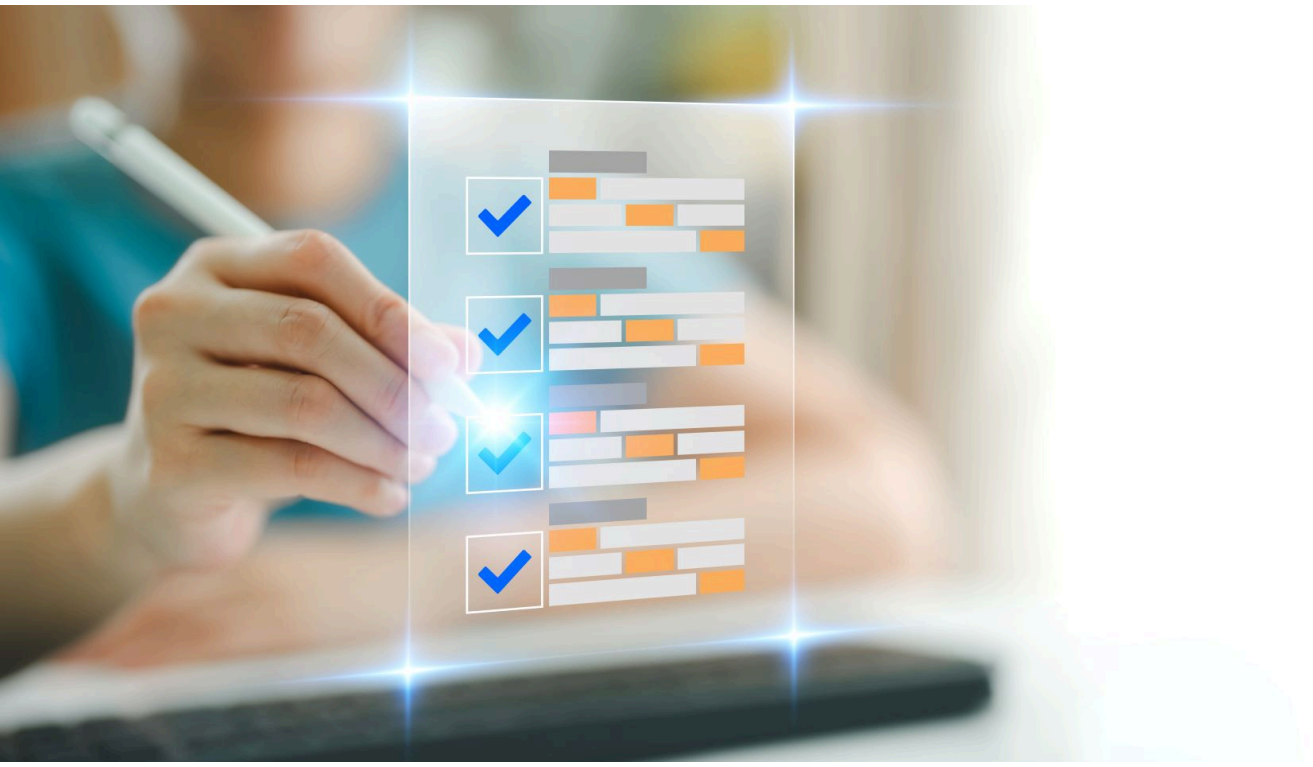
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Golden Rules of Being a Successful GMP Auditor

1-2 October 2025
+ 5-6 February 2026

Learn to conduct thorough audits, identify non-conformities, and recommend corrective actions while following the Golden Rules of successful GMP auditing.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Navigating thorough and successful GMP audits can be a challenging experience within the pharmaceutical industry. GMP auditors play a vital role in safeguarding public health by assessing and ensuring that manufacturing processes meet stringent regulatory standards. Therefore, Good Manufacturing Practices (GMP) are crucial for ensuring product safety, quality, and efficacy.

This training will equip you with the essential tools, strategies, and best practices needed to excel as a GMP auditor. Whether you are new to auditing or an experienced professional, this specially designed programme will guide you through the core principles that lead to successful GMP audits. You will learn how to effectively assess compliance with GMP standards, conduct thorough audits, identify non-conformities, and recommend corrective actions to drive continuous improvement.

Focusing on the "Golden Rules" for a successful GMP auditor, you will learn that these principles go beyond technical knowledge. They emphasise building strong communication, developing keen observational skills, and fostering a collaborative approach with auditees – all of which are essential for ensuring the highest compliance and quality in manufacturing environments.

By the end of this training, you will have a deeper understanding of the GMP audit process and an increased confidence in conducting audits with objectivity and professionalism. Additionally, you will have enhanced your ability to make impactful decisions that ensure compliance, quality, and safety.

Benefits of attending

- **Gain** a comprehensive understanding of the "Golden Rules" of GMP auditing and how they apply to the audit process
- **Learn** how to effectively identify GMP non-conformities, from documentation errors to deviations in manufacturing processes
- **Align** your auditing skills with global GMP standards, helping you stay compliant with industry regulations
- **Understand** how to assess audit findings and suggest practical, effective corrective actions
- **Develop** a risk-based mindset, allowing you to prioritise audit focus areas and address critical compliance issues that could impact product quality and safety

Who should attend

This training will suit those in the following departments:

- Quality Assurance
- Quality Control
- GMP Compliance
- Auditing
- IT
- Regulatory Affairs
- Engineering
- Supply Chain

Programme

Day 1

Introduction to GMP and the role of an auditor

- Overview of Good Manufacturing Practices (GMP) and their importance
- Understanding the role of GMP auditors in ensuring quality and compliance
- Key regulatory authorities (FDA, EMA, MHRA, WHO, PIC/S, TGA) and their GMP requirements

The golden rules of GMP auditing: core principles

- Rule 1: maintain objectivity and independence
- Rule 2: prepare thoroughly before the audit
- Rule 3: focus on critical areas and risks
- Rule 4: document findings accurately and clearly
- Understanding the importance of these principles in conducting effective audits

Planning and preparing for GMP audits

- How to define audit objectives and scope
- Creating effective audit checklists and planning strategies
- Pre-audit preparations: reviewing documents, data, and previous audit reports
- Communicating expectations with the audit team and auditees

Conducting the audit – techniques and best practices

- Rule 5: effective communication with auditees
- How to ask the right questions and observe processes
- Techniques for assessing facilities, equipment, and quality systems
- How to maintain professionalism and objectivity during the audit

Workshop - working on the draft audit agenda

- Hands-on workshop to practice preparing a GMP audit agenda

Day 2

Identifying GMP non-conformities and risks

- Rule 6: be thorough in identifying non-conformities
- Techniques for spotting GMP violations and quality issues
- Assessing risks associated with non-conformities and their potential impact on product quality
- Understanding the severity of findings and classifying risks

Corrective and preventive actions (CAPA)

- Rule 7: effective corrective and preventive actions
- Understanding CAPA and its importance in GMP auditing
- How to work with auditees to develop actionable CAPA plans
- Follow-up processes: verifying that corrective actions are implemented

Reporting audit findings and communicating results

- Rule 8: clear and objective reporting of findings
- Best practices for writing audit reports
- How to communicate audit findings effectively to management and auditees
- Handling discrepancies, disagreements, and difficult situations during the report phase

Workshop: working on the draft audit report

- Hands-on workshop to practice preparing a GMP audit report

Reporting audit findings and communicating results cont.

- Rule 9: learn from every audit
- How to build a culture of continuous improvement in the auditing process
- Self-assessment and reflection: improving your auditing skills over time
- How to measure and monitor the effectiveness and efficiency of GMP Audits
- Staying up-to-date with regulatory changes and GMP updates

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 his new book on ‘GMP Audits in Pharmaceutical and Biotechnology Industires’ will be published by Taylor & Francis in June 28, 2024.

Course dates

1-2 October 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 15600*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 27 Aug**
5-6 February 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15601*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 01 Jan**

How to book

Online:
ipi.academy/3228

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

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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