IPI Academy

MANAGEMENT forum

Presented by
Management Forum

How to Manage Internal GMP Audits

20-21 October 2025
+ 19-20 February 2026

This training programme provides essential skills for planning, managing, and executing internal Good Manufacturing Practices (GMP) audits.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

This intensive two-day training course will equip you with the essential skills and knowledge needed to effectively plan, manage, and execute internal GMP audits. As part of the pharmaceutical industry's commitment to producing safe and effective products, Good Manufacturing Practices (GMP) audits are crucial for maintaining compliance with regulatory standards and ensuring product quality. Internal GMP audits play a vital role in identifying potential risks, ensuring manufacturing processes adhere to the highest quality standards, and preparing your organisation for external regulatory inspections.

Whether you're new to auditing or looking to refine your existing processes, this programme will provide you with the tools needed to conduct thorough audits that assess compliance, identify non-conformities, and drive continuous improvement within your organisation.

By the end of this training, you will be able to confidently manage internal GMP audits, ensuring your company consistently meets regulatory requirements and maintains the highest levels of product quality and safety.

Benefits of attending

- **Gain** an understanding of the internal audit process, from planning and execution to reporting and follow-up
- **Learn** how to establish a structured internal audit program that aligns with GMP requirements
- **Develop** skills to create effective audit plans, define audit scope, and prioritise areas of focus based on risk and criticality, ensuring audits are thorough and efficient
- **Strengthen** your ability to identify non-conformities, assess risks, and mitigate potential issues before they escalate.
- **Understand** how to evaluate audit findings and develop actionable corrective and preventive action (CAPA) plans.
- **Identify** ways to streamline the internal audit process, saving time and resources while maintaining a high level of audit quality

Who should attend

This training will benefit those in the following departments:

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

Programme

Day 1

Introduction to internal GMP audits

- Overview of Good Manufacturing Practices (GMP) and their importance
- Role of internal audits in ensuring compliance and continuous improvement
- Key components of an internal GMP audit program

The role of internal audits in compliance and risk management

- How internal audits help identify risks and prevent compliance issues
- Aligning audits with regulatory requirements (FDA, EMA, WHO)
- Identifying critical GMP areas to focus on during audits

Planning for internal GMP audits

- Defining audit scope, objectives, and goals
- Risk-based approach to selecting areas for auditing
- Preparing audit checklists and audit tools
- Assigning roles and responsibilities within the audit team

Managing the audit process – best practices

- The key stages of an internal audit (planning, execution, reporting, follow-up)
- Preparing for the audit: document review and information gathering
- How to lead an audit team and maintain objectivity
- Conducting effective interviews and observations

Workshop - risk management practices in internal audit plan preparation

Day 2

Conducting the internal GMP audit

- Techniques for effective onsite auditing
- Identifying and evaluating non-conformities and compliance gaps
- Assessing facilities, equipment, and manufacturing processes
- Effective ways of interacting with staff and departments during the audit

Documenting audit findings and reporting

- How to document audit findings accurately and clearly
- Best practices for audit reporting: structuring and presenting results
- Ensuring transparency and objectivity in audit reports
- Reporting non-conformities, risks, and recommendations

Corrective and preventive actions (CAPA)

- Identifying root causes of non-conformities
- Developing effective corrective actions and preventive measures
- Working with departments to implement CAPA plans
- Verifying the implementation and effectiveness of CAPA

Post-audit follow-up and continuous improvement

- How to track progress on CAPA implementation
- Maintaining audit records and documentation for future reference
- Using audit results to foster a culture of continuous improvement
- Leveraging audits as a tool for enhancing quality and compliance

Managing challenging audit scenarios

- Handling resistance to audits and managing difficult auditees
- Navigating complex audits in high-risk areas
- How to manage audits in areas with a prior non-compliance history
- Dealing with audit failures and challenging findings

Workshop - risks of opening and closing meetings of internal audits

- Hands-on exercise: Conducting a mock internal GMP audit

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

20-21 October 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 15606*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 15 Sep**
19-20 February 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15607*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 15 Jan**

How to book

Online:
ipi.academy/3232

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

Email:
info@ipiacademy.com

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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

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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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