IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Data Integrity and Document Management

21 June 27
+ 13 December 27

Data integrity is a critical issue in document governance and is increasingly becoming a focus for regulatory inspections globally. This course will equip you with the necessary knowledge to identify and avoid potential data integrity issues before auditors do.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Document management and data integrity are a key focus of regulatory inspections, with both EU and FDA inspectors increasingly observing violations during GxP inspections. It has become a critical issue in document governance and regulators expect staff working in GxP roles to have been trained in this important area.

Ensuring data integrity is an important component of the pharma industry's responsibility to guarantee the safety, efficacy, and quality of drugs. Violations relating to document management and data integrity have led to numerous regulatory actions, in- cluding warning letters and critical inspection findings. To address these concerns, the FDA, EMA, MHRA and the World Health Organization (WHO) have all recently published data integrity guidelines.

This concise course covers the background to data integrity, why it is important and how its requirements affect both paper-based and computer-based systems. The programme will include discussion of the latest MHRA data integrity guide and EMA TMF guideline that should be considered by organisations involved in any aspect of the GxP pharmaceutical lifecycle (GCP, GMP, GLP and GvP). You will gain an understanding of the requirements for ensuring data integrity, review data integrity inspection findings, and get practical advice on defining and implementing an appropriate data governance process for compliance with data integrity requirements.

Benefits of attending

- **Understand** the importance of data integrity and good document practice
- **Ensure** you are compliant with the new EU trial master file (TMF) guideline
- **Be aware** of key regulations and guidelines
- **Discuss** QMS considerations for data integrity and document management
- **Review** document management and data integrity inspections to facilitate regulatory compliance
- **Consider** the requirements for document management and data integrity governance to prevent data integrity breaches

Who should attend

This course is designed for managers and staff from all GxP areas in the pharmaceutical and medical device industries who are responsible for the creation, review, approval and/or reporting of data to ensure data integrity, in particular those working in:

- Clinical trials
- Manufacturing
- Quality assurance/quality control
- Compliance
- Pharmacovigilance

QA personnel from CROs/CMOs and GxP auditors responsible for carrying out audits and self-inspections or external audits will also benefit from the programme.

Programme

Principles of data integrity and good documentation practice

- What is data integrity?
- Why is data integrity important?
- ALCOA principles
- Good documentation practice including paper and electronic records

Data integrity regulations and guidelines

- MHRA/WHO/FDA/EMA/PICS/ICH GCP R2 data integrity guidelines
- Group review and discussion of some key regulated documents including the latest MHRA data integrity guide

Document management and data integrity inspection findings

- MHRA, EMA findings, EU non-compliance reports
- FDA findings
- Group discussion on inspection findings

QMS considerations for data integrity and documentation

- What are the elements of QMS for data integrity?
- Risk management considerations
- Data governance
- Discussion of participants experience and best practice for QMS and data governance

Data integrity for computer systems

- Computer system validation considerations
- What is expected for compliance for GxP systems?

Discussion of document and data integrity issues

- Data integrity and digital signatures
- Certified copies/true copies
- Managing and preventing data integrity breaches

Presenter



Laura Brown

Dr Laura Brown MBA, BSc, PhD, is a pharmaceutical QA and training consultant and Senior Lecturer for the MSc in Clinical Research at the School of Pharmacy, University of Cardiff. She has more than 20 years' experience of quality assurance in the pharmaceutical industry and has worked for several companies, including GSK, Hoechst Marion Roussel, Farmitalia and Phoenix International. Laura has a particular expertise in quality assurance including risk-based approaches to quality systems, data integrity and quality project management implementation in the pharmaceutical industry. She was Chair of the ACRPI GCP Forum for six years and regularly writes on pharmaceutical regulatory and quality issues including for the Research Quality Assurance Association's journal.

Course dates

21 June 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17252*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 26 Apr**
13 December 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 17561*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 18 Oct**

How to book

Online:
ipi.academy/2303

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Laura was very good, easy to understand and answered any questions

Derek Farrell
Quality Technician
Fire1 Foundry
Dec 18 2025

★★★★★

It was a very very informative webinar which I certainly will recommend to others

Nanna Sommer
Clinical Trial Assistant
Minervax ApS
Jul 14 2025

★★★★★

Laura Brown's webinar gave me more confident in data integrity she presented all the necessary information to gain my confident. I really appreciate it.

Kheira Heddi
Quality Assurance Officer
SGSUK
Jul 24 2023

★★★★☆

The content was very useful for my daily work. The presentation was well prepared and the speaker made it easy to listen online.

Christiane Rederath
Clinical Research Associate
MSD Animal Health Innovation GmbH
Jul 24 2023

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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