Temperature Mapping Study

3-day classroom course (24 hours)

This course can be customized for your company and delivered at the location of your choice.

Temperature mapping is a process of identifying the differences and changes in temperature that occur within a designated storage area. A temperature mapping exercise for any new temperature-controlled storage area shall be carried out before its use, according to the international regulations such as WHO, EU Good Distribution Practices Guidelines (GDP) and International Society for Pharmacoepidemiology (ISPE).

During this course you will gain theoretical and practical knowledge on how to conduct a temperature mapping study related to storage areas designated for temperature-controlled healthcare products.

Objectives

Upon completion of this course you will be able to:

Enhance your understanding of pharma specific requirements in the area of in-transit and/or cross dock storage

Provide insights in practical application and enhance audit readiness

Discuss regulatory requirements, national and international related to storage of Time and Temperature Sensitive Pharmaceutical Products (TTSPPs)

Identify levels of application of these requirements for GHAs, airlines and forwarders in air freight supply chain

Relate practical insight from mapping study Protocol preparation to final Temperature mapping Report

Select the best strategy for deciding on type and number of EDLMS, where to place control devices according to risk assessment

Target audience

- Pharma responsible personnel
- Quality assurance managers
- Warehouse and operation managers

Key topics

- Regulatory requirements for storage of medicinal products
- General requirements for storage areas for Time and Temperature Controlled Products
- Use of Electronic Data Logging Monitor (EDLMS)
- Pharma specific storage area requirements
- Temperature mapping study preparation and execution

Activities

- Group exercises
- Practical review

Prerequisites

Participants are recommended to have prior knowledge of GDP for pharma and healthcare products and CEIV training.

Recommended level

- Management
- Professional

IATA Training

Certificate awarded

An IATA Certificate is awarded upon successful completion of the course and final examination

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Regulatory requirements for storage of medicinal products

- Understand and get updates on regulatory requirements for temperature qualification of storage premises
- Industry best practices and recommendations for Temperature Mapping

General requirements for storage areas for TTSPP

- Types of storage premises and industry terminology
- What are the general requirements and how to implement them in the handling/storage process?

Use of EDLMS - Electronic Data Logging Monitor

- Temperature Monitoring requirements
- Types, models, purpose
- How to select the EDLMS suitable for your purpose
- Calibration

Monitoring system requirements

- Maintenance and calibration
- Validation master plan
- Data integrity

Pharma specific storage area requirements

- Highlights on specific Good Storage Practice (GSP) related to storage of pharma shipments
- "My warehouse", scope, capacity management, segregation, premises security, premises type

Temperature mapping study preparation and exercise

- Temperature Mapping Protocol: purpose, scope, content and template
- Defining the mapping study scope and acceptance criteria
- Acceptance criteria evaluation and follow up actions
- Corrective and Preventative Action (CAPA) system
- Temperature mapping report: purpose, scope, follow up activities
- Premises floor plan analysis and risk assessment
- Exam

A day in the warehouse - Practical exercise

- Practical session – "A day in the warehouse". Findings from the floor plan review and risk assessment (premises size, purpose, doors, systems, power supply, capabilities, if more than one; connectivity, interchangeability, processes)
- Compliance – Apply "GSP - Premises Evaluation Form".
- Apply Gemba Walk check list
- Group work on defining recommendations for temperature mapping study (number of EDLMSs, positioning according risk assessment, scope of the study)
- Facts and data collection and final group work remarks

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Please contact us www.iata.org/cs if you have any questions

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