

Pharmaceutical Data Integrity (1 day)

An intensive one day course in the requirements of data integrity in today's laboratory

Who should take this course?

This course is designed for laboratory personnel responsible for ensuring and auditing integrity of data in today's laboratory. It will also be useful for managers and other staff involved in the process. For those workers who need to be aware of this area but are not directly responsible, this class will give an insight into the requirements of data integrity. Those with some laboratory experience will benefit from this course more than those with no experience

What does it cover?

This 1 day course on data integrity auditing will provide you with everything you need to familiarise yourself with the key requirements and consequences of data integrity. Case studies and practical exercises will fully equip and prepare you for this complex but vital area of laboratory regulations and requirements. This course provides essential information on the MHRA and FDA guidance on data integrity and will help you discover what you need to do to protect both yourself and your company.

What will I get from this course?

You will learn and understand the requirements of data integrity. You will be able to make recommendations and implement suitable systems and working practices in your laboratory, in order to meet these requirements. By planning ahead, you will be able to better identify and avoid the pitfalls of this vital area.

Course Outline

Introduction and fraudulent data case studies
Extracts of FDA warning letters relevant to data integrity
The requirements of data integrity

- Sampling and traceability
- Informal testing (e.g. trial injections)
- Computerised systems –date stamps, audit trails and user accounts
- Laboratory data systems – data acquisition and processing methods
- Reporting and archiving results

Practical tips

- Auditing laboratory records
- Auditing laboratory data systems
- Auditing LIMS systems

Available as an in-house or off-site course. Contact us for details

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