IPI Academy

MANAGEMENT forum

Presented by
Management Forum

How to Deal with Difficult Situations in GMP Audits

6 November 2025
+ 5 March 2026, 28 September 2026

This training equips auditors with strategies to handle obstacles such as documentation errors, unethical behaviours, resistance, and time-wasting tactics, ensuring a smooth and productive audit process.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Planning GMP audits with a disciplined and meticulous approach offers numerous benefits for both the GMP auditor conducting the audit and the audited party. While GMP audits are an authority obligation, they also provide added value during internal audits. Additionally, external audits give the audited party the opportunity to discover facts they may not have been aware of.

A GMP auditor must be prepared to handle unexpected situations at any stage of the audit and must complete the qualification process by undergoing the necessary training in this field. While GMP auditors do not evaluate audits solely based on findings, the prejudices, unrest, lack of cooperation, and contrary behavioural patterns of the audited party may lead the auditor to evaluate the audit from a different perspective.

In difficult situations, the auditor should remain polite but firm, maintaining self-control and full command of the audit. This training aims to provide insight from the GMP auditor's perspective, help the audited party cope with challenging situations, and offer strategies for overcoming them.

Benefits of attending

- **Learn** effective communication strategies to maintain a positive relationship with auditors, even during tense or difficult moments
- **Gain** tools for resolving conflicts in a calm and professional manner, helping to avoid misunderstandings or escalations during GMP audits
- **Learn** how to identify potential compliance risks and address them proactively during an audit, minimising the chance of significant issues
- **Improve** your ability to build trust and rapport with auditors, leading to better working relationships and smoother audit outcomes
- **Discuss** the legal and regulatory frameworks surrounding GMP audits, so you're better prepared to respond effectively and stay compliant
- **Consider** strategies for turning challenging situations into opportunities for improvement, leading to positive audit results and a more robust quality system

Who should attend

This training would suit those in the following professional roles:

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

Programme

GMP audits and inspections in brief

- Why we need to perform GMP audits
- Audits vs inspections
- How to perform GMP audits
- International GMP guidelines for GMP audits

Pre-audit and post-audit difficult situations

- What is a difficult situation in the eyes of a GMP Auditor?
- List of difficult situations (Problems during planning the audit, executing the audit, interviews, opening & closing meetings, audit reporting, CAPAs)
- How to prioritise the selected difficult situations

The GMP auditor's roles and responsibilities in difficult situations

- What should be the first reaction to difficult auditees
- How to behave
- Silence, ice-breaking, reprisal and hostility
- Best approaching methods for conflicts

The GMP auditee's roles and responsibilities in difficult situations cont.

- What should be the first reaction to difficult auditors
- How to behave
- Silence, ice-breaking, reprisal and hostility
- Best approaching methods for conflicts

Workshop

- The possible reactions of the GMP auditor to an unexpected situation encountered during a GMP audit will be defined and solution suggestions will be discussed

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

6 November 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15624*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 02 Oct**
5 March 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15625*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 29 Jan**
28 September 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 16207*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 24 Aug**

How to book

Online:
ipi.academy/3230

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

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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.

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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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