RAC-Drugs Exam Study Checklist

Instruction:

Use this checklist to track your progress when preparing for the RAC-Drugs 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 – Exam Weighting approximately 24%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Evaluate the regulatory environment and provide internal advice throughout the life cycle of the product (e.g., concept, development, manufacturing, marketing) to ensure compliance.			
Perform risk/benefit analysis on product development concept for initial product viability.			
Determine endpoints for safety and efficacy testing at the feasibility phase to determine the ability to comply with regulatory standards.			
Advise research and development programs to ensure regulatory compliance.			
Provide regulatory intelligence to develop local, regional, and global regulatory strategies that include determination of regulatory classification, submission type (e.g., eCTD, electronic, paper) for regulatory applications, due diligence, and internal/external license opportunities.			
Evaluate the regulatory outcomes of initial product concepts and make recommendations for future actions.			

Evaluate and interpret regulatory decisions in a similar product category to assess regulatory implications for approval.			
Identify and engage appropriate regulatory authorities for submission of data concerning the product being developed.			
Assess impact of local, regional, and global requirements and considerations on the regulatory dossiers.			
Consult with multidisciplinary teams to develop indications for use, intended use, and product claims (e.g., target product profile, product requirements).			
Evaluate the regulatory merits of domestic versus regional or global submission strategies (e.g., simultaneous filings, joint reviews, mutual recognition agreements, assessment of similarity or dissimilarity of requirements) to define market feasibility.			
Anticipate regulatory issues arising from trade-related matters (e.g., applicable treaty law, international conventions, "for export only" status).			
Develop strategies for regulatory authority interactions (e.g., FDA/CA meetings, correspondence, documenting verbal communication or commitments) to guide product development life cycle management.			
Ensure regulatory compliance of company standard operating procedures impacting internal stakeholders.			
Provide internal trainers with information on regulatory requirements to incorporate in ongoing training programs.			
Domain II: Pre-marketing – Exam Weighting approximately 37%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Manufacturing Section			
Determine applicable regulatory requirements for manufacturing and/or development of drug products.			
Review documentation of raw materials to ensure compliance with regulatory requirements (e.g., API/drug substance, novel excipients, animal-derived materials).			
Review documentation (e.g., stability data, specifications, investigational labeling) for adequacy to support IND/CTA submission.			

Ensure regulatory compliance of manufacturing and release of investigational products for clinical use.			
Nonclinical Section			
Determine nonclinical test requirements (e.g., GLP, toxicology studies) and ensure compliance with applicable guidance, standards, and regulations for product-specific requirements.			
Evaluate adequacy of nonclinical data and risk management activities to support initiation of clinical trials.			
Clinical Section			
Determine requirements for clinical development and ensure compliance with applicable guidance, standards, and regulations for product-specific requirements (e.g., ICH, GCPs, monitoring, auditing, ethics committee, safety reporting, informed consent, financial disclosure).			
Ensure that reporting procedures are in place to report adverse events that occur during clinical trials/ investigations to appropriate regulatory bodies.			
Generate and ensure regulatory compliance of product labeling.			
Inform stakeholders of regulatory implications regarding ongoing clinical trials/investigations (e.g., protocol amendments, ICF amendments).			
General Section			
Advise stakeholders of regulatory requirements for quality, nonclinical, and clinical data to meet applicable regulations.			
Assess the acceptability and completeness of quality, nonclinical, and clinical documentation for submission filing to comply with applicable regulations (e.g., IND/ CTA, NDA/BLA/MAA submission, manufacturing transfer).			
Initiate and monitor the process to obtain nonproprietary (e.g., USAN, INN) and proprietary names.			
Manage outsourcing strategy (e.g., contract research organizations, subcontractors, test facilities, consultants) using appropriate communication tools throughout the product development life cycle.			

Compile and review regulatory submission packages in accordance with applicable regulations.			
Prepare or review study data and manufacturing information to ensure compliance with local, regional, national, and international regulatory requirements.			
Maintain authorization for ongoing clinical trials/ investigations (e.g., amendments, annual reports, updates) and monitor the progress of the regulatory authority review process.			
Evaluate proposed manufacturing changes on nonclinical and clinical development and regulatory submission strategies.			
Facilitate the development of appropriate and timely responses to regulatory authority queries and actions to ensure compliance with company procedures.			
Participate in developing a risk management system (e.g., vigilance) to ensure that local, regional, and global regulatory requirements as applicable are met for the development program.			
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.			
Participate in audits/inspections by regulatory authorities and contribute to responses to audit findings as required.			
Domain III: Post-marketing – Exam Weighting approximately 28%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Evaluate advertising and promotional materials for adherence to regulations, guidelines, and standard operating procedures to ensure compliance.			
Generate and evaluate product labeling (e.g., package insert, instructions for use) for adherence to regulations, guidelines, and standard operating procedures to ensure compliance.			
Submit notifiable changes and supplemental dossiers and follow up with the appropriate regulatory authorities to achieve compliance.			

Ensure that appropriate standard operating procedures are in place to manage product-associated events, complaints, adverse drug reports, recalls, market withdrawals, and vigilance reports in accordance with regulatory requirements.			
Provide regulatory input for risk management strategy 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).			
Implement regulatory strategy for handling communication to stakeholders for notifiable product-associated events, complaints, adverse drug reports, and recalls (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 to maintain compliance.			
Report product safety issues/failures to regulatory authorities to comply with local, regional, and global regulations.			
Engage regulatory authorities and comply with product post-marketing commitments and requirements to meet conditions of approval.			
Participate in crisis/issue management team (e.g., product recall, counterfeiting) and assess the regulatory impact and resolution of product- related events.			
Review regulatory aspects (e.g., quality, product complaints, recalls, vigilance) of contracts for product manufacturing and distribution to ensure compliance.			
Control access to regulatory documentation to ensure confidentiality and protection of proprietary information.			
Maintain licenses (e.g., registration and listings, 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.			

Ensure compliance with regulatory requirements for lot distribution and release.			
Provide regulatory oversight of quality system compliance (e.g., ISO, GXPs, SOPs).			
Comply with import and export requirements.			
Ensure compliance with applicable market controls and requirements (e.g., controlled substances, veterinary use only).			
Ensure adequacy of product traceability systems.			

Domain IV: Interfacing – Exam Weighting approximately 11%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Advise on regulatory strategy for risk management process to mitigate impact to company.			
Coordinate company presentations and development of briefing documentation for regulatory advisory committee, agency representatives, and other government agencies to facilitate regulatory compliance.			
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.			
Manage regulatory authority inspections to ensure company personnel are well-prepared and understand inspection processes.			
Evaluate legislation, regulations, guidelines, standards, and related issues to facilitate compliance on regulated products and to support strategic planning.			
Advise stakeholders on the impact of current and proposed legislation, regulations, guidelines, and standards and provide training when necessary to facilitate regulatory compliance.			
Communicate with legal counsel and company officials when appropriate to minimize exposure to legal liability.			
Participate on cross-functional product development teams (e.g., individuals from CMC, quality, labeling, research and development, clinical, nonclinical, marketing, legal) to provide regulatory affairs expertise.			

Please note:

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

a. Regulatory intelligence

b. Product development

c. Risk management

d. Licesing, registration, and maintenance

e. Post-market activities