PDA
Parenteral Drug Association

The Parenteral Drug Association presents:

2015 PDA Europe Conference

Managing Risk in Aseptic Processing

2 July | **Particle Identification in Parenterals** *One-Day Training Course*
2 July | **Cleaning & Disinfection** *One-Day Training Course*

europe.pda.org/ManagingRisk2015

PLUS Education Program

Conference | Exhibition
30 June - 1 July 2015
Sheraton Hotel
Tel Aviv | Israel

Scientific Program Planning Committee

Karen Ginsbury, *PCI Pharma, Chair*

Georg Roessling, *PDA Europe*

Melanie Decker, *PDA Europe*

Contacts

For additional conference information please contact:

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- **Membership Management**
- **Interest Group**
- **General Event Information**

Melanie Decker
Director Events & Exhibitions
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- **Call for Papers**
- **Presentations**
- **Speaker Biographies**
- **Event Agenda**
- **Committee Information**

Creixell Espilla-Gilart
Manager Exhibition & Sponsorship
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- **Exhibition Information**
- **Sponsoring Opportunities**

To Exhibit:

Exhibition and Sponsorship Opportunities are available. PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibit at PDA events and let your company's products or services become a valuable tool or resource for our attendees.

General Address

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin, Germany
Tel: +49 30 4365508-0
Fax: +49 30 4365508-66

Venue

The Sheraton Tel Aviv Hotel
115 Hayarkon Street
Tel Aviv, 63573-03
Israel
Tel.: + (972)(3) 5211111
http://www.sheratontelaviv.com/

2015 PDA Joint Conference

Vaccines

1-2 December, Berlin | Germany & Bethesda | USA

Tuesday, 30 June 2015

9:00	**Welcome and Introduction**	Georg Roessling, *PDA Europe* PDA Israel Chapter President

Session 1: Regulatory Update — *Moderator:* **Richard Johnson,** *PDA*

This session will look at the proposed revision as well as review current inspection findings, PDA points to consider for aseptic processing and a comparison of various regulations and GMP requirements pertaining to aseptic processing.

9:15	**Microbial Issues in Annex (revision), water systems, media fills,…**	Di Morris, *Pharmaceutical Solutions*
09:45	**Inspections Observations**	Speaker, *AEMPS - invited*
10:15	**Q & A, Discussion**	
10:30	**Coffee Break & Exhibition**	

Session 2: Facilities, Manufacturing Environment, Utilities and Equipment — *Moderator:* **Karen Ginsbury,** *PCI Pharma*

This session will address current issues, requirements and expectations pertaining to the manufacturing and control environment – physical facility and equipment. Some unique solutions will be presented that provide enhanced risk management and reduce the likelihood of contamination arising from ageing facilities and / or operator proximity to product.

11:00	**Isolator & RABS (Barrier Separation Technology- Isolators and RABS): Overview of Principles, Application and GMP Compliance**	James Drinkwater, *Franz Ziel*
11:45	**Risk Assessment for Sterilized and Surface Bio-Decontaminated Processes**	Sergio Mauri, *Fedegari*
12:30	**Q & A, Discussion**	
13:00	**Lunch Break & Exhibition**	

Session 3: Quality Aspects in Manufacturing-Mediafills, Environmental Monitoring — *Moderator:* **Georg Roessling,** *PDA Europe*

Two different media or is TSA enough? Two incubation temperatures or one? Length of media fill – 5 micron particles of importance or not? Microbiological monitoring throughout fill or not? By which methods? The arguments continue, the inspectional findings are repeated and there is right and wrong on both sides. What does risk management require of you – do you need to perform growth promotion test on all incoming media and if so which isolates – pharmacopoeial – what about the isolates you recover in your facility? This session will address these and other issues and of course you can bring along your own, specific problems such as "how much EM is enough for non-sterile manufacturing…"

14:00	**Quality Oversight of Performance of Aseptic Operations-A Holistic Approach**	Heike Merget-Millitzer, *Cilag*
14:45	**Modern Concepts of Sterility Assurance for Aseptic Process: Aspects of Improved Environmental Monitoring Technologies**	Gilberto Dalmaso, *PMT*
15:30	**Q & A, Discussion**	
15:45	**Coffee Break & Exhibition**	

16:15	**Mediafills Testing using NIR Headspace**	Derek Duncan, *Lighthouse*
17:00	**Particle Identification**	Markus Lankers, *rap.ID*
17:45	**Q & A, Discussion**	
18:00	**End of Day 1**	

Wednesday, 1 July 2015

Session 4: Sterilization and Disinfection and Bio- Contamination Control *Moderator:* **Karen Ginsbury,** *PCI Pharma*

This session will look at ways to use sterilization and disinfection to prevent contamination. The highly experienced speakers will share their years of technical experience and throughout understanding of the mechanisms of inactivation of contaminants to demonstrate novel and established but underutilized methods which can greatly enhance the sterility assurance level in your facility. Mold contamination could become a thing of the past even in ageing facilities!

9:00	**Decontamination of Cleanroom surface including RABS and Isolators**	Jim Polarine, *Steris*
9:45	**The Use of NO2 in Parenteral Sterilization**	Steve Storey, *Noxilizer*
10:30	**Q & A, Discussion**	
10:45	**Coffee Break & Exhibition**	
11:15	**Cleaning and Disinfection**	Peter Koger, *Veltek Associates*
12:00	**Bringing the Cleanroom Online after a Worst Case Event**	Jim Polarine, *Steris*
12:45	**Q & A, Discussion**	
13:00	**Lunch Break & Exhibition**	

Session 5: Single Use Systems *Moderator:* **Richard Johnson,** *PDA*

Come and hear about systems you may not yet know exist which can provide solutions for shared facilities and bio-manufacturing.

14:00	**PDA Technical Report Aspects**	Richard Johnson, *PDA* *Georg Roessling, PDA Europe*
15:00	**Single Use Systems in Manufacturing (Biotech and Fill Finish)**	Speaker, *CMC Biologics - invited*
15:45	**Q & A, Discussion**	
16:00	**Farewell Remarks & End of Conference**	

The Parenteral Drug Association presents...

PDA Education Program

2 July 2015
One-Day Training Course
Particle Identification in Parenterals

Faculty:
Markus Lankers, *PhD, rap.ID*

2 July 2015
One-Day Training Course
Cleaning & Disinfection

Faculty:
Peter Koger, *Veltek Associates*

Thursday, 2 July 2015 **9:00 -18:00**

Cleaning and Disinfection

A practical approach

This Training Course

- Describes the ubiquitous importance of cleaning and disinfection in pharmaceutical manufacturing processes
- Explains the role and importance of the total package of **Contamination Control** measures
- Describes various possible root causes for loss of control and how to counteract them
- Discusses **Regulatory Requirements** and expectations with regards to cleaning and disinfection
- Explains the interpretation of **Environmental Monitoring** and **Risk Analysis** with regards to cleaning and disinfection
- Discusses all **Validation** requirements and expectations
- Discusses the basis of chemical selection, use and application; **Sanitizers, Disinfectants and Sporicides** – What are they?
- Explains: **What should be cleaned?** And **what should be disinfected?** The difference between Cleaning and Disinfection and their relationships are presented
- Lists the appropriate application methods (spraying, mopping, wiping, fogging,…) and discusses pros and cons of each
- Details the cleaning frequency and proper order of cleaning and disinfection
- Reveals cleaning and disinfection **myths**
- Discribes **Surfaces:** Non product contact surfaces versus indirect and direct product contact surfaces
  Discusses surface compatibility and surface quality issues
- Describes **classified and non-classified Clean Rooms** and their approach in cleaning and disinfection
- Presents **Water Requirements** (quality, drains, dilution effects, …)
- Presents Cleaning and Disinfection supplies and tools
- Discusses and exchanges **Case Studies**

These and much more experiences, issues and case studies will be discussed and shared during the PDA Training Course on Cleaning and Disinfection

Thursday, 2 July 2015	9:00 -18:00
9:00	**Welcome & Introduction**
9:10	**Subject Introduction** **General Framework** **Directives, Guidelines, Regulatory Expectations**
10:30	**Coffee Break**
11:00	**Environmental Monitoring and Risk Analysis** **Selection Criteria** **Validation of used Chemicals and Methods**
12:30	**Lunch Break**
13:30	**Root Cause of Contamination** **Means and Methods**
15:30	**Coffee Break**
16:00	**Practical Approach Aspects** **Supplies and Tools** **Case studies**
18:00	**End of Training Course**

Faculty

Peter Koger, *Veltek Associates*
Peter Koger has been active in the life science industry for over 30 years. He spent the first 12 years working in different microbiology laboratories, and the remainder working for various international organizations active in the life science/pharmaceutical industry. For about 15 years, Peter was a technical resource to the pharmaceutical industry in relation to viable monitoring and cleaning & disinfection, and other aspects related to contamination control. Since 2002, he has been a frequent industry speaker and since 2004, Peter has been a faculty member of PDA and other training institutes. In 2005, Peter started working with Veltek Associates Inc., a leading manufacturer of disinfectants, detergents, viable monitoring equipment and several other innovative products focused on contamination control for the pharmaceutical industry. In his role, Peter is Technical Sales Manager responsible for Europe and Asia.

Thursday, 2 July 2015 **9:00 -18:00**

Particle Identification in Parenterals

Overview

In recent years we have seen a strong increase in particle related recalls. Besides the loss of product, the impact on reputation can generate immense losses.

This one day comprehensive training program will be taught by two industry experts, Markus Lankers and Oliver Valet. The program will provide the training and the foundational information needed to properly control, document, and investigate foreign particulate matter to ensure compliance with current good manufacturing practices. This program will provide the perfect balance of hands-on laboratory and lecture training, equipping you with tools and actual experience you can apply immediately on the job.

Markus Lankers will guide you through the different stages of a particle classification scheme as part of a life cycle model to control foreign particulate matter in parenteral drug formulations which support compliance to USP and current regulatory expectations. First, you will learn to see particles and document their physical appearance in the container. In a second stage, you will learn techniques to isolate the previously seen particles and their characterization with a microscope. You will also learn how to document the physical appearance and include a digital image to the document.

Oliver Valet will guide you through the collection of chemical evidence by means of spectroscopy. To recognize the chemical structure and composition of a particle, several different spectroscopic methods are necessary. In the training course, you will practically perform Raman spectroscopy on individual particles. Root cause investigation, sampling strategies, comparisons of the particle materials with sources from manufacturing or packaging will be covered in the training as well.

Faculty

Markus Lankers, *PhD, rap.ID*
Oliver Valet, *PhD, rap.ID*

Thursday, 2 July 2015	9:00 -18:00
9:00	**Welcome & Introduction**
9:10	**Short Review on Visual Inspection Covering USP 790 and 1790** **Importance of Particle Classification and Characterization**
10:30	**Coffee Break**
11:00	**Strategies for Particle Classification in Process Lifecycle** **Characterization in Closed Container** **Particle Isolation**
12:30	**Lunch Break**
13:30	**Microscopic Characterization and Identification** **Use of Spectroscopic Tools**
15:30	**Coffee Break**
16:00	**Common Sources of Particulates** **Root Cause Investigations**
18:00	**End of Training Course**

Markus Lankers, *PhD,*
rap.ID GmbH

Markus Lankers is one of the co-founders of rap-ID Particle Systems GmbH, a company that develops, manufactures and sells rapid particle identification systems. Within rap.ID Markus Lankers is responsible for the research and development of specific solutions of particle analysis. Prior to this position he worked as scientist in different development departments with Schering AG, Berlin, Germany. He has published and presented work in the field of analytical methods for particle analysis and spectroscopic analysis. As an active member of the PDA, he helped to establish the Visual Inspection of Parenterals Interest Group in Europe and to setup the first company independent Visual Inspection trainings course. He served as program co-chair for the Scientific Conference on Visual Inspection of Parenterals 2001-2007 in Europe and USA.

PDA
Parenteral Drug Association

The Parenteral Drug Association presents:

2015 PDA Europe Conference

Particles in Injectables

europe.pda.org/Particles2015

8-9 Sept
Training Course
An Introduction to Visual Inspection

Register by 14 August 2015 and SAVE!

10-11 September 2015
Berlin | Germany

Your Contact Person is
Melanie Decker at PDA Europe
decker@pda.org

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

4 WAYS TO REGISTER

1. **ONLINE: https://europe.pda.org/ManagingRisk2015**
2. **FAX: +49 30 4365508-66**
3. **EMAIL: petzholdt@pda.org**
4. **MAIL: PDA Europe, Am Borsigturm 60, 13507 Berlin, Germany**

1 Your Contact Information

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

☐ Mr. ☐ Ms. ☐ Dr. ☐ Nonmember ☐ PDA Member ID Number

☐ **I want to become a PDA Member.** Please send me a subsription form

Name (Last, First, MI) *

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Fax

☐ Substituting for

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

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

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 People in Israel - Fee + VAT. Payment only through Bioforum.
All Others in the World - Fee without VAT. Thanks for considering!

All fees given excluding VAT (17 %)

		Euro
Conference (30 June-1 July)		
PDA Member	☐	**895**
Nonmember (including 1 year PDA membership)	☐	**1195**
Particle Identification in Parenterals (2 July) One-Day Training Course		
PDA Member	☐	**495**
Nonmember (including 1 year PDA membership)	☐	**795**
Cleaning & Disinfection (2 July) One-Day Training Course		
PDA Member	☐	**495**
Nonmember (including 1 year PDA membership)	☐	**795**
Exhibition- table top only (30 June - 1 July)		
no conference ticket included	☐	**1295**

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be provided. The fee does not include the hotel accommodation.

Group Registration Discount Register 5 colleagues for the conference at the same time and receive the **5th registration free.** For more information on group discounts please contact Antje Petzholdt at petzholdt@pda.org. Other discounts cannot be applied.

Join PDA and receive the Membership Rate Today!
Please go to:
www.pda.org/membership

3 Payment Options

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☐ **By PDA Europe Bank Transfer (only in Euro)**
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PDA Europe VAT I.D.: DE254459362

Billing Address: ☐ Same as contact information address above.
If not, please send your billing address to: **petzholdt@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.** You must have a written confirmation (including invoice) to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. Payment must be received or guaranteed by Purchase Order or credit card details on 1st day of event, at the very latest. **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 per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **1 June 2015,** 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 work 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 **info-europe@pda.org or fax to +49 30 4365508-66 . DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

The Parenteral Drug Association presents...

PDA Europe Upcoming Activities and Events

2015

2-3 June	Advanced Therapy Medicinal Products	Conference, Exhibition	Amsterdam The Netherlands
9-11 June	Virus / TSE Safety Forum	Conference, Exhibition	Lisbon (Cascais) Portugal
23-24 June	Quality & Regulations	Conference, Exhibition	Brussels Belgium
30 June - 1 July	Managing Risk in Aseptic Processing	Conference	Tel Aviv Israel
10-11 September	Particles in Injectables	Conference, Exhibition	Berlin Germany
15-16 September	Pharmaceutical Freeze Drying Technology	Conference, Exhibition	Munich Germany
22-23 September	8th Workshop on Monoclonal Antibodies	Workshop, Exhibition	Berlin Germany
6-7 October	Pharmaceutical Cold & Supply Chain Logistics	Conference, Exhibition	Amsterdam The Netherlands
3-4 November	The Universe of Pre-filled Syringes & Injection Devices	Conference, Exhibition	Vienna Austria
17-18 November	Outsourcing / Contract Manufacturing	Conference, Exhibition	Copenhagen Denmark
1-2 December	Vaccines	Conference, Exhibition	Berlin Germany

For latest info: https://europe.pda.org Subject to change Shortlist 18 May 2015

Additional training courses will accompany most conferences. For details, please use the QR-Code or go to www.europe.pda.org

Get a quick overview of all PDA Europe activities with the myPDA-WebApp.
For Apple iPhone & iPad, Android and Windows Mobile7 smartphones: www.my-pda.eu

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