

APPENDIX A: RAC (DEVICES) DETAILED EXAMINATION CONTENT OUTLINE

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

Domain I: Strategic Planning – Exam Weighting approximately 29%

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

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

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

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

- Task 1: Review advertising and promotional materials for regulatory compliance.
- Task 2: Review and provide input to labeling to comply with regulatory requirements.
- Task 3: Submit notifiable changes and supplemental dossier to the appropriate regulatory authorities to update product information and/or instructions for use to reflect current state of product.
- Task 4: Verify that appropriate standard operating procedures are in place to manage product associated events, complaints, recalls, market withdrawals, and safety reports.
- Task 5: Provide input to the risk assessment associated with product issues and implement appropriate regulatory steps to address issues (e.g., consumer information, advertising, labeling changes, warnings, alerts, product changes, recalls, withdrawals).
- Task 6: Participate in implementing regulatory strategy for handling recalls and communication to stakeholders (e.g., dear healthcare provider letters, patient letters, distributor letters, health authorities).
- Task 7: Report notifiable manufacturing product-associated events (e.g., failures, recalls, corrective actions resulting from inspections) to regulatory authorities as required.
- Task 8: Report product safety issues to regulatory authorities as required to comply with local, regional, and global regulations.

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

Domain IV: Interfacing – Exam Weighting approximately 8%

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

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

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