IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Good Distribution Practices of Pharmaceuticals and APIs

20-21 May 27
+ 15-16 November 27

Gain a comprehensive understanding of industry-leading practices, ensuring precision in distribution from manufacturer to end user. Navigate complex supply chains, focus on compliance, and elevate your commitment to quality assurance throughout the entire distribution process.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

It is crucial that pharmaceutical products adhere not only to high-quality standards as per Good Manufacturing Practice but also maintain their quality and integrity throughout the entire supply chain, up to the patient.

In today's pharmaceutical landscape, ensuring the safe and reliable distribution of medicinal products is more critical than ever. The complexities of the pharmaceutical supply chain, coupled with the rising threat of counterfeit drugs infiltrating legitimate channels, underscore the necessity for robust Good Distribution Practice (GDP) standards. Good Storage and Distribution Practices (GSP, GDP) are paramount throughout the life cycle of pharmaceutical products and Active Pharmaceutical Ingredients (APIs).

European regulations state the importance of implementing quality systems, risk management principles, and clearly defined processes to safeguard pharmaceutical integrity. Pharmaceutical distributors must establish comprehensive quality systems that define roles, processes, and risk management strategies to mitigate these challenges effectively.

This training course addresses the imperative for pharmaceutical distributors to adhere to GDP guidelines meticulously. Participants will gain thorough understanding of the roles responsible for implementing these practices and the critical junctures within the supply chain where they are most crucial. Discussions will focus on practical strategies for maintaining the quality, potency, integrity, and identity of pharmaceutical products from raw materials through to final distribution, ensuring compliance and safeguarding patient safety.

Benefits of attending

- **Gain** comprehensive understanding of international GDP guidelines and regulations
- **Explore** supply chain risks and effective mitigation strategies
- **Identify** causes and explore solutions for drug shortages
- **Acquire** knowledge on cargo security protocols
- **Receive** expert guidance on detecting and preventing counterfeit drugs in the supply chain
- **Learn** storage and transportation requirements for pharmaceutical products in alignment with current pharmacopoeias
- **Understand** risks associated with transporting temperature-sensitive pharmaceuticals
- **Obtain** detailed insights into equipment qualification for storage, transport, and distribution

Who should attend?

Pharmaceutical personnel involved in the distribution of pharmaceuticals and APIs, including:

- Responsible persons
- Quality assurance specialists
- Quality control officers
- Regulatory affairs professionals
- Engineers
- Supply chain managers
- Logistics coordinators
- Warehouse and distribution managers
- Contracted warehouse and distribution centre operators

Programme

Day 1

Introduction to GDP and supply chain

- What is GDP, GSP?
- Regulatory Guidelines
  - GDP, GSP (EMA, PIC/S, MHRA, TGA, WHO, FDA, EU GMP Annex 11, 15), USP 1079
- Industry
  - APIC, IPEC, PDA, IATA, CEIV, ISPE, ASTM,
- Introduction to the pharmaceutical supply chain
- How to determine and mitigate the pharmaceutical supply chain risks?
  - What are the main risks available?
  - Should disaster recovery be a requirement?
  - How to implement contingency planning & business continuity?

Drug shortages and counterfeiting

- How to prevent drug shortages?
- How to detect counterfeiting in legal supply chain?
  - How to manage fake medicines e.g. during the Covid-19 pandemic?

Storage of pharmaceuticals and biologics

- What is the optimum storage condition for pharmaceuticals, biologicals?
- How to manage time & temperature sensitive pharmaceutical, biological products?
- What to do when planning to design a cold room?
- How to qualify warehouse and distribution equipment?
- What factors must be taken into consideration to execute a temperature mapping study?
  - Developing a Validation Plan
  - Considering areas at risk
  - Developing a protocol
  - Calibration of data loggers
  - Studying duration of the mapping
  - Determining the measuring range
  - Good Documentation Practices
  - Collecting Data Loggers
  - Downloading data
  - Analysing data (21 CFR Part 11, EU GMP Annex 11, GAMP5)
  - Preparing mapping report
  - How to avoid temperature mapping mistakes?
  - Where to locate temperature mapping devices?
  - How to handle temperature & humidity excursions?
- What is Mean kinetic Temperature (MKT)?
  - Is it necessary for every temperature ranges?
  - Is it globally accepted?
- Is humidity a mandatory requirement in warehouses and cold rooms?
- How to choose the best temperature monitoring device?

Temperature mapping study

Group exercise 1: Risk assessment application to the pharmaceutical supply chain

- Critique of format
- Critique of content

Workshop: Risk assessment

- Breakout groups to review and suggest improvement in risk assessment.

Group exercise 2: Temperature risk management

- Critique of format
- Critique of content

Day 2

Active and passive systems

- How to choose active and passive temperature-controlled systems?
  - Do you think that you know much about dry ice?
  - Does it make sense to start with a Validation Master Plan?

Lane qualification & cargo security considerations

- What is a route /lane qualification?
- What are the transportation risks?
  - How to ensure security on the road?
- How is transport validation different from transport verification?
- What is the main purpose of cloud-based temperature monitoring?
- What are the pros and cons of road, sea, air transport?
- Determining air freight and ocean freight challenges

GDP for pharmaceuticals

- Are they known?
- Are they followed?
- Are they enforced?

GDP for Active Pharmaceutical Ingredients (APIs)

- Interpretation of API GDP requirements
- Responsibilities of involved parties
- What is new for API manufactures?
- Implementation status
- Compliance expectations from API manufacturers

Data integrity and Good Documentation Practices

- Data Integrity for temperature-controlled pharmaceuticals

Supplier and customer qualification

- How to qualify a third-party logistics service provider
  - Are you looking for a partner or supplier?
  - Selecting the best 3PLSP
  - How to audit warehouses and 3PLSPs?

Regulatory inspections and cases

- What do the regulatory inspectors expect to see during an inspection?

Group exercise 1: Truck qualification plan

- Critique of format
- Critique of content

Group exercise 2: How to switch from air to ocean transport

- Critique of format
- Critique of content

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

20-21 May 27	**Live online** 09:30-17:15 **UK (London)** (UTC+01) *Course code 17268*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 25 Mar**
15-16 November 27	**Live online** 09:30-17:15 **UK (London)** (UTC+00) *Course code 17487*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 20 Sep**

How to book

Online:
ipi.academy/2787

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

Reviews

★★★★☆

Very comprehensive and informative course. With a high level of detail and examples given by a very knowledgeable trainer.

Christopher Brend
Abbott Healthcare Product B.V.
Abbott Healthcare Products B.V
Mar 17 2025

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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