IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Data Integrity Auditor Masterclass

17-18 October 2024

During this course, data integrity will be discussed from the perspective of GxP audits, with practical advice for successful data integrity audits given.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Data integrity has received more attention than ever before in the last decade and has become the most critical audit topic for health authorities. Although data integrity has started to gain importance in recent years, its history dates back approximately 30 years. Data integrity breaches at Barr Laboratories and later Able reveal this issue is older than it seems. As the health authorities began to question data integrity in audits more and more, pharmaceutical manufacturers started to increase their focus on data integrity, especially in GMP audits, and they started to seek ways to train their internal audit teams with this in mind. This approach acts to detect the deficiencies and deviations that will be found in internal audits prior to the health authority audits.

Although there are numerous data integrity training courses available, the training rarely discusses the audits in detail, which leaves companies trying to solve their problems with a little guesswork based on their own knowledge and experience.

In this course, the concept of data integrity will be discussed from the perspective of GxP audits, and practical advice for successful data integrity audits will be provided. Important guidance about data integrity concepts and guidelines will be covered, and the skills required by personnel performing the audits will be discussed. The programme will also advise in which departments data integrity audits should be carried out. Data integrity audits of the; warehouse, production, quality control, quality assurance, critical utilities, and engineering departments in pharmaceutical production facilities will be covered, with sample applications and question lists, and the most critical audit findings encountered in health authority audits will be examined. During this two-day training programme, the participants will analyse case studies and scenarios, which will aid the learning process.

Benefits of attending

- **Learn** the requirements of data integrity audits and health authority expectations
- **Evaluate** the concept of data integrity from a completely different perspective
- **Understand** the requirements of the role and necessary skills of the data integrity auditor
- **Explore** how to audit and prepare for external data integrity audits in the following departments; warehouse, manufacturing, quality control, quality assurance, critical utilities, and engineering.

At the end of the course, there will be a short assessment exam with case studies and audit scenarios which will be analysed during the course, and those delegates who are successful in the assessment exam will receive the title of 'Certified Data Integrity Auditor'.

Who should attend?

Personnel from the following departments will benefit from this course:

- Quality assurance and quality control
- Validation
- R&D
- Audit
- Regulatory
- IT
- Warehouse and supply chain
- Engineering
- Procurement

As well as:

- Health authority inspectors

Programme

Day 1

Welcome and introduction

GMP guidelines and regulations for data integrity (DI)

- Pharmaceutical Inspection Co-operation Scheme (PIC/S), EU, WHO, MHRA, FDA data integrity regulations
- Parenteral Drug Association (PDA), International Society for Pharmaceutical Engineering (ISPE)
- Association for Professionals in Infection Control (APIC), International Pharmaceutical Excipients Council (IPEC) Guidelines
- Regulatory inspection – focus on data integrity (DI)
- How to prepare your facility for regulatory inspection
- How to prepare SMEs for DI questions

Data integrity principles

- What is ALCOA and ALCOA + (Attributable, Legible, Contemporaneous, Original & Accurate)
- Beyond ALCOA

Data integrity Issues in pharmaceutical companies

- How to manage DI in manufacturing
- How to manage DI in laboratories
- How to manage DI in warehouse & logistics
- How to manage DI in the supply chain

FDA's pre-approval inspection (PAI) and data integrity issues

- What is the most important thing in PAI and DI?

Audit planning and team building

- How to prepare a risk based DI audit plan?
- How to select DI audit team?
- How to be a good DI auditor?

Hints, tips and clues to performing successful DI audits

Virtual DI audits

- DI Gap analysis
- DI checklist

Workshop 1: data Integrity sourcing to laboratory equipment

Day 2

Recap of day one

DI auditing of warehouse and critical utilities

DI auditing of manufacturing

- DI auditing of calibrations

DI auditing of an analytical chemistry laboratory

- Chromatography data system
- Chromatography falsification
- DI audit of stability
- Can we audit audit trails?
- Can we detect DI risks?

DI auditing of a microbiology laboratory

- DI auditing of endotoxin testing
- Revealing DI breaches in a microbiology laboratory

Supplier DI auditing

- API DI audits
- Excipient DI audits

Electronic records and electronic signatures (ERES) DI auditing

- Standard operating procedure (SOP) for electronic audit trail review
- Audit trail review – Fourier Transform Infrared (FT-IR)
- Audit trail review questions
- E-records self-inspection

IT Infrastructure and cloud DI auditing

- System security, data generation, back-up and spreadsheets
- Stand alone systems, and DI audits

Workshop 2: data falsification investigation

DI audit report preparation and distribution

Case Studies and lessons learnt from regulatory inspections

Exam

Presenter

Mustafa Edik

Mustafa Edik is an Independent GMP Consultant and Auditor.

After graduating as a Chemist from university, Mustafa began his 25 year plus career as a Laboratory Supervisor at Bayer, a German Pharmaceutical Company. After 15 years of working as a Quality Assurance Assistant Manager, Laboratory Supervisor, Pharmaceutical Quality Management Systems, and GMP Lead Auditor, he decided to continue his career as a Consultant. He has served the Turkish Atomic Energy Authority (TAEA) as Principal GMP Auditor and Consultant for 6 years. TAEA was audited by the Republic of Turkey Ministry of Health and granted GMP Certificate for 5 Radiopharmaceuticals. This success has won great acclaim from all health authorities and industry.

He has prepared and presented various training courses and workshops to more than 8000 individuals from 150 International and local Pharmaceutical, Medical Device, and Cosmetics companies on GMP, GDP and Pharmaceutical Quality Management Systems. He has taken part in several International Pharmaceutical Facility Establishment projects as GMP Consultant and has also set up various Quality Management Systems for Local Pharmaceutical and Medical Device Companies.

While he was the Vice President of Quality and Technical Operations at a Quality Academia Training and Consultancy firm, he acquired and converted it into a 100 % Turkish Company. As the only IRCA Certificated Pharmaceutical Quality Management Systems and GMP Lead Auditor in Turkey, he currently conducts API, Excipient, Packaging Materials Suppliers and Manufacturers, Third Party Logistics Service Providers, Sterile and Non-Sterile Manufacturing Facilities Audits according to FDA, EMA, PIC /S, TMMDA, MHRA, TGA Health Canada, and WHO regulations and guidelines.

He finished his second university degree in Biopharmaceutical Sciences BSc (Hons) at Atlantic Technological University - Ireland. He is the author of chapter 6 of the book published by PDA named “Good Distribution Practices” and he is preparing his latest book on ‘GMP Audits’ which will be published by Taylor & Francis in 2023.

Course date

17-18 October 2024	**Live online** 09:30-16:30 **UK (London)** (UTC+01) *Course code 14274*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,026** ~~2,338~~ **Until 12 Sep**

How to book

Online:
ipi.academy/2706

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

Email:
info@ipi.academy

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+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% 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

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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