IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Essential Documentation Skills for Clinical Research Compliance

Documentation is crucial for regulatory compliance, ensuring accuracy and integrity in clinical trials and laboratory work. GDP has evolved over time, guided by ALCOA & ALCOA-plus principles.

Format:
Bespoke training

CPD:
1.5 hours for your records (depending on your requirements)

Certificate of completion

Overview

Good Documentation Practice (GDocP) is essential for regulatory compliance, ensuring accuracy and integrity in clinical trials and laboratory work. Over time, GDocP has evolved, guided by Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA and ALCOA-plus) principles. Key aspects include maintaining essential records, proper data collection, recording, and ensuring data integrity. Reviewing, reporting, and correcting errors are also crucial for compliance. Effective document control involves handling GMP documents, data backup, retention, and implementing systems to prevent errors. Additionally, auditing and monitoring play a vital role in ensuring quality, with regular monitoring visits, Corrective and Preventive Actions (CAPA), and adverse event reporting helping maintain compliance and data reliability.

Benefits of attending

- **Understand** the importance of GDocP in regulatory compliance
- **Learn** the GDocP essential principles
- **Implement** accurate, complete, and compliant records in clinical research and laboratory settings

Who should attend?

- Clinical research professionals, including clinical research associates, investigators, and study coordinators
- Medical writers, regulatory writers, and publication professionals
- Quality assurance specialists and compliance officers in pharmaceutical and clinical research organisations
- Anyone involved in clinical trial documentation, regulatory submissions, or scientific publications seeking to improve their understanding of good practices and ethical guidelines

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:



ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



YESIM NURKO
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



Harry ALTAMONT
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com