



Regulatory Affairs Certification

CANDIDATE GUIDE



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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. The RAC is intended for individuals employed in regulatory agencies, industry, consultancies and other settings involved with the regulation of healthcare products.

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

About Regulatory Affairs Certification (RAC)

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 7,000 individuals have earned the RAC, some holding multiple credentials.

Value of the RAC

The RAC is the only credential for the regulatory professional in the healthcare product sector. 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' 2016 Scope of Practice & Compensation survey for the Regulatory Profession, RAC holders in North America reported earning an average of 11% more than their counterparts who do not hold the credential.

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.

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

RAC Examination Overview

Four different examinations and resulting credentials are available: RAC United States (US), RAC European Union (EU), RAC Canada (CAN) and RAC Global. 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.

The examinations address pharmaceuticals, biologics and biotechnology, medical devices, *in vitro* devices (IVDs) and regulatory functions throughout the product lifecycle. Each examination consists of 100 multiple-choice questions to be answered in a two-hour time period. Each examination presents a balanced mix of questions about product types, and those requiring critical thinking and analysis that can be applied to any healthcare product. Each examination is reviewed and revised annually and content is updated for the October/November exam cycle. For RAC exams administered in 2018, examination content is based on regulations and guidelines in effect on 31 December 2016.

The three regional RAC examinations (US, EU and Canada) address the specific laws, regulations, policies and guidelines for healthcare products, including medical devices, pharmaceuticals and biotechnology products in their respective regions. The RAC Global tests general knowledge of the full product lifecycle for medical devices, IVDs, pharmaceutical and medicinal products, and biologics as well as guidelines and standards from the International Conference on Harmonisation (ICH), International Medical Device Regulatory Forum (IMDRF), Global Harmonisation Task Force (GHTF), World Health Organization (WHO) and the International Organization for Standardization (ISO). See the table below for a comparison of the different RAC examinations.

	 RAC (US)	 RAC (EU)	 RAC (CAN)	 RAC (Global)
Knowledge required and regulatory basis	<ul style="list-style-type: none"> • Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceuticals and biologics • FDA regulations • Critical thinking and analytical skills 	<ul style="list-style-type: none"> • Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, medicinal products (e.g., pharmaceuticals, biologics) • European regulations and guidances from the European Commission, EMA, competent authorities • Critical thinking and analytical skills 	<ul style="list-style-type: none"> • Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceuticals, medicinal products and biologics • Health Canada regulations • Critical thinking and analytical skills 	<ul style="list-style-type: none"> • Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceuticals, medicinal products and biologics • ICH, IMDRF, WHO and ISO guidelines and standards • Critical thinking and analytical skills
Best suited for	Regulatory professionals submitting to, or involved with, regulatory authorities in the US	Regulatory professionals submitting to, or involved with, regulatory authorities in the EU	Regulatory professionals submitting to, or involved with, regulatory authorities in Canada	Regulatory professionals not currently involved with regulatory authorities in the US, EU or Canada

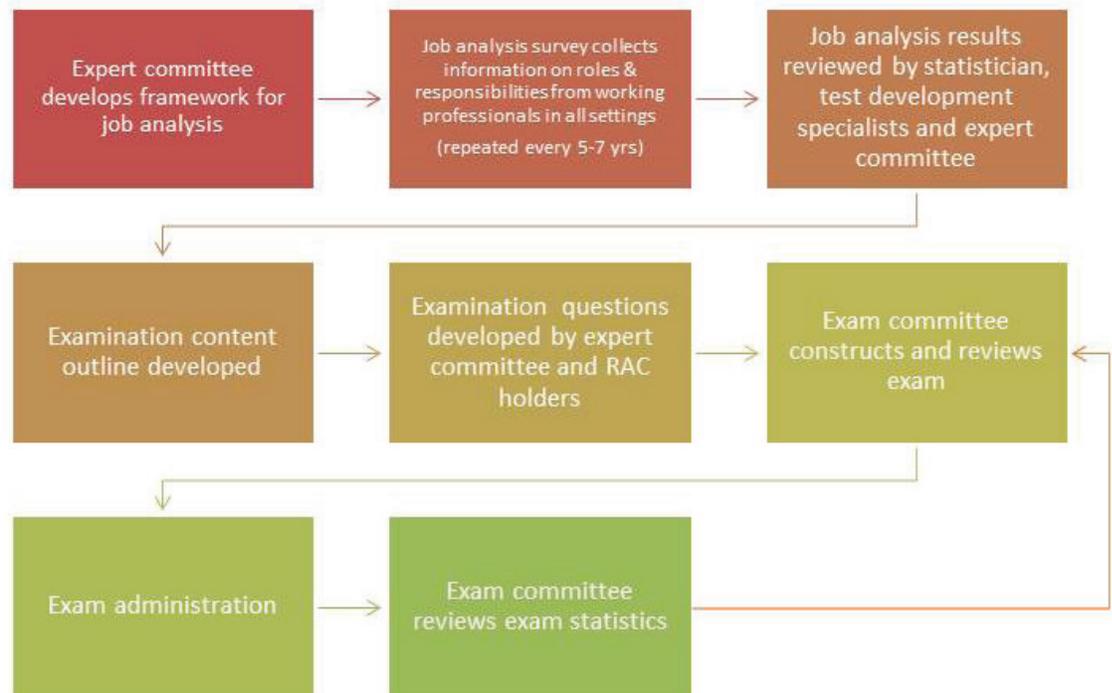


The RAC (US) examination is accredited by the National Commission for Certifying Agencies (NCCA)

RAC Examination Development Process

The Regulatory Affairs Certification Board (RACB) oversees the development of the RAC examinations. Each examination is developed by an examination committee comprised of practicing regulatory experts knowledgeable about the relevant regulations for the region.

The process outlined in the diagram below is performed for each of the RAC examinations.



The examination content outlines and the RAC examinations are based on job analysis (role delineation) studies undertaken by the RAC program. These studies are guided by experts in testing and measurement. The job analysis studies are completed before an examination is created and repeated as needed to determine whether there are changes in the role and scope of practice of regulatory professionals that would require adjustment of the examination content.

The job analysis study is used to develop the content outline for each examination and determine the number and type of questions to be included in each content area.

While the examination content outlines may be used for a period of several years, the questions on the examinations are updated every year to reflect current regulations, guidelines and practice. For RAC exams administered in 2018, examination content is based on regulations and guidelines in effect on 31 December 2016.

The content outlines for the examinations are appended to this guide and available at RAPS.org/rac.

Applying for the Examination

Eligibility Requirements

Please review the eligibility requirements carefully prior to starting the application process.

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.

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.

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

Testing Window	Application Deadline
1 October–30 November 2018	1 September 2018
22 April–31 May 2019	21 March 2019
21 October–30 November 2019	24 September 2019

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

RAPS Member	\$465 (US)
List	\$585 (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.

General Application Instructions

Include your name on the application as it appears on your government-issued photo identification (ID). You will be required to show your government-issued photo ID at the testing center and the name on your ID must match the name on your application.

Provide an 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. If you make changes to your email address in your RAPS account, you will still need to notify the RAC program office about the change to ensure that you receive all communications about your examination.

Complete the RAC examination application fully. As part of the application process, you must attest that you have met the eligibility requirements, have read and agree to abide by the policies outlined in this Candidate Guide, and have read and accept 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 c/o Suntrust Lockbox Dept. P.O. Box 79546 Baltimore, MD 21279-0546 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, Richmond, VA. 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 will 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** of 1 March for the spring testing cycle, or 1 September for the autumn testing cycle. 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 of 1 March for the spring testing cycle or 1 September for the autumn testing cycle.

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 (10 June for spring and 10 December for autumn). 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.

Examination Scheduling

Scheduling Your Examination

You will schedule your examination online directly with RAPS' contracted testing vendor, Castle Worldwide. You will receive a "Notice to Schedule" email from Castle Worldwide 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 request a testing center location, test date and time.

Testing in the US and Canada

When scheduling your examination at a testing center in the US or Canada, once you log into the Castle Worldwide 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 email.

International Testing

When scheduling your examination at a testing center outside of the US or Canada, you will select your preferred testing center location, date and time. You may submit up to three preferred international testing centers, dates and times. Once you have submitted your preferences, Castle Worldwide will send a confirmation email within five business days. Submission of your preferences does not confirm that you are scheduled to test on your selected date or time. Castle Worldwide cannot guarantee availability of any international testing center or date during the designated testing cycle. If none of your preferred selections are available, Castle Worldwide will contact you to offer an alternate date/location for approval. Upon approval, Castle Worldwide will issue you a confirmation email.

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

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

Changing Your Examination Appointment

If you wish to change the date, time or location of a scheduled examination, you will need to go to the link on your appointment confirmation email. If you have difficulty rescheduling online, you can contact Castle Worldwide by telephone. A fee of \$50 (US) for each change is required, payable to Castle Worldwide. 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. Only one emergency transfer will be allowed and 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 E and F) 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.

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. The examination content outline contains the content domains, competency statements and number of questions in each domain. For RAC exams administered in 2018, examination questions are based on regulations and guidelines effective 31 December 2016. A detailed content outline for each examination is appended to this guide and available online at RAPS.org/RAC.

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.

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.

On Examination Day

What to Bring to the Testing Center

You should arrive at the testing center at least 30 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.

Your identification must match your name exactly as it appears on the examination appointment confirmation notification provided by Castle Worldwide. 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

The following are **unacceptable** forms of identification:

- gym membership cards
- warehouse store cards
- school identification cards
- credit cards
- identification cards with signature only and no photo
- social security card
- library card
- insurance cards

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 or 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
- food and beverages
- coats and jackets
- 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 paper and pencil or erasable noteboards and markers at the test center. You will have access to an abbreviations table during testing. The abbreviations table includes information about the abbreviations used on the examination.

Please note that Castle Worldwide 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, Castle Worldwide will post the [information on their website](#). Candidates scheduled at a site operating on a delay will receive an email from Castle Worldwide. Should the site be closed entirely, Castle Worldwide 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 Castle Worldwide 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 Castle Worldwide 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.

Because the questions on current versions of the examinations may be more difficult or easier than questions on former versions, RAPS uses advanced statistical procedures to equalize the different versions and the scores candidates achieve on the examinations. This ensures that candidates are not rewarded or penalized when one version of an examination may be more or less difficult than another version.

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. The spring testing cycle closes on 31 May and the autumn testing cycle on 30 November. You will receive an email notification with your pass or fail results. Approximately four to eight weeks following the close of the testing cycle, you will receive a confirmation of your scaled score. 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 and long as you maintain your RAC 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.

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 550
Rockville, MD 20852
USA
Tel +1 301 770 2920, ext. 200
Fax +1 301 770 2924
Email: certification@raps.org

Castle Worldwide Inc.

900 Perimeter Park Drive, Suite G
Morrisville, NC 27560
+1 919 572 6880
email: testing@castleworldwide.com

Overview of RAC Examination Content Outlines

Development of the RAC Examinations

The content outlines and the RAC examinations are based on job analysis (role delineation) studies undertaken by the RAC program. The job analysis studies are completed before an examination is created and repeated as needed to determine whether there are changes in the role and scope of practice of regulatory professionals. If the studies determine there are significant changes in practice, the examination content outlines are revised accordingly.

The results of the job analysis studies are also used to determine the number and type of questions for each content area.

While the content outlines may be used for a period of several years, the questions on the examinations are updated every year to reflect current regulations, guidelines and practice. New examination content is added for the October/November testing cycle.

Question Types

The examinations consist of 100 multiple-choice questions. There are three types of questions included on each examination:

- 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.



Appendix A: RAC (US) Detailed Examination Content Outline

The RAC (US) examination is organized into four major domains, with associated tasks and responsibilities typically undertaken by a regulatory professional. The approximate distribution of types of questions for each domain is shown in the following outline. Questions on the examination will address the tasks and activities presented in this outline.

Domain I: Strategic Planning

Approximately 28 questions for a 100-question examination (percent of items on examination: 28%)

Regulatory Framework

- Evaluate proposed products for regulatory classification (drug/device/biologic/combination/OTC/predicate devices, etc.) and jurisdiction (CDER/CDRH/CBER, etc.).
- Monitor and assess the regulatory environment (product specific guidances, competitor products, etc.) to propose regulatory path forward (generic/OTC/predicate device, etc.).
- Evaluate US regulatory implications for non-US (global) development and marketing.
- Provide input to FDA and industry (PhRMA, AdvaMed, etc.) and standards (USP, ASTM, ICH, etc.) organizations to influence the US regulatory environment (legislation, regulations, guidance documents, standards, etc.).

Regulatory Pathways and Options

- Determine requirements (local, national, international) and options for regulatory submissions (NDA/BLA/PMA/510k, electronic/paper, 505(b)(2), etc.), approvals (priority review, user fees, etc.), and compliance activities (registration, listings, etc.).
- Advise management on timelines, benefits/risk assessment and financial implications of the proposed regulatory strategy.
- Investigate and communicate to management the availability of incentives (pediatric, orphan, fast track, HDE, etc.) to support product development.
- Develop optimal strategy for Agency interactions during product development and life cycle management.
- Advise internal stakeholders (marketing, manufacturing, R&D, etc.) regarding current/pending guidances, regulations, Agency/industry initiatives, etc. to ensure regulatory strategy is in alignment with company objectives.
- Consult with marketing/project team to develop intended use and claims (target product profile).
- Assess quality systems (e.g., CE marking, ICH, GMP/QSR, ISO, etc.) by performing audits to determine compliance to Quality System Regulations (QSR) and Drug GMP, assuring compliance to established SOPs for QSR and drug GMPs [e.g., failure investigations, etc], and making recommendations for improvement of quality systems, based on audit findings and QSR or GMP requirements.
- Develop/deliver/assure in-house training programs for all company personnel for regulatory compliance (Refers to GXP).
- Assure implementation and documentation of training programs including identification of training needs (job-specific and general GMP training) and training schedules.
- Provide trainers with updated information on regulatory requirements to incorporate in on-going training programs.

Interaction With Other Companies

- Conduct regulatory due diligence and advise senior management during product or company acquisitions and collaborations.
- Ensure regulatory obligations are met for in- and out-licensing of products.
- Ensure regulatory obligations are met for contract activities (manufacturing, complaint handling, regulatory operations, consultants, etc.).

Domain II: Preapproval

Approximately 25 questions for a 100-question examination (percent of items on examination: 25%)

Nonclinical Development

- Determine test requirements (GLP/non-GLP, biocompatibility, carcinogenicity studies specific to drug/biologic/device, etc.) and identify applicable guidances and resources for such requirements.
- Ensure compliance with nonclinical safety requirements (GLPs) and applicable performance standards (ISO, ASTM, ANSI, ICH, etc.).
- Determine adequacy of nonclinical data and risk analysis to support initiation of clinical trials including any appropriate risk management.
- Assess quality systems (e.g., CE marking, ICH, GMP/QSR, ISO, etc.) by performing audits to determine compliance to Quality System Regulations (QSR) and Drug GMP, assuring compliance to established SOPs for QSR and drug GMPs [e.g., failure investigations, etc.], and making recommendations for improvement of quality systems, based on audit findings and QSR or GMP requirements.

Clinical Development

- Determine requirements with regard to clinical safety and efficacy (GCPs).
- Ensure compliance with all clinical standards (GCPs, clinical trial monitoring and auditing), IRBs, safety reporting, informed consent, financial disclosure, etc.).
- Advise project team of regulatory recommendations for ongoing aspects of clinical trials/ investigations (amendments to protocol, etc.).
- Identify non-US country specific requirements for impact to US submissions (IND/IDE, annual report, etc.).
- Prepare and/or review information included in IND/IDE submission such as label, clinical investigation plan/protocol, case report form, investigators brochure, informed consent, etc.
- Ensure that any identified safety risks have been appropriately addressed with the clinical development program.
- Ensure that CFR requirements for adverse event reporting are established and being followed.
- Evaluate need for and contribute to the development of Pediatric Development Plan and/or waivers/deferrals, Orphan Designation Applications, etc.

CMC/Device Design and Manufacturing

- Determine regulatory requirements for manufacturing /quality system certifications (clinical trial supplies, manufacture, dosage forms, device classification, DMFs, etc.).
- Ensure compliance with cGMPs and QSR (SOPs, record retention, calibration, etc.).
- Verify device Design History File complies with regulatory requirements including risk management.
- Ensure regulatory compliance of manufacture and release of investigational products for clinical use.
- Review completeness of documentation to support IND/IDE submissions.
- Ensure specifications for testing of API/drug substance/drug product and documentation of raw materials (novel excipients, animal derived materials, etc.) comply with regulatory requirements.
- Ensure specifications for device components, manufacturing process and product have been defined and meet regulatory requirements (including product and quality system software).
- Evaluate manufacturing changes for compliance with appropriate change control systems/process and determine regulatory filing strategy.
- Review and monitor regulatory compliance for suppliers (contract manufacturers, CROs, etc.).

Agency Interaction

- Prepare premarket submissions (IDE/IND) and master files for drugs/biologics/devices including investigational labeling.

- Ensure that the project is in compliance regarding submission format (CTD/eCTD, etc.).
- Review application for completeness according to “refuse-to-file” guidelines.
- Negotiate/interact as appropriate with Agency during development/submission process (Pre-IDE/IND, End of Phase 2, Meetings, Respond to Agency comments, etc.).
- Monitor and maintain ongoing IDE/IND applications (e.g., amendments, annual reports, updates).
- Determine requirements for export/import of investigational products (customs, USDA, etc.).
- Ensure that the identified risks have been appropriately flagged and monitored.
- Initiate process to obtain nonproprietary (USAN) and proprietary names.

Domain III: Approval

Approximately 24 questions for a 100-question examination (percent of items on examination: 24%)

Nonclinical Section

- Assess and verify adequacy of nonclinical data to support approval.
- Assemble non-clinical reports and prepare nonclinical summary documentation as appropriate.

Clinical Section

- Assess and verify the adequacy of clinical safety and efficacy data to support approval and desired label claims.
- Assemble clinical reports submission and prepare summary documentation as appropriate.
- Ensure clinical trial monitoring and clinical trial audits are performed and documented.

CMC/Device Design and Manufacturing

- Assess and verify the adequacy of data to support submission approval and desired label claims/product specifications.
- Assess and verify the readiness of the drug/device manufacturing facility for PAI (Ensure compliance with GMP and QSR).
- Assemble CMC documentation for submission and prepare summary documentation as appropriate.

Submission and Review Process

- Prepare and schedule presubmission meetings with the Agency at the appropriate stage of the submission (e.g., pre-IND/IDE, end of Phase 2, etc) to reach agreement on content, format, and other issues/proposals.
- Guide project regarding submission format (CTD/eCTD, paper, etc.).
- Negotiate/interact as appropriate with Agency during the submission process (120 Day Safety Report, Respond to Agency comments, 100 Day Review, etc.).
- Prepare for and participate in Advisory Committee Meeting/Advisory Panel Meeting if requested.
- Drive the creation of draft labeling that meets regulatory requirements and negotiate final labeling with FDA at end of review period (SPL).
- Develop postapproval regulatory plans and negotiate agreement with FDA (e.g., risk evaluation and mitigation strategy (REMS) and postmarket clinical follow up plan).
- Provide guidance to project teams on FDA review practices and current thinking (refusal to file, priority review assignment, FDA’s Best Review Practices, etc.).

Domain IV: Postapproval

Approximately 23 questions for a 100-question examination (percent of items on examination: 23%)

Postmarketing/Maintenance

- Submit required licensing fees, drug and device listings, periodic reports and updates (e.g., PSURS, master files, etc.).
- Comply with product postmarketing approval requirements/condition of approval studies (Phase IV Studies).
- Prepare, implement and monitor strategy for alerts/notifications/recalls/market withdrawal.
- Advise management on alerts/notifications/recalls.
- Provide regulatory input on postapproval change management.
- Assess documentation to support product and process changes and determine regulatory category of change (PAS, CBE, Annual Reports, etc).
- Prepare and submit supplements/design change applications and notifications to NDA, BLA, PMA.
- Maintain and record changes to the technical file/design dossier or NDA/BLA.
- Ensure compliance with Risk Evaluation and Mitigation Strategy (REMS).

Postmarketing Surveillance/Vigilance

- Evaluate reports of product complaints.
- Ensure that appropriate systems are in place to document and track product complaints and ADR reports.
- Ensure implementation of necessary corrective actions based on results of inspections, audits, failure analysis and consent decrees.
- Report product safety issues/failures to regulatory agencies as required [e.g., ADEs].
- Review adverse drug reaction reports and medical device reports.

Advertising/Promoting/Labeling

- Review and approve revised labeling and claims, public communications, press releases, advertising and promotional items for regulatory compliance.
- Evaluate data to support comparative claims in advertising and implications of off-label use.

Distribution

- Ensure compliance with regulatory requirements for supply, handling, storage, distribution, import and export of materials.
- Ensure compliance with applicable requirements/regulations for distribution of controlled substances.
- Review regulatory aspects of contracts for product distribution (e.g., product complaints, product tracking, etc.).
- Advise on the issues related to drug/product/lot releases (Annual Product Review, Device History Record).

Crisis Management

- Advise management regarding the regulatory impact of a crisis event.
- Develop regulatory plan to address the crisis event.
- Advise management on regulatory implications of proposed crisis resolution strategies.

Agency Interaction

- Facilitate coordination of outside consultants and company personnel in response to Agency comments (PAI, 483 responses, conduct of clinical studies, etc.).
- Negotiate with Agency wording of inspection findings.
- Manage/accompany/chaperone inspection teams or auditors.
- Advise internal functional groups regarding regulatory compliance (e.g., FDA 483's, warning letters and consent decrees) and communicate corrective follow-up actions to management.
- Prepare strategy/briefing documents for panel hearings and informational meetings (Advisory Committee).
- Communicate/refer external requests for information.
- Develop Freedom of Information Act strategy regarding confidentiality and protection of proprietary information and document requests.



Appendix B: RAC (EU) Detailed Examination Content Outline

The RAC (EU) examination is organized into three major domains, with associated tasks and responsibilities typically undertaken by a regulatory professional. The approximate distribution of types of questions for each domain is shown in the following outline. Questions on the examination will address the tasks and activities presented in this outline.

Domain I: Strategic Planning

Approximately 31 questions for a 100-question examination (percent of items on examination: 31%)

Regulatory Framework

- Determine the regulatory classification status in European Union markets where the product may be launched.
- Monitor and assess the regulatory environment in European Union markets where the product may be launched (including additional national requirements such as legal status) and initiate changes within the company.
- Investigate and communicate when it is necessary to request technical and scientific guidance from relevant organisations.
- Evaluate regulatory requirements for markets outside of the European Union that recognize EU requirements.
- Provide input to trade associations and standards organizations to influence the European regulatory environment (legislation, guidance documents and standards).
- Perform Competitor Surveillance (e.g., EPAR, SmPCs, claims, indications) to evaluate potential changes, issues and strategies.
- Contribute to in-house training programmes for company personnel to ensure regulatory and quality compliance.

Regulatory Pathways and Options

- Advise management on requirements and options for regulatory submissions, approvals and conformity.
- Assessments (e.g., local, national, international options).
- Advise management on timelines, risks and financial implications of the proposed regulatory strategy.
- Investigate and communicate the availability of incentives (e.g., financial, data/market exclusivity) to support product development.
- Develop effective regulatory submission strategies for timely product approval.
- Advise colleagues on compliance with relevant regulatory legislation, guidelines, standards, etc.

Health Economics

- Provide input to and advise senior management regarding Comparative Effectiveness/Health Technology Assessment.
- Advise senior management regarding pricing and reimbursement issues.

Interaction With Other Companies

- Advise senior management during product or company acquisitions and collaborations.
- Conduct regulatory due diligence during acquisitions and collaborations.
- In- and out-licensing of products from/to a third party.

Crisis Management

- Advise management regarding the regulatory impact of a crisis event (e.g., plant shut down) and propose a resolution strategy.
- Participate in the development and functioning of the crisis management program.

Domain II: Design and Development

Approximately 36 questions for a 100-question examination (percent of items on examination: 36%)

Manufacturing/Quality (CMC)

- Define and communicate regulatory requirements for the scope of manufacturing authorizations/quality system certifications (e.g., clinical trial supplies, operations allowed, pharmaceutical forms, design, manufacture, device types).
- Review completeness of production documentation to support CTA/MAA submissions/manufacturing transfer.
- Ensure that available stability data supports intended shelf-life of product.

Nonclinical and Clinical Development

- Advise sponsor of regulatory requirements for clinical trials/investigations.
- Determine adequacy of nonclinical data and risk analysis to support approval to conduct clinical trials/investigations.
- Identify national/local requirements and prepare clinical trials/investigations submissions to CA/EC.
- Prepare or review study information such as IMPD/technical file/design dossier, label, clinical investigation plan/protocol, case report form, investigators brochure, patient information letter and informed consent to comply with local, regional, national, European and international regulatory requirements.
- Interact with and coordinate the use of CROs, subcontractors, test facilities and consultants.
- Respond to questions/comments from CA/EC.
- Ensure regulatory compliance of manufacture and release of investigational products for clinical use.
- Ensure that reporting procedures are in place to report adverse events that occur during clinical trials/investigations to CA/EC.
- Review clinical data from literature and other sources.
- Report trial/investigation results to CA/EC.
- Maintain authorization for on-going clinical trials/investigations (e.g., amendments, annual reports, updates).
- Evaluate need for and contribute to the development of Paediatric Investigation Plans/waivers/deferrals.

Preregistration/CE Marking Interfacing

- Evaluate need for and coordinate Protocol Assistance/Scientific Advice Meetings with CAs.
- Liaise with project team to develop project plans including submission timelines, deliverables, etc.
- Liaise with marketing/project team to develop target product profile and determine the claims that can and cannot be made based on available data.
- Participate in audits/inspections by NBs/CAs and contribute to responses to audit findings as required.
- Evaluate and communicate relevant legislation and guidelines (e.g., EMA, scientific, harmonized standards and essential requirements).

Registration/CE Marking

- Ensure adequate documentation to support MAA/Technical File/Design dossier.
 - Proof of concept/animal model
 - Nonclinical safety/biocompatibility
 - Clinical safety and performance/efficacy
 - Product quality/design verification and validation
 - Administrative data, forms, manufacturer authorizations/certifications, declarations and essential requirements checklists
 - Labeling/product information (including readability testing)
 - Risk Management Plan/File
 - Vigilance system
 - Postmarket surveillance plan
 - Environmental risk assessment

- Compliance with other applicable directives (e.g., WEEE, ROHS, machinery, battery)
- Prepare MAA/Design Dossier/Technical File.
- Submit MAA (incl. eCTD requirements)/Design Dossier to CA/NB.
- Monitor /track submission progress (procedural timelines).
- Respond to questions/comments from CA/NB.
- Meet with CA/NB to negotiate during review process.
- Coordinate product information (i.e. label, carton, and leaflet/IFU) translations.
- Review approval documents/certificates.

Domain III: Postapproval

Approximately 33 questions for a 100-question examination (percent of Items on examination: 33%)

Advertising/Promoting/Labeling

- Review and approve revised labeling and claims, public communications, press releases, advertising and promotional items for regulatory compliance
- Provide regulatory input to commercial and marketing strategies.
- Review and evaluate advertising, labeling and claims of competitors.
- Provide regulatory input to tender applications (e.g., overview of licensing status, product quality, product shelf life, declaration of conformance).
- Evaluate and communicate to management the implications of off-label use.

Postmarketing Surveillance and Vigilance

- Evaluate reports of product failures and complaints.
- Write field safety notices and report product failures and recalls /field safety corrective actions to CAs.
- Maintain vigilance and ensure postmarket surveillance activities are conducted.
- Ensure that Periodic Safety Update Reports (PSUR) are compiled and submitted to CAs according to regulatory timelines.
- Ensure regulatory compliance of postapproval clinical studies.
- Ensure implementation and monitor effectiveness of safety alerts, notifications, field safety corrective actions and recalls.
- Consider use of information gained in the postmarket phase for broadening product indications.

Supply Chain

- Ensure compliance with regulatory requirements for supply, handling, distribution, import and export of materials.
- Review regulatory aspects of supplier and distributor contracts (e.g., complaints, traceability, changes, etc.).

Product-specific Crisis Management

- Advise management regarding the regulatory impact of a crisis event (e.g., batch failure).
- Advise management on regulatory implications of proposed crisis resolution strategies.

Postapproval Regulatory Compliance

- Advise the Management Representative/Qualified Person regarding regulatory requirements.
- Ensure quality system SOPs meet regulatory requirements.
- Assess whether new or revised legislation, guidelines, monographs and harmonized standards affect certain functions, activities or products.
- Initiate, monitor, document and submit changes where applicable to ensure compliance with new or revised legislation, guidelines, monographs and harmonized standards.
- Review and monitor contractual obligations and agreements with NBs to ensure regulatory compliance.
- Negotiate wording of audit findings.



Appendix C: RAC (Canada) Detailed Examination Content Outline

The RAC (CAN) examination is organized into four major domains, with associated tasks and responsibilities typically undertaken by a regulatory professional. The approximate number of questions for each domain is shown in the following outline. Questions on the examination will address the tasks and activities presented in this outline.

Domain I: Strategic Planning

Approximately 23 questions for a 100-question examination

- Provide internal advice based on the understanding of limits imposed by regulatory environment in order to ensure product concept compliance.
- Perform benefit risk analysis on product development concept for initial product viability, in order to make recommendations respecting current/future internal/external investments.
- Determine endpoints for safety and efficacy testing (feasibility) in order to determine the ability to comply with regulatory standards.
- Advise stakeholders on research and development programs in order to ensure applicable regulatory compliance.
- Develop global regulatory strategy including components involving regulatory intelligence, due diligence, and internal/external license opportunities from a regulatory perspective in order to assist in current/future planning.
- Continue to revisit and compare regulatory outcomes with initial product concepts in order to make recommendations on future actions.
- Understand, investigate and evaluate regulatory history/background of class, disease/therapeutic/diagnostic context (more general, class or domain of products) through means of research in order to assess regulatory implications for approval.
- Identify lead regulatory authority/body for submission of data concerning applicable product (e.g., biologics, combination products, natural health products, etc.).
- Assess impact on regulatory dossier of federal, provincial, territorial (sub-national) requirements and considerations (e.g., PMPRB, provincial electrical safety requirements, NAPRA, provincial formularies, third party insurers) in order to make recommendations.
- Evaluate regulatory advantages/disadvantages of global versus domestic development, e.g., simultaneous filings, joint reviews, mutual recognition agreements, assessment of similarity or dissimilarity of requirements.
- Determine trade issues to anticipate regulatory obstacle, e.g., applicable treaty law, international conventions, 'for export only' status.
- Advise internal personnel on requirements and options for submissions/approvals in order to ensure most efficient review process, product development and corporate objectives, e.g., standard, accelerated, conditional.
- Assist in the development of a code of ethics for the organization in interfacing with stakeholders to minimize regulatory liability.
- Assist in the development and review of SOPs for compliance with regulatory affairs practice.

Domain II: Premarketing

Approximately 26 questions for a 100-question examination

- Advise responsible personnel of regulatory requirements for quality, preclinical and clinical data requirements for clinical study applications or marketing applications in order to meet Canadian regulatory requirements through internal correspondence.
- Assess the acceptability of quality, preclinical and clinical documentation for submission filing in order to comply with regulatory requirements for clinical trials, marketing applications and corporate goals so as to secure submission approval.

- Negotiate/interact as appropriate through internal/external correspondence (e.g., meetings, email) with regulatory authorities during the development and review process to ensure submission approval.
- Facilitate SAP approvals when necessary with HPFB.
- Determine acceptability of submissions, e.g., drug, biologic, medical device, natural health product through the preparation/review of applicable sections to comply with Canadian regulatory requirements.
- Compile/prepare regulatory submissions according to applicable HPFB guidelines and submit to the appropriate regulatory authorities in order to meet corporate goals and secure submission acceptability.
- Monitor applications under regulatory authority review through frequent communication to track internal/external performance target dates.
- Follow company procedures to ensure appropriate responses to regulatory authority queries/decisions.
- Evaluate proposed preclinical, clinical and manufacturing changes for regulatory filing strategies.
- Monitor and submit applicable reports to regulatory authorities (e.g. SAEs, Notice of Change) to comply with regulatory requirements through frequent communication.

Domain III: Postmarketing

Approximately 26 questions for a 100-question examination

- Approve advertising and promotional items for compliance before release.
- Generate and approve labeling for compliance before release.
- Submit notifiable changes and supplemental NDSs to update product monograph and/or instructions for use to reflect current state of product knowledge.
- Assure that appropriate SOPs are in place to document, prioritize, categorize and track product associated events, complaints, recalls, market withdrawals and ADR reports.
- Define scope of product associated problems, assess risks, detect trends and determine safety signals, develop options for risk mitigation to be presented to decision-makers, implement appropriate regulatory steps for selected option (e.g., consumer information, advertising or labeling changes, warnings or alerts, product changes, recalls, withdrawals).
- Participate in initiation, strategy and policy of recalls and “Dear Healthcare Professional” letters to ensure that the message is clear.
- Report product associated events which satisfy regulatory criteria for reportability, failures, recalls and/or corrective actions resulting from inspections to regulatory agencies as required.
- Report product safety issues to regulatory agencies as required in order to comply with regulations.
- Assure that PSUR reports are available annually for submission on request to comply with regulations.
- Comply with product postmarketing approval requirements for conditional NOCs in order to meet the approval commitment.
- Approve change controls to determine the level of change and consequent submission requirement.
- Submit notifiable changes and supplemental NDS for postmarketing quality changes.
- Advise in the development and functioning of the crisis management/issue management program, e.g. regulatory impact of an event and implications of resolution.
- Review regulatory aspects of contracts for product distribution, e.g., product complaints, recalls, ADRs, etc.
- Implement access to information defence regarding confidentiality and protection of proprietary information and document requests.
- File access to information requests as required.
- Maintain annual licenses (e.g., establishment, narcotic, controlled) and submit annual DIN notifications.
- File new and amended patent forms to update patent information with applicable regulatory authorities, (i.e., Health Canada) in order to meet applicable legislative policies and guidelines.

- Provide submission documents for preparation of submission to PMPRB and/or provincial authorities by other functional areas.
- Submit documentation and samples, if required, for lot release of biologics.
- Ensure that quality systems are in place for medical devices as per ISO requirements.
- Comply with import and export requirements.
- Assure compliance with applicable market controls and requirements (e.g., controlled substances, veterinary use only, illicit markets).
- Assure adequacy of product traceability systems.
- Channeling information about product use and distribution to be used in risk management.

Domain IV: Interfacing

Approximately 25 questions for a 100-question examination

- Communicate and negotiate with regulatory authorities (i.e., Health Canada) and stakeholders in order to facilitate compliance on health product regulatory matters.
- Conduct the meeting for technical presentations to health regulatory advisory committees/agencies and other government agencies to defend or facilitate regulatory compliance.
- Participate in the development of new legislation, regulations, guidelines and/or standards to be followed by industry and Health Canada to ensure consistent and clear application of requirements.
- Support and/or coordinate responsibilities respecting the provision of data (e.g. clinical trials, preapproval site inspection).
- Accompany inspection team as required.
- Maintain records on legislation, regulations, guidelines and/or standards or related issues for background purposes in order to facilitate compliance on health product regulatory matters or to support strategic planning.
- Review public communications, press releases, etc. from a regulatory perspective.
- Advise or problem-solve with appropriate individuals within the organization regarding the acceptability of claims or other regulatory matters relating to the sale of the product in order to enhance compliance.
- Advise stakeholders on the impact of current, newly finalized or proposed legislation, regulations, guidelines, and standards and provide training where necessary in order to facilitate the implementation of any required actions.
- Notify, consult, or brief legal counsel and officials when appropriate in order to limit legal liability.
- Advise appropriate company personnel when a regulatory body exceeds its authority.
- Communicate regulatory agency/industry positions within the organization.
- Participate in medical review committees.
- Develop “early warning system” to identify potential regulatory problems affecting the company/agency and advise affected internal functional groups.
- Identify the standards developing organizations that are appropriate for the company’s product.
- Negotiate/interact as appropriate with standards developing organizations.
- Review draft documents when routed for comment.



Appendix D: RAC (Global) Detailed Examination Content Outline

The RAC (Global) examination is organized into four major domains, with associated tasks and responsibilities typically undertaken by a regulatory professional. The approximate number of questions for each domain is shown in the following outline. Questions on the examination will address the tasks and activities presented in this outline.

Domain I: Strategic Planning

Approximately 25 questions for a 100-question examination

- Evaluate the regulatory environment and provide internal advice throughout the lifecycle of the product (e.g., concept, development, manufacturing, marketing) to ensure product compliance.
- Perform risk/benefit analysis on product development concept for initial product viability.
- Determine endpoints for safety and efficacy testing at the feasibility phase to determine the ability to comply with regulatory standards.
- Advise research and development programs to ensure applicable regulatory compliance.
- Provide regulatory intelligence to develop local, regional and global regulatory strategies that include due diligence and internal/external license opportunities.
- Revisit the regulatory outcomes and compare them with initial product concepts and make recommendations for future actions.
- Investigate, research, evaluate and interpret regulatory decisions in a similar product category to assess regulatory implications for approval.
- Identify appropriate regulatory authorities for submission of data concerning the product being developed.
- Assess impact of local, regional and global requirements and considerations on the regulatory dossiers.
- Evaluate the regulatory merits of domestic vs. regional or global development (e.g., simultaneous filings, joint reviews, mutual recognition agreements, assessment of similarity or dissimilarity of requirements) to define market feasibility.
- Anticipate regulatory obstacles arising from trade issues (e.g., applicable treaty law, international conventions, “for export only” status).
- Provide alternative strategies for product development and submission to ensure timely approval and advise internal stakeholders on the requirements.
- Develop and review regulatory department SOPs (i.e., standard operating procedures) to ensure regulatory compliance.
- Assist other departments to develop SOPs to ensure regulatory compliance.

Domain II: Premarketing

Approximately 30 questions for a 100-question examination

- Advise stakeholders of regulatory requirements for quality, preclinical and clinical data to meet applicable regulations.
- Assess the acceptability of quality, preclinical and clinical documentation for submission filing to comply with applicable regulations.
- Negotiate and interact through appropriate communication tools (e.g., meetings, email) with regulatory authorities before and during the development and review process to facilitate submission approval.
- Determine acceptability of submission package through the preparation and review of relevant sections to comply with applicable regulations.
- Compile and prepare regulatory submissions according to applicable regulatory guidelines and submit to the appropriate regulatory authorities to ensure compliance to guidelines.

- Monitor the progress of the regulatory authority review process through appropriate communication with the agency.
- Evaluate proposed manufacturing changes on preclinical and clinical development and regulatory submission strategies.
- Facilitate the development of appropriate and timely responses to regulatory authority queries and actions to ensure compliance with company procedures.
- Participate in developing a risk management system (e.g., vigilance) to ensure that local, regional and global regulatory requirements as applicable are met.
- Identify, monitor and submit applicable reports (e.g., Serious Adverse Events) or notifications (e.g., changes in manufacturing) to regulatory authorities to comply with regulations.

Domain III: Postmarketing

Approximately 23 questions for a 100-question examination

- Ensure regulatory compliance of advertising and promotional items.
- Generate and ensure regulatory compliance of labeling.
- 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 knowledge.
- Assure that appropriate standard operating procedures (SOPs) are in place to manage product associated events, complaints, recalls, market withdrawals and vigilance reports.
- Develop regulatory options for risk mitigation to be presented to stakeholders and implement appropriate regulatory steps for selected options (e.g., consumer information, advertising, labeling changes, warnings, alerts, product changes, recalls, withdrawals).
- Participate in implementing regulatory strategy for handling recalls and communication to stakeholders (e.g., “Dear Healthcare Professional” letters, patient letters, distributor letters, Health Authorities).
- Report notifiable manufacturing product-associated events (e.g., failures, recalls, corrective actions resulting from inspections) to regulatory authorities as required.
- Report product safety issues to regulatory authorities as required to comply with local, regional and global regulations.
- Assure that single case or aggregate safety reports are submitted to comply with local, regional and global regulations or upon request by regulatory authorities.
- Comply with product postmarketing surveillance requirements to meet conditions of approval.
- Evaluate change controls documents to determine the level of change and consequent submission requirement.
- Define and submit notifiable changes and supplemental dossiers to local, regional and global regulatory authorities for postmarketing changes.
- Participate in crisis/issue management team (e.g., product recall, counterfeiting) and assess the regulatory impact of an event and proposed resolution.
- Review regulatory aspects (e.g., quality, product complaints, recalls, vigilance) of contracts for product manufacture and distribution.
- Control access to regulatory documentation ensuring confidentiality and protection of proprietary information.
- Maintain licenses (e.g., establishment, narcotics, controlled substances) and submit renewals as required.
- File new and amended patent/trademark forms to update information with applicable regulatory authorities to meet applicable regulations.
- Provide required information (e.g., clinical data) in support of product reimbursement requests.
- Submit documentation and samples for lot release, if required, for customs clearance.
- Ensure that quality systems are in place (e.g., ISO 13485 for medical devices).
- Comply with import and export requirements.
- Assure compliance with applicable market controls and requirements (e.g., controlled substances, veterinary use only).
- Assure adequacy of product traceability systems.

Domain IV: Interfacing

Approximately 22 questions for a 100-question examination

- Communicate and negotiate with regulatory authorities and stakeholders to facilitate compliance on regulated products.
- Coordinate company presentations to regulatory advisory committees/agencies representatives and other government agencies to facilitate regulatory compliance.
- Provide input on proposed legislation, regulations, guidelines and/or standards to be followed by industry and regulatory authorities to ensure consistent and clear application of requirements.
- Coordinate responses to queries from regulatory authorities.
- Accompany inspection team as required.
- Maintain records on legislation, regulations, guidelines, standards and related issues for background purposes to facilitate compliance on regulated products and to support strategic planning.
- Review public communications, press releases, etc. to ensure regulatory compliance.
- Advise or problem-solve with appropriate individuals within the organization regarding the acceptability of claims or other regulatory matters relating to the sale of the product to ensure compliance.
- Advise stakeholders on the impact of current and proposed legislation, regulations, guidelines and standards and provide training when necessary to facilitate regulatory compliance.
- Communicate with legal counsel and company officials when appropriate to minimize exposure to legal liability.
- Inform appropriate company personnel (e.g., legal, management) and stakeholders when a regulatory body exceeds its authority or fails to meet obligations.
- Communicate regulatory agency and industry positions within the organization.
- Participate in internal product review committees (e.g., labeling, quality, launch).
- Develop early warning systems to identify potential regulatory compliance issues affecting the company and advise affected internal functional groups.
- Identify and interact with the standards-developing organizations that are appropriate for the company's product.

Appendix E: 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)

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 _____



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