

RAPS Regulatory Affairs Certification - Drugs (RAC-Drugs) Practice Test (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 does the term "pharmaceutical equivalence" mean?**
 - A. Two drug products contain different active ingredients**
 - B. Two products with the same active ingredient in the same dosage form**
 - C. Two drugs with identical branding and packaging**
 - D. Two formulations that work similarly in the body**
- 2. In which scenario would the FDA likely require a human factors validation study?**
 - A. When a drug is completely novel and untested.**
 - B. Only when the marketed product fails.**
 - C. To support marketing authorization of combination products.**
 - D. When modifications are made to manufacturing processes.**
- 3. Investigational combination products that include a device constituent part are subject to which provision of 21 CFR part 820?**
 - A. Quality System Regulations**
 - B. Design Controls (21 CFR 820.30)**
 - C. Product Quality Assurance**
 - D. Labeling Requirements**
- 4. What should a biotechnology company submit with the Marketing Authorisation Application dossier for a follow-on biologic?**
 - A. Only a summary of the clinical trials**
 - B. Full quality dossier supplemented by the demonstration of comparability**
 - C. Financial documents regarding the product launch**
 - D. A marketing plan for the biologic**
- 5. What document is essential when submitting a variation for a change in manufacturing process?**
 - A. A detailed clinical study report.**
 - B. A justification letter for the change.**
 - C. An expert statement and CV from a quality expert.**
 - D. A market analysis report.**

6. FDA CDER encourages submission of a human factors validation protocol for review. What is the most appropriate mechanism for the feedback?

- A. Submit the protocol to the IND.**
- B. Contact the FDA directly over the phone.**
- C. Include it with a New Drug Application submission.**
- D. Post it to the FDA website for public comment.**

7. What is the threshold for a life-threatening condition to be considered rare in the European Union?

- A. Affecting not more than five in 5,000 people**
- B. Affecting not more than five in 10,000 people**
- C. Affecting not more than five in 15,000 people**
- D. Affecting not more than five in 20,000 people**

8. Which statement is TRUE regarding expedited programs for regenerative medicine therapy products?

- A. They provide immediate approval for all types of therapies**
- B. They reduce the length of clinical trials**
- C. Advantages of the RMAT Designation include all benefits of Fast Track and Breakthrough Therapy Designations**
- D. They ensure market exclusivity for regenerative medicine products**

9. What is the purpose of a "preclinical study"?

- A. To test a drug's marketability**
- B. To assess safety and efficacy before testing in humans**
- C. To finalize packaging and branding**
- D. To conduct surveys on drug effectiveness**

10. What process should a sponsor use to gain permission from FDA for an ANDA that differs from the RLD?

- A. New Drug Application**
- B. Suitability Petition**
- C. Investigation Request**
- D. Compliance Notification**

Answers

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

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Explanations

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1. What does the term "pharmaceutical equivalence" mean?

- A. Two drug products contain different active ingredients
- B. Two products with the same active ingredient in the same dosage form**
- C. Two drugs with identical branding and packaging
- D. Two formulations that work similarly in the body

Pharmaceutical equivalence refers to the relationship between drug products that contain the same active ingredient(s) in the same dosage form and strength. This is crucial in the context of regulatory affairs because it ensures that the pharmacological effects and safety profiles of the products are likely to be similar, provided they are used appropriately. When two products are considered pharmaceutical equivalents, they are manufactured under similar conditions, thereby supporting consistent therapeutic outcomes. This aspect is significant for establishing generic drugs, as it allows for the substitution of brand-name medications with generics, assuming they are manufactured to requisite quality standards and undergo the necessary bioequivalence testing. In this context, the other options do not accurately capture the essence of pharmaceutical equivalence. Products containing different active ingredients would obviously not be considered equivalent, identical branding and packaging do not ensure the same pharmacological effect, and formulations that work similarly do not necessarily indicate they contain the same active ingredient in the same dosage form. Thus, the definition encapsulated in the correct choice aligns closely with regulatory standards and the fundamental principles of drug equivalence.

2. In which scenario would the FDA likely require a human factors validation study?

- A. When a drug is completely novel and untested.
- B. Only when the marketed product fails.
- C. To support marketing authorization of combination products.**
- D. When modifications are made to manufacturing processes.

The FDA would likely require a human factors validation study primarily to support the marketing authorization of combination products. Combination products, which integrate drug, device, and/or biological components, must demonstrate that users can safely and effectively operate them. Human factors validation studies assess how real users interact with these products to identify any potential use-related risks that could compromise safety or efficacy. In this context, the study evaluates user interface design, instructions, and the overall user experience, ensuring that the intended users can utilize the device and medication as intended without confusion or error. Adequate validation is especially important in combination products due to the complexity of interactions between different components. As such, the requirement for these studies helps ensure patient safety and product effectiveness in real-world usage. The other scenarios either do not specifically necessitate a human factors study or are not directly related to the safety and efficacy of user interactions with the product.

3. Investigational combination products that include a device constituent part are subject to which provision of 21 CFR part 820?

- A. Quality System Regulations**
- B. Design Controls (21 CFR 820.30)**
- C. Product Quality Assurance**
- D. Labeling Requirements**

Investigational combination products that include a device constituent part must adhere to the Design Controls specified in 21 CFR 820.30. This section is critical because it requires manufacturers to establish and maintain a design control process that ensures the safety and effectiveness of the device component being developed. It encompasses various stages of product development, including design planning, input, reviews, verification, validation, and design transfer, all of which are essential for regulatory compliance when assessing the combination product. Adopting these design controls helps to ensure that both the drug and device components of the investigational combination product meet the intended specifications and regulatory requirements. By following these regulations, the developers can mitigate risks associated with the technical and regulatory challenges present in combination products. This adherence is fundamental in the clinical development phase to ensure that the combination product is both safe for human use and functionally viable as intended. Other provisions such as quality system regulations, product quality assurance, and labeling requirements apply in broader contexts, but specific compliance with design controls is essential for successfully navigating the complexities of combination products that contain a device component.

4. What should a biotechnology company submit with the Marketing Authorisation Application dossier for a follow-on biologic?

- A. Only a summary of the clinical trials**
- B. Full quality dossier supplemented by the demonstration of comparability**
- C. Financial documents regarding the product launch**
- D. A marketing plan for the biologic**

A biotechnology company is required to submit a full quality dossier along with a demonstration of comparability for a follow-on biologic in the Marketing Authorisation Application (MAA) dossier. This is crucial because follow-on biologics, also known as biosimilars, must demonstrate that they are highly similar to the reference product in terms of quality, safety, and efficacy. The full quality dossier contains detailed information about the manufacturing process, controls, and characterizations of the biological product. This is essential for regulatory authorities to assess the consistency and reliability of the product. The demonstration of comparability, which includes analytical studies, non-clinical studies, and sometimes clinical trials, is needed to establish that any differences between the follow-on biologic and the reference product do not impact the safety or efficacy. This comprehensive approach helps ensure that the follow-on biologic can be considered therapeutically equivalent to the reference biologic, providing assurance to prescribers and patients regarding its use. Thus, the requirements emphasize the importance of extensive data on quality and the demonstration of similarity to the reference product.

5. What document is essential when submitting a variation for a change in manufacturing process?

- A. A detailed clinical study report.
- B. A justification letter for the change.
- C. An expert statement and CV from a quality expert.**
- D. A market analysis report.

When submitting a variation for a change in the manufacturing process, an expert statement and CV from a quality expert is essential. This document provides regulatory authorities with assurance that the proposed changes will not compromise the quality, safety, or efficacy of the drug product. The quality expert's assessment can help demonstrate that the new manufacturing process meets all regulatory requirements and guidelines. In regulatory practices, changes to manufacturing processes are scrutinized to ensure that such modifications do not adversely affect the product or its production method. Thus, having an expert statement that details the implications of the change from a quality perspective can be pivotal in satisfying regulatory concerns. While the other choices might have their own relevance in different contexts or submissions, they do not specifically address the requirement for evaluating a change in manufacturing. For instance, a detailed clinical study report is more pertinent for clinical changes rather than manufacturing, a justification letter is helpful but may not carry the weight of expert validation, and a market analysis report doesn't pertain directly to manufacturing process changes. The presence of a quality expert's statement and CV ensures that the decision-making process aligns with the industry standards for compliance and quality assurance.

6. FDA CDER encourages submission of a human factors validation protocol for review. What is the most appropriate mechanism for the feedback?

- A. Submit the protocol to the IND.**
- B. Contact the FDA directly over the phone.
- C. Include it with a New Drug Application submission.
- D. Post it to the FDA website for public comment.

Submitting a human factors validation protocol to the Investigational New Drug (IND) application is indeed the most appropriate mechanism for obtaining FDA feedback. This approach allows the FDA to review the protocol in the context of the specific clinical development plan and ensure that the proposed human factors studies are aligned with regulatory expectations. The IND process is designed to facilitate communication and collaboration between the sponsor and the FDA, enabling the agency to provide guidance on aspects critical to the safety and efficacy of the drug under investigation. This submission also allows the sponsor to incorporate any feedback early in the development process, which can help streamline the eventual New Drug Application (NDA) submission. The feedback received can provide valuable insights into how well the protocol meets regulatory requirements for usability, which is essential in ensuring that the drug's labeling and use instructions are clear and effective for the intended user population. Other methods, such as contacting the FDA directly over the phone or posting the protocol for public comment, do not offer the structured and formal opportunity for feedback as submitting through the IND does. Phone conversations may provide quick replies but lack the formal documentation that is crucial for regulatory affairs. Similarly, public comment mechanisms do not focus on the specific developmental context of a single drug and are not tailored to assist individual sponsors directly.

7. What is the threshold for a life-threatening condition to be considered rare in the European Union?

- A. Affecting not more than five in 5,000 people**
- B. Affecting not more than five in 10,000 people**
- C. Affecting not more than five in 15,000 people**
- D. Affecting not more than five in 20,000 people**

The threshold for a life-threatening condition to be considered rare in the European Union is defined as affecting not more than five in 10,000 people. This classification is crucial for regulatory purposes, particularly in the context of orphan drug designation and incentives for the development of treatments for rare diseases. In the EU's regulatory framework, rare diseases are those that affect a small percentage of the population, and establishing a clear threshold helps in identifying which conditions might qualify for special attention and research funding. This definition supports the development of targeted therapies, ensuring that patients with such conditions have access to necessary medications. Choosing the correct numerical threshold is essential, as it directly relates to how regulatory bodies view rare diseases and the allocation of resources towards their research and treatment. In contrast, the other options provided reflect thresholds that are not aligned with the established EU policy regarding the classification of rare diseases.

8. Which statement is TRUE regarding expedited programs for regenerative medicine therapy products?

- A. They provide immediate approval for all types of therapies**
- B. They reduce the length of clinical trials**
- C. Advantages of the RMAT Designation include all benefits of Fast Track and Breakthrough Therapy Designations**
- D. They ensure market exclusivity for regenerative medicine products**

The statement that advantages of the Regenerative Medicine Advanced Therapy (RMAT) Designation include all benefits of Fast Track and Breakthrough Therapy Designations is true. The RMAT designation is aimed at regenerative medicine products that show the potential to address unmet medical needs. This designation not only expedites the development and review process, but it also provides various benefits that enhance the likelihood of clinical and regulatory success. By incorporating advantages from both the Fast Track and Breakthrough Therapy Designations, RMAT allows for more frequent interactions with the FDA, a rolling submission of the biologics license application, and potential eligibility for accelerated approval. This synergy of benefits underlines the supportive framework designed specifically to facilitate the development of regenerative therapies, which can often be complex and technologically advanced. It's important to note that the other statements do not accurately reflect the specifics of expedited programs for regenerative medicine products. For example, immediate approval does not occur across all therapy types, as safety and efficacy must still be demonstrated, and expedited programs work to streamline, not eliminate, regulatory processes. Similarly, while expedited programs may help reduce the length of clinical trials, they do not guarantee a reduction in duration. Lastly, while RMAT designation does confer some degree of market exclusivity, it is not

9. What is the purpose of a "preclinical study"?

- A. To test a drug's marketability
- B. To assess safety and efficacy before testing in humans**
- C. To finalize packaging and branding
- D. To conduct surveys on drug effectiveness

A preclinical study serves a critical role in the drug development process, as it is designed to evaluate the safety and efficacy of a drug candidate before it enters clinical trials involving human participants. This phase typically involves laboratory research and animal testing to gather essential data about the pharmacological properties of the drug, dosages, toxicity levels, and potential side effects. By gathering this information, researchers can identify the appropriate dose range and assess whether the drug has enough therapeutic effect to justify moving forward into clinical studies. The results from preclinical studies are vital as they help regulatory authorities, such as the FDA, to determine if the drug is safe enough to transition to human trials, ultimately ensuring participant safety and promoting effective treatments. Therefore, assessing safety and efficacy prior to human trials is a fundamental goal of preclinical research, thus making the identification of this process a crucial foundation in drug development.

10. What process should a sponsor use to gain permission from FDA for an ANDA that differs from the RLD?

- A. New Drug Application
- B. Suitability Petition**
- C. Investigation Request
- D. Compliance Notification

To gain permission from the FDA for an Abbreviated New Drug Application (ANDA) that differs from the Reference Listed Drug (RLD), the appropriate process is through a suitability petition. A suitability petition is required when the proposed generic formulation includes controlled substances, consists of a different strength or dosage form, or utilizes a different route of administration compared to the RLD. This allows the sponsor to justify the differences and request permission to pursue an ANDA based on the unique characteristics of their product. The suitability petition mechanism helps ensure that the FDA thoroughly evaluates the differing aspects of the new formulation and assesses its safety and efficacy in comparison to the RLD. It streamlines the path for generics while maintaining a focus on public health and safety, as the differences may impact therapeutic equivalence. In contrast, a New Drug Application involves submitting comprehensive data to support a new drug that does not have an existing marketing application, while an Investigation Request generally pertains to inquiries for clinical trials. Compliance Notifications are mechanisms for informing the FDA about certain compliance matters, but they are not applicable for seeking approval for an ANDA that deviates from the RLD's specifications.

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://rapsracdrugs.examzify.com>

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

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