



# RAC-Devices Exam Study Checklist

## Instruction:

Use this checklist to track your progress when preparing for your RAC certification exam.

1. When you begin your studying, review each task statement and place a checkmark in the box that best describes your study needs for each task. The associated knowledge areas are listed below the checklist.
2. If you are not familiar with or do not regularly perform the content in the listed task, you most likely need extensive review and should check the 'needs extensive review' box.
3. If the content listed is a task that you perform regularly as part of your job, you most likely need less review and should check the 'need minimal review' box.
4. Once you complete your review of the content in the listed task, check the 'review complete' box.

Domain I: Strategic Planning – 27%			
Task	Needs Minimal Review	Needs Extensive Review	Review Complete
Evaluate the regulatory environment and provide internal advice from concept to obsolescence of the product to facilitate product compliance.			
Prepare regulatory strategies for global commercialization.			
Research competitor and predicate/equivalent devices.			
Differentiate between product designations.			
Review proposed product claims and associated testing strategies.			
Interact early with regulatory agencies on proposed strategy.			
Differentiate between products categorized as devices and their specific regulatory requirements.			
Evaluate regulatory needs for devices intended to be used for special patient populations or use environments.			

## Domain II: Design and Development – 27%

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

### Domain III: Process for Licensing, Registration, and Renewals – 23%

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

### Domain IV: Post-Market Activities – 23%

Task	Needs Minimal Review	Needs Extensive Review	Review Complete
Assess and document product, process, and quality management system changes for regulatory impact.			
Apply or interpret impact of external changes.			
Support health authority/notified body commitments.			

Support risk assessment and reportability of event determination.			
Assess the regulatory impact of labeling changes, including advertising and promotional materials.			
Negotiate and interact with regulatory authorities through appropriate communication tools.			
Develop and/or maintain regulatory standard operating procedures for on-going compliance.			
Maintain and update the medical device files, technical device files, and dossiers.			
Evaluate key components of a product change and impact on market authorization.			
Participate in internal product review committees.			
Perform ongoing review of contracts for regulatory aspects for product manufacture and distribution.			
Submit documentation/samples for import and export requirements, legal requests, and product reimbursement requests.			