RAC (Global) Examination
Study Checklist

Instructions: Use this checklist to track your progress when preparing for the RAC (Global) 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 (approximately 25% of exam)			
Task	**Needs minimal review**	**Needs extensive review**	**Review complete**
1. Evaluate the regulatory environment and provide internal advice throughout the life cycle of the product (e.g., concept, development, manufacturing, marketing) to endure product compliance (Knowledge areas: 1,2,3,4)			
2. Perform risk/benefit analysis on product development concept for initial product viability. (Knowledge areas: 5,6)			
3. Determine endpoints for safety and efficacy testing at the feasibility phase to determine the ability to comply with regulatory standards. (Knowledge areas: 1,2,3)			
4. Advise research and development programs to ensure applicable regulatory compliance. (Knowledge areas: 1,2,3,6, 12,13)			
5. Provide regulatory intelligence to develop local, regional, and global regulatory strategies that include due diligence and internal/external license opportunities. (Knowledge areas: 1,7,8,9)			
6. Revisit the regulatory outcomes and compare them with initial product concepts and make recommendations for future actions. (Knowledge areas: 1,9,10,11)			
7. Investigate, research, evaluate, and intercept regulatory decisions in a similar product category to assess regulatory implications for approval. (Knowledge areas: 1,12)			
8. Identify appropriate regulatory authorities for submission of data concerning the product being developed.			

(Knowledge areas: 1,2,3,12)			
9. Assess impact of local, regional, and global requirements and considerations on the regulatory dossiers. (Knowledge areas: 1)			
10. 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. (Knowledge areas: 1,14)			
11. Anticipate regulatory obstacles arising from trade issues (e.g., applicable treaty law, international conventions, "for export only" status). (Knowledge areas: 1,14)			
12. Provide alternative strategies for product development and submission to ensure timely approval and advise internal stakeholders on the requirements. (Knowledge areas: 1,2,3,10)			
13. Develop and review regulatory department SOPs (i.e., standard operating procedures) to ensure regulatory compliance. (Knowledge areas: 1,2,6,11)			
14. Assist other departments to develop SOPs to ensure regulatory compliance. (Knowledge areas: 1,2,6,11)			
Domain II: Premarketing (approximately 30% of exam)			
Task	**Needs minimal review**	**Needs extensive review**	**Review complete**
1. Advise stakeholders of regulatory requirements for quality, preclinical, and clinical data to meet applicable regulations. (Knowledge areas: 1,2,3)			
2. Assess the acceptability of quality, preclinical, and clinical documentation for submission filing to comply with applicable regulations. (Knowledge areas: 1)			
3. Negotiate and interact through appropriate communication tools (e.g., meetings, email) with regulatory authorities before and during the development and review processes to facilitate submission approval. (Knowledge areas: 1,2,3)			
4. Determine acceptability if submission package through the preparation and review of relevant sections to comply with applicable regulations. (Knowledge areas: 1,2,11,15)			

5. Compile and prepare regulatory submissions according to applicable regulatory guidelines and submit to the appropriate regulatory authorities to ensure compliance to guidelines. (Knowledge areas: 1,2,3,10,11,15)			
6. Monitor the progress of the regulatory authority review process through appropriate communication with the agency. (Knowledge areas: 1,2,3,10,11)			
7. Evaluate proposed manufacturing changes on pre-clinical and clinical development and regulatory submission strategies. (Knowledge areas: 1,2,3,16)			
8. Facilitate the development of appropriate and timely responses to regulatory authority queries and actions to ensure compliance with company procedures. (Knowledge areas: 1,2,3,11)			
9. Participate in developing a risk management system (e.g., vigilance) to ensure that local, regional, and global regulatory requirements as applicable are met.)Knowledge areas: 1,2,3,16)			
10. 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. (Knowledge areas: 11,12)			
Domain III: Postmarketing (approximately 23% of exam)			
Task	**Needs minimal review**	**Needs extensive review**	**Review complete**
1. Ensure regulatory compliance of advertising and promotional items. (Knowledge areas: 1,2,3)			
2. Generate and ensure regulatory compliance of labeling. (Knowledge areas: 1,2,3)			
3. Submit notifiable changes and supplemental dossier to the appropriate regulatory authorities to update product information and/or instructions for use to reflect the current state of product knowledge. (Knowledge areas: 1,2,3)			
4. Assure that appropriate standard operating procedures (SOPs) are in place. (Knowledge areas: 1,2,3)			

5. 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). (Knowledge areas: 1,3,5,11)			
6. Participate in implementing regulatory strategy for handling recalls and communication to stakeholders (e.g., Dear Healthcare Professional letters, patient letters, distributor letters, Health Authorities). (Knowledge areas: 1,2,3)			
7. Report notifiable manufacturing product-associated events (e.g., failures, recalls, corrective actions resulting from inspections) to regulatory authorities as required. (Knowledge areas: 1,2,3)			
8. Report product safety issues to regulatory authorities as required to comply with local, regional, and global regulations. (Knowledge areas: 1,2,3)			
9. Assure that single case or aggregate safety reports are submitted to comply with local, regional, and global regulations or upon request by regulatory authorities. (Knowledge areas: 1,3)			
10. Comply with product post-marketing surveillance requirements to meet conditions of approval. (Knowledge areas: 1,2,3,10)			
11. Evaluate change control documents to determine the level of change and consequent submission requirement. (Knowledge areas: 1,2,3)			
12. Define and submit notifiable changes and supplemental dossiers to local, regional, and global regulatory authorities for post-marketing changes. (Knowledge areas: 3,10,12)			
13. Participate in crisis/issue management team (e.g., product recall, counterfeiting) and assess the regulatory impact of an event and proposed resolution. (Knowledge areas: 1,2,5,17)			
14. Review regulatory aspects (e.g., quality, product complaints, recalls, vigilance) of contracts for product manufacture and distribution. (Knowledge areas: 1, 2)			
15. Control access to regulatory documentation ensuring confidentiality and protection for proprietary information. (Knowledge areas: 1,2,3)			
16. Maintain licenses (e.g., establishment, narcotics, controlled substances) and submit renewals as required.			

(Knowledge areas: 1,2,3)			
17. File new and amended patent/trademark forms to update information with applicable regulatory authorities to meet applicable regulations. (Knowledge areas: 1,2,3)			
18. Provide required information (e.g. clinical data) in support of product reimbursement requests. (Knowledge areas: 18,19)			
19. Submit documentation and samples for lot release, if required, for customs clearance. (Knowledge areas: 1,2,3)			
20. Ensure that quality systems are in place (e.g., ISO 13485 for medical devices). (Knowledge areas: 1,3)			
21. Comply with import and export requirements. (Knowledge areas: 13, 14)			
22. Assure compliance with applicable market controls and requirements (e.g., controlled substances, veterinary use only). (Knowledge areas: 13, 20)			
23. Assure adequacy of product traceability systems. (Knowledge areas: 16)			
Domain IV: Interfacing (approximately 22% of exam)			
Task	**Needs minimal review**	**Needs extensive review**	**Review complete**
1. Communicate and negotiate with regulatory authorities and stakeholders to facilitate compliance on regulated products. (Knowledge areas: 1,5,7,18)			
2. Coordinate company presentations to regulatory advisory committees/agencies representatives and other government agencies to facilitate regulatory compliance. (Knowledge areas: 1,2,10)			
3. 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. (Knowledge areas: 11,18)			
4. Coordinate responses to queries from regulatory authorities. (Knowledge areas: 1,2,15)			
5. Accompany inspection team as required. (Knowledge areas: 1,15)			

6. Maintain records on legislation, regulations, guidelines, standards, and related issues for background purposes to facilitate compliance on regulated products and to support strategic planning. (Knowledge areas: 1,19)			
7. Review Public communications, press releases, etc. to ensure regulatory compliance. (Knowledge areas: 1,2)			
8. 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. (Knowledge areas: 1,2,9)			
9. Advise stakeholders on the impact of current and proposed legislation, regulations, guidelines, and standards and provide training when necessary to facilitate regulatory compliance. (Knowledge areas: 1,2,9)			
10. Communicate with legal counsel and company officials when appropriate to minimize exposure to legal liability. (Knowledge areas: 1,2,9)			
11. Inform appropriate company personnel (e.g., legal, management) and stakeholders when a regulatory body exceeds its authority or fails to meet obligations. (Knowledge areas: 1,2,9)			
12. Communicate regulatory agency and industry positions within the organization. (Knowledge areas: 1,2,6,9)			
13. Participate in internal product review committees (e.g., labeling, quality, launch). (Knowledge areas: 1,2,9)			
14. Develop early warning systems to identify potential regulatory compliance issues affecting the company and advise affected internal functional groups. (Knowledge areas: 1,2,9)			
15. Identify and interact with the standards-developing organizations that are appropriate for the company's product. (Knowledge areas: 1,2)			

RAC (Global) Examination Knowledge Areas

Competent performance of the task statements listed above is supported by an understanding of the content in certain knowledge areas. Each knowledge area below is associated with a task statement. Review the knowledge areas along with the associated task statements as needed.

1. Regulatory guidelines, policies, and regulations; rationale for establishment of specific regulatory requirements; lifecycle of the regulations, legislation and guidelines; local, regional, and global special requirements and considerations

2. Product specifications, processes, and regulatory history; competitive intelligence; product profiles

3. Current internal/external standards, practices and precedents

4. Product life cycle

5. Fundamental processes, standards, and practices for risk assessment; risk analysis strategies and methodologies; limitations and strengths of various types of market interventions

6. Paradigms and values (e.g., economic, societal, regulatory agency, corporate); company code of ethics

7. Communication networks; routes of communication

8. Key people and contacts (e.g., markets, market history/behavior, medical/technical experts)

9. Regulatory and corporate history; company policies

10. Project management; supervision and team building techniques; principles of team dynamics; presentation principles; performing due diligence

11. Business processes; business goals; technical writing skills; business acumen and organizational awareness; business systems used by organizations; resource allocation; business environmental assessment; cost recovery; standard operating procedures

12. Internal regulatory environment (e.g., organizational, responsibilities, mandates, jurisdictions, roles, classifications systems); internal constraints; research methods

13. External regulatory environment (e.g., patient groups, trade associations, other corporations, technology issues); external constraints

14. Export/import regulations; relevant international treaties, domestic legislation, and trade practices; trade agreements

15. Electronic submission guidelines; appeals processes; submission requirements

16. Manufacturing and quality control; ISO standards; information technology as applied to product distribution

17. Crisis management fundamentals and techniques; creative alternatives

18. Legislation and policy related to product reimbursement; difference in legislative authorities; impact analysis

19. Location of documents; documentation management systems

20. Relevant market conditions, off-label uses of product, patterns of misuse and abuse