

COLD CHAIN & TEMPERATURE MANAGEMENT: Assessment and Validation of Cold Chain Insulated Containers

Introduction

Cold Chain Insulated Containers represent one of the most challenging components of the pharmaceutical cold chain. 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 is required for maintenance of the cold chain. This ensures that medicines are transported within the required temperature range to ensure patient safety and regulatory requirements. 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:

- Regulatory Requirements and Guidelines Overview – Local regulations (SAHPRA and SAPC) stipulate base requirements for validation of insulated containers, in order to understand the detailed requirements this course will cover requirements/ guidelines from international bodies including WHO, PDA and ISPE.
- Introduction to Thermodynamics and Insulated Container Design – As insulated containers are typically passive cooling solutions it is imperative to have a basic understanding of thermodynamic principles to support the analysis and review of validation study results.

- Validation of Cold Chain Insulated Containers – Validation of cold chain insulated containers requires a significantly different approach to that of cold chain storage equipment. In this section we will discuss the best practice approach to validating cold chain insulated containers including practical considerations for a South African context.
- On-going Performance Monitoring – Cold Chain Insulated Containers operate in a constantly changing environment, it is therefore imperative to have an effective on-going performance monitoring strategy, including temperature monitoring, performance qualification and risk analysis.