

# US Regulatory Affairs Certification (RAC) Practice Exam (Sample)

## Study Guide



**Everything you need from our exam experts!**

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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. What governs ethical principles in medical research involving human subjects?**
  - A. Declaration of the Rights of Man**
  - B. Declaration of Helsinki**
  - C. Good Clinical Practice Guidelines**
  - D. International Conference on Harmonisation**
  
- 2. What type of market exclusivity does the Orphan Drug Act offer after FDA approval?**
  - A. Three years**
  - B. Five years**
  - C. Seven years**
  - D. Ten years**
  
- 3. What is a key principle of Good Laboratory Practice (GLP)?**
  - A. Conducting studies in a commercial lab**
  - B. Ensuring compliance with clinical trial standards**
  - C. Regulations governing nonclinical laboratory studies**
  - D. Improving data management practices**
  
- 4. What does "grandfathered" refer to in regulatory terms?**
  - A. Approval for drugs and devices marketed before specific regulatory dates**
  - B. Drugs that require no further testing**
  - C. Drugs that are exempt from clinical trials**
  - D. Devices that do not require approval due to prior market presence**
  
- 5. Which part of the regulations is focused on medical devices?**
  - A. 21 CFR parts 200s**
  - B. 21 CFR parts 700s**
  - C. 21 CFR parts 800s**
  - D. 21 CFR 807**

- 6. What does a Pre-Sub Meeting provide to applicants?**
- A. An opportunity to discuss manufacturing practices**
  - B. Feedback on intended submission from the FDA**
  - C. A chance to guarantee approval**
  - D. Consultation on pricing strategies**
- 7. A patient registry may be considered a part of which controls for certain devices?**
- A. General controls**
  - B. Special controls**
  - C. Premarket approvals**
  - D. Clinical trials**
- 8. Which act provided FDA authority to require pediatric studies of drugs?**
- A. Pediatric Research Equity Act (PREA)**
  - B. Hatch-Waxman Act**
  - C. Orphan Drug Act**
  - D. FDA Amendments Act**
- 9. What is the main focus of Phase I clinical trials?**
- A. Effectiveness of a drug in a large population**
  - B. Long-term safety monitoring**
  - C. Initial safety studies in healthy volunteers**
  - D. Evaluation of drug interactions**
- 10. What is the purpose of guidance documents published by the FDA?**
- A. To recruit new manufacturers**
  - B. To provide definitive regulations**
  - C. To offer current interpretations of regulations**
  - D. To approve new drugs**

## Answers

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

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## **Explanations**

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## 1. What governs ethical principles in medical research involving human subjects?

- A. Declaration of the Rights of Man
- B. Declaration of Helsinki**
- C. Good Clinical Practice Guidelines
- D. International Conference on Harmonisation

The Declaration of Helsinki is a set of ethical principles specifically designed to guide medical research involving human subjects. Established by the World Medical Association, it emphasizes the importance of prioritizing the welfare and rights of participants in clinical trials. This document outlines essential aspects such as informed consent, the necessity for scientific soundness, and the requirement for risk assessment versus potential benefits to participants. In contrast, other options, while significant in their own rights, do not primarily govern ethical principles in medical research. The Declaration of the Rights of Man pertains to broader human rights and is not specific to medical research ethics. Good Clinical Practice Guidelines establish standards for conducting clinical trials, but they focus more on regulatory and procedural aspects rather than ethical considerations. The International Conference on Harmonisation provides guidelines related to the registration of pharmaceuticals but is not solely concerned with ethical issues in human research. Thus, the Declaration of Helsinki stands out as the primary document addressing ethical concerns directly related to human subjects in medical research.

## 2. What type of market exclusivity does the Orphan Drug Act offer after FDA approval?

- A. Three years
- B. Five years
- C. Seven years**
- D. Ten years

The Orphan Drug Act provides a market exclusivity period of seven years for drugs that are designated as orphan drugs. This exclusivity applies once the drug receives FDA approval, meaning that for this seven-year period, no other manufacturer can market the same drug for the same indication. This legislation was enacted to encourage the development of treatments for rare diseases, which may not be economically viable for pharmaceutical companies to pursue without the promise of exclusivity. By ensuring a seven-year period without competition, the Orphan Drug Act incentivizes developers to invest in research and development for these lesser-known conditions, ultimately leading to improved access to treatment for patients with rare diseases. While the other options refer to different potential exclusivity periods, they do not align with the framework established by the Orphan Drug Act. For instance, three-year exclusivity might pertain to other circumstances, but it is not representative of orphan drugs. Thus, the seven-year exclusivity tied to orphan drug status is a critical point for understanding the regulatory landscape of rare disease treatments.

### 3. What is a key principle of Good Laboratory Practice (GLP)?

- A. Conducting studies in a commercial lab
- B. Ensuring compliance with clinical trial standards
- C. Regulations governing nonclinical laboratory studies**
- D. Improving data management practices

A key principle of Good Laboratory Practice (GLP) is the establishment of regulations governing nonclinical laboratory studies. GLP ensures that laboratory studies are carried out consistently, reliably, and ethically, particularly in the context of safety assessments for pharmaceuticals, chemicals, and other products. This framework is essential for ensuring that data generated from nonclinical studies can be trusted, which in turn supports regulatory submissions and decisions about the safety of products. The application of GLP involves detailed guidelines that laboratories must follow regarding study protocols, quality control, data collection, and record-keeping. By promoting standardization across nonclinical laboratories, GLP helps assure regulatory bodies, researchers, and the public about the integrity and reproducibility of the studies conducted. This is crucial for public health and safety, particularly when products are intended for human consumption or exposure. Other choices are not aligned with the primary focus of GLP. Conducting studies in a commercial lab may be a setting for GLP but does not define its principles. Ensuring compliance with clinical trial standards pertains more to Good Clinical Practice (GCP), which focuses specifically on research involving human subjects. Improving data management practices, while important for effective laboratory work, is more of a tactic to enhance research quality rather than a defining principle.

### 4. What does "grandfathered" refer to in regulatory terms?

- A. Approval for drugs and devices marketed before specific regulatory dates**
- B. Drugs that require no further testing
- C. Drugs that are exempt from clinical trials
- D. Devices that do not require approval due to prior market presence

The term "grandfathered" in regulatory terms refers specifically to the concept that certain drugs and devices that were already on the market prior to the implementation of new regulatory standards or changes to the law do not need to meet the new requirements to remain available for sale. When drugs or devices are "grandfathered," it means they can continue to be marketed without having to undergo the latest approval processes that apply to new products entered after those regulatory changes. This recognition allows for continuity of access to products that have been deemed safe and effective based on their existing market history. In the context of this question, the first choice accurately encapsulates the definition of "grandfathered" by stating it relates to the approval of drugs and devices marketed before specific regulatory dates. The other options, while they touch on related concepts, do not align perfectly with the widely accepted regulatory understanding of "grandfathering" in the industry. For instance, options regarding exempting drugs from clinical trials or requiring no further testing would not necessarily be true of all grandfathered products, as they may still be subject to certain oversight depending on their classification and risk category.

**5. Which part of the regulations is focused on medical devices?**

- A. 21 CFR parts 200s
- B. 21 CFR parts 700s
- C. 21 CFR parts 800s**
- D. 21 CFR 807

The focus of the correct choice is on 21 CFR parts 800s, which specifically pertain to medical devices. This segment of the Code of Federal Regulations outlines the framework for the regulation of various medical devices, including specifications for their marketing, labeling, and manufacturing standards. It is an essential part of the regulations that ensures medical devices are safe and effective for public use before they can enter the market. In contrast, 21 CFR parts 200s generally deal with drug regulations, including standards for pharmaceuticals and the approval process for new drugs. Meanwhile, 21 CFR parts 700s focus on cosmetics, outlining regulations that ensure consumer safety regarding cosmetic products. Finally, 21 CFR 807 specifically addresses the premarket notification (often referred to as 510(k)) process for certain categories of medical devices to demonstrate that they are substantially equivalent to devices already on the market. While 21 CFR 807 is relevant to medical devices, it is more specific in its application and not as broad as the regulations under 21 CFR parts 800s, which cover a wider range of device-related regulations.

**6. What does a Pre-Sub Meeting provide to applicants?**

- A. An opportunity to discuss manufacturing practices
- B. Feedback on intended submission from the FDA**
- C. A chance to guarantee approval
- D. Consultation on pricing strategies

A Pre-Submission (Pre-Sub) Meeting offers applicants a valuable opportunity to receive feedback directly from the FDA regarding their intended submission. This meeting occurs before the formal submission of a device or product and is particularly beneficial for applicants who want to clarify the agency's expectations and ensure that they are on the right track. During this meeting, applicants can discuss their proposed studies, address any specific questions they might have, and seek guidance about the appropriate regulatory pathway for their device. This interaction can help to identify potential issues early in the process and ultimately enhance the quality and success of the submission. While discussions about manufacturing practices and consultation on pricing strategies may be relevant to the overall product development process, they are not the primary focus of a Pre-Sub Meeting. Furthermore, it is essential to understand that a Pre-Sub Meeting does not guarantee approval; it only provides guidance and feedback, which may aid applicants in preparing their submissions more effectively.

**7. A patient registry may be considered a part of which controls for certain devices?**

- A. General controls**
- B. Special controls**
- C. Premarket approvals**
- D. Clinical trials**

A patient registry is considered a part of special controls for certain devices because it plays a crucial role in monitoring the long-term safety and effectiveness of medical devices that are already on the market. Special controls are meant to provide additional safeguards for devices that may not fit the criteria for general controls but still require further oversight. These may include performance standards, postmarket surveillance, patient registries, or compliance with specific guidelines. Patient registries help to gather data on device performance in real-world settings, allowing for ongoing safety assessments and the ability to track complications or adverse events over time. This information can be vital for manufacturers and regulators alike to ensure that devices continue to meet safety and effectiveness standards after they have been approved and marketed. In contrast, general controls apply to all medical devices and provide a broad level of assurance regarding their safety but may not account for more specific postmarket concerns that a patient registry addresses. Premarket approvals are focused solely on the evaluation of a device before it enters the market, and clinical trials are part of the premarket process used for regulatory submissions, not ongoing surveillance.

**8. Which act provided FDA authority to require pediatric studies of drugs?**

- A. Pediatric Research Equity Act (PREA)**
- B. Hatch-Waxman Act**
- C. Orphan Drug Act**
- D. FDA Amendments Act**

The Pediatric Research Equity Act (PREA) is the act that specifically granted the FDA the authority to require drug manufacturers to conduct pediatric studies for new drug applications and specific supplemental applications. This legislation aims to ensure that drugs are properly tested for safety and efficacy in children, addressing the historical lack of pediatric data for many medications. PREA was enacted in response to concerns that medications often used in children were not adequately evaluated for this population, leading to potential safety risks and ineffectiveness. By empowering the FDA to request studies, PREA plays a crucial role in ensuring that pharmaceutical products are appropriately labeled for pediatric use and that the unique physiological differences in children are taken into consideration during drug development. The other acts listed do not specifically focus on pediatric studies. The Hatch-Waxman Act primarily deals with drug patenting and market exclusivity. The Orphan Drug Act encourages the development of treatments for rare diseases without a direct emphasis on pediatrics. The FDA Amendments Act reinforces the FDA's authority to regulate drug safety but does not specifically mention pediatric studies as a requirement.

## 9. What is the main focus of Phase I clinical trials?

- A. Effectiveness of a drug in a large population
- B. Long-term safety monitoring
- C. Initial safety studies in healthy volunteers**
- D. Evaluation of drug interactions

The main focus of Phase I clinical trials is to conduct initial safety studies in healthy volunteers. This phase is crucial as it aims to evaluate the safety profile, determine a safe dosage range, and identify side effects associated with the drug, primarily focusing on how the drug is metabolized and eliminated from the body. During this stage, researchers observe how the drug interacts biologically within a controlled group of participants, which is typically comprised of healthy individuals, to minimize the variability seen in patients with underlying health conditions. Phase I trials are foundational in the drug development process, providing essential data that informs later phases, where the drug's efficacy and interactions in broader and patient populations are assessed. In subsequent phases, the focus will distinctly shift towards evaluating effectiveness and long-term safety in more diverse populations.

## 10. What is the purpose of guidance documents published by the FDA?

- A. To recruit new manufacturers
- B. To provide definitive regulations
- C. To offer current interpretations of regulations**
- D. To approve new drugs

The purpose of guidance documents published by the FDA primarily revolves around providing current interpretations of regulations. These documents serve as a means for the FDA to communicate its recommendations, approaches, and expectations regarding compliance with regulatory requirements. They address specific aspects of regulatory processes, assisting stakeholders such as manufacturers, researchers, and healthcare providers in understanding how to comply with the laws and regulations governing their activities. Guidance documents are not legally binding but represent the FDA's current thinking on a particular topic, making them valuable resources for those in the industry seeking to ensure they are meeting regulatory expectations. By clarifying the agency's stance on various issues, these documents help reduce uncertainty and risks associated with regulatory submissions and product development. While options like recruiting manufacturers, providing definitive regulations, or approving new drugs are important aspects of the FDA's broader mission, they do not accurately reflect the specific intent and function of guidance documents. Instead, the focus of these documents is to interpret existing regulations and provide clarity, ensuring stakeholders can navigate the regulatory landscape effectively.

## 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](mailto:hello@examzify.com).**

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

**<https://usrac.examzify.com>**

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

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