RAC-Drugs 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: Regulatory Intelligence and Research – 27%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Determine and evaluate requirements for quality, nonclinical and clinical development and ensure compliance with applicable guidance, standards, and regulations.			
Evaluate regulatory pathways and the timelines associated with those pathways.			
Identify health authority systems (i.e., CDER NextGen Portal, EU CTIS, FDA ESG, DRUGS@FDA).			
Evaluate and interpret regulatory decisions in a relevant product category to assess regulatory implications for approval.			
Evaluate the regulatory environment and provide internal advice throughout the life cycle of the product.			
Assess impact of local, regional, and global requirements and considerations on regulatory dossiers.			
Identify appropriate regulatory authorities for submission of data.			

Assess how combination product regulations (e.g., in vitro diagnostic (IVD) and investigation device exemption (IDE) regulations) may impact drug development.			

Domain II: Submissions – 27%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Analyze submission requirements and prepare regulatory submission packages.			
Manage regulatory lifecycle.			
Report notifiable events to regulatory authorities to maintain compliance.			

Domain III: Collaboration – 13%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Advise research and development programs.			
Participate in cross-functional product teams.			
Advise stakeholders of regulatory requirements for quality, nonclinical, and clinical data.			
Participate in risk management activities and assess the regulatory impact.			
Describe different types of regulatory authority inspections and the inspection process.			
Understand the regulatory implications that might present legal liabilities and collaborate with legal representatives.			

Domain IV: Strategy – 22%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Perform risk/benefit and gap assessments relative to regulatory requirements.			
Develop appropriate responses to regulatory authority queries and actions in conjunction with stakeholders when necessary.			

Manage product post-marketing commitments and requirements.			
Coordinate preparation for health authority meetings including developing briefing documents and presentations.			
Domain V: Project Management – 11%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
Maintain different regulatory trackers or databases.			
Ensure regulatory SOPs and work instructions are in place.			
Manage regulatory timelines.			
Manage vendors and external contracts.			