IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Advanced GMP & GDP Auditor Masterclass

12-14 April 27
+ 12-14 October 27

An intensive three-day master class designed to develop advanced GMP & GDP auditing skills for managing evolving regulations, complex supply chains, and high-risk pharmaceutical operations.

Format:
Live online

CPD:
18 hours for your records

Certificate of completion

Course overview

In the highly regulated pharmaceutical and life sciences industries, patient safety and product efficacy depend entirely on the integrity of the manufacturing and supply chain processes. Compliance with Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) is not merely a legal checkbox; it is a critical operational standard that safeguards global health.

This comprehensive, three-day master class is designed to transform industry professionals into elite, forward-thinking auditors. Delivered by expert trainer, Mustafa Edik, this course bridges the gap between theoretical regulatory text and hard-hitting, real-world inspection strategies.

The landscape of pharmaceutical regulation is evolving at a breakneck pace. With the recent, stringent overhauls of EU/PIC/S GMP Annex 1 (Sterile Manufacturing), the global push toward automated technologies under Annex 11, and the heightened scrutiny on Data Integrity (DI), standard auditing checklists are no longer sufficient.

Furthermore, international cross-border supply chains have become incredibly complex. Moving a product from raw Active Pharmaceutical Ingredients (APIs) to the patient's bedside requires flawless oversight of contract manufacturers, third-party logistics (3PL) providers, and multi-modal cold chain transportation networks. This course equips you with the strategic mindset and tactical tools required to identify vulnerabilities before regulatory authorities do.

This master class is meticulously structured around four critical dimensions of pharmaceutical quality oversight:

- **Global Regulatory Harmonization:** Mastery over the overlapping and distinct requirements of major health authorities, including the FDA (USA), EMA / EU GMP, TİTCK (Turkey), and PIC/S frameworks. You will learn to navigate ICH guidelines
  - Risk Management
  - Quality Systems
  - Analytical Procedure Development, and
  - Stability
- **The Auditor Mindset:** Shifting from a 'policeman' auditing style to a constructive, risk-based investigator. You will learn how to build an objective audit scope, manage team dynamics, and handle high-pressure scenarios, such as opening/closing meetings and challenging corporate cultures.
- **Specialised Technical Competence:** Moving beyond basic warehouse and facility walkthroughs. You will deep-dive into advanced technical auditing, including qualifying API/excipient suppliers, validating complex computerised systems, and inspecting high-tech biotechnology facilities (e.g., mRNA vaccine lines, Monoclonal Antibodies (mAbs), and blood products).
- **Defensive CAPA & Crisis Management:** Understanding how to respond to critical non-conformances, FDA Form 483s, or official warning letters. You will learn the mechanics of bulletproof Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) tracking to satisfy international inspectors.

Benefits of attending

- **Develop** an elite, risk-based investigator mindset for managing complex audit dynamics
- **Master** auditing of automated systems, data integrity frameworks, and global distribution networks
- **Gain** practical understanding of FDA, EMA/EU GMP, PIC/S, and TİTCK regulatory expectations
- **Apply** advanced ICH guidelines across risk management, quality systems, analytical procedures, and stability
- **Identify** quality, compliance, and data integrity vulnerabilities before regulatory inspections
- **Ensure** effective oversight of cold chain logistics, CMOs, CDMOs, and complex supply chains
- **Maintain** readiness for evolving EU/PIC/S GMP Annex 1 and global data integrity requirements
- **Maximise** audit efficiency by focusing resources on critical high-risk technical areas

Who should attend

This course is designed specifically for mid-to-senior level professionals looking to achieve or renew

- Quality Assurance (QA) Directors, Managers, and Specialists
- Quality Control (QC) Laboratory Heads
- Qualified Persons (QPs) and Responsible Persons (RPs)
- Regulatory Affairs Professionals
- Supply Chain, Logistics, and Vendor Qualification Managers
- Pharma Consultants and Independent Auditors

Programme

Day 1

Introduction to quality systems

- Defining quality vs. price, cost, and design in the pharmaceutical landscape

Quality management models and global regulations

- Adapting international quality benchmarks to modern pharma
- Overview of the ISO 9000 series, ISO 9001 standard implementation, and complementary quality models
- EU GMP, and PIC/S guidelines

Pharmaceutical QMS and GMP synergy

- Connecting corporate quality approach with standard operating practices
- Core elements of a Pharmaceutical Quality System (PQS) under ICH Q10

What is a GMP Audit?

- Defining audit definitions, scopes, criteria, and the underlying logic of compliance

The strategic necessity of auditing

- Why do we audit? Driving continuous process improvement instead of mere routine tracking
- Overview of contract manufacturing/analysis risk prevention and exporting safely to foreign markets

Wrap-up and evaluation

- Daily assessment to track the retention of foundational quality concepts

Day 2

Roles, responsibilities, and audit preparation

- The Auditor's mindset: selection of the audit team, defining timelines, and objective scoping
- Ethics, impact, and the balance of power in audits

Audit requirements and laboratory control

- Crucial tips for auditing Quality Control (QC) laboratories

Audit execution and post-audit action items

- Opening and closing meetings protocols, recording non-conformances, and generating the Audit Report
- Real-Life CAPA and follow-up management post-audit. Handling Form 483s, warning letters, responding to health authorities, and crisis management

Supplier auditing - APIs and excipients

- Deep dive into qualifying Active Pharmaceutical Ingredient (API) and excipient manufacturers
- Auditing experiences across diverse cultures and multinational companies. Overcoming language barriers, cultural misunderstandings, and distinct corporate behaviors between US, European, and Asian facilities.

Supplier auditing - packaging materials

- Audit strategies for qualifying primary and secondary packaging component suppliers

Wrap-up and evaluation

- Assessment checking knowledge on audit execution, supplier qualification, and CAPA logic

Day 3

Computerised systems and data integrity (DI)

- Auditing automated processing networks, digital footprints, and software infrastructure
- Integrating EU GMP Annex 11 and FDA Computer Software Assurance (CSA) regulations

Deep dive into GDP and supply chain validations

- Auditing air, sea, and land cargo channels for pharmaceuticals
- Cold chain validation and transportation validation: ensuring stability and security throughout distribution channels

Special technical module: sterility and contamination control (EU/PIC/S Annex 1)

- Auditing sterile spaces, cleanroom classifications, cleanroom garment management, and cleaning/sterilization vendors
- Building and evaluating a Contamination Control Strategy (CCS) during inspections

High-tech and biotech facility inspections

- Audit blueprints for advanced manufacturing sites: Vaccine facilities (mRNA, subunit, protein-based), Monoclonal Antibodies (mAb) lines (from cell bank to finished vial), Blood/Plasma products, and Radiopharmaceuticals
- Integrating the latest ICH updates (ICH Q2, Q9(R1) Risk Management, Q14, and Q1A-Q1F Stability testing guidelines)

Future outlook: The next 5 years of GMP/GDP regulations

- Anticipated regulatory adaptations by EMA, FDA, and TİTCK.

Final masterclass evaluation

- Comprehensive evaluation covering all core topics of the 3-day class

Presenter



Mustafa Edik

Mustafa Edik is a leading pharmaceutical, biotechnoloy, medical device quality and GXP expert with over 28 years of hands-on leadership in GMP, GDP, GCP, GLP, and broader GxP compliance across the pharmaceutical, biotechnology, and medical device industries.

As Turkey's first IRCA-certificated Lead Auditor for GMP and Pharmaceutical Quality Management Systems (PQMS), he brings unmatched credibility and depth to audits, compliance strategies, and regulatory readiness. Holding a BSc in Chemistry, and a BSc (Hons) in Biopharmaceutical Sciences & Engineering from Atlantic Technological University (Ireland), and an Executive MBA, Mustafa combines strong scientific foundations with strategic business acumen.

His career highlights include senior roles at Bayer Türkiye, where he progressed from Quality Control Lab Supervisor to Deputy QA Manager, and GMP Lead Auditor to Global GMP Lead Auditor, managing complex quality operations and audits in a multinational environment. He has personally led more than 4,200 hours of GxP audits across over 200 facilities worldwide.

Today, as Founder and Lead Consultant at Quality Academia Eğitim & Danışmanlık, Mustafa delivers high-impact consulting, training, and project management services to local and global clients. His expertise spans across:

- GMP/GDP audits and supplier qualification
- Validation, qualification, and quality risk management (ICH Q9)
- Root cause analysis, CAPA, OOS/OOT, change control, and data integrity
- Sterile/non-sterile manufacturing, process improvement, and cost-of-quality optimisation
- Clinical trials (GCP & ICH E6), pharmacovigilance, and third-party manufacturing
- Regulatory alignment with FDA, EMA, PIC/S, MHRA, TGA, TMMDA, WHO, and ICH standards

Mustafa has trained over 9,000 professionals in GxP topics and designed certified auditor programs for Turkish authorities including Turkish MOH and Ministry of Agriculture and Foresty. He served as Principal GMP Consultant & Auditor at the Turkish Atomic Energy Authority, supporting successful TMMDA GMP approvals for 5 radiopharmaceutical products. As the first Turkish consultant selected by the Developing Countries Vaccine Manufacturers Network (DCVMN), he has led teams of 100+ engineers, auditors, and quality specialists while managing dozens of international projects.

A prolific author, Mustafa's works include:

- “Sorularla GMP Dokümantasyonu” – a practical guide to GMP documentation
- “GMP Audits in Pharmaceutical and Biotechnology Industries” (Taylor & Francis / CRC Press, June 2024) – a comprehensive reference on effective GMP auditing practices

Recognised internationally for his practical, risk-based approach and knowledge transfer focus, Mustafa Edik is dedicated to elevating pharmaceutical quality standards, helping companies achieve compliance excellence, reduce risks, and drive operational efficiency.

Course dates

12-14 April 27	**Live online** 08:30-17:00 **UK (London)** (UTC+01) *Course code 17604*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 15 Feb**
12-14 October 27	**Live online** 08:30-17:00 **UK (London)** (UTC+01) *Course code 17663*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 17 Aug**

How to book

Online:
ipi.academy/3405

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

Email:
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Phone:
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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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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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