

RAC GLOBAL SCOPE (RAC-GS) PRACTICE TEST (SAMPLE)

STUDY GUIDE



SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

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Table of Contents

Copyright	1
Table of Contents	2
Introduction	3
How to Use This Guide	4
Questions	5
Answers	8
Explanations	10
Next Steps	16

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Introduction

Preparing for a certification exam can feel overwhelming, but with the right tools, it becomes an opportunity to build confidence, sharpen your skills, and move one step closer to your goals. At Examzify, we believe that effective exam preparation isn't just about memorization, it's about understanding the material, identifying knowledge gaps, and building the test-taking strategies that lead to success.

This guide was designed to help you do exactly that.

Whether you're preparing for a licensing exam, professional certification, or entry-level qualification, this book offers structured practice to reinforce key concepts. You'll find a wide range of multiple-choice questions, each followed by clear explanations to help you understand not just the right answer, but why it's correct.

The content in this guide is based on real-world exam objectives and aligned with the types of questions and topics commonly found on official tests. It's ideal for learners who want to:

- Practice answering questions under realistic conditions,
- Improve accuracy and speed,
- Review explanations to strengthen weak areas, and
- Approach the exam with greater confidence.

We recommend using this book not as a stand-alone study tool, but alongside other resources like flashcards, textbooks, or hands-on training. For best results, we recommend working through each question, reflecting on the explanation provided, and revisiting the topics that challenge you most.

Remember: successful test preparation isn't about getting every question right the first time, it's about learning from your mistakes and improving over time. Stay focused, trust the process, and know that every page you turn brings you closer to success.

Let's begin.

How to Use This Guide

This guide is designed to help you study more effectively and approach your exam with confidence. Whether you're reviewing for the first time or doing a final refresh, here's how to get the most out of your Examzify study guide:

1. Start with a Diagnostic Review

Skim through the questions to get a sense of what you know and what you need to focus on. Your goal is to identify knowledge gaps early.

2. Study in Short, Focused Sessions

Break your study time into manageable blocks (e.g. 30 – 45 minutes). Review a handful of questions, reflect on the explanations.

3. Learn from the Explanations

After answering a question, always read the explanation, even if you got it right. It reinforces key points, corrects misunderstandings, and teaches subtle distinctions between similar answers.

4. Track Your Progress

Use bookmarks or notes (if reading digitally) to mark difficult questions. Revisit these regularly and track improvements over time.

5. Simulate the Real Exam

Once you're comfortable, try taking a full set of questions without pausing. Set a timer and simulate test-day conditions to build confidence and time management skills.

6. Repeat and Review

Don't just study once, repetition builds retention. Re-attempt questions after a few days and revisit explanations to reinforce learning. Pair this guide with other Examzify tools like flashcards, and digital practice tests to strengthen your preparation across formats.

There's no single right way to study, but consistent, thoughtful effort always wins. Use this guide flexibly, adapt the tips above to fit your pace and learning style. You've got this!

Questions

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- 1. When a device has serious complaints, what is the regulatory professional's first contact?**
 - A. Manufacturing department
 - B. Sales team
 - C. Quality assurance
 - D. Legal department

- 2. What key competency areas are emphasized in the RAC-GS exam?**
 - A. Technical writing, public speaking, research
 - B. Regulatory knowledge, global regulations, ethics, and compliance
 - C. Data analysis, project management, sales
 - D. Marketing strategies and health economics

- 3. What is a major area covered under global regulatory practices in the exam?**
 - A. Understanding of local government regulations
 - B. International Council for Harmonisation (ICH) guidelines
 - C. Consumer safety laws
 - D. Clinical trial management

- 4. How do you define "pharmaceutical equivalence"?**
 - A. When two products have different active ingredients
 - B. When two products contain the same active ingredient in the same dosage form and strength
 - C. When two products are marketed by different companies
 - D. When products are similar in price

- 5. A clinical trial of a medical device can begin how many days after notification is sent to the Competent Authority?**
 - A. 30 days
 - B. 45 days
 - C. 60 days
 - D. As soon as Ethical Committee approval is received

- 6. What is a pre-market approval (PMA) application?**
- A. A submission for new drug approval
 - B. A submission for the approval of high-risk medical devices
 - C. A report on post-market surveillance
 - D. A documentation of clinical trial results
- 7. What is an essential strategy for effective risk mitigation in regulatory practices?**
- A. Outsourcing product development
 - B. Regular monitoring and review of regulatory changes
 - C. Minimizing production costs
 - D. Focusing solely on customer feedback
- 8. What type of document serves as a framework for managing compliance in the regulatory environment?**
- A. Product Labeling Guidelines
 - B. Quality Management System Document
 - C. Market Analysis Report
 - D. Research and Development Protocol
- 9. What is the passing score range for the RAC-GS exam?**
- A. 50-60%
 - B. 65-75%
 - C. 75-85%
 - D. 80-90%
- 10. At the last internal audit, a regulatory affairs professional identified a need for a corrective action for the manufacturing process. Which of the following stakeholders should be notified FIRST?**
- A. Quality improvement
 - B. Quality assurance
 - C. Clinical affairs
 - D. Regulatory agency

Answers

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1. C
2. B
3. B
4. B
5. C
6. B
7. B
8. B
9. B
10. B

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Explanations

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1. When a device has serious complaints, what is the regulatory professional's first contact?

- A. Manufacturing department
- B. Sales team
- C. Quality assurance**
- D. Legal department

When a device has serious complaints, the regulatory professional's first contact is typically with the quality assurance department. This is because quality assurance is responsible for monitoring the compliance and performance of the device. They play a critical role in assessing any potential risks associated with the complaints, as well as investigating the root cause of the issues reported. Quality assurance teams are well-equipped to handle product complaints since they oversee the quality systems that ensure compliance with regulatory standards. They can quickly analyze the situation, initiate investigations, and determine whether corrective actions are necessary. Engaging with quality assurance allows for an informed and standardized approach to dealing with serious complaints, ensuring that all regulatory requirements are being met and that patient safety is prioritized. On the other hand, while the manufacturing department, sales team, and legal department are also important in their respective roles, they do not typically provide the immediate oversight needed for assessing the quality and safety of a device in response to complaints. The manufacturing department may eventually need to be informed if the issue relates to the production process, the sales team may need to communicate with customers, and the legal department may become involved if there are potential liabilities. However, the initial and most relevant contact for serious complaints lies with quality assurance.

2. What key competency areas are emphasized in the RAC-GS exam?

- A. Technical writing, public speaking, research
- B. Regulatory knowledge, global regulations, ethics, and compliance**
- C. Data analysis, project management, sales
- D. Marketing strategies and health economics

The key competency areas emphasized in the RAC-GS exam focus on regulatory knowledge, global regulations, ethics, and compliance. This reflects the exam's intention to assess a candidate's understanding of complex regulatory environments and the ability to navigate the numerous regulations that can differ by region, thus ensuring compliance in the global context. The emphasis on ethics is crucial as it underpins regulatory practices, fostering integrity and accountability in the field. Candidates are expected to demonstrate a strong grasp of these areas, as they are fundamental to the role of regulatory affairs professionals working on a global scale and are essential for maintaining compliance with diverse regulations impacting healthcare and related industries. The other options do not align with the primary focus of the RAC-GS exam, which is centered around regulatory affairs rather than technical writing, project management, marketing strategies, or sales.

3. What is a major area covered under global regulatory practices in the exam?

- A. Understanding of local government regulations
- B. International Council for Harmonisation (ICH) guidelines**
- C. Consumer safety laws
- D. Clinical trial management

The identification of the International Council for Harmonisation (ICH) guidelines as a major area covered under global regulatory practices is significant for several reasons. The ICH guidelines play a crucial role in harmonizing the regulatory requirements across different regions, facilitating a more unified approach to pharmaceuticals and biotechnology. They provide a framework that helps ensure that the safety, efficacy, and quality of medicines are consistently upheld, regardless of where they are developed or marketed. By understanding the ICH guidelines, professionals engaged in global regulatory practices are better equipped to navigate the complexities of various regulatory environments. This understanding is essential for ensuring compliance and improving the efficiency of the drug development process across multiple countries. The guidelines encompass important aspects such as preclinical and clinical study requirements, risk management, and product quality standards. In contrast, while local government regulations, consumer safety laws, and clinical trial management are all important areas in their own right, they do not have the same international impact and harmonization aspect associated with the ICH guidelines. Local regulations may vary significantly and do not provide the same unified framework that the ICH aims to achieve globally.

4. How do you define "pharmaceutical equivalence"?

- A. When two products have different active ingredients
- B. When two products contain the same active ingredient in the same dosage form and strength**
- C. When two products are marketed by different companies
- D. When products are similar in price

Pharmaceutical equivalence is defined as the condition in which two products contain the same active ingredient, are provided in the same dosage form, and have the same strength. This definition highlights the importance of the active ingredient's identity and the consistency in form and potency, ensuring that the products can be expected to have the same therapeutic effect in patients. When evaluating the other options, having different active ingredients would not satisfy the criteria for being considered equivalent, as the therapeutic effects and safety profiles could differ significantly. Products marketed by different companies or those that are similar in price do not necessarily pertain to their pharmaceutical equivalence, as these factors do not address the essential criteria of containing the same active ingredient and dosage specifications. Thus, the definitive understanding of pharmaceutical equivalence centers around the sameness in active ingredients and dosage, which is aptly captured in the correct response.

5. A clinical trial of a medical device can begin how many days after notification is sent to the Competent Authority?

- A. 30 days
- B. 45 days
- C. 60 days**
- D. As soon as Ethical Committee approval is received

The correct answer is based on the regulatory framework governing clinical trials for medical devices. In this context, a clinical trial can begin 60 days after the notification is sent to the Competent Authority if no objections are raised during that time period. The 60-day timeframe is essential for ensuring that the Competent Authority has adequate time to review the trial protocol and assess any potential risks associated with the medical device being tested. If the Competent Authority does not respond within these 60 days, the trial can proceed as planned. In contrast, starting the trial as soon as Ethical Committee approval is received does not take into account the requirement for notifying the Competent Authority, which is a crucial step in the regulatory process. Choosing a shorter timeframe like 30 or 45 days would not align with the established regulatory guidelines and would not provide a sufficient window for the authority to conduct a thorough review.

6. What is a pre-market approval (PMA) application?

- A. A submission for new drug approval
- B. A submission for the approval of high-risk medical devices**
- C. A report on post-market surveillance
- D. A documentation of clinical trial results

A pre-market approval (PMA) application is specifically designed for high-risk medical devices, which require a rigorous review process by the FDA before they can enter the market. This process ensures that the device is safe and effective for its intended use. The PMA process is more stringent than that of regular device approvals because it applies to products that are deemed to pose a significant risk to patients if they fail. Given the nature of these devices, the FDA necessitates comprehensive clinical evidence, which proving its safety and efficacy, to support the application. This includes data from clinical trials, manufacturing processes, and labeling information. Other options relate to different aspects of pharmaceutical and medical product regulation, but they do not accurately represent the specific purpose and focus of a PMA application. For instance, while a submission for new drug approval pertains to pharmaceuticals, this is not what a PMA involves. Reports on post-market surveillance are relevant after a product has been approved and is on the market, while documentation of clinical trial results is more aligned with initial study findings rather than the regulatory process for device approval itself. Thus, the emphasis on high-risk medical devices is what solidifies 'B' as the correct choice.

7. What is an essential strategy for effective risk mitigation in regulatory practices?

- A. Outsourcing product development
- B. Regular monitoring and review of regulatory changes**
- C. Minimizing production costs
- D. Focusing solely on customer feedback

Regular monitoring and review of regulatory changes is crucial for effective risk mitigation in regulatory practices because regulations are dynamic and can frequently change due to new policies, legal requirements, or industry standards. Staying informed about these changes allows organizations to promptly adjust their compliance strategies, practices, and procedures, thereby reducing the risk of non-compliance, penalties, and disruptions in operations. By actively tracking regulatory developments, a business can anticipate challenges, prepare for new requirements, and make informed decisions that align with legal expectations. This proactive approach helps maintain the integrity of products or services, ensures ongoing compliance, and fosters accountability and trust with regulatory bodies and stakeholders. In contrast, the other options do not directly address the need for continuous adaptation and responsiveness to the evolving regulatory landscape, making them less effective strategies for risk mitigation in this context.

8. What type of document serves as a framework for managing compliance in the regulatory environment?

- A. Product Labeling Guidelines
- B. Quality Management System Document**
- C. Market Analysis Report
- D. Research and Development Protocol

The Quality Management System Document serves as a framework for managing compliance in the regulatory environment because it outlines the policies, procedures, and responsibilities necessary to ensure that an organization meets regulatory standards and achieves its quality objectives. This document is integral to maintaining consistency and compliance across various functions within the organization, as it addresses both regulatory requirements and internal quality standards. Having a robust management system enables an organization to systematically identify, manage, and mitigate risks associated with regulatory compliance. It defines how compliance will be achieved, monitored, and improved over time, making it essential for organizations that operate in highly regulated sectors. In contrast, the other options, although important in their own contexts, do not serve the same comprehensive purpose related to compliance management. Product Labeling Guidelines focus specifically on the requirements for labeling products, which is a narrower aspect of compliance. A Market Analysis Report assesses the competitive landscape and market trends but does not address the internal compliance processes needed. Research and Development Protocols detail specific methodologies for conducting research but do not encompass the broader compliance framework across the organization.

9. What is the passing score range for the RAC-GS exam?

- A. 50-60%
- B. 65-75%**
- C. 75-85%
- D. 80-90%

The passing score range for the RAC-GS exam is indeed set between 65-75%. This range reflects the level of knowledge and understanding required for certification, ensuring that candidates possess a competent grasp of global regulatory requirements, quality systems, and post-market activities among other key topics relevant to regulatory affairs. Establishing the passing score at this level also aims to ensure that certified individuals can effectively manage the complexities of regulatory challenges in various global markets, as proficiency in these areas directly impacts compliance and the overall success of medical products. A score below this range may indicate that a candidate has not demonstrated sufficient knowledge to meet the expectations of the certification.

10. At the last internal audit, a regulatory affairs professional identified a need for a corrective action for the manufacturing process. Which of the following stakeholders should be notified FIRST?

- A. Quality improvement
- B. Quality assurance**
- C. Clinical affairs
- D. Regulatory agency

Notifying quality assurance first is essential because this team is primarily responsible for ensuring that all processes adhere to the regulatory requirements and internal standards. Quality assurance personnel are directly involved in overseeing the manufacturing process and can take immediate actions to evaluate and rectify any issues identified during the internal audit. When a corrective action is needed, quality assurance can assess the situation, investigate the root cause of the issue, and implement measures to mitigate any risks associated with the manufacturing process. They play a vital role in maintaining compliance and ensuring that product quality is not compromised throughout the manufacturing cycle. In contrast, while the other stakeholders have important roles, they are typically not the first to be notified in matters concerning immediate corrective actions related to the manufacturing process. For example, the quality improvement team may focus more on long-term process enhancements rather than immediate corrective measures. Clinical affairs may not be involved until the product is ready for use or requires clinical evaluation, and a regulatory agency would generally be notified later, particularly when reporting is necessary following internal compliance investigations or when regulatory actions are required.

Next Steps

Congratulations on reaching the final section of this guide. You've taken a meaningful step toward passing your certification exam and advancing your career.

As you continue preparing, remember that consistent practice, review, and self-reflection are key to success. Make time to revisit difficult topics, simulate exam conditions, and track your progress along the way.

If you need help, have suggestions, or want to share feedback, we'd love to hear from you. Reach out to our team at hello@examzify.com.

Or visit your dedicated course page for more study tools and resources:

<https://racglobalscope.examzify.com>

We wish you the very best on your exam journey. You've got this!

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