



RAC-Devices Exam Content Outline

Each exam 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 exam is reviewed and revised annually, and content is updated before the Summer exam window. Domain weighting percentages in the exam content outline are approximate and may be +/-2%. Exam content for the RAC-Devices exam is based on regulations and guidelines in:

Domain I: Strategic Planning—Exam Weighting approximately 27%

- Task 1: Evaluate the regulatory environment and provide internal advice from concept to obsolescence of the product to facilitate product compliance.
- Task 2: Prepare regulatory strategies for global commercialization.
- Task 3: Research competitor and predicate/equivalent devices.
- Task 4: Differentiate between product designations.
- Task 5: Review proposed product claims and associated testing strategies.
- Task 6: Interact early with regulatory agencies on proposed strategy.
- Task 7: Differentiate between products categorized as devices and their specific regulatory requirements.
- Task 8: Evaluate regulatory needs for devices intended to be used for special patient populations or use environments.

Domain II: Design and Development—Exam Weighting approximately 27%

- Task 1: Evaluate testing strategy for bench, pre-clinical and clinical.
- Task 2: Perform review and/or approval of design verification, and/or design validation activities, including deliverables.
- Task 3: Respond to inconsistency throughout documentation.
- Task 4: Confirm that testing results support product claims.
- Task 5: Evaluate substantial equivalence to predicate devices' performance and technology and/or state-of-the-art determination.
- Task 6: Review and identify potential risks for similar device types from regulatory databases.
- Task 7: Participate in design and risk review activities.
- Task 8: Evaluate regulatory impact of design and manufacturing changes during development..
- Task 9: Communicate with regulatory agencies during product development.
- Task 10: Interact with and document use of external organizations.
- Task 11: Assist with and verify quality management system (QMS) elements are in place to support design, development, transfer, and marketing activities.
- Task 12: Review regulatory aspects of contracts for product manufacturing and distribution.
- Task 13: Verify access controls exist for regulatory documentation, ensuring confidentiality, and protection of proprietary information and personal health information (PHI).
- Task 14: Assure marketing authorizations are in place prior to commercial launch.

Domain III: Process for Licensing, Registration, and Renewals—Exam Weighting approximately 23%

- Task 1: Determine the needed documentation for licensing, registration and renewals.
- Task 2: Engage the interdepartmental stakeholders for submission support.
- Task 3: Consolidate, assess acceptability of data and file format, and submit filing data to meet applicable regulatory requirements.
- Task 4: Determine and submit appropriate responses to deficiency requests.
- Task 5: Update licenses and registrations based on critical change determinations.
- Task 6: Monitor statuses for existing licenses, registrations, and renewals.
- Task 7: Periodically review and revise standard operating procedures based on regional requirements.
- Task 8: Communicate and negotiate with regulatory authorities and stakeholders during the license, registration and renewal process.
- Task 9: Communicate the status of license, registration and renewals to relevant parties.
- Task 10: Submit relevant documentation to comply with customs and import/export requirements.
- Task 11: Establish/update applicable market authorization traceability systems.

Domain IV: Post-Market Activities—Exam Weighting approximately 23%

- Task 1: Assess and document product, process, and quality management system changes for regulatory impact.
- Task 2: Apply or interpret impact of external changes.
- Task 3: Support health authority/notified body commitments.
- Task 4: Support risk assessment and reportability of event determination
- Task 5: Assess the regulatory impact of labeling changes, including advertising and promotional materials.
- Task 6: Negotiate and interact with regulatory authorities through appropriate communication tools.
- Task 7: Develop and/or maintain regulatory standard operating procedures for on-going compliance.
- Task 8: Maintain and update the medical device files, technical device files, and dossiers.
- Task 9: Evaluate key components of a product change and impact on market authorization.
- Task 10: Participate in internal product review committees.
- Task 11: Perform ongoing review of contracts for regulatory aspects for product manufacture and distribution.
- Task 12: Submit documentation/samples for import and export requirements, legal requests, and product reimbursement requests.