

2019 PDA EUROPE TRAINING

Temperature Controlled Distribution: An Interactive Walk Through



26-27 MARCH 2019
TOPA THERMAL
VOORHOUT, THE NETHERLANDS

Welcome to Voorhout



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**

Training & Education Program

europe.pda.org



PDA Education offers courses that are developed and taught by experts. They are uniquely targeted to professionals involved in the development and manufacturing of quality pharmaceutical and biopharmaceutical products.

Facts that Make a Difference

-  Up-to date training courses and workshops taught by internationally renowned experts
-  Wide range of training courses with hands-on experience to drive expertise, awareness, and innovation
-  Customized in-house training courses and workshops available



TRAINING LOCATION

Topa Thermal

Torenlaan 10
2215 RW Voorhout / Amsterdam
The Netherlands

CONTACT INFORMATION

Registration Customer Care

Tel: +49 30 436 55 08-10
registration-europe@pda.org

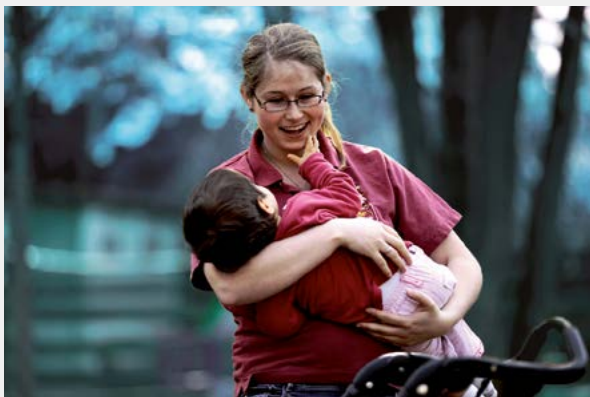
Education Program Inquiries

Elke von Laufenberg

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PDA Europe supports the children's hospice „Sonnenhof“

The Sonnenhof Hospice, located near PDA's office in Berlin, offers support and assistance to families with children suffering from incurable and/or debilitating diseases. At Sonnenhof, children, together with their families, can spend the time they have left as they wish and find some relief from their suffering. Instead of purchasing expensive gifts for the conference speakers, PDA has decided to donate this amount to the Sonnenhof Hospice. You can also contribute and help us increase the amount, it is easy:

buy a package of chewing gums at the registration desk. THANK YOU!

To know more about the Sonnenhof Hospice, please visit www.bjoern-schulz-stiftung.de



Für eine Zeit voller Leben

3 WAYS TO REGISTER

- 1 online: pda.org/eu/TCD2019
- 2 FAX: +49 30 436 55 08-66
- 3 Email: registration-europe@pda.org

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

1 Your Contact Information

If this form is an update to a previously submitted form, please check here.

Mr. Ms. Dr. Nonmember I want to become a PDA Member.
 PDA Member ID Number

Name (Last, First, MI)

Job Title

Company Department

Mailing Address

City Postal Code

Country Email

Business Phone Fax

Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

2 Registration

All fees given in Euro and excluding VAT (21%)

Two-Day Training Course (26-27 March 2019)

Temperature Controlled Distribution

1595

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

Your consent is important. We manage your personal data responsibly.
 For more information, please visit pda.org/privacy-policy

RESPONSE REQUIRED – By checking the box(es) below, I consent to:

- My contact information (name, company, job title, city, state, country) being printed on the attendee list distributed at the event.
- PDA recording and/or photographing me and using those recordings and/or photographs in future PDA promotional and marketing materials.
- PDA sending me promotional information via email.
- PDA sending me promotional information via post

3 Payment Options

By Credit Card

American Express MasterCard VISA

For your credit card information safety:

Please send your details by fax only (+49 30 436 55 08-66) or register online.

By Bank Transfer

Beneficiary: PDA Europe gGmbH

IBAN: DE73 1007 0024 0922 8735 00

BIC (SWIFT-Code): DEUTDE33

Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

By Purchase Order

Purchase Order Number

PDA Europe VAT I.D.: VAT-Registration in Progress

Billing Same as contact information address above. If not, please

Address: send your billing address to: registration-europe@pda.org

Your Company VAT I.D.:

This number starts by your country code with two characters
 (example: PDA Europe's country code starts with: DE | followed by the number)

Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A payment confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **24 February 2019** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at registration-europe@pda.org or fax to +49 30 436 55 08-66.

PDA EUROPE EVENTS



2019

18 March 19-20 March 21 March	Interest Group Meeting Pre-filled Syringes Parenteral Packaging Interest Group Meeting Packaging Science	★ Venice, Italy
16-17 May	Pharmacopoeia	★ Geneva, Switzerland
22-24 May 24 May	Visual Inspection Week Interest Group Meeting Visual Inspection	★ Berlin, Germany
4-5 June	Advanced Therapy Medicinal Products	★ Vilnius, Lithuania
24 June 25-26 June	Interest Group Meeting Quality Systems 4th PDA Europe Annual Meeting	Amsterdam, The Netherlands
3-4 September	BioManufacturing	★ Munich, Germany
5 September	Project Management in the Pharmaceutical Industry	★ Munich, Germany
24-25 September	Pharmaceutical Freeze Drying Technology	★ Berlin, Germany
24-25 September	Particles in Injectables	★ Berlin, Germany
22-23 October	The Universe of Pre-filled Syringes and Injection Devices	★ Gothenburg, Sweden
12-13 November	Outsourcing & Supply Chain	★ Lisbon, Portugal

Subject to change

For latest info: europa.pda.org

Shortlist 13 Dec 2018