



COLD CHAIN & TEMPERATURE MANAGEMENT: Fundamentals (Online)

Introduction

With increasing regulatory requirements, Cold Chain and Temperature Management in the pharmaceutical distribution industry is becoming more complex. Requirements such as validation, qualification, temperature mapping and monitoring necessitate an in depth understanding of what regulators and auditors are expecting. In order to support organizations in this endeavour, Strategnos is leveraging its many years of experience to offer Cold Chain training to the pharmaceutical industry. The Pharmacy Council recognizes the need for Cold Chain training and requires that all persons who work with/ handle temperature sensitive pharmaceutical products receive Cold Chain training.

Who should take this course?

This course has been designed for operations staff, responsible pharmacists, pharmacists and quality assurance managers within the retail, manufacturing, wholesale and distribution sectors of the pharmaceutical industry.

Course Content:

The Introduction to Cold Chain and Temperature Management will cover the following topics:

- Introduction to Cold Chain and Temperature Management – Cold chain management should be understood in the context of the key challenge in balancing operational and quality requirements. This section will provide a framework to assist organizations in maintaining this balance.
- Regulations and Guidelines – The myriad of regulations, standards and guidelines can make it difficult to establish what is required. This aspect of the training will dissect the practical implications of the regulatory environment.

- Facilities and Equipment – Effective cold chain management requires a baseline understanding of the facilities and equipment for temperature monitoring and control. This section provides a technical overview of HVAC, Air Conditioning, Cold Room Equipment and Temperature Monitoring Equipment and Systems.
- Temperature Mapping and Monitoring – Both these requirements entail the collection, analysis and reporting of a large amount of data. Insight into how to ensure compliant collection analysis and reporting of such data will be presented.
- Validation and Qualification – Validation and Qualification can be difficult to execute in a compliant manner. In this section a framework approach and methodology for the effective execution of validation protocols and reports will be provided.

Agenda:

The training will be conducted in 2 sessions on the Microsoft Teams platform.

Session 1 - 27th October 2021 (08:30am – 12:00pm)

- Introduction to Cold Chain Management
- Facilities, Equipment, Containers and Vehicle Considerations

Session 2 - 28th October 2021 (08:30am – 12:00pm)

- Temperature Mapping and Monitoring
- Analysis of Risk as a Mitigation Strategy
- Validation and Qualification