

Temperature Controlled Distribution

An interactive walk through

Overview

Correct storage and delivery of temperature sensitive pharmaceutical materials requires decision makers to be fully aware of the risks their products may face, the regulatory standards they must meet and the products and processes that need to be in place.

Over two days, course participants will be introduced to thermal packaging development and qualification, best practice methods for the introduction and review of data monitors and key insights into risk management, site implementation and handling strategies.

This learning experience will include lectures and case studies from experts in thermal packaging, data monitoring and pharmaceutical manufacturing and supply as well as interactive group exercises aimed to give participants hands-on insights into all areas of temperature controlled distribution.

Who Should Attend:

- Quality Managers Storage and Transportation
- Managers Pharma-Storage and Transportation
- Procurement Managers

Learning Objectives:

- Creating better requirement briefs that reflect your company needs
- Improving evaluation and selection of thermal packaging solutions
- Understanding the value of temperature monitor integration for storage and distribution
- How to successfully introduce temperature controlled solutions into your company
- Evaluating real world distribution and making improvements for the future



Neil Malkin, PCT Qualification Engineer Global Logistics, AstraZeneca

Neil Malkin has over 20 years of experience within AstraZeneca. He is a Qualification Engineer at working for Global Logistics in the UK, in this role Neill is responsible for the establishment and maintenance of global standards, processes and temperature requirements for the transportation of all AstraZeneca products. He is part of the AZ Process Controlled Transportation (PCT) team and his previous role was as a logistics Specialist, he was responsible for assessing routes, monitoring & evaluating performance, understand trends, managing temperature complaints & supporting the global network performance. Neill is a certified green belt in Six Sigma and has been involved in the qualification and implementation of numerous temperature-controlled shipping systems.



Richard Harrop, Development Manager, Topa Thermal

Holding the position of Development Manager at Topa Thermal, Richard is responsible for all product management and new product development activities. His qualifications in design and over 15 years' experience creating thermal packaging have led to him being involved in the development and implementation of several successful temperature-controlled solutions for many of the world's leading pharmaceutical and biotech corporations. Richard also spends much of his time sharing his knowledge and experiences through his published work in industry journals, at conference events or through training courses.



Paul DellaVilla, Product Marketing Manager, Onset Data Loggers

Paul has over 10 years of industry experience as a GMP and GDP project management consultant within the pharmaceutical supply chain. He has managed projects in a variety of regions including, North America, South America, Europe, Asia, Africa and Australia, giving him a solid understanding of the global cold chain regulatory environment. In addition to supply chain documentation development, evaluation and improvement, Paul's skill set includes supply chain audits, equipment validation and facility qualifications and mappings. Paul holds an Bachelor of Science Degree in Management Engineering from Worcester Polytechnic Institute as well as a Master of Business Administration Degree from Northeastern University

Competition Clause: We ask you for your understanding that participants of competing companies cannot take part in the training course.

Tuesday, 26 March 2019

9:00 – 17:00

- 09:00 **Welcome**
- 09:15 **Exploring Thermal Packaging Materials**

- 10:15 **Coffee Break**

- 10:45 **An Introduction to Data Monitors and Indicators**

- 11:45 **Practical Exercise**
 - Thermal Packaging Development - Part 1

- 12:30 **Lunch Break**

- 13:30 **Interactive Discussion**
 - Defining requirements & creating a strong brief

- 14:30 **Coffee Break**

- 15:00 **Thermal & Mechanical Test Centre Tour**

- 15:30 **Practical Exercise**
 - Thermal Packaging Development - Part 2

- 16:30 **Day 1 Wrap-up and Review**

- 17:00 **End of Day 1**

Wednesday, 27 March 2019

9:00 – 16:00

- 09:00 **Day 1 Recap**
- 09:15 **Step by Step - Effective Data Monitoring Practices**

- 10:15 **Coffee Break**

- 10:45 **Moving from DQ to OQ - The Power of the Protocol**

- 11:45 **Practical Exercise**
 - Thermal Packaging Development - Part 3

- 12:30 **Lunch Break**

- 13:30 **Planning and Executing the Perfect PQ and Implementation**

- 14:15 **Beyond Implementation – How to Ensure You Are Ready for What's Next**

- 14:45 **Course Wrap-up**
 - incl. Q&A and open discussion

- 15:30 **Closing Drinks Reception**

- 16:00 **End of Course**