

REGULATORY AFFAIRS CERTIFICATION (RAC) – DEVICES PRACTICE EXAM (SAMPLE)

STUDY GUIDE



SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

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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. How is a "clinical trial" defined concerning medical devices?**
 - A. A carefully controlled study to assess the safety and effectiveness of a medical device on subjects.
 - B. A market study focusing on the pricing strategy of the device.
 - C. An analysis of competitor devices in the market.
 - D. A survey on the design preferences of users.
- 2. What are the three classes of medical devices as categorized by the FDA?**
 - A. Class I, Class II, and Class III
 - B. Class A, Class B, and Class C
 - C. Class Low, Class Moderate, and Class High
 - D. Class I, Class II, and Class IV
- 3. If a patient was hospitalized with acute sepsis after treatment with a device, how soon must the manufacturer report the event to the FDA?**
 - A. 5 calendar days
 - B. 15 calendar days
 - C. 30 calendar days
 - D. The next quarterly or annual report
- 4. In a Non-Significant Risk device clinical trial, which of the following is NOT required before starting the trial?**
 - A. Informed consent of trial participants
 - B. IRB approval of the trial
 - C. Financial disclosure by investigators
 - D. Submission of the trial protocol to FDA for approval
- 5. What is a major difference between an HDE and a PMA application?**
 - A. Application form and content
 - B. Labeling requirements
 - C. Supplemental applications
 - D. Effectiveness requirements

- 6. What is the role of the European Medicines Agency (EMA) with respect to medical devices?**
- A. To oversee the regulation of medicines and medical devices within the EU
 - B. To provide marketing authorization for all medical devices
 - C. To conduct clinical trials for medical devices
 - D. To set pricing standards for medical devices in the EU
- 7. What are the essential components of a Regulatory Strategy?**
- A. Understanding regulations
 - B. Defining marketing strategies
 - C. Identifying competition
 - D. Conducting customer surveys
- 8. What is the primary purpose of a traditional 510(k) submission?**
- A. To prove that a new device is safe and effective
 - B. To seek marketing clearance for a device similar to one already on the market
 - C. To report adverse events associated with a device
 - D. To apply for a premarket approval
- 9. Which regulation is NOT part of the establishment, performance and auditing of a human-use clinical device trial?**
- A. 21 CFR 50 Protection of Human Subjects
 - B. 21 CFR 56 IRB
 - C. 21 CFR 807 Establishment Registration
 - D. 21 CFR 812 IDE Exemptions
- 10. How often must a Quality Management System (QMS) be audited for compliance with ISO 13485?**
- A. Every six months
 - B. Annually
 - C. Every two years
 - D. Every three years

Answers

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

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Explanations

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1. How is a "clinical trial" defined concerning medical devices?

- A. A carefully controlled study to assess the safety and effectiveness of a medical device on subjects.**
- B. A market study focusing on the pricing strategy of the device.
- C. An analysis of competitor devices in the market.
- D. A survey on the design preferences of users.

A clinical trial is defined as a carefully controlled study aimed at evaluating the safety and effectiveness of a medical device on human subjects. This process is crucial in the regulatory landscape, particularly for device approval, as it provides empirical evidence regarding how the device performs in real-world scenarios. Clinical trials are typically structured to gather data on various endpoints, such as patient outcomes, adverse effects, and comparison with existing standards of care. The results from these trials are essential for regulatory authorities, like the FDA, as they determine whether a medical device can be deemed safe for public use and whether it works as intended. The other options do not align with the definition of a clinical trial. A market study focusing on pricing strategies, for instance, does not involve the assessment of safety or effectiveness and instead analyzes market dynamics. An analysis of competitor devices in the market is more about understanding the competitive landscape rather than assessing a device's performance. Similarly, surveys about design preferences focus on user experience and feedback and do not involve safety or effectiveness assessments.

2. What are the three classes of medical devices as categorized by the FDA?

- A. Class I, Class II, and Class III**
- B. Class A, Class B, and Class C
- C. Class Low, Class Moderate, and Class High
- D. Class I, Class II, and Class IV

The classification of medical devices by the FDA into Class I, Class II, and Class III is based on the level of control necessary to assure the safety and effectiveness of the device. Class I devices are those that pose the lowest risk and are subjected to the least regulatory control. They generally require simple controls to ensure their safety, such as good manufacturing practices. Examples include tongue depressors and band-aids. Class II devices have a moderate risk, and they require more regulatory controls than Class I devices to provide reasonable assurance of their safety and effectiveness. This often includes special labeling requirements, mandatory performance standards, and post-market surveillance. Examples include electric wheelchairs and infusion pumps. Class III devices are the most complex and pose the highest risk. They usually require premarket approval, which involves demonstrating the safety and effectiveness of the device through clinical trials. This category is for devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or that present a potential unreasonable risk of illness or injury. An example of a Class III device is a pacemaker. The identification of the three classes is crucial for regulatory compliance and guides manufacturers on the necessary steps to take in order to bring a device to market.

3. If a patient was hospitalized with acute sepsis after treatment with a device, how soon must the manufacturer report the event to the FDA?

- A. 5 calendar days
- B. 15 calendar days
- C. 30 calendar days**
- D. The next quarterly or annual report

The requirement for manufacturers to report adverse events related to medical devices is dictated by FDA regulations. In the case of a serious adverse event, such as a patient being hospitalized with acute sepsis after treatment with a device, the manufacturer is obligated to report the event within a specific timeframe. The correct answer highlights that the manufacturer must submit a report within 30 calendar days of becoming aware of the adverse event. This aligns with the FDA's guidelines for the reporting of serious adverse events, ensuring that potential risks associated with medical devices are communicated promptly to the regulatory body. This timeframe allows the FDA to monitor the safety of devices, investigate potential links between devices and adverse events, and take necessary actions to protect public health. In contrast, the other options suggest shorter or longer reporting periods that do not meet the FDA's requirements for serious adverse events. For instance, the 5-day reporting timeframe is applicable to events that are deemed "immediate," but not to cases like acute sepsis that require a 30-day report. The quarterly or annual report options are also incorrect, as they do not specify the urgency of reporting immediate safety concerns regarding serious adverse events following device use. Thus, the 30-day guideline is essential for maintaining timely oversight of device safety.

4. In a Non-Significant Risk device clinical trial, which of the following is NOT required before starting the trial?

- A. Informed consent of trial participants
- B. IRB approval of the trial
- C. Financial disclosure by investigators
- D. Submission of the trial protocol to FDA for approval**

In a Non-Significant Risk (NSR) device clinical trial, the submission of the trial protocol to the FDA for approval is not a requirement before starting the trial. This is due to the nature of NSR studies, which are considered to pose a lesser risk to participants compared to Significant Risk studies. Informed consent from trial participants is essential in all clinical trials to ensure participants are fully aware of the risks and benefits associated with their participation. Additionally, approval from an Institutional Review Board (IRB) is required to ensure that the study meets ethical standards and that participants are adequately protected. Financial disclosure by investigators is also mandatory to promote transparency and mitigate conflicts of interest, ensuring the integrity of the study. Since NSR trials do not necessitate prior FDA approval of the protocol, this step can be omitted for such studies, leading to the conclusion that it is the only option not required before initiating the trial.

5. What is a major difference between an HDE and a PMA application?

- A. Application form and content
- B. Labeling requirements
- C. Supplemental applications
- D. Effectiveness requirements**

The correct choice highlights a key distinction between Humanitarian Device Exemptions (HDE) and Premarket Approval (PMA) applications in terms of effectiveness requirements. HDEs are designed for devices intended to treat or diagnose conditions affecting fewer than 8,000 individuals per year in the United States. Because these devices are aimed at rare conditions or diseases, the FDA allows for a different approach regarding efficacy. Specifically, HDE does not require the applicant to demonstrate the same level of effectiveness that a PMA would necessitate. For PMA applications, the manufacturer must provide substantial evidence of safety and effectiveness for the device to receive FDA approval, which involves rigorous preclinical and clinical testing. In contrast, an HDE application only needs to demonstrate that the device is safe and that there is a reasonable assurance of its safety, along with showing that it provides a significant benefit, implying that it could help treat a condition that otherwise might not have sufficient treatment options. This relaxed standard reflects the unique nature of devices intended for rare diseases and supports innovation in areas where conventional approval trials might not be feasible. The other choices focus on technical aspects of the applications, such as content, labeling requirements, and supplemental applications, but the notable difference lies in how

6. What is the role of the European Medicines Agency (EMA) with respect to medical devices?

- A. To oversee the regulation of medicines and medical devices within the EU**
- B. To provide marketing authorization for all medical devices
- C. To conduct clinical trials for medical devices
- D. To set pricing standards for medical devices in the EU

The European Medicines Agency (EMA) plays a pivotal role in the regulation of medicinal products within the EU, which includes overseeing the regulatory processes for both medicines and certain medical devices, particularly those that deliver medicinal products or have a medicinal purpose. While the EMA does not provide marketing authorization for all types of medical devices—this responsibility largely falls under the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR), which are overseen by notified bodies—it does have a significant role in the regulatory landscape pertaining to medical devices, especially for combination products. The EMA also engages in scientific evaluation and guidance regarding these products, ensuring that they meet the established safety and efficacy standards. This involvement is critical for maintaining the quality and safety of healthcare products available in the EU market. The other options do not accurately characterize the EMA's responsibilities. For instance, while the EMA may be involved in clinical trials related to medicinal products, it does not conduct clinical trials for medical devices itself, nor does it set pricing standards for medical devices in the EU, as pricing is typically managed by national authorities or other entities. Thus, the choice that best aligns with the EMA's role is its oversight in the regulation of medicines and certain medical devices within the European Union.

7. What are the essential components of a Regulatory Strategy?

- A. Understanding regulations**
- B. Defining marketing strategies
- C. Identifying competition
- D. Conducting customer surveys

The essential components of a Regulatory Strategy start with understanding regulations, making it the most crucial element. A comprehensive grasp of the relevant laws, guidelines, and standards that govern medical devices is foundational for any regulatory strategy. This understanding ensures that companies can navigate the complex landscape of regulatory requirements, which varies by country and type of device. Compliance with these regulations is critical for obtaining approvals and bringing products to market successfully. A thorough understanding of regulations helps organizations anticipate potential challenges during the submission process, align their product development with regulatory expectations, and employ best practices in quality management. This foundational knowledge also allows teams to effectively communicate with regulatory agencies, improving the chances of successful outcomes when seeking device approvals or clearances. Other components, such as defining marketing strategies, identifying competition, and conducting customer surveys, may play important roles in the overall business strategy but are secondary to the core aspect of regulatory compliance. These factors do not directly influence the regulatory process itself, whereas a solid understanding of regulations is essential for ensuring that a company's products meet the necessary safety and efficacy standards set forth by regulatory bodies.

8. What is the primary purpose of a traditional 510(k) submission?

- A. To prove that a new device is safe and effective
- B. To seek marketing clearance for a device similar to one already on the market**
- C. To report adverse events associated with a device
- D. To apply for a premarket approval

The primary purpose of a traditional 510(k) submission is to seek marketing clearance for a device that is substantially equivalent to a device that is already legally marketed in the United States. By demonstrating substantial equivalence, the manufacturer is asserting that their new device is similar in intended use and technology to a predicate device. This process allows for a faster pathway to market compared to other regulatory pathways, like premarket approval, which requires more extensive evidence of safety and efficacy. The focus of the 510(k) process is to ensure that the new device does not pose any additional risks compared to the predicate device, thereby streamlining the approval process while maintaining patient safety. This is a critical mechanism that supports innovation while ensuring that new medical devices can enter the market efficiently.

9. Which regulation is NOT part of the establishment, performance and auditing of a human-use clinical device trial?

- A. 21 CFR 50 Protection of Human Subjects
- B. 21 CFR 56 IRB
- C. 21 CFR 807 Establishment Registration**
- D. 21 CFR 812 IDE Exemptions

The regulation pertaining to the establishment, performance, and auditing of a human-use clinical device trial primarily focuses on protecting human subjects, overseeing Institutional Review Boards (IRBs), and the investigational device exemption processes. The regulation concerning establishment registration, which is referenced as 21 CFR 807, deals with the requirements for manufacturers and importers to register their establishment with the FDA and list their devices. While this regulation is critical for regulatory compliance, it pertains more to the manufacturing and marketing of devices rather than the specific procedures and ethical considerations of conducting clinical trials involving human subjects. On the other hand, regulations like 21 CFR 50 focus on the protection of human subjects, ensuring their safety and rights during clinical research. 21 CFR 56 outlines the requirements for IRBs, which play a fundamental role in reviewing and approving clinical trial protocols to safeguard participant welfare. 21 CFR 812 addresses the IDE (Investigational Device Exemption) regulations that govern the use of devices in clinical trials. Therefore, the focus of the question is on regulations that ensure the ethical and operational aspects of clinical trials, making establishment registration, as detailed in 21 CFR 807, the regulation that does not directly fit within that scope.

10. How often must a Quality Management System (QMS) be audited for compliance with ISO 13485?

- A. Every six months
- B. Annually**
- C. Every two years
- D. Every three years

A Quality Management System (QMS) must be audited annually for compliance with ISO 13485. This standard outlines the requirements for a QMS where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and regulatory requirements. Annual audits are critical in ensuring that the QMS remains effective and continues to meet the necessary standards and regulatory requirements. These audits help in identifying areas for improvement and ensuring that processes are followed correctly. Regular audits foster an environment of continuous improvement, which is essential in the highly regulated medical device industry. Moreover, annual audits align with the principles of quality management embodied in ISO 13485, emphasizing the importance of maintaining compliance and handling any non-conformities promptly. This frequency also allows organizations to be proactive in addressing any potential issues that could lead to violations or product failures, thereby protecting both consumer safety and the manufacturer's integrity.

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://racdevices.examzify.com>

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

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