IPI Academy

MANAGEMENT forum

Presented by
Management Forum

How to Pass International Health Authority Inspections

8-9 October 2025
+ 12-13 February 2026

This training course prepares professionals in pharmaceuticals, healthcare, and manufacturing to navigate regulatory inspections by major health authorities including the FDA, MHRA, WHO, and EMA.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Designed to equip you with the knowledge and skills necessary to excel in inspections by major health authorities, including the FDA, MHRA, PIC/S, ANVISA, WHO, and EMA, this training course serves as a pathway to mastering international health authority inspections and setting your organisation up for success. In today's global marketplace, pharmaceutical companies, healthcare organisations, and manufacturers must navigate complex regulatory landscapes to ensure product safety, quality, and compliance.

Whether you are preparing for your first inspection or seeking to enhance your existing compliance strategies, this training course offers actionable insights to help you pass international inspections with confidence. It focuses on understanding the specific requirements of each health authority and the best practices to meet their expectations.

By the end of this course, you will be empowered to manage inspections effectively, proactively address potential compliance issues, and maintain continuous readiness for audits. Our goal is to ensure you are fully prepared to navigate regulatory inspections and uphold the highest standards of quality and safety in your operations.

Who should attend

This course will suit those in the following departments:

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

Benefits of attending

- **Gain** in-depth knowledge of the specific inspection criteria and requirements of major health authorities, including the FDA, MHRA, PIC/S, ANVISA, WHO, and EMA
- **Learn** proactive strategies to maintain inspection readiness throughout the year
- **Discover** best practices for maintaining a robust quality management system, proper documentation, and self-inspections
- **Master** how to manage interactions with health authority inspectors effectively
- **Understand** the common pitfalls in inspections and how to address them
- **Discuss** how to pass inspections efficiently with minimal disruptions to your operations
- **Stay ahead** of evolving regulations and industry standards, ensuring your organisation remains in full compliance with the latest requirements, ultimately safeguarding the quality and safety of your products

Programme

Day 1

Introduction to regulatory inspections

- Understanding the importance of health authority inspections in ensuring safety and quality
- Overview of the major international regulatory bodies (FDA, MHRA, PIC/S, ANVISA, WHO, EMA)
- Key similarities and differences between the authorities' requirements

Preparing for audits: key principles

- The inspection lifecycle: from preparation to post-inspection follow-up
- Key concepts of regulatory compliance and risk management
- Documentation requirements and maintaining effective quality systems
- Self-inspection processes: how to self-assess and identify potential weaknesses

Understanding FDA inspections

- Key requirements for FDA inspections
- Focus areas: Good Manufacturing Practices (GMP), 21 CFR compliance, and safety standards
- Common pitfalls and how to avoid them
- Case studies of successful FDA Inspections

Understanding MHRA and EMA inspections

- Key focus areas for MHRA and EMA Inspections
- Differences in approach: EU regulations vs. UK regulations post-Brexit
- Compliance with EU GMP and EMA's approach
- Real-life examples from past MHRA and EMA inspections

Understanding PIC/S and WHO inspections

- Introduction to the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and its global impact
- WHO's role in international health and safety standards
- Key regulations and their impact on global compliance
- Handling PIC/S and WHO Inspections effectively

Workshop - how to respond to FDA 483s

Day 2

Understanding ANVISA inspections

- Overview of Brazil's ANVISA and its regulations for pharmaceutical manufacturers
- Differences in ANVISA's inspection style and how to prepare
- How to meet local regulations while maintaining international standards
- A successful ANVISA Inspection

Inspection communication and interaction with inspectors

- Best practices for effective communication with inspectors
- How to handle difficult situations during an inspection
- Understanding inspection findings and addressing non-conformances
- Building a cooperative relationship with regulatory bodies
- How to respond to inspection findings and observations
- Training and development strategies for teams

Workshop - problems between PIC/S and other health authorities

Preparing for inspections: simulation and role play

- Practical session: Role-playing common inspection scenarios
- Mock inspections to practice handling inspectors and responding to findings
- Q&A and feedback session to refine communication skills

Remote inspections and audits

- Are remote inspections really necessary?
- What are the points to consider when preparing for remote inspections?
- How does the Health Authority approach remote inspections?
- What are the lessons of Covid-19?

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

8-9 October 2025	**Live online** 09:30-17:15 **UK (London)** (UTC+01) *Course code 15603*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 03 Sep**
12-13 February 2026	**Live online** 09:30-17:15 **UK (London)** (UTC+00) *Course code 15604*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 08 Jan**

How to book

Online:
ipi.academy/3233

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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