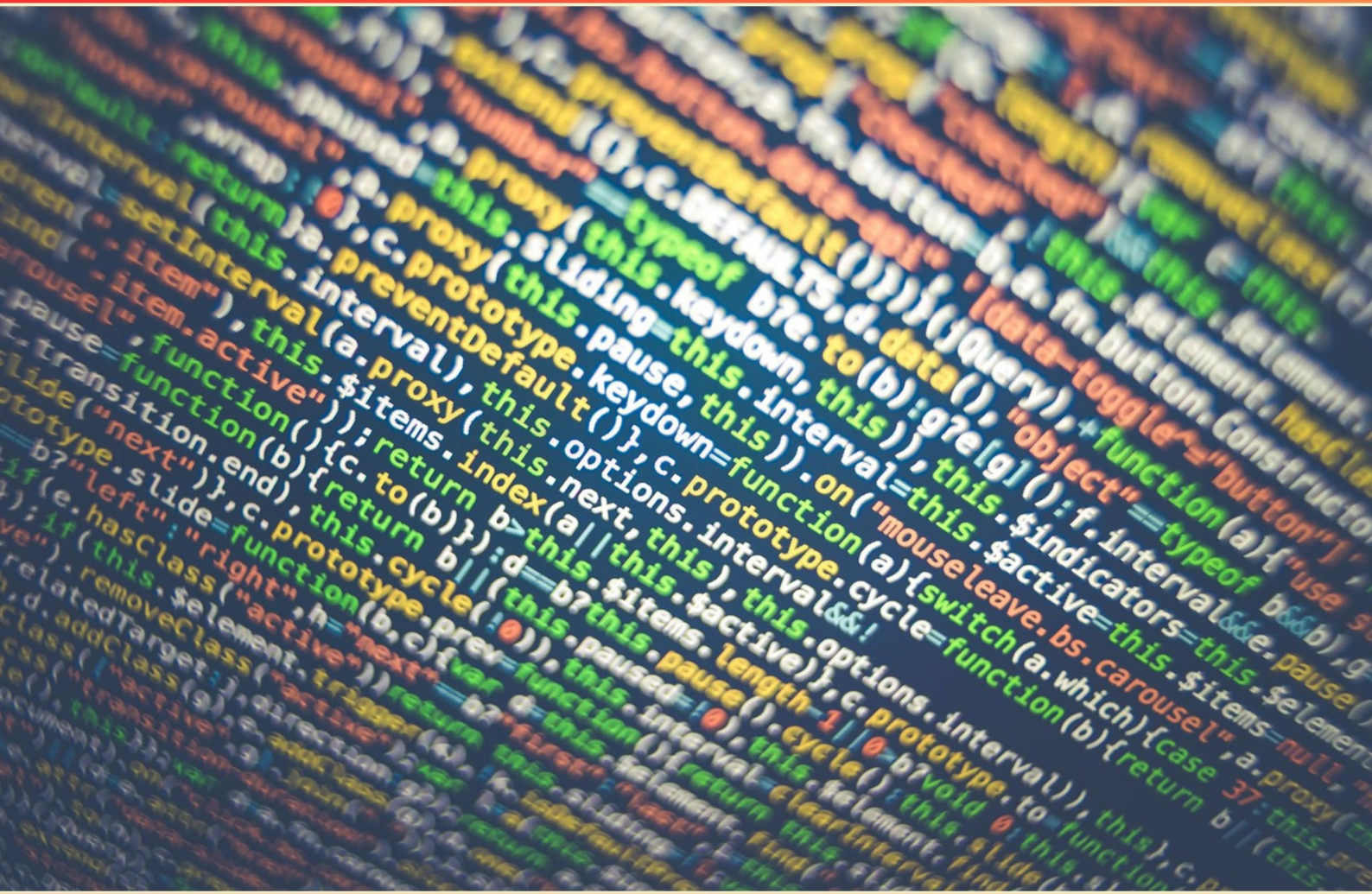


GCP OF DEVICES PRACTICE TEST (SAMPLE)

STUDY GUIDE



SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

VISIT US ONLINE FOR
THE FULL VERSION STUDY GUIDE

<https://gcpofdevices.examzify.com>



Copyright © 2026 by Examzify - A Kaluba Technologies Inc. product.

ALL RIGHTS RESERVED.

No part of this book may be reproduced or transferred in any form or by any means, graphic, electronic, or mechanical, including photocopying, recording, web distribution, taping, or by any information storage retrieval system, without the written permission of the author.

Notice: Examzify makes every reasonable effort to obtain accurate, complete, and timely information about this product from reliable sources.

SAMPLE

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

SAMPLE

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

SAMPLE

- 1. Which CFR part covers the disclosure of possible financial conflicts of interest by clinical investigators?**
 - A. 21 CFR 50
 - B. 21 CFR 54
 - C. 21 CFR 56
 - D. 21 CFR 803
- 2. Which storage option is best for cheap, long-term archival of telemetry data?**
 - A. BigQuery
 - B. Spanner
 - C. Cloud Storage
 - D. Datastore
- 3. How should you handle offline devices and intermittent connectivity?**
 - A. Store device state locally, queue telemetry until reconnected, and design idempotent cloud processing to cope with duplicates on reconnect.
 - B. Always send data when possible; no local storage.
 - C. Ignore duplicates.
 - D. Require manual re-sync.
- 4. Which protocols are commonly used for device-to-cloud telemetry in IoT?**
 - A. DNS and ICMP
 - B. MQTT and HTTP
 - C. FTP and FTPS
 - D. SMTP and POP3
- 5. What devices are considered Significant Risk in device studies?**
 - A. Studies involving non-significant risk devices.
 - B. Device studies that involve a significant risk device.
 - C. Postmarket surveillance studies.
 - D. In vitro studies only.

6. Manufacturers can show that a device to be marketed is substantially equivalent to a marketed product that was on the market prior to 28 May 1976, by submitting which of the following?

- A. Premarket Notification
- B. Investigational Device Exemption
- C. Premarket Approval
- D. Clinical Trial Authorization

7. Study-oriented Inspections

- A. Study-oriented inspections are directed toward review of study data for a pending marketing application, and audit other study-related practices including protection of human research subjects and compliance with regulations. The FDA typically inspects the top enrolling sites and randomly picks ten percent of the remaining sites for inspection.
- B. Focused on the specific clinical investigator conducting the trial
- C. Focused on institutional review board compliance only
- D. An inspection of facility equipment and safety procedures

8. Which task is a clinician using a HUD to treat or diagnose patients responsible for?

- A. Submitting medical device reports to the HDE holder
- B. Obtaining IRB approval for routine care
- C. Designing HUD product labels
- D. Conducting pre-market trials

9. How is Institutional Review Board (IRB) defined by FDA?

- A. A committee that audits research budgets
- B. Any board designated to review, approve initiation, and conduct ongoing review of biomedical research involving human subjects
- C. A regulatory agency
- D. A patient advocacy group

10. Medical Device Reporting is governed by which CFR part?

- A. 21 CFR 807
- B. 21 CFR 814
- C. 21 CFR 803
- D. 21 CFR 820

Answers

SAMPLE

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

SAMPLE

Explanations

SAMPLE

1. Which CFR part covers the disclosure of possible financial conflicts of interest by clinical investigators?

- A. 21 CFR 50
- B. 21 CFR 54**
- C. 21 CFR 56
- D. 21 CFR 803

Disclosing potential financial conflicts of interest in clinical research is governed by 21 CFR 54. This regulation requires investigators to reveal significant financial interests related to the study to the sponsor and to the FDA, so that any possible bias can be identified and managed. The purpose is to promote transparency and protect the integrity of the research and the welfare of subjects. It outlines what counts as a significant financial interest and how these disclosures should be reported and reviewed, often triggering sponsor COI policies and IRB oversight. The other regulations cover different aspects of clinical research oversight: informed consent from participants is governed by 21 CFR 50, institutional review boards are governed by 21 CFR 56, and 21 CFR 803 deals with medical device reporting of adverse events.

2. Which storage option is best for cheap, long-term archival of telemetry data?

- A. BigQuery
- B. Spanner
- C. Cloud Storage**
- D. Datastore

When you need inexpensive, long-term storage for telemetry data that you'll rarely access, pick Cloud Storage using the Archive storage class. This tier is built for data that's retained for extended periods and accessed infrequently, offering the lowest cost per gigabyte among Cloud Storage options. Telemetry streams are typically stored for compliance or later analysis and may not require quick retrieval, so the Archive tier minimizes ongoing costs. You can even automate data lifecycle rules to move older telemetry files into Archive as they age, further optimizing spend. Retrieval during rare access will take longer and incur retrieval costs, which is acceptable for archival but not ideal for routine analytics. Other services like BigQuery, Spanner, or Datastore are designed for active analytics or transactional workloads and storage in those systems tends to be more expensive and less suited for vast, long-term archiving compared with a cost-optimized object store. Cloud Storage thus provides the best balance of low cost and long-term durability for this use case.

3. How should you handle offline devices and intermittent connectivity?

- A. Store device state locally, queue telemetry until reconnected, and design idempotent cloud processing to cope with duplicates on reconnect.**
- B. Always send data when possible; no local storage.
- C. Ignore duplicates.
- D. Require manual re-sync.

When devices can go offline or have intermittent connectivity, build resilience by buffering data locally, queuing telemetry until a connection is available, and making cloud processing idempotent so re-delivered data doesn't cause duplicates. Storing device state and a local queue ensures no data is lost during offline periods and allows efficient bursts of uploads when connectivity returns. On the cloud side, idempotent processing means the same event won't corrupt state if it's delivered more than once due to reconnects or retries; this is typically achieved with unique event IDs, sequence numbers, and operations that are safe to repeat, such as upserts. This approach is superior because it handles variability in network access without requiring human intervention, provides reliable data delivery, and keeps the system robust against duplicate arrivals. In contrast, always sending data only when the connection is present ignores offline periods and risks data loss; ignoring duplicates can corrupt state, and requiring manual re-sync is impractical for scalable devices.

4. Which protocols are commonly used for device-to-cloud telemetry in IoT?

- A. DNS and ICMP
- B. MQTT and HTTP**
- C. FTP and FTPS
- D. SMTP and POP3

In IoT, devices send small, frequent updates to the cloud, so the protocols used for this telemetry need to be lightweight, efficient, and reliable over sometimes lossy networks. MQTT fits perfectly because it's a lightweight publish/subscribe protocol that minimizes overhead and supports QoS levels, which makes streaming telemetry from many devices to a cloud broker practical and scalable. HTTP (typically over HTTPS) is also widely used for telemetry since it's universal, firewall-friendly, and easy to integrate with cloud services through RESTful endpoints; it's especially common when devices push data directly to an ingestion service or when working with APIs and webhooks. The other options aren't suited for device-to-cloud telemetry. DNS and ICMP are network-layer tools used for name resolution and network diagnostics, not for transferring telemetry data. FTP and FTPS are designed for file transfers and involve heavier connections and state, which isn't ideal for continuous, real-time telemetry streams. SMTP and POP3 are email protocols and aren't intended for real-time data ingestion from devices; they're not designed for streaming telemetry to a cloud platform.

5. What devices are considered Significant Risk in device studies?

- A. Studies involving non-significant risk devices.
- B. Device studies that involve a significant risk device.**
- C. Postmarket surveillance studies.
- D. In vitro studies only.

Significant Risk refers to devices whose use in a study could pose a serious risk to a participant's health or safety. This typically includes devices that are implanted, life-sustaining, life-supporting, or involve substantial potential for harm due to the device's novelty or complexity. When a study involves such a device, it's classified as a Significant Risk device study, which triggers stricter regulatory requirements (like FDA's Investigational Device Exemption and IRB oversight) to protect participants. In this question, the statement that aligns with that concept is the one describing a study that involves a device deemed to carry significant risk. That directly identifies the SR scenario. The other options don't fit because non-significant risk devices are not considered SR, postmarket surveillance is a study type and not a definition of the device's risk, and in vitro studies don't involve human subjects or device use in people and thus aren't assessed as SR device investigations.

6. Manufacturers can show that a device to be marketed is substantially equivalent to a marketed product that was on the market prior to 28 May 1976, by submitting which of the following?

- A. Premarket Notification**
- B. Investigational Device Exemption
- C. Premarket Approval
- D. Clinical Trial Authorization

The key idea is that you demonstrate substantial equivalence to a device that was legally marketed before May 28, 1976 by filing a Premarket Notification, commonly known as a 510(k). This pathway is used when the new device has the same intended use and similar technological characteristics as a predicate device that was already on the market, or is otherwise found to be substantially equivalent to such a device. The date matters because pre-1976 devices formed the basis for these predicate comparisons under the 510(k) process. Other routes serve different purposes—for example, Investigational Device Exemption covers clinical studies of a device not yet marketed; Premarket Approval is for new, higher-risk devices requiring more comprehensive evidence; and there isn't a standard FDA pathway called Clinical Trial Authorization for devices in this context.

7. Study-oriented Inspections

- A. Study-oriented inspections are directed toward review of study data for a pending marketing application, and audit other study-related practices including protection of human research subjects and compliance with regulations. The FDA typically inspects the top enrolling sites and randomly picks ten percent of the remaining sites for inspection.
- B. Focused on the specific clinical investigator conducting the trial
- C. Focused on institutional review board compliance only
- D. An inspection of facility equipment and safety procedures

Study-oriented inspections examine the data and practices that support a pending marketing submission, not just who conducted the trial at a single site. The inspector reviews the study data itself, source documents, and how the trial was conducted across multiple sites to ensure data integrity and compliance with regulations, as well as proper protection of human subjects. Because the marketing package hinges on the overall trial results, focus is placed on the data and study-wide processes rather than on a single investigator or a single regulatory body like an IRB, or on equipment alone. In practice, the FDA prioritizes the sites with the most enrollees and then randomly selects a subset of the remaining sites for inspection, ensuring representative validation of the study's conduct and results. This broader, data-centric approach is what distinguishes study-oriented inspections from other types of inspections that target specific investigators, IRB activities, or facility equipment.

8. Which task is a clinician using a HUD to treat or diagnose patients responsible for?

- A. Submitting medical device reports to the HDE holder
- B. Obtaining IRB approval for routine care
- C. Designing HUD product labels
- D. Conducting pre-market trials

When a clinician uses a HUD device under a humanitarian device exemption, there is a regulatory expectation that safety and performance issues observed in patient care be fed back to the device sponsor. Submitting medical device reports to the HDE holder fits this flow: the clinician collects adverse events or device-related problems during routine treatment, and the HDE holder—the sponsor—reviews these reports and coordinates any required regulatory reporting to authorities. This ties directly to the ongoing post-market surveillance that follows the adoption of HUD devices in clinical practice. The other options aren't about daily patient care responsibilities for a clinician using HUD. IRB approval is for research ethics oversight and applies to studies, not standard care. Designing HUD product labels is a manufacturing and regulatory task handled by the sponsor or manufacturer, not by a clinician. Conducting pre-market trials occurs before a device is approved and is conducted by the sponsor, not by clinicians after approval.

9. How is Institutional Review Board (IRB) defined by FDA?

- A. A committee that audits research budgets
- B. Any board designated to review, approve initiation, and conduct ongoing review of biomedical research involving human subjects**
- C. A regulatory agency
- D. A patient advocacy group

The main idea being tested is the formal FDA definition of an Institutional Review Board. An IRB is a committee designated to review, approve initiation, and conduct ongoing review of biomedical research involving human subjects. This captures the core function: safeguarding the rights and welfare of participants through initial ethical review and continuous oversight of the study as it progresses, including monitoring for risks, informed consent, and any changes to the protocol. This is the best answer because it accurately reflects that an IRB is a designated committee with oversight responsibilities for human-subject research. It's not about auditing research budgets, not a regulatory agency itself, and not a patient advocacy group, all of which describe different roles unrelated to the formal review and oversight function that defines an IRB.

10. Medical Device Reporting is governed by which CFR part?

- A. 21 CFR 807
- B. 21 CFR 814
- C. 21 CFR 803**
- D. 21 CFR 820

Medical Device Reporting is the regulation that sets how device-related problems are reported to the FDA after a device is on the market. It specifies who must report (manufacturers, importers, and user facilities), what kinds of events must be reported (deaths, serious injuries, and certain malfunctions that could cause serious harm), and the procedures for filing those reports. The goal is to enable timely post-market surveillance and safety signals so the agency can take action if needed. Other CFR parts cover different regulatory areas: for example, one part handles device establishment registration and listing, another governs the premarket approval process for devices, and another sets the quality system requirements for manufacturers. Those topics are distinct from the post-market reporting requirements, so the part that governs Medical Device Reporting is 21 CFR 803.

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://gcpofdevices.examzify.com>

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

SAMPLE