RAC (Devices) Examination Study Checklist

Instructions: Use this checklist to track your progress when preparing for the RAC (Devices) certification examination. 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.

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. 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. Once you complete your review of the content in the listed task, check the 'Review complete' box.

Domain I: Strategic Planning – Exam Weighting approximately 29%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Determine the proposed product classification by using the relevant regulation to prepare for regulatory pathway and submission strategy.			
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.			
Provide input regarding comparative effectiveness/health technology assessment associated with reimbursement.			
Perform risk/benefit analysis on product development concept for initial product viability.			

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.			
Collaborate with and advise research and development programs regarding applicable regulatory compliance.			
Provide regulatory intelligence to develop local, regional, and global regulatory strategies.			
Evaluate the regulatory outcomes from the initial product concepts and make recommendations for future actions.			
Research and interpret regulatory decisions in a similar product category to assess regulatory approval implications.			
Identify appropriate regulatory authorities for submission of data for product being developed.			
Assess impact of local, regional, and global requirements and considerations on the content of regulatory submission/dossiers.			
Evaluate global filing strategy (e.g., simultaneous filings, joint reviews, mutual recognition agreements, assessment of similarity or dissimilarity of requirements) to define market feasibility.			
Anticipate regulatory concerns arising from trade issues (e.g., applicable treaty law, international conventions, “for export only” status).			
Provide alternative strategies for product development and submission to ensure timely approval and advise internal stakeholders on the requirements.			

Develop and review regulatory department standard operating procedures to achieve regulatory compliance.			
Participate in internal training programs for company personnel to achieve regulatory and quality compliance.			
Assist other departments to develop standard operating procedures to achieve regulatory compliance.			

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

Task	Needs Minimal Review	Needs Extensive Review	Review Complete
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).			
Advise stakeholders of regulatory requirements for quality, bench, preclinical, and clinical data.			
Assess the acceptability of quality, bench, preclinical, and clinical documentation for submission filing to meet regulatory requirements.			
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.			
Determine acceptability of submission package through the preparation and review of relevant sections to comply with applicable requirements.			

Compile and prepare regulatory submissions according to relevant guidelines and submit to the appropriate regulatory authorities.			
Monitor the progress of the regulatory authority review process through appropriate communication with the agency.			
Evaluate the impact on the regulatory submission strategies of proposed manufacturing changes during the preclinical development and clinical studies.			
Facilitate the development of appropriate and timely responses to regulatory authority queries and actions to meet regulatory requirements.			
Participate in developing a risk management system to ensure that local, regional, and global regulatory requirements are met.			
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.			
Interact with other companies associated with acquisitions and collaborations.			
Interact with and record the use of contract research organizations, subcontractors, test facilities, and consultants.			
Review documentation of raw materials to ensure compliance with regulatory requirements.			

Domain III: Post-marketing – Exam Weighting approximately 38%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Review advertising and promotional materials for regulatory compliance.			
Review and provide input to labeling to comply with regulatory requirements.			
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.			
Verify that appropriate standard operating procedures are in place to manage product associated events, complaints, recalls, market withdrawals, and safety reports.			
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).			
Participate in implementing regulatory strategy for handling recalls and communication to stakeholders (e.g., dear healthcare provider letters, patient letters, distributor letters, health authorities).			
Report notifiable manufacturing product-associated events (e.g., failures, recalls, corrective actions resulting from inspections) to regulatory authorities as required.			

Report product safety issues to regulatory authorities as required to comply with local, regional, and global regulations.			
Submit single case or aggregate safety reports to comply with local, regional, and global regulations or upon request by regulatory authorities.			
Comply with product post-marketing surveillance requirements to meet conditions of approval.			
Proceduralize the regulatory assessment process to define notifiable changes to comply with local, regional, and global regulatory authorities for post-marketing changes.			
Evaluate change control documents to determine the level of change and consequential submission requirement.			
Participate in crisis/issue management team (e.g., product recall, counterfeiting) and assess the regulatory impact of an event and proposed resolution.			
Review regulatory aspects of contracts (e.g., quality, product complaints, recalls, vigilance) for product manufacture and distribution.			
Control access to regulatory documentation, ensuring confidentiality and protection of proprietary information.			
Maintain licenses (e.g., establishment, narcotics, controlled substances) and submit renewals as required.			
File new and amended patent/trademark forms to update information with applicable regulatory authorities to meet regulations.			

Provide required information (e.g., clinical data) in support of product reimbursement requests.			
Submit documentation and samples for lot release, if required, for customs clearance.			
Demonstrate that quality systems are in place (e.g., ISO 13485 for medical devices).			
Comply with import and export requirements.			
Demonstrate compliance with applicable market controls and requirements (e.g., controlled substances, veterinary use only).			
Assess adequacy of product traceability systems.			
Domain IV: Interfacing – Exam Weighting approximately 8%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Communicate and negotiate with regulatory authorities and stakeholders to facilitate compliance on regulated products.			
Review public communications, press releases, etc., to ensure regulatory compliance.			
Participate in internal product review committees (e.g., labeling, quality, launch).			

Develop early warning systems to identify potential regulatory compliance issues affecting the company and advise affected internal functional groups.			
Identify and interact with the standards-developing organizations that are appropriate for the company's product.			

Please note:

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