



Regulatory Affairs Certification

Candidate Guide

EXAM OVERVIEW

- 100 multiple-choice questions for the RAC exams.
- Two hours to complete each exam.
- Administered by computer.
- Administered only in English.

WHAT THE EXAMS ASSESS

The three regional RAC examinations (US, EU and CAN) are knowledge-based examinations addressing laws, regulations, policies and guidelines affecting regulated healthcare products, including medical devices, pharmaceuticals, biologics and biotechnology in their respective regions. The RAC General Scope also is a knowledge-based exam, but does not focus on a particular national or regional regulatory system. The RAC General Scope exam tests general knowledge of the full product lifecycles for medical devices, IVDs, pharmaceutical and medicinal products and biologics as well as ICH, GHTF, WHO and ISO guidelines and standards. All four RAC exams assess knowledge of regulations and regulatory processes related to biopharma and medical technology products, as well as critical thinking skills in applying the relevant regulations to various scenarios throughout all stages of the product lifecycle.

The examinations each consist of 100 items, presented in multiple-choice format. Each examination is reviewed and revised annually and content is updated for the October/November exam window. Examination content is based on information effective 31 December of the prior year.

RAC EXAM TESTING WINDOWS AND DEADLINES

Testing Window	Standard Deadline	Late Deadline
1 April–31 May	15 February	8 March
1 October–30 November	15 August	8 September

Exam Fees

	Application Fees	
	Standard Deadline	Late Deadline
RAPS Member	\$325 (US)	\$425 (US)
Nonmember	\$535 (US)*	\$635 (US)*

**Includes one year of RAPS membership (membership may be waived, however fee remains the same)*

A cancellation fee of \$100 (US) will be assessed on any cancelled application. No cancellations will be accepted after 8 March for the April/May exam or after 8 September for the October/November exam.

CONTACT INFORMATION

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THE FOUR RAC CREDENTIALS—AN OVERVIEW

	RAC (US)	RAC (EU)	RAC (CAN)	RAC (General Scope)
Knowledge required and regulatory basis	<ul style="list-style-type: none"> ▪ Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceutical, 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, GHTF, 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 without an RAC credential, not currently involved with regulatory authorities in the US, EU or Canada
Eligibility	Baccalaureate degree (or equivalent) or 3–5 years regulatory experience			
The exams	Two hours, 100 multiple-choice questions, administered at locations worldwide			
Application fee (In US\$)	RAPS members: \$325; \$425 late registration Nonmembers*: \$535; \$635 late registration <i>* Includes one year RAPS membership</i>			
Credential maintenance	RAC-credentialed professionals must accumulate 36 recertification credits every three years after initial certification to maintain RAC status.			

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INTRODUCTION

About the RAC Credential

Regulatory Affairs Certification, known as the RAC, is the only post-academic professional certification specifically for regulatory professionals in the healthcare product sector. The RAC exams are developed based on the actual work of regulatory professionals in the field. The RAC credential is a professional distinction that denotes commitment to excellence, pursuit of knowledge and career advancement. RAC-credentialed professionals are among the current and rising leaders in the regulatory profession. They work in all parts of the world and in many settings, including industry, government and academic organizations. To date, nearly 6,000 individuals have earned the RAC, some holding multiple credentials.

Four different certifications are available:

- RAC (US): knowledge of US regulations
- RAC (EU): knowledge of European Union regulations
- RAC (CAN): knowledge of Canadian regulations
- RAC (General Scope): knowledge and critical thinking skills related to the general scope of practice of regulatory professionals throughout the product lifecycle, with reference to global standards from ICH, GHTF, WHO and ISO.

The RAC credential initially is earned by passing one of the four examinations, US, EU, CAN or General Scope. Candidates may take multiple RAC examinations. The RAC is maintained through continuing professional development.

RAC Exam Content

Each of the four RAC examinations is based on extensive study 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 all regulated healthcare products (e.g., pharmaceuticals, medical devices, biologics, etc.) and regulatory professional functions throughout the lifecycle of a product. They are balanced with respect to product types and general critical thinking skills of regulatory professionals. The exams are organized by domains related to product lifecycle, beginning with regulatory strategy, preapproval and postapproval responsibilities. See the appendices of this guide for detailed content outlines of each examination. These content outlines are also available online at RAPS.org/rac.

RAC Recognition

Candidates who pass the RAC (US), (EU), (CAN) or (General Scope) examination may use the RAC designation after their names. All RAC credentialed professionals are listed on the RAPS/RAC website at RAPS.org/rac, and a listing of newly certified RACs is published twice annually in *Regulatory Focus*, the monthly, flagship magazine of RAPS.

Why Get RAC-Certified?

The RAC is the only certification specifically for regulatory professionals in the healthcare products sector. A mark of professional distinction, the RAC credential denotes a commitment to excellence in regulatory practice, expertise, and a steadfast pursuit of knowledge and career advancement. RAC-credentialed professionals are recognized as regulatory experts and are among the current leaders in the regulatory profession. Additionally, regulatory professionals with the RAC credential earn 6% more than their peers at the same professional level who do not have the RAC¹.

The RAC Credential:

- Establishes professional standards for the regulatory profession
- Identifies individuals who meet these standards and demonstrate essential regulatory knowledge
- Encourages professional growth and continuing learning, which are critical to the profession and the healthcare product sector

¹ Average based on RAPS 2010 Scope of Practice & Compensation Report for the Regulatory Profession (US respondents).

APPLYING FOR THE EXAM

Eligibility Requirements

To be eligible for the RAC examination you **must** have:

- Bachelor's (Baccalaureate) degree or its equivalent
- or
- at least three years of regulatory experience

Applications from individuals who do not meet these basic requirements will **not** be accepted.

RAC Application Deadlines

Testing Window	Application Deadline	Final Application Deadline*
1 April–30 May	15 February	8 March
1 October–30 November	15 August	8 September

*Additional later registration fees apply

Applying for the Exam

The RAC exam application is available online at RAPS.org/rac. Candidates may apply online, and submit registration fees by credit card, or may print a copy of the application form for submission by fax or mail. It is the responsibility of the candidate to contact RAPS to confirm receipt of applications submitted via fax or mail. No applications will be accepted after the final deadline.

The RAC exam application must be fully completed by the applicant. Applicants must acknowledge that they meet the eligibility requirements and have read the Code of Ethics for Regulatory Professionals.

Applications must be received by the deadlines listed above. All deadlines are postmark dates. For purposes of clarity, the term “postmark date” includes system date/time stamps for online, email and faxed applicants. Applications will not be accepted after 11:59 pm (US Eastern Time) on the final deadline date.

Applicants will receive email notification of whether or not their application is accepted within 10 business days of receipt of application by the RAC Program Office. Questions regarding application receipt should be directed to the RAC Program office.

Special Accommodations for the Exam

Candidates who require special accommodations to take the exam due to disability, handicap or other conditions must notify the RAC Program Office at the time of application or no later than the final registration deadline. Those requesting special accommodations must submit supporting medical or other appropriate documentation.

Exam Fees and Cancellation/Refund Policy

	First Time Application	
	Standard Deadline	Late Deadline
RAPS Member	\$325 (US)	\$425 (US)
Nonmember*	\$535 (US)	\$635 (US)

*Includes one year of RAPS membership (membership may be waived however, the fee remains the same)

Cancellation/Refunds

A cancellation fee of \$100 (US) will be assessed on any cancelled application. No cancellations will be accepted after the final application deadline for the exam cycle (i.e., 8 March or 8 September).

Payment Methods

Exam fees are due at the time of application submission. Applicants may pay by credit card (Visa, MasterCard or American Express) or by check or money order. Checks and money orders should be made payable to RAPS. Candidates' names must appear on all payments made by money order, certified or cashier's check, personal check or organizational check. If fees for more than one candidate are paid by a single check or money order, a list of all candidates' names and primary contact telephone numbers (including area codes) must be included with the check and the application materials. Checks and money orders received without proper candidate identification may be returned to the senders unprocessed.

Checking Application Status

Candidates with questions about the receipt of their application should contact the RAC Program Office directly at certification@raps.org or +1 301 770 2920, ext. 200. It is the responsibility of candidates applying via mail or fax to confirm receipt of their application by the RAC Program Office.

Incomplete Applications

Candidates submitting incomplete applications will receive email notification from the RAC Program office detailing the additional information needed to complete the application. To become eligible to take the exam, candidates must submit the required information by the final application deadline and pay a \$20 (US) resubmission fee. Payment instructions will be provided in the incomplete notification email. Candidates who do not rectify the application deficiencies by the date indicated will be deemed ineligible and issued a refund of their examination fees, less a non-refundable \$100 (US) application fee.

Application Refusal

Applications for the RAC exams may be refused due to one or more of the following:

- failure to meet eligibility requirements or deadlines, or submit a complete application
- falsification of application information
- use of fraud or deception in an attempt to obtain certification and/or knowingly assisting another person in obtaining or attempting to obtain certification by fraud or deception
- illegal use of the credential certificate or falsification of credentials
- unauthorized possession or distribution of any official RAC examination materials, including copying or reproduction of any part of the exam
- exhibiting unethical or inappropriate behavior during prior examinations
- conviction of a felony or a crime of moral turpitude in a court of law
- revocation of a professional license
- debarment under state, federal or territorial laws

There is no appeal process for candidates who do not meet the minimum eligibility requirements.

Applicants refused due to any of the above reasons will be refunded exam fees, less the nonrefundable \$100 application fee.

Applications postmarked after the late deadline will be returned unprocessed.

Transferring to Another Testing Cycle

Candidates may transfer to the immediate next testing cycle. One transfer is permitted and the request must be received in writing by the final application deadline date. Refunds and transfers are **NOT** permitted after the final deadline date.

Application Withdrawal

Candidates must submit written request for withdrawal of their application by the final application deadline date to receive a refund, less the \$100 nonrefundable fee.

Candidates who do not submit a written notification of withdrawal by the final registration deadline date will **not** receive a refund but may submit a new application for a future testing window.

EXAM SCHEDULING

Eligible candidates will receive a confirmation of acceptance via email within 10 business days after receipt of a completed application by the RAC Program Office.

Candidates should review the information in the confirmation email to ensure accuracy of name and key contact information as this information will be used to access examination scheduling websites and for testing site confirmation. Candidates should immediately notify the RAC Program office to correct any information (+1 301 770 2920, ext. 200, or email certification@raps.org).

Test Site, Date, Time Selection

Eligible candidates will receive instructions via email from the testing service, **CASTLE Worldwide**, with a website link, login ID and password unique to each candidate. ***This email is sent within seven days after the final application deadline (close of the application window). Candidates must use this site to select the testing center location and to request a test date and time.***

Scheduling requests must be submitted at least 15 days prior to the desired examination date.

Applicants must select a testing site from the list provided. In most cases, applicants will be assigned to the requested site. Applicants will be notified if the requested site is not available and will be advised of the nearest open testing location.

Candidates may submit a request for a testing center in a city not included in the available listing. This request must be made to **CASTLE Worldwide** at the opening of the notification to schedule. It may not be possible to establish a satisfactory testing facility at new locations during an active testing cycle. Further, candidates may be charged additional fees incurred to establish a site. Candidates will be notified in advance of any additional charge for these sites.

Changing Your Exam Appointment

Applicants must contact **CASTLE Worldwide** to make changes to the date, time or location of a scheduled examination. There is a fee of \$50 (US) for each change, payable to **CASTLE Worldwide** for changes to location, time or date. Changes may not be made less than four business days before the candidate is scheduled to take the exam. Candidates may only reschedule to another date within the current testing window.

Emergency Situations

Candidates who experience a documented severe medical emergency or have a death in their immediate family may request to transfer to the next testing window. Appropriate documentation must be received at the RAC Program Office within 60 days of the original RAC examination date. Candidates may reschedule the exam once due to emergency situations. A \$79 rescheduling fee applies.

No-show Candidates

Candidates who fail to schedule an exam appointment within the testing cycle for which they applied, who do not appear for their scheduled exam appointment, who arrive more than 15 minutes late for their appointment, who appear with improper ID or who cancel their appointment later than 12:00 pm (US Eastern Time) four business days before the scheduled exam without a documented personal or medical emergency will be considered no-shows and will forfeit all fees. No-show candidates must submit a new application for a future testing window.

Testing Site Cancellations

CASTLE Worldwide reserves the right to cancel any testing site. In the event of a cancelled site, candidates will be notified by **CASTLE Worldwide**.

PREPARING FOR THE RAC EXAM

Detailed content outlines for each of the four RAC examinations are included as appendices to this guide and available online at RAPS.org/rac.

For additional information and useful resources to help prepare to take one or more of the RAC exams, visit RAPS.org/rac and click on the RAC Exam Preparation section.

EXAM DAY

Candidates should arrive at the testing location at least 30 minutes before their scheduled appointments and must adhere to the requirements listed below.

Proof of Identity

All candidates must present proof of identity by providing an unexpired government-issued photo ID with a signature, such as a driver's license with a photograph, a military photo ID, a passport or valid national identification card. Credit cards with photos and Social Security cards are not acceptable forms of identification.

Candidates who cannot present an unexpired government-issued photo ID should contact the RAC Program Office at least 10 business days before the exam.

The candidate's name on the identification must match the name appearing on the exam-scheduling notification. Candidates with hyphenated last names whose photo IDs show only one of the last names may be admitted if the single name matches part of the hyphenated name and the signature and photograph clearly match. Candidates whose middle names are spelled out on their ID but are listed with an initial on the application may be admitted as long as the initial matches the first letter of the middle name and the signature and photograph match. This also applies to candidates who use their middle name instead of their first name on their application but their ID displays their first, middle and last name.

Test Center Rules

The following rules are enforced at all test centers to ensure a fair and consistent test experience for all test takers:

- Candidates must arrive at the test center at least 30 minutes before scheduled reporting time.
- Candidates must present an unexpired government-issued ID bearing the candidate's photo and signature to be admitted to the test center.
- Candidates must bring a copy of the exam appointment confirmation email.
- Admittance to the test center is by appointment only. Candidates must be present at the time and location of their appointment to be admitted.
- No test materials, documents or memoranda of any sort may be taken into or from the test room.
- Smoking is prohibited.
- Candidates may not ask questions about exam content.
- All exams are monitored and may be recorded in both audio and video format.
- No breaks are scheduled during the exam. Candidates who have to leave the testing room to take a break will not be given extra time on the exam and must present ID as they sign out and back into the testing room.
- Food, drinks, purses, briefcases, notebooks, calculators, pagers, mobile telephones, recording devices and photography equipment are not allowed into the testing room.
- It is expressly prohibited to disclose, publish, reproduce or transmit any part of the exam, in any form, by any means, verbal or written, for any purpose, without the express written permission of the RAC Program Office. Violation may result in civil or criminal prosecution.
- Religious headwear may be worn into the testing room; however, it may be subject to inspection by a test center administrator before entry into the testing room is permitted.
- The RAC Program reserves the right to cancel any test score believed to be obtained in a questionable manner.

AFTER THE EXAM

Test Scoring, Passing Standards

RAC examinations are scored by an independent testing agency. RAC examinations are scored after the close of the testing cycle and are not scored at testing centers. A statistical report of scoring is reviewed by the testing contractor and the examination committee to assure ongoing quality of the RAC exams.

The pass point or cut score for each RAC examination is based on a criterion-referenced approach, considered by experts to be the best method for use with professional credential testing. Since the certification examinations are revised annually, the content and difficulty levels of the examination may change slightly. Test developers use an equating procedure which equates new versions of the examinations to the initial or anchor version. This method of linear equating ensures that candidates are not rewarded or penalized for taking different versions of the examination. The adjusted passing score for the RAC examinations is 75.

Candidate Notification

RAC examination results typically are available four weeks after the end of the testing cycle (i.e. 31 May or 30 November). Candidates will receive an email notification when RAC examination results are processed and available. Candidates will be notified of instructions for accessing a special secured website with their examination results. This personal site will include a notice presenting their pass/fail status and a summary report of their performance. Results, including scores are released only to candidates. No results will be reported over the telephone or by fax.

No information is released or accessible on candidates who do not pass the examination **except** to the candidate.

Listing of RAC Professionals

A listing of all RAC-credentialed professionals is available online at RAPS.org/rac. Newly credentialed professionals are added after all candidates are notified about their status. A listing is also published in *Regulatory Focus* magazine. These listings only contain the names of candidates who pass the examination.

Re-examination

Candidates who do not pass the RAC examination are eligible to retake the exam. 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.

Use of the RAC Credential

Once candidates pass an RAC examination they are granted the RAC credential. They may use the RAC after their names as a professional credential. The RAC may also be used on resumes, CVs and other professional records. RAC-credentialed professionals may also provide additional information on the specific RAC credential(s) they have received (e.g. US, EU, CAN or General Scope).

The RAC credential cannot be used by individuals who fail to maintain the required recertification requirements.

MAINTAINING PROFESSIONAL CERTIFICATION

Once certified, the RAC designation is maintained through continued learning and involvement in professional activities. It is the responsibility of the RAC-certified individual to recertify on time. RAC professionals who maintain current, up-to-date contact information with RAPS will receive periodic email reminders about their recertification submission year and status. Please see the RAC Recertification Guide for more information.

Continual learning, knowledge enhancement and professional development are vital to regulatory professionals. Thus, to maintain the RAC credential, an RAC-certified professional must accumulate 36 RAC credits and submit a recertification report every three years. Credits may be accumulated in many ways, including participation in continuing education and/or self-study courses, public speaking on regulatory topics, professional writing and involvement with professional organizations.

RAC-certified professionals who hold more than one of the four designations (US, EU, CAN, General Scope) only need to recertify once every three years for all certifications, maintaining the recertification date of the first designation earned, with a total of 36 credits.

For detailed information on earning credits, recertification instructions, including fees, and mailing information, the Recertification Guide is available online at RAPS.org/rac or by contacting RAPS.

CERTIFICATION PROGRAM ADMINISTRATION

The Regulatory Affairs Certification Board (RACB) and its examination committees are responsible for the content, policies, standards and administration of the RAC Program. The RACB and the examination committees for each of the four exams are composed of regulatory professionals who have achieved RAC certification. A professional testing firm is used in the technical areas of occupational research, test construction and validation, statistical analyses, and test administration and scoring. The RAC Program is managed by professional staff working closely with the RACB, examination committees and the testing services contractor. The RAC (US), RAC (EU), RAC (CAN) and RAC (General Scope) examination committees use job analysis studies of regulatory professionals, published policies and other technical resources to develop examinations that reflect the demands and knowledge requirements of the workplace. Each examination is revised annually and carefully reviewed based upon content analyses of the test design, topic/subject mix and accuracy of questions. These procedures assure the quality, reliability and validity of the RAC examinations.

Release of Information

The RAC Program maintains strict procedures for ensuring the confidentiality of candidates' records. Information on prospective candidates is not released to anyone other than the candidates themselves. Candidates' scores are only released to the candidate and are not released by telephone or fax. The RAC Program reserves the right to publish a listing of individuals who successfully earn the RAC designation. However, under no circumstances will information be released on individuals who have not earned the RAC credential.

Nondiscrimination

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

Due Process Appeals

Concerns or complaints about the certification process, an applicant or an RAC designation will be addressed by the RACB. Concerns must be submitted in writing to the RAC Program Office. The RAC Board will review all complaints and will respond directly to the individual. If warranted, the RACB may appoint a special committee to review and/or respond to concerns.

OVERVIEW OF RAC CONTENT OUTLINES

Development of the RAC examinations

The RAC examinations, and the content outlines presented in the following appendices, are based on the extensive job analysis (role delineation) studies undertaken by the RAC program. These studies are guided by experts in testing and measurement. The role delineation studies are completed before an exam is created and are repeated at intervals of about five to seven years to adjust the examination outline based upon changes in the scope of practice of regulatory professionals.

Role delineation studies are used to develop the detailed outline for the examination and 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 exam content is added for the October/November testing window and covers any regulations in effect as of 31 December of the previous year. The April/May testing cycle includes the same content as the previous year's autumn administration.

Question types

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

- 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. Approximately 25–33% of the exam questions will be recall.

Application questions require relating specific knowledge to a situation that may be encountered in the scope of practice of a regulatory professional. Approximately 33–45% of RAC exam questions are considered application type questions.

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. Approximately 30–35% of the examination will contain analysis.

Balance of healthcare products

The RAC examinations are balanced by products and cover the range of regulated healthcare products, including medical devices; in vitro diagnostics (IVDs); pharmaceuticals, including patent protected products; generics; over-the-counter drugs; orphan products; biologics; and biotechnology. Many of the RAC examination questions actually test general understanding of regulatory processes and the role of the regulatory professional. While a specific product type may be used, the question tests logical thinking and understanding of the steps and actions to be taken by the professional.

Appendix A: RAC (US) Detailed Exam 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 exam will address the tasks and activities presented in this outline.

Domain I: Strategic Planning

Approximately 10 recall questions, 9 application questions, and 9 analysis questions for a 100-question examination (percent of items on exam: 28%)

- A. Regulatory Framework
 - i. Evaluate proposed products for regulatory classification (drug/device/biologic/combination/OTC/predicate devices, etc.) and jurisdiction (CDER/CDRH/CBER, etc.).
 - ii. Monitor and assess the regulatory environment (product specific guidances, competitor products, etc.) to propose regulatory path forward (generic/OTC/predicate device, etc.).
 - iii. Evaluate US regulatory implications for non-US (global) development and marketing.
 - iv. 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.).
- B. Regulatory Pathways and Operations
 - i. 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.).
 - ii. Advise management on timelines, benefits/risk assessment and financial implications of the proposed regulatory strategy.
 - iii. Investigate and communicate to management the availability of incentives (pediatric, orphan, fast track, HDE, etc.) to support product development.
 - iv. Develop optimal strategy for Agency interactions during product development and life cycle management.
 - v. 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.
 - vi. Consult with marketing/project team to develop intended use and claims (target product profile).
 - vii. 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.
 - viii. Develop/deliver/assure in-house training programs for all company personnel for regulatory compliance (Refers to GXP).
 - ix. Assure implementation and documentation of training programs including identification of training needs (job-specific and general GMP training) and training schedules.
 - x. Provide trainers with updated information on regulatory requirements to incorporate in on-going training programs.
- C. Interaction With Other Companies
 - i. Conduct regulatory due diligence and advise senior management during product or company acquisitions and collaborations.
 - ii. Ensure regulatory obligations are met for in- and out-licensing of products.
 - iii. Ensure regulatory obligations are met for contract activities (manufacturing, complaint handling, regulatory operations, consultants, etc.).

Domain II: Pre-Approval

Approximately 9 recall questions, 8 application questions, and 8 analysis questions for a 100-question examination (percent of items on exam: 25%)

- A. Non-clinical Development
 - i. Determine test requirements (GLP/non-GLP, biocompatibility, carcinogenicity studies specific to drug/biologic/device, etc.) and identify applicable guidances and resources for such requirements.
 - ii. Ensure compliance with non-clinical safety requirements (GLPs) and applicable performance standards (ISO, ASTM, ANSI, ICH, etc.).
 - iii. Determine adequacy of non-clinical data and risk analysis to support initiation of clinical trials including any appropriate risk management.
 - iv. 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.

- B. Clinical Development
 - i. Determine requirements with regard to clinical safety and efficacy (GCPs).
 - ii. Ensure compliance with all clinical standards (GCPs, clinical trial monitoring and auditing), IRBs, safety reporting, informed consent, financial disclosure, etc.).
 - iii. Advise project team of regulatory recommendations for ongoing aspects of clinical trials/investigations (amendments to protocol, etc.).
 - iv. Identify non-US country specific requirements for impact to US submissions (IND/IDE, annual report, etc.).
 - v. 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.
 - vi. Ensure that any identified safety risks have been appropriately addressed with the clinical development program.
 - vii. Ensure that CFR requirements for adverse event reporting are established and being followed.
 - viii. Evaluate need for and contribute to the development of Pediatric Development Plan and/or waivers/deferrals, Orphan Designation Applications, etc.

- C. CMC/Device Design and Manufacturing
 - i. Determine regulatory requirements for manufacturing /quality system certifications (clinical trial supplies, manufacture, dosage forms, device classification, DMFs, etc.).
 - ii. Ensure compliance with cGMPs and QSR (SOPs, record retention, calibration, etc.).
 - iii. Verify device Design History File complies with regulatory requirements including risk management.
 - iv. Ensure regulatory compliance of manufacture and release of investigational products for clinical use.
 - v. Review completeness of documentation to support IND/IDE submissions.
 - vi. 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.
 - vii. Ensure specifications for device components, manufacturing process, and product have been defined and meet regulatory requirements (including product and quality system software).
 - viii. Evaluate manufacturing changes for compliance with appropriate change control systems/process and determine regulatory filing strategy.
 - ix. Review and monitor regulatory compliance for suppliers (contract manufacturers, CROs, etc.).

- D. Agency Interaction
 - i. Prepare pre-market submissions (IDE/IND) and master files for drugs/biologics/devices including investigational labeling.
 - ii. Ensure that the project is in compliance regarding submission format (CTD/eCTD, etc.).
 - iii. Review application for completeness according to “refuse-to-file” guidelines.
 - iv. Negotiate/interact as appropriate with Agency during development/submission process (Pre-IDE/IND, End of Phase 2, Meetings, Respond to Agency comments, etc.).
 - v. Monitor and maintain ongoing IDE/IND applications (e.g., amendments, annual reports, updates).
 - vi. Determine requirements for export/import of investigational products (customs, USDA, etc.).
 - vii. Ensure that the identified risks have been appropriately flagged and monitored.
 - viii. Initiate process to obtain non proprietary (USAN) and proprietary names.

Domain III: Approval

Approximately 8 recall questions, 8 application questions, and 8 analysis questions for a 100-question examination (percent of items on exam: 24%)

- A. Non-clinical Section
 - i. Assess and verify adequacy of non-clinical data to support approval.
 - ii. Assemble non-clinical reports and prepare non-clinical summary documentation as appropriate.
- B. Clinical Section
 - i. Assess and verify the adequacy of clinical safety and efficacy data to support approval and desired label claims.
 - ii. Assemble clinical reports submission and prepare summary documentation as appropriate.
 - iii. Ensure clinical trial monitoring and clinical trial audits are performed and documented.
- C. CMC/Device Design and Manufacturing
 - i. Assess and verify the adequacy of data to support submission approval and desired label claims/product specifications.
 - ii. Assess and verify the readiness of the drug/device manufacturing facility for PAI (Ensure compliance with GMP and QSR).
 - iii. Assemble CMC documentation for submission and prepare summary documentation as appropriate.
- D. Submission and Review Process
 - i. Prepare and schedule pre-submission 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.
 - ii. Guide project regarding submission format (CTD/eCTD, paper, etc.).
 - iii. Negotiate/interact as appropriate with Agency during the submission process (120 Day Safety Report, Respond to Agency comments, 100 Day Review, etc.).
 - iv. Prepare for and participate in Advisory Committee Meeting/Advisory Panel Meeting if requested.
 - v. Drive the creation of draft labeling that meets regulatory requirements and negotiate final labeling with FDA at end of review period (SPL).
 - vi. Develop post approval regulatory plans and negotiate agreement with FDA (e.g., risk evaluation and mitigation strategy (REMS) and post market clinical follow up plan).
 - vii. 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: Post-Approval

Approximately 8 recall Questions, 8 application questions, and 7 analysis questions for a 100-question examination (percent of items on exam: 23%)

- A. Postmarketing/Maintenance
 - i. Submit required licensing fees, drug and device listings, periodic reports and updates (e.g., PSURS, master files, etc.).
 - ii. Comply with product post-marketing approval requirements/condition of approval studies (Phase IV Studies).
 - iii. Prepare, implement and monitor strategy for alerts/notifications/recalls/market withdrawal.
 - iv. Advise management on alerts/notifications/recalls.
 - v. Provide regulatory input on post-approval change management.
 - vi. Assess documentation to support product and process changes and determine regulatory category of change (PAS, CBE, Annual Reports, etc).
 - vii. Prepare and submit supplements/design change applications and notifications to NDA, BLA, PMA.
 - viii. Maintain and record changes to the technical file/design dossier or NDA/BLA.
 - ix. Ensure compliance with Risk Evaluation and Mitigation Strategy (REMS).
- B. Postmarketing Surveillance/Vigilance
 - i. Evaluate reports of product complaints.
 - ii. Ensure that appropriate systems are in place to document and track product complaints and ADR reports.
 - iii. Ensure implementation of necessary corrective actions based on results of inspections, audits, failure analysis and consent decrees.
 - iv. Report product safety issues/failures to regulatory agencies as required [e.g., ADEs].
 - v. Review adverse drug reaction reports and medical device reports.

- C. Advertising/Promoting/Labelling
 - i. Review and approve revised labelling and claims, public communications, press releases, advertising, and promotional items for regulatory compliance.
 - ii. Evaluate data to support comparative claims in advertising and implications of off-label use.
- D. Distribution
 - i. Ensure compliance with regulatory requirements for supply, handling, storage, distribution, import, and export of materials.
 - ii. Ensure compliance with applicable requirements/regulations for distribution of controlled substances.
 - iii. Review regulatory aspects of contracts for product distribution (e.g., product complaints, product tracking, etc.).
 - iv. Advise on the issues related to drug/product/lot releases (Annual Product Review, Device History Record).
- E. Crisis Management
 - i. Advise management regarding the regulatory impact of a crisis event.
 - ii. Develop regulatory plan to address the crisis event.
 - iii. Advise management on regulatory implications of proposed crisis resolution strategies.
- F. Agency Interaction
 - i. Facilitate coordination of outside consultants and company personnel in response to Agency comments (PAI, 483 responses, conduct of clinical studies, etc.).
 - ii. Negotiate with Agency wording of inspection findings.
 - iii. Manage/accompany/chaperone inspection teams or auditors.
 - iv. 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.
 - v. Prepare strategy/briefing documents for panel hearings and informational meetings (Advisory Committee).
 - vi. Communicate/refer external requests for information.
 - vii. Develop Freedom of Information Act strategy regarding confidentiality and protection of proprietary information and document requests.

Appendix B: RAC (EU) Detailed Exam 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 exam will address the tasks and activities presented in this outline.

Domain I: Strategic Planning

Approximately 11 recall questions, 10 application questions, and 10 analysis questions for a 100-question examination (percent of items on exam: 31%)

- A. Regulatory Framework
 - i. Determine the regulatory classification status in European Union markets where the product may be launched.
 - ii. 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.
 - iii. Investigate and communicate when it is necessary to request technical and scientific guidance from relevant organisations.
 - iv. Evaluate regulatory requirements for markets outside of the European Union that recognize EU requirements.
 - v. Provide input to trade associations and standards organizations to influence the European regulatory environment (legislation, guidance documents, and standards).
 - vi. Perform Competitor Surveillance (e.g., EPAR, SmPCs, claims, indications) to evaluate potential changes, issues, and strategies.
 - vii. Contribute to in-house training programmes for company personnel to ensure regulatory and quality compliance.
- B. Regulatory Pathways and Options
 - i. Advise management on requirements and options for regulatory submissions, approvals, and conformity assessments (e.g., local, national, international options).
 - ii. Advise management on timelines, risks and financial implications of the proposed regulatory strategy.
 - iii. Investigate and communicate the availability of incentives (e.g., financial, data/market exclusivity) to support product development.
 - iv. Develop effective regulatory submission strategies for timely product approval.
 - v. Advise colleagues on compliance with relevant regulatory legislation, guidelines, standards, etc.
- C. Health Economics
 - i. Provide input to and advise senior management regarding Comparative Effectiveness/Health Technology Assessment.
 - ii. Advise senior management regarding pricing and reimbursement issues.
- D. Interaction with Other Companies
 - i. Advise senior management during product or company acquisitions and collaborations.
 - ii. Conduct regulatory due diligence during acquisitions and collaborations.
 - iii. In- and out-licensing of products from/to a third party.
- E. Crisis Management
 - i. Advise management regarding the regulatory impact of a crisis event (e.g., plant shut down) and propose a resolution strategy.
 - ii. Participate in the development and functioning of the crisis management programme.

Domain II: Design and Development

Approximately 12 recall questions, 12 application questions, and 12 analysis questions for a 100-question examination (percent of items on exam: 36%)

- A. Manufacturing/Quality (CMC)
 - i. Define and communicate regulatory requirements for the scope of manufacturing authorisations/quality system certifications (e.g., clinical trial supplies, operations allowed, pharmaceutical forms, design, manufacture, device types).
 - ii. Review completeness of production documentation to support CTA/MAA submissions/manufacturing transfer.
 - iii. Ensure that available stability data supports intended shelf-life of product.
- B. Nonclinical and Clinical Development
 - i. Advise sponsor of regulatory requirements for clinical trials/investigations.
 - ii. Determine adequacy of nonclinical data and risk analysis to support approval to conduct clinical trials/investigations.
 - iii. Identify national/local requirements and prepare clinical trials/investigations submissions to CA/EC.
 - iv. 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.
 - v. Interact with and coordinate the use of CROs, subcontractors, test facilities, and consultants.
 - vi. Respond to questions/comments from CA/EC.
 - vii. Ensure regulatory compliance of manufacture and release of investigational products for clinical use.
 - viii. Ensure that reporting procedures are in place to report adverse events that occur during clinical trials/investigations to CA/EC.
 - ix. Review clinical data from literature and other sources.
 - x. Report trial/investigation results to CA/EC.
 - xi. Maintain authorisation for on-going clinical trials/investigations (e.g., amendments, annual reports, updates).
 - xii. Evaluate need for and contribute to the development of Paediatric Investigation Plans/waivers/deferrals.
- C. Preregistration/CE Marking Interfacing
 - i. Evaluate need for and coordinate Protocol Assistance/Scientific Advice Meetings with CAs.
 - ii. Liaise with project team to develop project plans including submission timelines, deliverables, etc.
 - iii. Liaise with marketing/project team to develop target product profile and determine the claims that can and cannot be made based on available data.
 - iv. Participate in audits/inspections by NBs/CAs and contribute to responses to audit findings as required.
 - v. Evaluate and communicate relevant legislation and guidelines (e.g., EMA, scientific, harmonized standards, and essential requirements).
- D. Registration/CE Marking
 - i. Ensure adequate documentation to support MAA/Technical File/Design dossier.
 - a. Proof of concept/animal model
 - i. Nonclinical safety/biocompatibility
 - b. Clinical safety and performance/efficacy
 - c. Product quality/design verification and validation
 - d. Administrative data, forms, manufacturer authorisations/certifications, declarations and essential requirements checklists
 - e. Labeling/Product Information (including readability testing)
 - f. Risk Management Plan/File
 - g. Vigilance system
 - h. Post-market surveillance plan
 - i. Environmental risk assessment
 - j. Compliance with other applicable directives (e.g., WEEE, ROHS, machinery, battery)
 - ii. Prepare MAA/Design Dossier/Technical File.
 - iii. Submit MAA (incl. eCTD requirements)/Design Dossier to CA/NB.
 - iv. Monitor /track submission progress (procedural timelines).
 - v. Respond to questions/comments from CA/NB.
 - vi. Meet with CA/NB to negotiate during review process.
 - vii. Coordinate product information (i.e. label, carton, and leaflet/IFU) translations.
 - viii. Review approval documents/certificates.

Domain III: Postapproval

Approximately 11 recall questions, 11 application questions, and 11 analysis questions for a 100-question examination (percent of Items on exam: 33%)

- A. Advertising/Promoting/Labelling
 - i. Review and approve revised labelling and claims, public communications, press releases, advertising, and promotional items for regulatory compliance
 - ii. Provide regulatory input to commercial and marketing strategies.
 - iii. Review and evaluate advertising, labelling, and claims of competitors
 - iv. Provide regulatory input to tender applications (e.g., overview of licensing status, product quality, product shelf life, declaration of conformance)
 - v. Evaluate and communicate to management the implications of off-label use
- B. Postmarketing Surveillance and Vigilance
 - i. Evaluate reports of product failures and complaints
 - ii. Write field safety notices and report product failures and recalls /field safety corrective actions to CAs
 - iii. Maintain vigilance and ensure post-market surveillance activities are conducted.
 - iv. Ensure that Periodic Safety Update Reports (PSUR) are compiled and submitted to CAs according to regulatory timelines.
 - v. Ensure regulatory compliance of post-approval clinical studies
 - vi. Ensure implementation and monitor effectiveness of safety alerts, notifications, field safety corrective actions, and recalls.
 - vii. Consider use of information gained in the post-market phase for broadening product indications
- C. Supply Chain
 - i. Ensure compliance with regulatory requirements for supply, handling, distribution, import and export of materials.
 - ii. Review regulatory aspects of supplier and distributor contracts (e.g., complaints, traceability, changes, etc.)
- D. Product-specific Crisis Management
 - i. Advise management regarding the regulatory impact of a crisis event (e.g., batch failure)
 - ii. Advise management on regulatory implications of proposed crisis resolution strategies
- E. Postapproval Regulatory Compliance
 - i. Advise the Management Representative/Qualified Person regarding regulatory requirements.
 - ii. Ensure quality system SOPs meet regulatory requirements
 - iii. Assess whether new or revised legislation, guidelines, monographs and harmonized standards affect certain functions, activities, or products
 - iv. Initiate, monitor, document and submit changes where applicable to ensure compliance with new or revised legislation, guidelines, monographs, and harmonised standards
 - v. Review and monitor contractual obligations and agreements with NBs to ensure regulatory compliance
 - vi. Negotiate wording of audit findings

Appendix C: RAC (CAN) Detailed Exam 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 exam will address the tasks and activities presented in this outline.

Domain I: Strategic Planning

Approximately 23 questions for a 100-question exam

- A. Provide internal advice based on the understanding of limits imposed by regulatory environment in order to ensure product concept compliance.
- B. Perform benefit risk analysis on product development concept for initial product viability, e.g., as per EN1441 standard for benefit risk analysis, in order to make recommendations respecting current/future internal/external investments.
- C. Determine endpoints for safety and efficacy testing (feasibility) in order to determine the ability to comply with regulatory standards.
- D. Advise stakeholders on research and development programs in order to ensure applicable regulatory compliance.
- E. 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.
- F. Continue to revisit and compare regulatory outcomes with initial product concepts in order to make recommendations on future actions.
- G. 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.
- H. Identify lead regulatory authority/body for submission of data concerning applicable product (e.g., biologics, combination products, natural health products, etc.).
- I. 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.
- J. 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.
- K. Determine trade issues to anticipate regulatory obstacle, e.g., applicable treaty law, international conventions, 'for export only' status.
- L. 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.
- M. Assist in the development of a code of ethics for the organization in interfacing with stakeholders to minimize regulatory liability.
- N. Assist in the development and review of SOPs for compliance with regulatory affairs practice.

Domain II: Premarketing

Approximately 26 questions for a 100-question exam

- A. 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.
- B. 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.
- C. Negotiate/interact as appropriate through internal/external correspondence (e.g., meetings, email) with regulatory authorities during the development & review process to ensure submission approval.
- D. Facilitate SAP approvals when necessary with HPFB.
- E. 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.
- F. 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.
- G. Monitor applications under regulatory authority review through frequent communication to track internal/external performance target dates.
- H. Follow company procedures to ensure appropriate responses to regulatory authority queries/decisions.
- I. Evaluate proposed preclinical, clinical & manufacturing changes for regulatory filing strategies.
- J. 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 exam

- A. Approve advertising and promotional items for compliance before release.
- B. Generate and approve labelling for compliance before release.
- C. Submit notifiable changes and supplemental NDSs to update product monograph and/or instructions for use to reflect current state of product knowledge.
- D. Assure that appropriate SOPs are in place to document, prioritize, categorize, and track product associated events, complaints, recalls, market withdrawals, and ADR reports.
- E. 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 labelling changes, warnings or alerts, product changes, recalls, withdrawals).
- F. Participate in initiation, strategy and policy of recalls and Dear Healthcare Professional Letters to ensure that the message is clear.
- G. Report product associated events which satisfy regulatory criteria for reportability, failures, recalls, and or corrective actions resulting from inspections to regulatory agencies as required.
- H. Report product safety issues to regulatory agencies as required in order to comply with regulations.
- I. Assure that PSUR reports are available annually for submission on request to comply with regulations.
- J. Comply with product post-marketing approval requirements for conditional NOCs in order to meet the approval commitment.
- K. Approve change controls to determine the level of change and consequent submission requirement.
- L. Submit notifiable changes and supplemental NDS for post-marketing quality changes.
- M. Advise in the development and functioning of the crisis management/issue management program, e.g. regulatory impact of an event and implications of resolution.
- N. Review regulatory aspects of contracts for product distribution, e.g., product complaints, recalls, ADRs, etc.
- O. Implement access to information defence regarding confidentiality and protection of proprietary information and document requests.
- P. File access to information requests as required.
- Q. Maintain annual licenses (e.g., establishment, narcotic, controlled) and submit annual DIN notifications.
- R. 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.
- S. Provide submission documents for preparation of submission to PMPRB and/or provincial authorities by other functional areas.
- T. Submit documentation and samples, if required, for lot release of biologics.
- U. Ensure that quality systems are in place for medical devices as per ISO requirements.
- V. Comply with import and export requirements.
- W. Assure compliance with applicable market controls and requirements (e.g., controlled substances, veterinary use only, illicit markets).
- X. Assure adequacy of product traceability systems.
- Y. Channelling information about product use and distribution to be used in risk management.

Domain IV: Interfacing

Approximately 25 questions for a 100-question exam

- A. Communicate and negotiate with regulatory authorities (i.e., Health Canada) and stakeholders in order to facilitate compliance on health product regulatory matters.
- B. Conduct the meeting for technical presentations to health regulatory advisory committees/agencies and other government agencies to defend or facilitate regulatory compliance.
- C. 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.
- D. Support and/or coordinate responsibilities respecting the provision of data (e.g. clinical trials, pre-approval site inspection).
- E. Accompany inspection team as required.
- F. 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.
- G. Review public communications, press releases, etc. from a regulatory perspective.
- H. 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.
- I. 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.
- J. Notify, consult, or brief legal counsel and officials when appropriate in order to limit legal liability.
- K. Advise appropriate company personnel when a regulatory body exceeds its authority.
- L. Communicate regulatory agency/industry positions within the organization.
- M. Participate in medical review committees.
- N. Develop “early warning system” to identify potential regulatory problems affecting the company/agency and advise affected internal functional groups.
- O. Identify the standards developing organizations that are appropriate for the company’s product.
- P. Negotiate/interact as appropriate, with standards developing organizations.
- Q. Review draft documents when routed for comment.

Appendix D: RAC (General Scope) Detailed Exam Content Outline

The RAC (General Scope) 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 exam will address the tasks and activities presented in this outline.

Domain I: Strategic Planning

Approximately 25 questions for a 100-question exam

- A. Evaluate the regulatory environment and provide internal advice throughout the life cycle of the product (e.g., concept, development, manufacturing, marketing) to ensure product compliance.
- B. Perform risk/benefit analysis on product development concept for initial product viability.
- C. Determine endpoints for safety and efficacy testing at the feasibility phase to determine the ability to comply with regulatory standards.
- D. Advise research and development programs to ensure applicable regulatory compliance.
- E. Provide regulatory intelligence to develop local, regional, and global regulatory strategies that include due diligence and internal/external license opportunities.
- F. Revisit the regulatory outcomes and compare them with initial product concepts and make recommendations for future actions.
- G. Investigate, research, evaluate, and interpret regulatory decisions in a similar product category to assess regulatory implications for approval.
- H. Identify appropriate regulatory authorities for submission of data concerning the product being developed.
- I. Assess impact of local, regional, and global requirements and considerations on the regulatory dossiers.
- J. 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.
- K. Anticipate regulatory obstacles arising from trade issues (e.g., applicable treaty law, international conventions, “for export only” status).
- L. Provide alternative strategies for product development and submission to ensure timely approval and advise internal stakeholders on the requirements.
- M. Develop and review regulatory department SOPs (i.e., standard operating procedures) to ensure regulatory compliance.
- N. Assist other departments to develop SOPs to ensure regulatory compliance.

Domain II: Premarketing

Approximately 30 questions for a 100-question exam

- A. Advise stakeholders of regulatory requirements for quality, preclinical, and clinical data to meet applicable regulations.
- B. Assess the acceptability of quality, preclinical and clinical documentation for submission filing to comply with applicable regulations.
- C. 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.
- D. Determine acceptability of submission package through the preparation and review of relevant sections to comply with applicable regulations.
- E. Compile and prepare regulatory submissions according to applicable regulatory guidelines and submit to the appropriate regulatory authorities to ensure compliance to guidelines.
- F. Monitor the progress of the regulatory authority review process through appropriate communication with the agency.
- G. Evaluate proposed manufacturing changes on pre-clinical and clinical development and regulatory submission strategies.
- H. Facilitate the development of appropriate and timely responses to regulatory authority queries and actions to ensure compliance with company procedures.
- I. Participate in developing a risk management system (e.g., vigilance) to ensure that local, regional, and global regulatory requirements as applicable are met.
- J. 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 exam

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

Domain IV: Interfacing

Approximately 22 questions for a 100-question exam

- A. Communicate and negotiate with regulatory authorities and stakeholders to facilitate compliance on regulated products.
- B. Coordinate company presentations to regulatory advisory committees/agencies representatives and other government agencies to facilitate regulatory compliance.
- C. 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.
- D. Coordinate responses to queries from regulatory authorities.
- E. Accompany inspection team as required.
- F. Maintain records on legislation, regulations, guidelines, standards, and related issues for background purposes to facilitate compliance on regulated products and to support strategic planning.
- G. Review public communications, press releases, etc. to ensure regulatory compliance.
- H. 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.
- I. Advise stakeholders on the impact of current and proposed legislation, regulations, guidelines, and standards and provide training when necessary to facilitate regulatory compliance.
- J. Communicate with legal counsel and company officials when appropriate to minimize exposure to legal liability.
- K. Inform appropriate company personnel (e.g., legal, management) and stakeholders when a regulatory body exceeds its authority or fails to meet obligations.
- L. Communicate regulatory agency and industry positions within the organization.
- M. Participate in internal product review committees (e.g., labeling, quality, launch).
- N. Develop early warning systems to identify potential regulatory compliance issues affecting the company and advise affected internal functional groups.
- O. Identify and interact with the standards-developing organizations that are appropriate for the company's product.

¹ Additional later registration fees apply