

Regulatory Affairs Certification (Devices)

CANDIDATE GUIDE



CONTENTS

Welcome.....	3
Introduction.....	3
Value of the RAC.....	3
About Certification.....	3
Preparing for the Exam.....	4
RAC Examination Overview	4
Preparing for the Examination.....	4
Question Types.....	5
Computer-Based Testing.....	5
Your Journey	5
Applying for the Examination.....	6
RAC Application Process.....	6
Testing Windows and Application Deadlines.....	6
Eligibility Requirements	6
General Application Instructions.....	7
Submitting Payment.....	8
Application Receipt Confirmation.....	8
Application Audit.....	8
Incomplete Applications.....	8
Application Rejection	8
Application Withdrawal/Cancellation and Refunds.....	8
Transferring to Another Testing Cycle.....	9
Appeals Process.....	9
Nondiscrimination Policy.....	9
Examination Scheduling.....	10
Scheduling Your Examination.....	10
Testing	10
International Testing.....	10
Changing Your Examination Appointment After it Has Been Scheduled.....	10
Emergency Situations.....	11
Failure to Schedule an Examination or Appear for Your Examination Appointment	11
Special Accommodations for the Examination.....	11
On Examination Day	12
What to Bring to the Testing Center	12
Items Prohibited at the Testing Center	12
Other Considerations.....	12
Cancellation Due to Inclement Weather	13
Examination Security and Confidentiality	13
Termination of Examination Administration/Dismissal From the Testing Center	13
Problems at the Testing Center	13
After the Examination.....	14
Examination Scoring	14
Notification of Examination Results.....	14
RAC Recognition	14
Use of the RAC Designation.....	14
Retaking the Examination.....	14
Release of Information.....	14
Recertify	15
Maintaining Your RAC Credential	15
Appendix A: RAC (Devices) Detailed Examination Content Outline	16
Appendix B: Special Accommodations Request.....	19
Appendix C: Documentation of Disability-Related Needs	20
Appendix D: Code of Ethics.....	21

WELCOME

Introduction

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

This guide contains information about:

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

Regulatory Affairs Certification (RAC), is the only post-academic professional 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 is a professional credential that denotes commitment to excellence, pursuit of knowledge and career advancement. Success on the RAC examinations 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.

RAC-credentialed professionals are among the current and rising leaders in the regulatory profession. To date, more than 8,500 individuals have earned the RAC, some holding multiple credentials.

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 and RAC-credentialed professionals earn higher salaries than those who do not hold the credential.*

In RAPS' 2018 *Scope of Practice & Compensation survey for the Regulatory Profession*, RAC holders in North America reported earning an average of 18% more than their counterparts who do not hold the credential.*

*Based on data from the 2018 RAPS *Scope of Practice & Compensation Survey of the Regulatory Profession*

About Certification

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

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

PREPARING FOR THE EXAM

RAC Examination Overview

Each examination is based on a survey of the scope of practice and specific roles and responsibilities of regulatory professionals in the workplace with at least three years of regulatory experience. Each examination is reviewed and revised annually and content is updated for the Spring exam cycle. Examination content for RAC exam is based on regulations and guidelines in effect on December 31 of the year prior. So exams taken in 2019 will be based on regulations 'on the books' on December 31, 2018.

<p>Knowledge required and regulatory basis</p>	 <p>RAC (Devices)</p>
	<ul style="list-style-type: none"> • Knowledge of the full product development and lifecycle requirements for medical devices, and IVDs. • Knowledge of US FDA requirements (30%); European regulations and guidances from the European Commission and competent authorities (30%); and globally applicable regulatory practices* (40%). (*IMDRF, WHO and ISO guidelines and standards). • Critical thinking and analytical skills.

Preparing for the Examination

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

Review the examination content outline (see p. 16). The examination content outline contains the content domains, competency statements and number of questions in each domain. Examination questions are based on guidelines and regulations effective 31 December of the prior year.

Assess the scope and depth of your knowledge and experience. Use the test content outline as a checklist and evaluate your areas of strength and weakness. This will help focus your study on the areas you need most.

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

Question Types

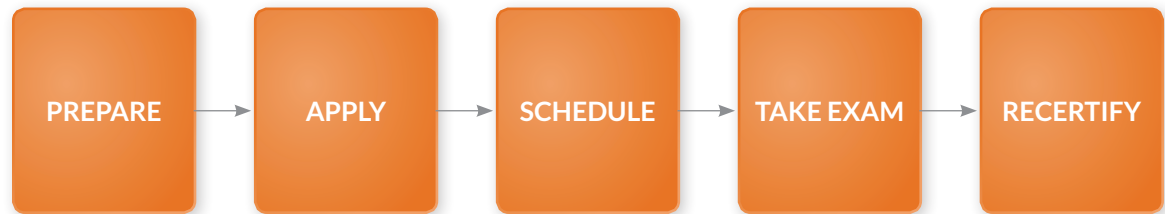
The examinations consist of 100 multiple-choice questions, answered in a two-hour time limit. There are three question formats which may be used in the RAC Exams.

Recall	Application	Analysis
Recall questions ask for specific information, typically about regulations and guidance that are important aspects of the regulatory process. These questions may relate to any stage of product development and may relate to regulations specific for 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

The RAC examinations are computer-based and administered only at testing centers selected and confirmed by the testing vendor. RAC examinations will not be stored or accessible through the internet and will not be offered at facilities that are not pre-selected and qualified for security measures.

Your Journey



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

APPLYING FOR THE EXAMINATION

RAC Application Process

You may apply for the RAC online or submit the printable application form available on the RAC exam schedules webpage.

Testing Windows and Application Deadlines

Application Deadline	Testing Window
24 September 2019	21 October–30 November 2019
27 February 2020	23 March–1 May 2020
18 June 2020	13 July–21 August 2020
8 October 2020	2 November–11 December 2020

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

Examination Fees 2020 Prices

- RAPS Member \$485 (US)
- List \$605 (US)

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

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

Eligibility Requirements

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

Baccalaureate or equivalent first university degree and a minimum of three years of regulatory or regulatory-related work experience*

Master's degree and a minimum of two years of regulatory or regulatory-related work experience*

Doctorate degree and a minimum of one year of regulatory or regulatory-related work experience*

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

General Application Instructions

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

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

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

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

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

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

Submitting Payment

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

Payment type	Application submission method
Credit card	Apply online, by fax or postal mail to: Regulatory Affairs Professionals Society Attn: RAC Program Office 5635 Fishers Lane Suite 550 Rockville, MD 20852 USA
Check or money order	Postal mail only to: Regulatory Affairs Professionals Society RAC 5635 Fishers Lane, Suite 400 Rockville, MD 20852 USA
International wire transfer	Fax a completed application form and copy of bank wire confirmation to confirm your application to: RAPS Account #1000043228997; ABA #061000104 Swift Code SNTRUS3A; Suntrust Bank, 303 Peachtree St. NE, Atlanta, GA 30308. Must reference name of candidate. All bank charges are the responsibility of the payer. For all wire payments: fax (+1 301 770 2924) or email (certification@raps.org) a completed form and copy of bank wire confirmation to confirm your registration.

Application Receipt Confirmation

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

Application Audit

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

Incomplete Applications

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

Application Rejection

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

Application Withdrawal/Cancellation and Refunds

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

Transferring to Another Testing Cycle

A request to transfer to the next testing cycle may be made without charge before the application deadline. Requests to transfer to the next testing cycle after the application deadline but before the end of the testing window will incur a transfer fee of \$250. Transfers will be allowed up to 10 days after the end of the testing window. After this period transfers will not be allowed and applicants will be required to pay a new application fee at full price. For individuals who require a transfer due to an unavoidable emergency please see the 'Emergency Situations' section.

Appeals Process

Candidates have the right to appeal any adverse decision made by the RAC program office. An appeal must be submitted in writing not more than 30 days following the date of notification of the adverse decision. Appeals should be sent to the RAC program office at certification@raps.org or via US mail to RAPS headquarters. All appeals will be addressed by the RACB. Decisions about appeals made by the RACB will be final.

Nondiscrimination Policy

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

EXAMINATION SCHEDULING

Scheduling Your Examination

You will schedule your examination online directly with RAPS' contracted testing vendor, Scantron. You will receive a "Notice to Schedule" email from Scantron approximately 15 days prior to the start of the testing cycle with instructions about how to schedule your examination. Please be sure that your email address can accept emails from testing@castleworldwide.com. This email will contain a website link, unique login ID and password. You will use this site to schedule a testing center location, test date and time.

Testing

To schedule your examination at a testing center, log into the Scantron scheduling site, you will be shown the available dates and times at your selected testing center and you will select your preferred testing date and time. Once you submit your selection you will receive a confirmation e-mail.

You should schedule your examination as soon as possible for the best chance of receiving your preferred testing date and location. You must submit your test scheduling request at least four days prior to your preferred testing date. All examinations must be scheduled four days prior to the close of the testing cycle. Once you have scheduled your examination, you will receive a confirmation email from Scantron. You must bring a copy of the confirmation email with you to the testing center on test day.

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

International Testing

Applicants looking to schedule an examination outside of the US or Canada should follow the the instructions to schedule through the Scantron scheduling site. However, should international sites/dates be unavailable at your preferred international location, you may click on the "More International Sites" button to see a full list of sites in our network. Consider locations that you may be traveling to for business or pleasure if you cannot find a location near your home or office. You may then submit three (3) preferred international site/date options. Scantron cannot guarantee availability of any international site/date during the designated testing period. Within five (5) business days, Scantron will issue a confirmation notice for one of the preferred sites/dates. If none of the preferred site/dates are available, Scantron will offer an alternate site/date for your approval. Upon approval, Scantron will issue a confirmation notice.

Changing Your Examination Appointment After it Has Been Scheduled

If you wish to change the date, time or location of an examination that has already been scheduled, and that you wish to take in the same examination window, you will need to go to the link on your appointment confirmation email. If you have difficulty rescheduling online, you can contact Scantron by telephone at +1 919 572 6880. A fee of \$50 (US) for each change is required, payable to Scantron. Changes may not be made less than five business days before your scheduled examination date. You may only reschedule to another date within the current testing cycle. If you wish to reschedule to another testing window, please see 'Transferring to Another Testing Cycle.'

Emergency Situations

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

If an applicant cannot take the RAC exam for one of the following reasons:

- A documented, personal medical emergency
- A death in your immediate family
- Unexpected military deployment

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

A personal medical emergency means that the candidate has experienced a medical issue. Transfer requests are not applicable for medical issues affecting family members. To apply for a transfer waiver the appropriate documentation must be submitted to the RAC program office no later than 30 days of your scheduled examination date. Candidates will not be eligible for a refund following a transfer. Work-related emergencies do not qualify for this exception.

Failure to Schedule an Examination or Appear for Your Examination Appointment

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

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

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

Special Accommodations for the Examination

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

ON EXAMINATION DAY

What to Bring to the Testing Center

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

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

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

The following are acceptable forms of government-issued identification:

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

Items Prohibited at the Testing Center

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

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

You will be provided with:

1. paper and pencil or erasable noteboards and markers at the test center
2. have an abbreviations table

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

Other Considerations

- Smoking is prohibited.
- You may not ask questions about examination content.
- All examinations are monitored and may be recorded in both audio and video format.

- No breaks are scheduled during the examination. If you need to leave the testing room to take a break, you will not be given extra time to finish the examination. You may be required to present your ID when returning to the testing room.

Cancellation Due to Inclement Weather

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

Examination Security and Confidentiality

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

Termination of Examination Administration/Dismissal From the Testing Center

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

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

Problems at the Testing Center

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

AFTER THE EXAMINATION

Examination Scoring

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

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

Notification of Examination Results

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

RAC Recognition

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

Use of the RAC Designation

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

Retaking the Examination

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

Release of Information

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

RECERTIFY

Maintaining Your RAC Credential

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

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

Contact Information

Regulatory Affairs Professionals Society
Attention: RAC Program Office
5635 Fishers Lane, Suite 400
Rockville, MD 20852
USA
Tel +1 301 770 2920, ext. 200
Fax +1 301 770 2924
Email: certification@raps.org

Scantron
6001 Hospitality Court, #100
Morrisville, NC 27560
+1 919 572 6880
email: testing@castleworldwide

APPENDIX A: RAC (DEVICES) DETAILED EXAMINATION CONTENT OUTLINE

Each examination is based on a survey of the scope of practice and specific roles and responsibilities of regulatory professionals in the workplace with at least three years of regulatory experience. Each examination is reviewed and revised annually and content is updated for the October/November exam cycle. Examination content for the RAC (Devices) exam is based on regulations and guidelines in:

Domain I: Strategic Planning – Exam Weighting approximately 29%

- Task 1: Determine the proposed product classification by using the relevant regulation to prepare for regulatory pathway and submission strategy.
- Task 2: Evaluate the regulatory environment and provide internal advice throughout the life cycle of the product (e.g., concept, development, manufacturing, marketing) to facilitate product compliance.
- Task 3: Provide input regarding comparative effectiveness/health technology assessment associated with reimbursement.
- Task 4: Perform risk/benefit analysis on product development concept for initial product viability.
- Task 5: Provide direction for safety and effectiveness testing (e.g., bench, preclinical, clinical) at the feasibility phase to determine the ability to comply with regulatory requirements.
- Task 6: Collaborate with and advise research and development programs regarding applicable regulatory compliance.
- Task 7: Provide regulatory intelligence to develop local, regional, and global regulatory strategies.
- Task 8: Evaluate the regulatory outcomes from the initial product concepts and make recommendations for future actions.
- Task 9: Research and interpret regulatory decisions in a similar product category to assess regulatory approval implications.
- Task 10: Identify appropriate regulatory authorities for submission of data for product being developed.
- Task 11: Assess impact of local, regional, and global requirements and considerations on the content of regulatory submission/dossiers.
- Task 12: Evaluate global filing strategy (e.g., simultaneous filings, joint reviews, mutual recognition agreements, assessment of similarity or dissimilarity of requirements) to define market feasibility.
- Task 13: Anticipate regulatory concerns arising from trade issues (e.g., applicable treaty law, international conventions, “for export only” status).
- Task 14: Provide alternative strategies for product development and submission to ensure timely approval and advise internal stakeholders on the requirements.
- Task 15: Develop and review regulatory department standard operating procedures to achieve regulatory compliance.
- Task 16: Participate in internal training programs for company personnel to achieve regulatory and quality compliance.
- Task 17: Assist other departments to develop standard operating procedures to achieve regulatory compliance.

Domain II: Pre-marketing – Exam Weighting approximately 25%

- Task 1: Evaluate need for and contribute to product development for special patient populations (e.g., pediatric investigation plan/waivers/deferral, orphan devices, and humanitarian device exemptions).
- Task 2: Advise stakeholders of regulatory requirements for quality, bench, preclinical, and clinical data.
- Task 3: Assess the acceptability of quality, bench, preclinical, and clinical documentation for submission filing to meet regulatory requirements.
- Task 4: Negotiate and interact through appropriate communication tools (e.g., meetings, email) with regulatory authorities before and during the product development and review process to facilitate submission approval.
- Task 5: Determine acceptability of submission package through the preparation and review of relevant sections to comply with applicable requirements.
- Task 6: Compile and prepare regulatory submissions according to relevant guidelines and submit to the appropriate regulatory authorities.
- Task 7: Monitor the progress of the regulatory authority review process through appropriate communication with the agency.
- Task 8: Evaluate the impact on the regulatory submission strategies of proposed manufacturing changes during the preclinical development and clinical studies.
- Task 9: Facilitate the development of appropriate and timely responses to regulatory authority queries and actions to meet regulatory requirements.
- Task 10: Participate in developing a risk management system to ensure that local, regional, and global regulatory requirements are met.
- Task 11: Identify and monitor events and processes and, as applicable, submit reports (e.g., serious adverse events, periodic reports, final study reports) or notifications (e.g., changes in manufacturing) to regulatory authorities to comply with regulations.
- Task 12: Interact with other companies associated with acquisitions and collaborations.
- Task 13: Interact with and record the use of contract research organizations, subcontractors, test facilities, and consultants.
- Task 14: Review documentation of raw materials to ensure compliance with regulatory requirements.

Domain III: Post-marketing – Exam Weighting approximately 38%

- Task 1: Review advertising and promotional materials for regulatory compliance.
- Task 2: Review and provide input to labeling to comply with regulatory requirements.
- Task 3: Submit notifiable changes and supplemental dossier to the appropriate regulatory authorities to update product information and/or instructions for use to reflect current state of product.
- Task 4: Verify that appropriate standard operating procedures are in place to manage product associated events, complaints, recalls, market withdrawals, and safety reports.
- Task 5: Provide input to the risk assessment associated with product issues and implement appropriate regulatory steps to address issues (e.g., consumer information, advertising, labeling changes, warnings, alerts, product changes, recalls, withdrawals).
- Task 6: Participate in implementing regulatory strategy for handling recalls and communication to stakeholders (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 as required.
- Task 8: Report product safety issues to regulatory authorities as required to comply with local, regional, and global regulations.

- Task 9: Submit single case or aggregate safety reports to comply with local, regional, and global regulations or upon request by regulatory authorities.
- Task 10: Comply with product post-marketing surveillance requirements to meet conditions of approval.
- Task 11: Proceduralize the regulatory assessment process to define notifiable changes to comply with local, regional, and global regulatory authorities for post-marketing changes.
- Task 12: Evaluate change control documents to determine the level of change and consequential submission requirement.
- Task 13: Participate in crisis/issue management team (e.g., product recall, counterfeiting) and assess the regulatory impact of an event and proposed resolution.
- Task 14: Review regulatory aspects of contracts (e.g., quality, product complaints, recalls, vigilance) for product manufacture and distribution.
- Task 15: Control access to regulatory documentation, ensuring confidentiality and protection of proprietary information.
- Task 16: Maintain licenses (e.g., establishment, narcotics, controlled substances) and submit renewals as required.
- Task 17: File new and amended patent/trademark forms to update information with applicable regulatory authorities to meet regulations.
- Task 18: Provide required information (e.g., clinical data) in support of product reimbursement requests.
- Task 19: Submit documentation and samples for lot release, if required, for customs clearance.
- Task 20: Demonstrate that quality systems are in place (e.g., ISO 13485 for medical devices).
- Task 21: Comply with import and export requirements.
- Task 22: Demonstrate compliance with applicable market controls and requirements (e.g., controlled substances, veterinary use only).
- Task 23: Assess adequacy of product traceability systems.

Domain IV: Interfacing – Exam Weighting approximately 8%

- Task 1: Communicate and negotiate with regulatory authorities and stakeholders to facilitate compliance on regulated products.
- Task 2: Review public communications, press releases, etc., to ensure regulatory compliance.
- Task 3: Participate in internal product review committees (e.g., labeling, quality, launch).
- Task 4: Develop early warning systems to identify potential regulatory compliance issues affecting the company and advise affected internal functional groups.
- Task 5: Identify and interact with the standards-developing organizations that are appropriate for the company's product.

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

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

APPENDIX B: SPECIAL ACCOMMODATIONS REQUEST

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 you qualify for special accommodations.

Please type or print

Name _____
First Last MI

Address _____
Street Mail Stop/Suite/Apt

_____ City State/Province Zip

Country _____

Phone (with area/country code) _____

Email address _____

For which of the following examinations are you requesting accommodations?

- RAC (US)
- RAC (EU)
- RAC (CAN)
- RAC (Global)
- RAC (Devices)
- RAC (Drugs)

Type of accommodation you are requesting _____

Have you previously received accommodations in any educational or testing situation?

- Yes
- No

If yes, please describe the accommodations received _____

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) examination. The Regulatory Affairs Professionals Society requires that candidates requesting testing accommodations provide documentation of the disability from a person qualified to assess the disability.

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

Candidate Name _____
First Last MI

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:

Name _____

Contact Email/Phone _____

Signature _____ Date _____

APPENDIX D: CODE OF ETHICS

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

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

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

Statement of Personal Responsibility

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

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

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

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

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

Fundamental Principles

As a regulatory professional I aspire to:

- To ensure my employer’s activities are conducted in compliance with the laws and regulations of the authorities under which we operate, consistent with advancing, preserving and protecting public health.
- Be competent to perform the services I have been hired or retained to perform. As a regulatory professional, I hereby commit myself to continual learning while being able to acknowledge areas outside my expertise.

- Act in an objective manner. As a regulatory professional, I will base decisions on factual information. I will not be unduly influenced by competing or conflicting interests and I will clearly communicate competing or conflicting interests when appropriate.
- Have integrity. As a regulatory professional, I must be principled and consistent in applying my views. I must live up to my commitments, and be trustworthy and scrupulous at all times.
- Be honest in all dealings with my employers and others with whom I interact. As a regulatory professional, I must ensure all information and communications, whether oral or written, are accurate and complete. I acknowledge and affirm personal and institutional credibility is crucial to my success.
- Have the courage to make difficult decisions. As a regulatory professional, I will present all relevant information to my organization to promote wise decisions. I must be able to withstand challenges to my views, while at the same time being accountable for my mistakes.
- Be fair in my dealings with all parties. As a regulatory professional, I must apply legal and regulatory standards equitably. I must be just in considering the interests of all parties in decision processes.
- Be respectful of others. I must treat all individuals with dignity and courtesy.

Duty

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

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

Regulatory professionals have a duty to:

Disseminate and interpret relevant governmental regulations, industry standards and good practice guidelines without bias.

Ensure products are safe and beneficial to patients, while maintaining the long-term interests of our employers.

Ensure, to the extent possible, the benefits justify the risks for those who participate in clinical studies and who use regulated products.

Provide physicians and other healthcare professionals with accurate and complete information about the safety and effectiveness of products.

Maintain the long-term integrity of our profession and strive to deserve the public's confidence and respect.

Competence

Competence means a regulatory professional has the knowledge, experience, ability and skill necessary to effectively identify, analyze and solve or recommend solutions to regulatory challenges. Regulatory professionals must be dedicated and flexible enough to adapt to the 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.
- Taking into account 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 where ever 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



5635 Fishers Lane
Suite 400
Rockville, MD 20852
USA

RAPS.org/RAC