RAC-Drugs Exam Content Outline

Each exam is based on a survey of the scope of practice and specific roles and responsibilities of regulatory professionals in the workplace with at least three years of regulatory experience. Each exam is reviewed and revised annually; content is updated before the Summer exam window. Domains and weighting percentages approximate and may be +/-2%. Content for the RAC-Drugs exam is based on regulations and guidelines in the following areas:

Domain I: Regulatory Intelligence and Research—Exam Weighting approximately 27%

Task 1: Determine and evaluate requirements for quality, nonclinical and clinical development and ensure compliance with applicable guidance, standards, and regulations.

Task 2: Evaluate regulatory pathways and the timelines associated with those pathways.

Task 3: Identify health authority systems (i.e., CDER NextGen Portal, EU CTIS, FDA ESG, DRUGS@FDA)

Task 4: Evaluate and interpret regulatory decisions in a relevant product category to assess regulatory implications for approval.

Task 5: Evaluate the regulatory environment and provide internal advice throughout the life cycle of the product.

Task 6: Assess impact of local, regional, and global requirements and considerations on regulatory dossiers.

Task 7: Identify appropriate regulatory authorities for submission of data.

Task 8: Assess how combination product regulations (e.g., in vitro diagnostic (IVD) and investigation device exemption (IDE) regulations) may impact drug development.

Domain II: Submissions—Exam Weighting approximately 27%

Task 1: Analyze submission requirements and prepare regulatory submission packages.

Task 2: Manage regulatory lifecycle.

Task 3: Report notifiable events to regulatory authorities to maintain compliance.

Domain III: Collaboration—Exam Weighting approximately 13%

Task 1: Advise research and development programs.

Task 2: Participate in cross-functional product teams.

Task 3: Advise stakeholders of regulatory requirements for quality, nonclinical, and clinical data.

Task 4: Participate in risk management activities and assess the regulatory impact.

Task 5: Describe different types of regulatory authority inspections and the inspection process.

Task 6: Understand the regulatory implications that might present legal liabilities and collaborate with legal representatives.

Domain IV: Strategy—Exam Weighting approximately 22%

Task 1: Perform risk/benefit and gap assessments relative to regulatory requirements.

Task 2: Develop appropriate responses to regulatory authority queries and actions in conjunction with stakeholders when necessary.

Task 3: Manage product post-marketing commitments and requirements.

Task 4: Coordinate preparation for health authority meetings including developing briefing documents and presentations.

Domain V: Project Management—Exam Weighting approximately 11%

Task 1: Maintain different regulatory trackers or databases.

Task 2: Ensure regulatory SOPs and work instructions are in place.

Task 3: Manage regulatory timelines.

Task 4: Manage vendors and external contracts.