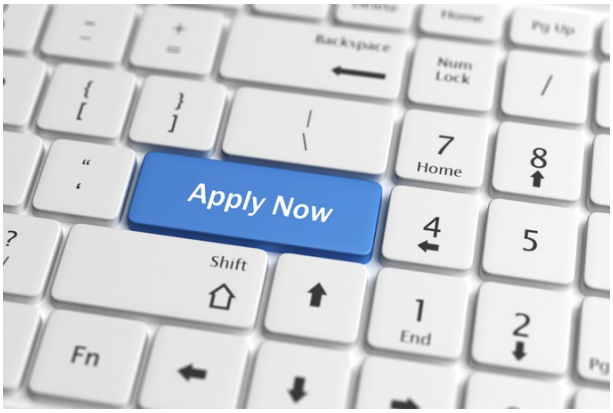
*Regulatory-related experience may include quality assurance, quality control, clinical research related to the approval of health products or health product project management.

General Application Instructions

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

Provide a valid email address. If using a work email address, please keep in mind that any change in employment during the application process could affect access to that email account.

All communications about the exam, including scheduling and results information, are electronic. Please contact the RAPS Program Office with email address changes.



In 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.
- I acknowledge and agree to RAPS examination policies and certification policies.
- 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 provide cause for denial of this application or loss of the RAC credential.
- I allow RAPS to use information from my application and from the exam for the purpose of aggregate statistical analysis, provided that any personal information or identifiers are removed.
- I authorize RAPS to publish my name in the public certification directory if I successfully complete my examination.
- I understand and agree to the policies related to withdrawing from the exam.
- I acknowledge that I have read and understand the tenets outlined in the RAPS Code of Ethics.

See the Appendix for the Code of Ethics for Regulatory Professionals.

Key Application Facts

- Make sure your name matches your provided government-issued ID
- Use an email with long-term access; personal emails are often more effective than work emails
- 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" email signifies application completion. The RAC Program Office will contact you if there are 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, you will receive an email detailing additional documentation requirements. Noncompliance by the stated deadline will result in your not being allowed to test. You 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 and you 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. If you are rejected on these grounds you will be issued an exam refund minus the administration fee. Penalties and sanctions may also apply.

Nondiscrimination Policy

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

Application Withdrawals and Refunds

There is an administrative fee for withdrawn applications. Requests to withdraw after the application deadline will be declined. You are ineligible for refunds following a transfer.

To withdraw your application, complete the following steps:

1. Submit a written request to the RAPS Program Office before the application deadline (prior to any transfers)
2. If you have a scheduled exam with Pearson VUE, login to their portal and cancel your exam.

Transferring to Another Testing Window

A request to transfer to the next testing window may be made by contacting the RAPS Program Office no later than the final day of the testing window. If you have a scheduled exam with Pearson VUE, you must also login to their portal to cancel your exam. Pearson Vue requires cancellation 48 hours in advance for in-person exams. You risk being subject to a cancellation fee if you do not cancel your in-person exam appointment 48 hours in advance.

Only two transfers are permitted. For example, if you transfer from the spring to the summer window, that is one transfer. If you transfer from the spring to the autumn window, that is two transfers. Additional transfers will require re-applying to the program at full price.

Requests to transfer to the next testing window are free if they are made before the exam application deadline. Transfer fees apply if the transfer is made after the application deadline. Transfers will not be permitted after the final day of the testing window. If you request to transfer after the final day of the testing window you must re-apply to the program at full price. All fees can be found in Appendix G.

If you need to transfer because of an emergency, consult the "Emergency Situations" section.

Appeals Process

You have the right to request reconsideration of any adverse decision made by the RAPS Program Office, including decisions related to examination security reviews and examination result invalidation.

A request for reconsideration must be submitted to the RAPS Program Office within 30 days after adverse decision notification using the form in the Appendix. RAPS will acknowledge such requests in writing within 10 days.

The Regulatory Affairs Certification Board (RACB) will address the reconsideration. Reconsideration outcome notifications will be provided within 90 days of receipt. RACB decisions are final.

Exam Scheduling

Authorization to Test Email

Exams are scheduled directly with the contracted testing vendor, Pearson VUE, who will send an "Authorization to Test" email after the application deadline.

The email will contain a website link where you will go to set up your account and schedule your exam.

Applicants should add PearsonVUEConfirmation@e.pearson.com and Americas.css@pearson.com to their email safe list.

Exam Scheduling

Log in to the Pearson VUE scheduling site and choose between in-person and online testing.

Candidates should schedule their exam as soon as they receive their Authorization to Test email to maximize date, time, and location options. Pearson VUE does not guarantee availability at their in-person testing centers.

All exams must be scheduled at least two days before the testing window closes.

Change a Testing Appointment

You should sign into their Pearson VUE account to change the date, time, or location of the appointment within the same testing window.

To move to a different testing window, consult the "Transferring to Another Testing Window" section.

Change the Exam Type or Modality

To change exam type (e.g., from RAC-Devices to RAC-Drugs or vice versa) you must submit the request to the RAPS Program Office by the application deadline. Note that a change fee will apply.

To change the testing modality (i.e., from online to in person testing or vice versa) log in to your Pearson VUE account to make that change.

Emergency Situations

Under certain emergency situations as outlined, the Program Office may, at its discretion, transfer an applicant's exam to the next testing window and waive the transfer fee. If you cannot take the RAC exam for one of the following reasons you 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)

In such circumstances, you must contact the RAPS Program Office no more than three days after the end of the window. The appropriate documentation must be submitted. Work-related emergencies do not qualify for this exception.

Failure to Schedule or Keep an Appointment

Such failures are considered a no-show and result in all exam fees being forfeited. The following are no-show situations:

- Failure to schedule an exam appointment during the testing window or by the appointment deadline
- Failure to fulfill a scheduled appointment
- Arriving at the testing site more than 30 minutes late
- Arriving to your online appointment more than 30 minutes late
- Failure to produce appropriate government-issued ID at the exam appointment

No-shows must reapply to take the exam at full price.

Special Accommodations for the Exam

If you require special accommodations under the Americans with Disabilities Act (ADA) you must send the completed "Special Accommodations Request" with "Disability-Related Needs" forms completed by a qualified professional, to the RAPS Program Office at the time of application. The request must indicate the nature of the disability and specify the type of accommodation requested. You will be notified in writing if your request is approved. Consult the Appendices for more information.

In Person Testing

Testing Center Arrival

Arrive at the testing center at least 30 minutes early with a valid form of government issued ID that lists your name as it appears in your confirmation email.

If you arrive more than 30 minutes after your appointment time and are refused admission, the exam and delivery fees are nonrefundable.

In case of an incorrect name, contact RAPS immediately at +1 301 770 2920, ext. 200. Candidates who cannot produce exact matching ID forfeit their exam fees and will not be permitted to take the exam. Note that the RAPS office is open Monday-Friday 9am-5pm Eastern Time USA.

Items at the Testing Center

No personal items may be taken into the testing room. This includes all bags, books, notes, phones, pagers, watches and wallets.

For a list of items that are allowed without pre-approval, please view the comfort aid list here: https://www.pearsonvue.com/us/en/test-takers/accommodations/comfort-aid-list.html

You will be provided with an abbreviations table.

Pearson VUE 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
- Questions about exam content are not allowed
- Exam sessions are monitored and recorded in both audio and video formats
- If breaks are allowed, the clock keeps running

Test Center Closure

If you are impacted by a test center closure, you will receive an email with information on how to reschedule your exam.

Exam Security and Confidentiality

The RAC exams are the sole and exclusive property of the RAPS 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, reproducing, distributing, or disclosing exam content in any form is considered a violation of the exam security and confidentiality policy and may result in disciplinary action, including termination of a testing session, invalidation of test results, denial or revocation of certification, and/or restrictions on future testing.

RAPS reserves the right to review examination results and related testing data when information suggests a potential violation of examination security requirements or irregular testing behavior. Such reviews may include evaluation of testing data, testing vendor security reports, and statistical or psychometric analyses. Examination results may be placed on administrative hold while a review is conducted. Candidates are required to cooperate fully with any examination security review or investigation.

Following a review, RAPS may release the examination result, request additional information, require retesting, invalidate examination results, deny future testing privileges, revoke certification, or impose other sanctions permitted under applicable certification policies.

Problems at the Testing Center

Contact the proctor immediately about any technical difficulties during the exam.

Termination of Exam/Dismissal

You are expected to always conduct yourself 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 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 requirements explained in this Candidate Guide.
- Refusing to comply with examination security procedures or investigation requirements.
- In addition to dismissal from a testing session, RAPS reserves the right to review examination results and testing data when information suggests a potential violation of examination security requirements or irregular testing behavior. Candidates may be required to cooperate with an examination security review or investigation. Following such a review, RAPS may release the examination result, require retesting, invalidate examination results, deny future testing privileges, revoke certification, or impose other sanctions permitted under applicable certification policies.

Online Testing

Before Exam Day

Be sure to read Pearson VUE's guide to taking your exam online to learn about the following:
https://www.pearsonvue.com/us/en/onvue/tips.html

- Equipment needed
- Acceptable ID
- Running a system test to ensure your computer is compatible and your internet service is sufficient
- Finding a quiet and private space where you can take your exam without interruptions
- Consenting to monitoring throughout your test via webcam and microphone
- Check in process

Review the list of items you are allowed to have in the room without pre-approval:
https://www.pearsonvue.com/us/en/test-takers/accommodations/comfort-aid-list.html

Read about the rules and requirements for taking your exam online:
https://wsr.pearsonvue.com/testtaker/registration/ExamPoliciesPage/MEASUREMENTRESE?conversationId=1671001

On Exam Day

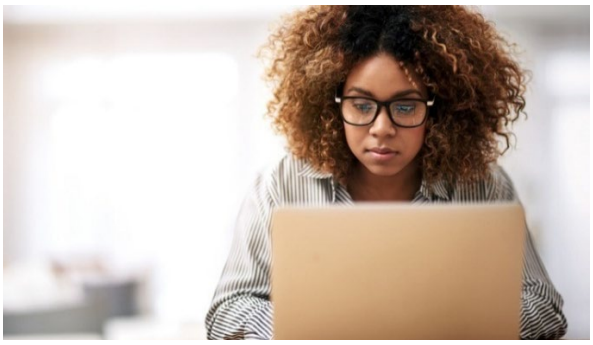
- Check in up to 30 minutes before your scheduled appointment time.
- If you are more than 15 minutes late for your appointment, you will not be able to check in.
- Show government-issued photo ID with a name exactly matching the name used for registration. You will take a photo when you check in that will be compared to your ID.
- Agree to terms and conditions
- Observe the environmental and behavioral rules

During the Exam

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

The proctor has complete access to your computer to monitor for unauthorized activities.

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



Room Environment

- Quiet location
- Only candidates in the room
- Working, powered, and connected computer matching requirement specifications
- Clear desk/test-taking surface
- Remain seated
- No hats, hoods, or other headgear, other than for religious purposes
- No coats or jackets

Other Considerations

All exam sessions are monitored and recorded in both audio and video formats

- Breaks are not permitted for online exams
- No note board or scratch paper is permitted

Online Testing Log-In Issues

Log-in issues for online tests occasionally occur. If you do need assistance, use the chat function on Pearson VUE's website to get help.

Online Testing Privacy Statement

By taking the online exam, you attest that you understand the exam session, including video, is recorded and may be saved for up to 30 days. By agreeing to take the exam online, you agree to exam session recording and review by the testing agency and testing program.

After the Exam

Exam Scoring

After the testing window closes, Pearson VUE scores all exams. A statistician and the exam committee then review the statistical scoring report to ensure the continued quality and fairness of the exams.

If you pass the exam, you will receive a pass notification. If you do not pass, you will receive a scaled score report that includes feedback for each domain. The scaled score does not represent the number of questions answered correctly or the percentage of incorrect answers. It is not possible to use the scaled score to determine how many questions you needed to answer correctly to pass.

For exam security reasons, we cannot provide any additional information about your exam beyond what is included in your report.

Notification of Exam Results

Preliminary Exam Results

Upon completing the exam, candidates will receive a preliminary (unofficial) pass/fail result at the test center. Preliminary results are subject to review and validation by RAPS.

Final Score Confirmation

Official exam results will be released by RAPS approximately 6 to 8 weeks after the testing window closes. Candidates will receive an email confirming their final result and, for those who pass, information regarding digital badges and certification status..

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 RAPS Program Office.

Use of the RAC Designation

After passing, you may use the "RAC-Devices" designation as a professional credential after your name, as well as on resumes, curriculum vitae, employment, and other professional records. This designation cannot be used by individuals who do not recertify. See raps.org for more information on the proper usage of the designation.



Retaking the Exam

If you fail the exam you are eligible to retake the exam in the following window. You cannot retake the exam during the same window. To apply to retake the exam, you must submit a new application. There is no limit on the number of times you may retake the exam.

Release of Information

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

Recertify

Maintain the RAC Credentials

Continual learning, knowledge enhancement and professional development are vital to regulatory professionals. Once certified, you maintain your RAC credentials through continued learning and involvement in professional activities. You must 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 your most recent RAC certification and the related recertification cycle. Detailed information about maintaining and renewing in the RAC Recertification Guide.



Appendix A

RAC-Devices 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, and content is updated before the Spring exam window. Domain weighting percentages in the exam content outline are approximate and may be +/-2%. Exam content for the RAC-Devices exam is based on regulations and guidelines in:

Domain I: Strategic Planning—Exam Weighting approximately 27%

Task 1: Evaluate the regulatory environment and provide internal advice from concept to obsolescence of the product to facilitate product compliance.
Task 2: Prepare regulatory strategies for global commercialization.
Task 3: Research competitor and predicate/equivalent devices.
Task 4: Differentiate between product designations.
Task 5: Review proposed product claims and associated testing strategies.
Task 6: Interact early with regulatory agencies on proposed strategy.
Task 7: Differentiate between products categorized as devices and their specific regulatory requirements.
Task 8: Evaluate regulatory needs for devices intended to be used for special patient populations or use environments.

Domain II: Design and Development—Exam Weighting approximately 27%

Task 1: Evaluate testing strategy for bench, pre-clinical and clinical.
Task 2: Perform review and/or approval of design verification, and/or design validation activities, including deliverables.
Task 3: Respond to inconsistency throughout documentation.
Task 4: Confirm that testing results support product claims.
Task 5: Evaluate substantial equivalence to predicate devices' performance and technology and/or state-of-the-art determination.
Task 6: Review and identify potential risks for similar device types from regulatory databases.
Task 7: Participate in design and risk review activities.
Task 8: Evaluate regulatory impact of design and manufacturing changes during development..
Task 9: Communicate with regulatory agencies during product development.
Task 10: Interact with and document use of external organizations.
Task 11: Assist with and verify quality management system (QMS) elements are in place to support design, development, transfer, and marketing activities.
Task 12: Review regulatory aspects of contracts for product manufacturing and distribution.
Task 13: Verify access controls exist for regulatory documentation, ensuring confidentiality, and protection of proprietary information and personal health information (PHI).
Task 14: Assure marketing authorizations are in place prior to commercial launch.

Domain III: Process for Licensing, Registration, and Renewals—Exam Weighting approximately 23%

Task 1: Determine the needed documentation for licensing, registration and renewals.

Task 2: Engage the interdepartmental stakeholders for submission support.

Task 3: Consolidate, assess acceptability of data and file format, and submit filing data to meet applicable regulatory requirements.

Task 4: Determine and submit appropriate responses to deficiency requests.

Task 5: Update licenses and registrations based on critical change determinations.

Task 6: Monitor statuses for existing licenses, registrations, and renewals.

Task 7: Periodically review and revise standard operating procedures based on regional requirements.

Task 8: Communicate and negotiate with regulatory authorities and stakeholders during the license, registration and renewal process.

Task 9: Communicate the status of license, registration and renewals to relevant parties.

Task 10: Submit relevant documentation to comply with customs and import/export requirements.

Task 11: Establish/update applicable market authorization traceability systems.

Domain IV: Post-Market Activities—Exam Weighting approximately 23%

Task 1: Assess and document product, process, and quality management system changes for regulatory impact.

Task 2: Apply or interpret impact of external changes.

Task 3: Support health authority/notified body commitments.

Task 4: Support risk assessment and reportability of event determination

Task 5: Assess the regulatory impact of labeling changes, including advertising and promotional materials.

Task 6: Negotiate and interact with regulatory authorities through appropriate communication tools.

Task 7: Develop and/or maintain regulatory standard operating procedures for on-going compliance.

Task 8: Maintain and update the medical device files, technical device files, and dossiers.

Task 9: Evaluate key components of a product change and impact on market authorization.

Task 10: Participate in internal product review committees.

Task 11: Perform ongoing review of contracts for regulatory aspects for product manufacture and distribution.

Task 12: Submit documentation/samples for import and export requirements, legal requests, and product reimbursement requests.

Appendix B

Special Accommodations Request Form

To the Applicant: 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 of the following examinations are you requesting accommodation? ◻ RAC-Devices. ◻ RAC-Drugs

1. Type of accommodation requested

2. 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 accommodation 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 regulatory professionals, we have the responsibility to maintain particularly high standards of professional conduct while exercising professional requirements and duties in upholding and clarifying the applicable laws and regulations. We strive to make a positive contribution to public health by using this code of ethics in our workplace(s). This is the RAPS Code of Ethics; regulatory professionals understand that their employers and others may have other codes of ethics that they may need to acknowledge, understand, and follow.

Our Code of Ethics was first initiated in 2003 and has been updated twice since then. We vow to regularly assess its applicability and refresh its content as the regulatory profession grows and evolves.

Fundamental Principles

As a regulatory professional I aspire to:

- Provide my employer with the complete regulatory requirements to ensure their activities are conducted in compliance with the laws and regulations of the respective authorities.
- Be competent in performing my duties as a regulatory professional.
- Base decisions on factual, up-to-date information and clearly communicate competing or conflicting concerns, as necessary. Have integrity. Be consistent in making decisions and be trustworthy.
- Be honest with employers and team members to ensure all information and communications are accurate and complete.
- Have the courage to make difficult decisions. Present all relevant information to my organization to promote decisions. Be able to withstand challenges to my views and be accountable for my errors.
- Be fair in my dealings with all stakeholders. Apply regulatory standards equitably. Consider all interests of all parties in the decision processes.
- Be respectful of others. Treat all individuals with dignity and courtesy.

RAPS members perceive eight core values that regulatory professionals use in conducting their professional responsibilities.

Duty

Our role is defined by our responsibility to advise individuals, team members, and organizations regarding the appropriate regulatory context for actions they may want to take. We also must heed our obligations as employees, consultants, and contractors for making products for patients; as members of teams conducting clinical & nonclinical studies; as regulators; and as members of our profession. Regulatory professionals have a duty to:

- Disseminate and interpret applicable government laws and regulations, industry standards and *good practice* guidelines without bias.
- Provide healthcare professionals (HCPs) with accurate and relevant information regarding the safety and effectiveness of products.
- Maintain the integrity of our profession and strive to preserve the public's trust.

Competence

Competence means the regulatory professional has the knowledge, experience, ability and skill sets to effectively identify, analyze, solve, or recommend solutions for regulatory challenges. We must be dedicated, yet flexible to adapt to the constantly changing requirements.

The diversity of individuals and organizations within the profession necessitates a commitment to evolve by a variety of options: continuing education, work experience, professional training, and certifications. Maintaining regulatory competence is a continual learning process. Regulatory professionals develop competence by:

- Being knowledgeable about current and future trends.
- Encouraging and supporting professional growth and development among peers and colleagues so all can gain and demonstrate competence in the profession.
- Participating in continuing education opportunities related to regulatory laws, guidance, standards, and other updates.

Objectivity

Regulatory professionals display objectivity by:

- Responding carefully to issues and recognizing other points of views and striving to offer an unbiased expression of facts.
- Presenting regulatory opinions, options and associated risks when developing regulatory strategies.
- Clearly delineating regulatory requirements, internal requirements and personal preferences.
- Appropriately disclosing new information.

Integrity

Regulatory professionals should not compromise their values or trustworthiness for personal gain or professional enhancement. Regulatory professionals shall develop and maintain integrity by:

- Keeping their commitments
- Giving credit for the work of others
- Maintaining confidentiality
- Seeking advice when uncertain
- Maintaining integrity without compromise
- Avoiding situations that put integrity at risk
- Accepting that best option may not be in their employer's short-term interest
- Avoiding conflicts of interest
- Adhering to their employer's Ethics and Compliance Standards

Honesty

Regulatory professionals shall exhibit honesty in all activities. Honesty requires acting free from deceit or deception, including dishonesty by omission or failing to provide comment when ethically required. Regulatory professionals shall build honesty and trust by:

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

Courage

Regulatory professionals must have courage to evaluate, conclude, and provide consistent and accurate advice. Regulatory professionals develop courage by:

- Encouraging an open exchange of all views, even if they challenge regulatory advice.
- Admitting mistakes, accepting accountability and promptly correcting any errors, miscommunications, or misperceptions.
- Delivering bad news quickly to management when necessary.
- Providing information to all stakeholders regarding risks and consequences if regulatory advice is overruled or ignored.

Fairness

Regulatory professionals strive to treat all persons fairly, equitably, and equally to create and maintain a healthy workplace, so that all people can thrive both personally and professionally. Regulatory professionals demonstrate fairness by:

- Respecting the letter and spirit of laws and regulations.
- Applying the appropriate 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 must respect the roles of their colleagues, and both recognize and acknowledge all. Regulatory professionals develop respect by:

- Listening.
- Treating all parties with dignity and courtesy.
- Accepting personal differences.
- Creating a positive environment where diversity, equity and inclusion thrive.
- Creating an environment where there is zero tolerance for harassment of any kind towards others.
- Finding creative ways to resolve conflict.
- Being patient and forgiving when others make mistakes and not assign blame.

Appendix E

Appeals Request Form

You have the right to request reconsideration of any adverse examination decisions made by the RAPS 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 RAPS 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 □ Autumn

□ 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

2027 Application Deadlines and Testing Window

Exam Window	Application Deadline	Exam Window Open Date	Exam Window Close Date	Transfer Deadline (without fee)
Spring 2027	Thursday, 18 February	Monday, 22 March	Friday, 23 April	Thursday, 18 February
Summer 2027	Thursday, 17 June	Monday, 12 July	Friday, 13 August	Thursday, 17 June
Autumn 2027	Thursday, 7 October	Monday, 1 November	Friday, 3 December	Thursday, 7 October

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

2027 Application, Transfer, and Other Fees

Application Fees

Pricing	RAPS Member	$620 (US)
	Nonmember	$780 (US)

You must be a RAPS member at the time of application submission to receive the member 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	$310
Form Change Fee	$50

Appendix H

Important Contact Information

Pearson VUE
Tel: +1 800-483-2855
Website: home.pearsonvue.com/raps

RAPS Program Office/Customer Support
Tel: +1 301 770 2920, ext. 200
Email: certification@raps.org