





Presented by **Management Forum** 

# **How to Perform Bullet-Proof Good** Distribution Practices (GDP) and Good Storage Practices (GSP) Audits

14-15 July 2025

+ 3-4 December 2025, 19-20 March 2026

This training will equip attendees with the practical skills necessary to implement regulatorycompliant distribution and storage systems, ensuring both pharmaceutical integrity and patient safety.



Format:

Live online

(1)

CPD:

12 hours for your records



Certificate of completion

### **Course overview**

Adhering to Good Distribution Practices (GDP) and Good Storage Practices (GSP) is essential to ensure that pharmaceutical products reach patients and healthcare providers in optimal condition, thereby safeguarding patient health and maintaining compliance with regulatory standards. In the pharmaceutical industry, it is as crucial to store, transport, and distribute products in a manner that preserves their quality and integrity as it is to manufacture them.

This training is designed to provide you with a comprehensive understanding of GDP and GSP principles and best practices. You will learn the key aspects of distribution and storage systems, including temperature control, traceability, documentation, and risk management, to ensure compliance with international regulations (such as those set by the FDA, WHO, and the EU) and industry standards.

By the end of this training, you will have the practical skills and knowledge to implement robust distribution and storage practices within your organisation. Whether you are managing a warehouse, overseeing logistics, or working in quality assurance, this programme will equip you to ensure that pharmaceutical products are handled and transported in full compliance with GDP and GSP requirements.

#### Benefits of attending

- Enhance your understanding of the key principles and regulations behind Good Distribution Practices (GDP) and Good Storage Practices (GSP)
- Get up-to-date with the latest global regulations and industry standards from regulatory bodies like the FDA, EMA, WHO, and ICH
- Learn how to assess and mitigate risks associated with product distribution and storage
- Discover how to implement best practices for ensuring the proper storage and transportation of temperature-sensitive products, such as vaccines and biologics
- Gain practical knowledge on the implementation and management of temperature-controlled storage and transportation systems
- Enhance your ability to oversee and manage the end-to-end distribution and storage processes

#### Who should attend

This training will suit those in the following departments/roles:

- Quality Assurance
- Quality Control
- GMP Compliance
- GDP and GSP Auditors
- Auditing
- IT
- Regulatory Affairs
- Engineering
- Supply Chain



### **Programme**

Day 1

### Introduction to good distribution practices (GDP) and good storage practices (GSP)

- Overview of GDP and GSP principles and regulations
- Importance of GDP and GSP in the pharmaceutical supply chain
- Key regulatory bodies: FDA, EMA, WHO, PIC/S, MHRA, ICH standards
- Role of GDP and GSP in ensuring product quality and safety

#### Regulatory framework and compliance requirements

- Detailed review of GDP and GSP regulations and guidelines
- Understanding the global regulatory landscape: FDA, EMA, WHO guidelines
- Common compliance challenges and how to address them
- Industry best practices for maintaining regulatory compliance

#### Risk management in distribution and storage

- Identifying and assessing risks in the distribution and storage process
- Importance of risk-based approach in GDP and GSP
- Temperature control, handling procedures, and risk mitigation strategies
- How to develop a risk management plan for your distribution and storage systems

#### Good storage practices (GSP) - key principles

- Best practices for warehouse and storage facility management
- Temperature and humidity control: the science behind storage conditions
- Stock rotation methods: First In, First Out (FIFO), Last In, First Out (LIFO), and First Expiry, First Out (FEFO)
- Handling and labelling requirements for pharmaceuticals

#### Temperature-controlled distribution systems

- Principles of temperature-controlled transportation and storage
- Best practices for managing refrigerated and frozen products
- Active-Passive Temperature Controlled Systems
- Temperature monitoring devices and validation of systems
- Case studies: Real-world examples of temperature excursions, Mean Kinetic Temperature (MKT) and how to handle them

#### Workshop - how to audit temperature mapping study

Day 2

#### Product traceability and documentation

- Importance of documentation for compliance and audit readiness
- Methods for ensuring full traceability of pharmaceutical products
- Documentation standards for GDP and GSP
- Implementing effective tracking systems and audit trails

#### Managing the supply chain and third-party logistics

- Collaborating with third-party logistics providers (3PL)
- Vetting and qualifying distribution partners
- Performance monitoring and quality assurance of external partners

#### Handling non-conformities and corrective actions

- Identifying and responding to product storage or distribution issues
- Corrective and Preventive Action (CAPA) in GDP and GSP
- Case studies: How to manage temperature excursions, damaged goods, or product recalls
- Communicating non-conformities and CAPA processes to stakeholders

#### Preparing for audits and regulatory inspections

- How to ensure GDP and GSP compliance during audits
- Key elements that auditors focus on in distribution and storage systems
- Best practices for maintaining audit-ready documentation and processes
- Preparing for external inspections by regulatory authorities (FDA, EMA, WHO)
- Trends in supply chain technology: Blockchain, IoT, and Al

#### Building a culture of quality and compliance

- How to foster a culture of quality and compliance in your organization
- Training staff on GDP and GSP: Continuous training, education and awareness
- Employee engagement in quality assurance and compliance efforts
- Best practices for ensuring ongoing compliance in changing regulatory landscapes

#### Workshop - how to audit airline cargo companies

### **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**

14-15 July 2025 Live online GBP **749** 09:30-17:15 **UK (London)** (UTC+01) EUR 1,049 USD 1,199 Course code 15629

3-4 December 2025 Live online GBP **549** <del>749</del> 09:30-17:15 **UK (London)** (UTC+00) EUR 769 1,049 USD 887 1,199 Course code 15630

Until 29 Oct

19-20 March 2026 GBP **549** <del>749</del> Live online 09:30-17:15 **UK (London)** (UTC+00) EUR **769** <del>1.049</del>

USD 887 1,199 Course code 15631 Until 12 Feb

#### How to book



#### Online:

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



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- 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**

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

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