CONCEPT

Cold Chain Management: Temperature-Controlled Storage and Distribution



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Technical depth: Practitioner · **Practical mode:** Inspection walkthrough

Introduction

Temperature-sensitive medicines, vaccines, biologics and chilled or frozen foods lose value, and sometimes safety, the moment a cold room, vehicle or shipper drifts outside its range. Most excursions trace back not to equipment failure but to unqualified storage, unvalidated packaging, weak handover points and monitoring data that nobody reviews. This Core Concept course equips cold chain practitioners to qualify, monitor and control temperature-controlled storage and distribution against recognised international guidance. Participants examine facilities, vehicles and shipping systems against structured criteria and leave with a Cold Chain Integrity Plan for one product flow in their own operation.

Course Objectives

- Classify temperature-sensitive products by storage range and stability profile, and map every control point from receipt to final delivery
- Apply WHO good storage and distribution practices and ICH Q9R1 quality risk management to storage, transport and outsourced activities
- Plan and interpret temperature mapping and qualification studies for cold rooms, freezers, vehicles and reefer containers
- Specify packaging, monitoring devices and data review routines for each shipping lane
- Investigate temperature excursions, evaluate product impact using mean kinetic temperature and raise corrective and preventive actions
- Produce a Cold Chain Integrity Plan ready for review by quality and operations management

Target Audience

- Warehouse and distribution supervisors operating temperature-controlled storage
- Quality assurance specialists responsible for good distribution practice and deviation handling
- Transport and fleet coordinators running refrigerated vehicles and reefer containers
- Hospital pharmacy and vaccine store officers managing cold rooms and freezers
- Food safety and logistics officers handling chilled and frozen products
- Validation and facilities technicians maintaining refrigeration and monitoring systems

Course Outline

Day 1: Cold Chain Fundamentals and Current-State Assessment

- Temperature Range Classification: Frozen, Refrigerated and Controlled Room Temperature
- Product Stability Data and Labelled Storage Condition Review
- End-to-End Cold Chain Process Map from Receipt to Last Mile
- Handover Point Vulnerability Analysis Using SIPOC
- Cold Chain Maturity Self-Assessment Checklist

Day 2: International Guidance and Standards

- WHO TRS 1025 Annex 7 Good Storage and Distribution Practices
- WHO TRS 961 Annex 9 Supplements for Storage and Transport Operations
- IATA Temperature Control Regulations for Air Shipments
- UNECE ATP Agreement and Codex HACCP Principles for Perishable Foods
- ISO 23412 Requirements for Refrigerated Parcel Delivery Services

Day 3: Storage, Packaging and Monitoring in Practice

- Temperature Mapping Protocol Design for Cold Rooms and Warehouses
- Equipment Qualification: IQ, OQ and PQ for Refrigerated Storage
- Passive and Active Shipper Selection and ISTA 7E Thermal Testing
- Data Logger Specification to EN 12830 and Calibration Records
- Continuous Monitoring System Alarm Set-Up and Data Review Routine

Day 4: Excursions, Risk and Optimisation

- Shipping Lane Risk Assessment Using ICH Q9R1 and FMEA
- Temperature Excursion Investigation and Root Cause Analysis
- Mean Kinetic Temperature Calculation Under USP <1079.2>
- Carrier Qualification and Quality Agreement Audit
- Cold Store Energy Efficiency and Refrigerant Management Plan

Day 5: Inspection Walkthrough and the Cold Chain Integrity Plan

- Cold Room Inspection Walkthrough Against a GDP Checklist
- Refrigerated Vehicle and Reefer Container Pre-Loading Inspection
- Vaccine Distribution Case: Last-Mile Excursion Review
- Cold Chain Integrity Plan Drafting for an Own Product Flow
- Peer Audit of Integrity Plans and Corrective Action Priorities

Skills You Will Gain

- Temperature Mapping
- Thermal Packaging Qualification
- Cold Chain Risk Assessment
- Excursion Investigation
- Monitoring Data Review
- Carrier Oversight
- Good Distribution Practice
- Refrigeration Asset Care

Why Attend This Course

- Leave with a Cold Chain Integrity Plan for a real product flow, already tested in a peer audit
- Decide on firm evidence whether product exposed to an excursion is released, quarantined or destroyed, and record the rationale
- Spot weak handover points and packaging choices before they turn into product losses
- Compare practice with peers from pharmaceutical, healthcare and food distribution

Conclusion

A cold chain is only as reliable as its weakest room, vehicle or handover. This course moves from classifying products and mapping the chain, through the international guidance that governs storage and transport, to qualification, monitoring, excursion investigation and carrier oversight. The final day applies these methods in inspection walkthroughs of storage and transport assets and turns them into a Cold Chain Integrity Plan, giving participants a documented basis for protecting product quality on every lane they manage.