

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 HPFEB.
- 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 HPFEB 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.