

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.