

Good Documentation Practice



Training
Online 4U



About this course:

This professionally developed Good Documentation Practice (GDocP) course explores data integrity and document requirements in detail and demonstrates how GDocP can be implemented into a number of roles. Good Documentation Practice is mandatory to ensure that documentation meets industry standards and other legal responsibilities in the pharmaceutical sector.

Learning Objectives

- To understand what GDocP is and why it is important
- To examine ICH GCP E6 R2 and its requirements in regards to documents, and how to archive documents according to ICH GCP standards
- To know about different types of documents and data
- To understand the regulations surrounding electronic signatures
- To understand the importance of data integrity and ALCOA+ and be able to implement these in your role
- To understand the role of security and data protection in GDocP

Module 1

- Introduction to GDocP
- GDocP in GMP
- Data
- Document Types
- Document Requirements

Module 2

- Data Integrity Issues and Breaches
- Data Error Prevention
- ALCOA+
- Documentation Control
- Electronic Records
- Security and Data Protection

Duration: Approx. 2 hours

As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.



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