

Good Documentation Practice and Data Integrity



Duration:
Approx.
2 hours

This comprehensive course on Data Integrity offers an in-depth exploration of the principles, regulations, and best practices essential for ensuring the accuracy, reliability, and security of data throughout its lifecycle.

Beginning with an introduction to data integrity and its importance, the course delves into key guidance and regulations, such as MHRA principles, Good Documentation Practices (GDocP), and the new ICH GCP E6 R3 guidance. It also covers the ALCOA++ principles and their historical context, and discusses data governance, technology, and metadata in relation to maintaining data integrity. The course emphasises the critical role of quality and issue management in preserving the integrity of data, particularly in clinical and research settings.

Through practical scenarios and assessments, participants will gain the knowledge and tools to implement effective data integrity strategies, ensuring reliable study results and regulatory compliance in line with the latest ICH GCP E6 R3 standards.

This course is designed for professionals involved in clinical research, data management, regulatory compliance, and quality assurance who want to deepen their understanding of data integrity principles and their application in real-world scenarios. It is ideal for those seeking to complement their ICH GCP E6 R3 certification, providing practical insights and tools to apply the guidelines effectively in the workplace.

Whether you're a clinical research associate, data manager, or quality assurance professional, this course will help bridge the gap between theoretical knowledge and practical implementation, ensuring you can maintain data accuracy, security, and compliance in your day-to-day work.

Learning Objectives

- Understand the core principles of data integrity: Recognise the importance of maintaining data accuracy, reliability, and security throughout the data lifecycle, and how to apply these principles in clinical and research settings.
- Comprehend key regulations and guidelines: Gain a thorough understanding of relevant regulatory frameworks, including MHRA principles, Good Documentation Practices (GDocP), and the new ICH GCP E6 R3 guidance, and their impact on data integrity practices.
- Apply the ALCOA++ principles: Learn to implement the ALCOA++ principles effectively in managing data, ensuring compliance with industry standards and improving the quality of study results.
- Implement best practices in data governance and issue management: Develop the skills to establish robust data governance frameworks, manage data integrity issues, and safeguard the integrity of study results through proactive quality control and risk management.

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COURSE CONTENTS:

MODULE ONE

Chapter 1— What is Data Integrity?

- What is Data Integrity?
- The importance of maintaining data integrity

Chapter 2 - Guidance and Regulations

- Guidance and regulations
- MHRA principles of data integrity

Chapter 3 - Good documentation practice and essential records

- Good documentation practice
- Essential records

Chapter 4 –The ALCOA++ principles

- Data integrity (ALCOA++)
- The history of ALCOA principles

Chapter 5 – Data

- Data
- Data lifecycle
- Data governance

Chapter 6— Technology and Metadata

- Technology
- Metadata

Chapter 7— Quality

- Quality
- Data integrity
- Issue management
- Impact of data integrity on study results

Chapter 8— Assessment

- Data integrity in practice
- Scenarios
- Glossary

- Assessment
- Accessing your certificate

Price: £39.99