



Audit and Quality for Temperature-Controlled Cargo

5-day classroom course (40 hours)

This course can be [customized for your company](#) and delivered at the location of your choice.

As your pharmaceutical handling operations expand to new markets, you will be subject to a spectrum of international, national, and industry audit requirements. This course provides a standard internal audit process you can immediately apply within your business to ensure compliance with common regulations and quality standards. Through course exercises, you will have the opportunity to use the IATA Temperature Controlled Audit Checklist and develop corrective actions based on your findings.

Objectives

Upon completion of this course you will be able to:

Implement all steps of an internal audit of your cold chain operations

Set up quality standards and metrics

Collect data and documenting your findings

Complete the IATA Temperature Controlled Cargo Audit Checklist

Write a professional audit report with conclusive data analysis

Apply audit findings to ensure quality across your operations

Target audience

- Cargo quality operations managers
- Airline, handler or freight forwarder operations managers
- Warehouse and ramp operations managers
- Pharmaceutical auditor managers

Recommended level

- Entry-level
- Intermediate

Key topics

- Quality management
 - Quality control concepts
 - Quality Risk Management (QRM) methodology
- Audit fundamentals
 - Collection of data
 - Data analysis
 - Interviewing skills
 - Conducting an audit, validation or assessment
- Audit findings
 - Writing an effective audit report
 - Identifying root cause
 - Applying corrective actions and comprehensive fixes
 - Identify residual or new risks

Activities

- Exercises using real audit checklists and templates
- Examination

Materials

- IATA Temperature Control Regulations current edition

Prerequisites

It is recommended that participants complete the [Temperature-Controlled Cargo Operations course](#) prior to attending this course.

Certificate awarded

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

Please note that this Certificate is only valid for 36 months

Table of contents

Standard and regulatory framework

- World Health Organization
- IATA Temperature Controlled Regulation
- EU GDP
- National regulation and guidelines
- The supply chain; Legal responsibilities
- Shippers requirements

Audit terminologies

Competence and evaluation of auditors assessment

- Internal audit, principles, implementation and procedures
- Auditor role and responsibilities
- Selecting team and audit methods
- Quality and competence for an auditor
- Communications skills

Auditor responsibilities and activities

- Lead auditor activities
- Independence of the auditors

Human factors – internal auditor

- Human behavior and motivation
- Communication skills
- Fatigue, time pressure, situational awareness and team work

Audit system and the system best approach

- Process definition and mapping
- Simple and complex mapping
- Symbols and notations of mapping
- Consideration of process mapping
- System definition and flow-charting rules
- Defining the customer

IATA Audit Checklist; The Audit Checklist criteria

 www.iata.org/training-tcgp30

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

Associated diplomas

You may also apply this course toward an IATA Diploma in [Pharmaceutical Handling](#)

The regulatory and international requirements

The checklist sections

- Quality management
- Personnel; Training
- Premises and equipment
- Documentation; Operations
- Complaints, returns, suspected falsified medicinal products and medicinal product recalls
- Outsourced activities; Self-inspections
- Transportation
- Specific provisions for broker

Case study: Complete Audit Checklist for:

- Ground handler; Freight forwarder
- Airlines; Warehouse; Truck company

Finding investigation and root cause analysis

Corrective action

- Measuring effectiveness
- Root cause analysis exercise

Audit and quality control principle

Quality management

Quality control

- Quality control assurance (PDCA)
- Setting quality standards
- Quality metrics
- Quality risk management

Path to “Premium Pharmaceutical Handling Center”