IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Good Distribution Practices of Pharmaceuticals and APIs

22-23 July 2024
+ 14-15 November 2024, 17-18 March 2025

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

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.

This is where Good Distribution Practice (GDP) comes into play. Good Storage and Distribution Practices (GSP, GDP) are paramount throughout the life cycle of pharmaceutical products and Active Pharmaceutical Ingredients (APIs). The pharmaceutical product network, as we know, is complex and involves multiple parties, compounded by increasing criminal activity introducing counterfeit drugs into the legal supply chain. European guidance emphasizes quality systems, risk management principles, and delineates clear responsibilities and processes. It is now inevitable for pharmaceutical distributors to establish a quality system by defining responsibilities, processes, and risk management principles related to their activities.

Given the distances medicinal products must travel and various external factors they may encounter post-production, licensed companies aim to ensure their products reach patients without spoilage or falsification. The primary objective of this training course is to offer a comprehensive perspective on who should implement these practices and when, along with discussing mechanisms to demonstrate the maintenance of quality, integrity, potency, and identity of the finished drug product from raw material to the supply chain's end.

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

- Responsible Persons
- Quality Assurance/Quality Control Specialists
- Regulatory Affairs Professionals
- Engineering Officers
- Supply Chain Personnel
- Logistics Personnel
- Warehouse & Distribution Professionals
- Compliance Officers
- Any pharmaceutical professionals involved in the storage and distribution of pharmaceutical products and APIs

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 & 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
  - Placing 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 & 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 & Good Documentation Practices

- Data Integrity for temperature-controlled pharmaceuticals

Supplier & 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 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 he is preparing his latest book on ‘GMP Audits’ which will be published by Taylor & Francis in 2023.

Course dates

22-23 July 2024	**Live online** 09:30-17:15 **UK (London)** (UTC+01) *Course code 15171*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 17 Jun**
14-15 November 2024	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15172*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 10 Oct**
17-18 March 2025	**Live online** 09:30-17:15 **UK (London)** (UTC+00) *Course code 15173*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 10 Feb**

How to book

Online:
ipi.academy/2787

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% 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.

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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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