





Presented by Management Forum

# How to Audit Pharmaceutical Suppliers (Material and Service)

**24-25 September 2025** + 26-27 February 2026

This training provides knowledge and practical skills to effectively audit material and service providers, covering key areas including raw materials, contract manufacturing, logistics, and packaging. <u>ک</u>ے

Format: Live online ()

**CPD:** 12 hours for your records റ്റി

Certificate of completion

# **Course overview**

Ensuring the quality and compliance of suppliers is crucial to maintaining the safety and efficacy of products in the

**pharmaceutical industry.** Supplier audits play a vital role in this process, as they assess whether material and service providers meet the stringent standards required for pharmaceutical manufacturing.

This training is designed to equip you with the knowledge and practical skills necessary to effectively conduct supplier audits, covering both materials and services. Whether you are responsible for auditing raw material suppliers, contract manufacturers, or service providers such as logistics and packaging suppliers, this programme will provide you with the tools to evaluate their processes, identify potential risks, and ensure compliance with regulatory requirements like Good Manufacturing Practices (GMP) and other industry standards.

By the end of this training, you will be better prepared to manage supplier relationships confidently, ensuring that all materials and services meet the highest industry standards, thereby protecting your company, products, and customers.

### **Benefits of attending**

- **Gain** a deep understanding of the purpose and scope of supplier audits in the pharmaceutical industry
- Learn how to evaluate both material suppliers and service providers to ensure compliance with regulatory standards
- **Develop** practical skills necessary to effectively plan, conduct, and document supplier audits
- **Discuss** potential risks in the supply chain, including quality and safety concerns
- **Understand** how to audit suppliers in alignment with international standards, reducing the risk of non-compliance
- **Navigate** how to streamline the audit process, from planning to reporting
- Master effective communication strategies for managing supplier audits, ensuring constructive feedback, and fostering a positive working relationship

### Who should attend

This training will best suit those in the following departments:

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



# Programme

### Day 1

#### Introduction to supplier audits in the pharmaceutical industry

- Why supplier audits are critical in ensuring product quality and regulatory compliance
- The role of supplier audits in risk management
- Overview of the key types of suppliers: material suppliers, service providers, and contract manufacturers

#### Understanding regulatory requirements for supplier audits

- Key regulations and standards: GMP (Good Manufacturing Practices), FDA, EMA, WHO, and ICH guidelines
- Understanding the importance of supplier qualification and ongoing monitoring
- Regulatory authority's expectations for supplier audits and their role in the supply chain

#### Scope and planning

- Defining the scope and objectives of an audit
- How to select suppliers for auditing based on risk and criticality
- Audit planning and creating audit checklists
- Understanding the audit process: from pre-audit preparation to post-audit follow-up
- How to prioritise audits based on risk (e.g., criticality of the product, supplier history, geographical location)
- Risk management strategies: evaluating suppliers with a risk-based mindset
- Techniques for focusing on high-risk areas during the audit

#### Auditing material suppliers - key focus areas

- Key areas to evaluate in raw material suppliers (e.g., manufacturing processes, quality control, traceability)
- Ensuring compliance with material specifications, storage conditions, and transportation
- How to assess documentation and product testing reports
- Identifying potential risks in the supply chain related to materials

### Workshop – risk based API supplier audit plan and prioritisation rules

• Practical, hands-on workshop where participants simulate a risk based (Active Pharmaceutical Ingredients) API supplier audit plan

### Day 2

### Auditing service providers (logistics, packaging, contract manufacturers)

- Evaluating service providers based on their impact on product quality and regulatory compliance
- Focus areas: service quality, process control, staff training, and compliance with specific service requirements
- How to evaluate contract manufacturers and other third-party service providers

### Audit execution and on-site techniques

- Conducting on-site audits: what to look for, how to ask the right questions
- How to gather evidence, observe operations, and interview key personnel
- Assessing facilities, equipment, and quality systems in place
- Techniques for maintaining objectivity and consistency during the audit process

### Identifying non-conformities and corrective actions

- How to identify non-conformities during an audit
- Best practices for reporting findings clearly and effectively
- Developing corrective and preventive action (CAPA) plans with suppliers
- How to manage supplier responses and follow-up audits to ensure compliance

#### Supplier relationship management and audit follow-up

- Building strong supplier relationships to ensure long-term quality and compliance
- Creating audit reports that foster collaboration rather than conflict
- Handling audit findings diplomatically and developing mutually beneficial action plans
- Importance of continuous supplier monitoring and periodic reaudits

### Interactive workshop: how and according to which guidelines are audits of service providers carried out

• Practical, hands-on workshop where participants discuss the best practices for auditing service providers

# 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**

24-25 September 2025	Live online 09:30-17:00 UK (London) (UTC+01) Course code 15621	GBP <b>1,299</b> <del>1,499</del> EUR <b>1,819</b> <del>2,099</del> USD <b>2,087</b> <del>2,399</del> Until 20 Aug
26-27 February 2026	<b>Live online</b> 09:30-17:00 <b>UK (London)</b> (UTC+00) <i>Course code 15622</i>	GBP <b>1,299</b> <del>1,499</del> EUR <b>1,819</b> <del>2,099</del> USD <b>2,087</b> <del>2,399</del> Until 22 Jan

### How to book

**Online:** 

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ipi.academy/3229

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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## III IPI Academy

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