

# RAC-Devices 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, and content is updated before the Summer exam cycle. Domain weighting percentages in the exam content outline are approximate and may be +/-2%. Exam content for the RAC-Devices exam is based on regulations and guidelines in:

## Domain I: Strategic Planning—Exam Weighting approximately 29%

- Task 1:** Determine the proposed product classification by using the relevant regulation to prepare for regulatory pathway and submission strategy.
- Task 2:** 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.
- Task 3:** Provide input regarding comparative effectiveness/health technology assessment associated with reimbursement.
- Task 4:** Perform risk/benefit analysis on product development concept for initial product viability.
- Task 5:** 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.
- Task 6:** Collaborate with and advise research and development programs regarding applicable regulatory compliance.
- Task 7:** Provide regulatory intelligence to develop local, regional, and global regulatory strategies.
- Task 8:** Evaluate the regulatory outcomes from the initial product concepts and make recommendations for future actions.
- Task 9:** Research and interpret regulatory decisions in a similar product category to assess regulatory approval implications.
- Task 10:** Identify appropriate regulatory authorities for submission of data for product being developed.
- Task 11:** Assess impact of local, regional, and global requirements and considerations on the content of regulatory submission/dossiers.
- Task 12:** Evaluate global filing strategy (e.g., simultaneous filings, joint reviews, mutual recognition agreements, assessment of similarity or dissimilarity of requirements) to define market feasibility.

**Task 13:** Anticipate regulatory concerns arising from trade issues (e.g., applicable treaty law, international conventions, "for export only" status).

**Task 14:** Provide alternative strategies for product development and submission to ensure timely approval and advise internal stakeholders on the requirements.

**Task 15:** Develop and review regulatory department standard operating procedures to achieve regulatory compliance.

**Task 16:** Participate in internal training programs for company personnel to achieve regulatory and quality compliance.

**Task 17:** Assist other departments to develop standard operating procedures to achieve regulatory compliance.

## Domain II: Pre-marketing—Exam Weighting approximately 25%

- Task 1:** 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).
- Task 2:** Advise stakeholders of regulatory requirements for quality, bench, preclinical, and clinical data.
- Task 3:** Assess the acceptability of quality, bench, preclinical, and clinical documentation for submission filing to meet regulatory requirements.
- Task 4:** 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.
- Task 5:** Determine acceptability of submission package through the preparation and review of relevant sections to comply with applicable requirements.
- Task 6:** Compile and prepare regulatory submissions according to relevant guidelines and submit to the appropriate regulatory authorities.
- Task 7:** Monitor the progress of the regulatory authority review process through appropriate communication with the agency.
- Task 8:** Evaluate the impact on the regulatory submission strategies of proposed manufacturing changes during the preclinical development and clinical studies.

# Raps Exam Preparation Guide

**Jin-Ying Zhang**



## **Raps Exam Preparation Guide:**

This book delves into Raps Exam Preparation Guide. Raps Exam Preparation Guide is a crucial topic that needs to be grasped by everyone, ranging from students and scholars to the general public. This book will furnish comprehensive and in-depth insights into Raps Exam Preparation Guide, encompassing both the fundamentals and more intricate discussions.

1. This book is structured into several chapters, namely:

- Chapter 1: Introduction to Raps Exam Preparation Guide
- Chapter 2: Essential Elements of Raps Exam Preparation Guide
- Chapter 3: Raps Exam Preparation Guide in Everyday Life
- Chapter 4: Raps Exam Preparation Guide in Specific Contexts
- Chapter 5: Conclusion

2. In chapter 1, this book will provide an overview of Raps Exam Preparation Guide. The first chapter will explore what Raps Exam Preparation Guide is, why Raps Exam Preparation Guide is vital, and how to effectively learn about Raps Exam Preparation Guide.
3. In chapter 2, the author will delve into the foundational concepts of Raps Exam Preparation Guide. The second chapter will elucidate the essential principles that must be understood to grasp Raps Exam Preparation Guide in its entirety.
4. In chapter 3, the author will examine the practical applications of Raps Exam Preparation Guide in daily life. The third chapter will showcase real-world examples of how Raps Exam Preparation Guide can be effectively utilized in everyday scenarios.
5. In chapter 4, the author will scrutinize the relevance of Raps Exam Preparation Guide in specific contexts. This chapter will explore how Raps Exam Preparation Guide is applied in specialized fields, such as education, business, and technology.
6. In chapter 5, the author will draw a conclusion about Raps Exam Preparation Guide. This chapter will summarize the key points that have been discussed throughout the book.

The book is crafted in an easy-to-understand language and is complemented by engaging illustrations. It is highly recommended for anyone seeking to gain a comprehensive understanding of Raps Exam Preparation Guide.

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