PDA
Parenteral Drug Association

8-9 Sept
Training Course
An Introduction to Visual Inspection

The Parenteral Drug Association presents:

2015 PDA Europe Conference

Particles in Injectables

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Special Registration Rate for HOSPITAL STAFF
1st Conference Day only 350 €

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10-11 September 2015

Courtyard by Marriott
Berlin | Germany

SCHEDULE AT A GLANCE

11 September 9:00 – 17:45 **12 September 8:30 – 16:35**	**Main Conference**	**Conference, Exhibition**
13 September 9:00 – 18:00 **14 September 9:00 – 16:00**	**An Introduction to Visual Inspection**	**Training Course**

For latest information, please visit: **europe.pda.org/Particles2015**

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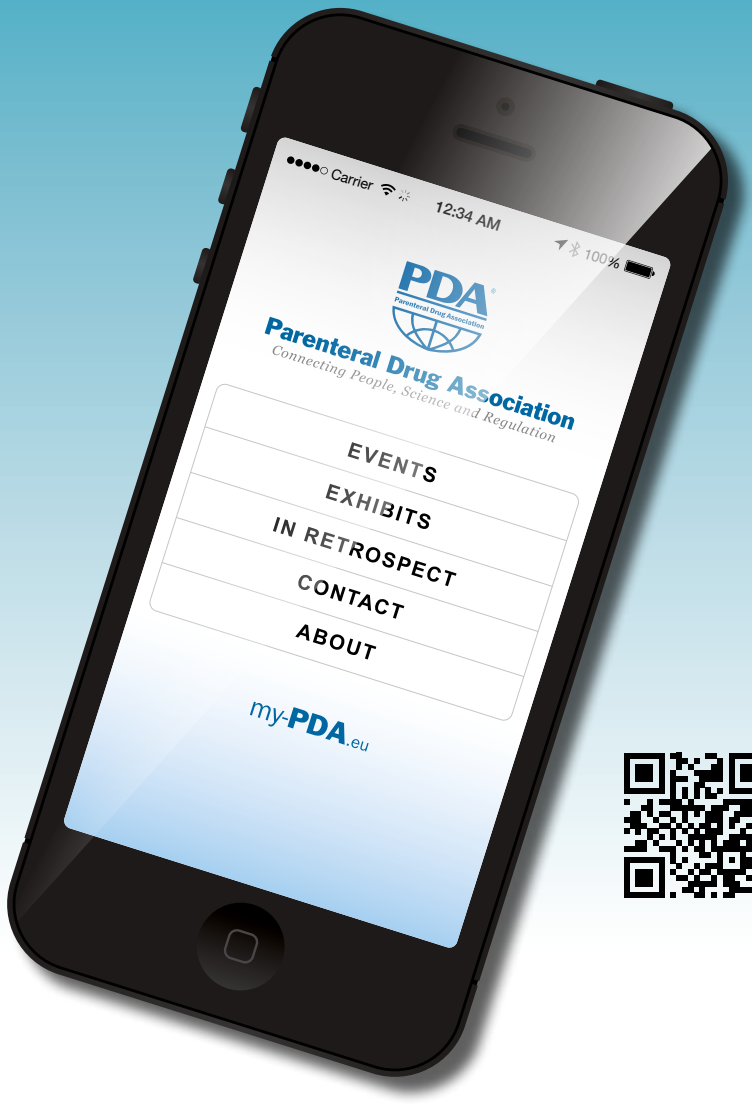

Scientific Program Planning Committee

Markus Lankers, *PhD, rap.ID, Germany, Co-Chair*

John G. Shabushnig, *PhD, Insight Pharma Consulting, Co-Chair*

Georg Roessling, *PDA Europe*

Melanie Decker, *PDA Europe*

Contacts

For additional conference information please contact:

Antje Petzholdt
Membership Management
petzholdt@pda.org

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

Melanie Decker
Director Events & Exhibitions
decker@pda.org

- **Call for Papers**
- **Presentations**
- **Speaker Biographies**
- **Event Agenda**
- **Committee Information**

Creixell Espilla-Gilart
Manager Exhibition & Sponsorship
Email: espilla@pda.org

- **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

Courtyard by Marriott Berlin City Center
Axel Springer Strasse 55
Berlin, 10117 Germany
Tel.: + 49 (30) 800928 2200
Fax: +49(30) 800928 2100
www.marriott.com/hotels/travel/bermt-courtyard-berlin-city-center/

Special rates
Single Room Euro **120 €** per room and night
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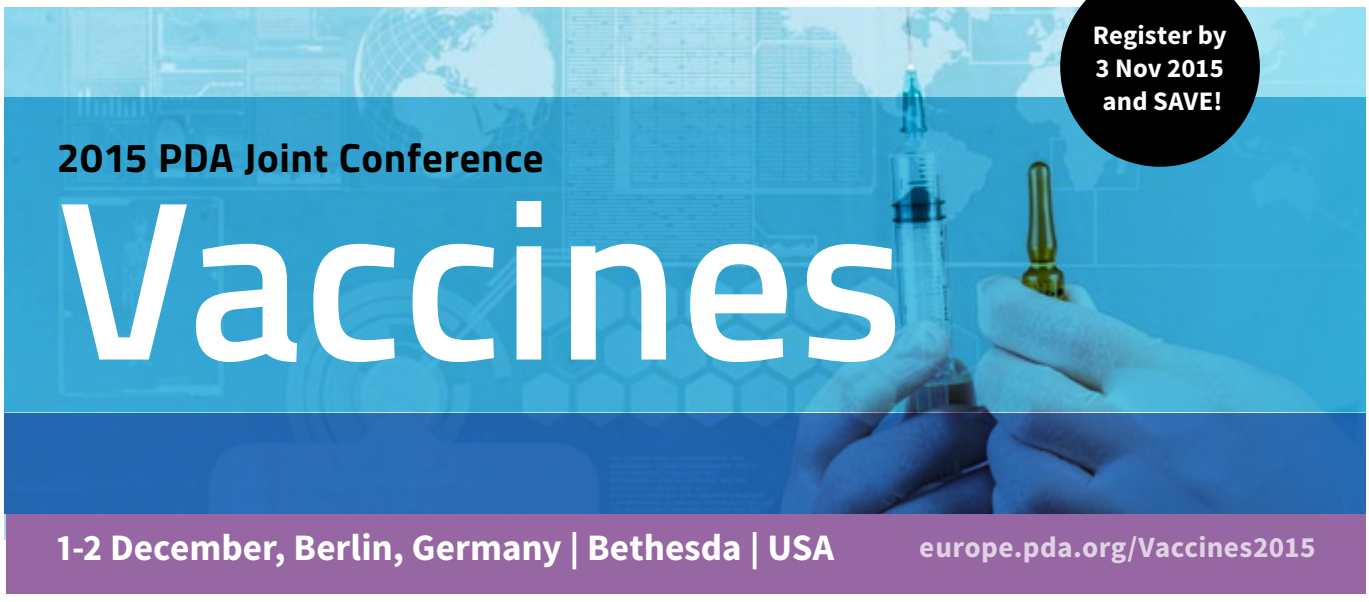
(including breakfast, WIFI public areas, VAT and Servicecharge – Citytax apply)

Room Reservations
PDA Europe has reserved a limited number of bedrooms until the **28 July 2015.**
Please reserve your room under the CodeWord: **"PDA**".
Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.



Thursday, 10 September 2015

9:00	**Welcome & Opening Remarks**	Georg Roessling, *PDA Europe*
9:15	**Introduction by the Program Chairs**	Markus Lankers, *rap.ID* John G. Shabushnig, *Insight Pharma Consulting*
9:30	**Medical Impact of Particulate Matter in Drugs**	John Ayres, *Eli Lilly*

Session 1: Results of a Clinical Study — *Moderator:* **Georg Roessling,** *PDA Europe*

The opening session provides a summary of information on the risks to human health associated with particulate matter. An overview about a clinical study on comparing effects of filtered and unfiltered infusion will be presented.

10:00	**Clinical Practice of Infusion Management**	Michael Sasse, *Hannover Medical School*
10:30	**Clinical Impact of Particulate Matter in Infusion: Clinical Study with 800 Patients**	Michael Sasse, *Hannover Medical School*
11:00	**Coffee Break & Exhibition**	
11:30	**Removing Particles by Inline Filtration**	Andreas Capewell, *Pall*
12:00	**Q&A, Discussion**	
12:30	**Lunch Break & Exhibition**	

Session 2: Sources of Particles — *Moderator:* **John Shabushnig,** *Insight Pharma Consulting*

Particulate matter, visible or subvisible, in sterile parenteral products is regarded a critical quality attribute, impacting patient safety. Particles can arise from many sources foreign, intrinsic, or inherent to the product. This session discusses the nature and sources of these particles in parenterals and in infusions sets used in the clinical study. The difference between particles in drugs and clinical infusions will be highlighted.

13:30	**Particles in Parenterals**	Markus Lankers, *rap.ID*
14:00	**Particle Analysis of the Clinical Infusion: Size Distribution and Chemical Nature**	Cornelia Keck, *University of Kaiserslautern* Markus Lankers, *rap.ID*
15:00	**Q&A, Discussion**	
15:30	**Coffee Break & Exhibition**	

Session 3: Particle Control and Particles in Components — *Moderator:* **Markus Lankers,** *rap.ID*

Packaging materials, such as glass vials, syringes and rubber stoppers, are known to be major sources of particulate contamination. This session discusses defects in packaging materials and strategies employed to detect and control them.

16:00	**Particles on Elstomers: An Industry case Study**	Speaker invited
16:30	**Particles in Infusion Equipment**	Speaker invited, *B.Braun*
17:00	**Particle Measurement on Elastomers and Proper Handling to Avoid Particle Generation**	Mike Schaefers, *West*
17:30	**Q&A, Discussion**	
17:45	**End of Day 1**	

Friday, 11 September 2015

Session 4: Regulatory Update — *Moderator:* **John Shabushnig,** *Insight Pharma Consulting*

The regulatory session provides current view on the regulatory position and considerations of the FDA as well as European regulatory bodies. In addition this session reviews the status and ongoing activities to support the USP expert panel proposed Chapter <1790> focused on clarifying manual visual inspection parameters through the pharmacopeial forum process. In addition this session reviews the current USP activities in the area of visible and sub visible particulates. Too complement this presentation an update on ongoing activities for the EFPIA position pear will be presented.

9:00	• **A PDA Survey of Visual Inspection Practices for Injectable Products** • **Global Recalls of Parenterals because of Particle Contamination**	John Shabushnig, *Insight Pharma Consulting*
10:00	**Requirements and Guidance on Visible Particles found in USP <790> and <1790>**	John Shabushnig, *Insight Pharma Consulting*
10:30	**Coffee Break & Exhibition**	
11:00	**Visual Inspection Challenges from an Industrial Perspective**	Romain Veillon, *GSK*
11:30	**Impact of Particles on Quality of Biotherapeutics and Current Approaches for Control**	Tapan Das, *Bristol-Myers Squibb*
12:00	**Q&A, Discussion**	
12:15	**Lunch Break & Exhibition**	

Session 5: Manual Inspection / Automated Inspection/ Technology — *Moderator:* **Markus Lankers,** *rap.ID*

Manual inspection continues to provide the critical reference method for all compendial inspection activity. This session will also look at use of particle standards to qualify manual and automated inspection systems. The control of critical inspection parameters and the development of an inspection method will be discussed for blow fill seal container, which are difficult to inspect due to their limited transparency.

13:15	**Title to be confirmed**	Paul Kinsey, *GSK, invited*
13:45	**Blow-Fill-Seal Inspection**	Heino Prinz, *rommelag*
14:15	**How to Reduce the Overall Particle Content in Pharmaceutical Packaging for Parenterals: a Practical Case**	Rob Swift, *Ompi*
14:45	**Cleaning Operations to Reduce Particles**	Markus Keller, *Fraunhofer Institute IPA Stuttgart*
15:15	**Q&A, Discussion**	
15:30	**Closing Remarks**	Georg Roessling, *PDA Europe*
15:35	**End of the Conference**	

An Introduction to Visual Inspection

A hands-on training course

Course Description:

The training course covers the fundamentals of visual inspection methods and their application to injectable products. It will be a combination of lecture/discussion and hands-on laboratory exercises used to develop and practice practical inspection skills. The skills developed through this course may be applied to both manual human inspection and automated machine inspection.

Join instructors John Shabushnig and Markus Lankers for this extremely informative and popular course! This course has sold out early the past three times it has run. Register early before this course is sold out again!

Upon completion of this course you will be able to:
Identify applicable international regulatory and compendial requirements for visual inspection.

- Apply the critical parameters which must be controlled for reproducible inspection results
- Use appropriate statistical tools to assess and compare inspection methods
- Develop consistent validation strategies for visual inspection processes and equipment

Who Should Attend

Pharmaceutical/Biopharmaceutical | Development | Engineering | Manufacturing | Packaging | Process Development | Quality | Technical Services | Validation | Inspection Equipment Suppliers | Applications Development | Machine Design | Purchasing

Trainer: John Shabushnig, *Insight Pharma Consulting* | **Markus Lankers,** *rap.ID*

Tuesday, 8 September 2015 — 9:00-18:00

9:00 **Introduction / Why We Inspect**
- Why We Inspect
- Regulatory Requirements: 1. FDA (Recalls / 483's, FD&C Act), 2. EMA (Annex 1)
- Compendial Requirements: USP / EP / JP
- Other Standards

10:30 **Coffee Break**

11:00 **Inspection Methods and Technologies**
- Manual Inspection
- Critical Parameters: Lighting, Duration / Speed, Contrast, Agitation
- Semi-automated Inspection
- Automated Inspection

12:30 **Lunch Break**

13:30 **Particle Identification**

14:30 **Laboratory: Manual Inspection Exercise**
Basic Inspection Method Instruction
Light Measurement
Effect of Critical Inspection Parameters on Particulate Inspection
- Time (5 sec, 15 sec)
- Lighting (2500 lux, 1250 lux)
- Agitation (with and without)

15:30 **Coffee Break**

16:00 **Continue Manual Inspection Exercise**

17:30 **Wrap-up Discussion / Q&A**

18:00 **End of Day 1**

Wednesday, 9 September 2015 — 9:00-16:00

9:00 **Inspection Data Review**
(from previous day's lab)

10:00 **Defect Classification Strategies**
Defect Definitions (Critical / Major / Minor)

10:30 **Coffee Break**

11:00 **Acceptance Sampling**
- Sampling Plan Variables (Operational Characteristic Curves, AQL's and UQL's, Sample Size)
- ANSI Z1.4
- Single and Double Sampling Plans

12:00 **Inspector Selection and Qualification**
- Vision Screening (Acuity, Correction, Color Blindness)
- Initial Training
- Initial Qualification
- Periodic Requalification

12:30 **Lunch Break**

13:30 **Inspection Strategies**
- Reinspection
- 2-Stage Inspection
- Focused Inspection
- Empty Vial Inspection

14:00 **Inspection Validation Methods**
- Comparing Inspection Methods
- Acceptance Criteria

14:30 **Coffee Break**

15:00 **Mythbusting**

15:30 **Wrap-up Discussion / Q&A**

16:00 **End of Training Course**

We wish to thank the companies Bosch/Eisai and MicroMeasurements Laboratories for their donation of equipment and materials used in this course.

Biographies

John G. Shabushnig, *PhD, Principal Consultant*
Insight Pharma Consulting, LLC

John is the founder and Principal Consultant of Insight Pharma Consulting, providing expert guidance in all aspects of visual inspection. He has over 28 years of industry experience including Sr. Manager/Team Leader in Pfizer's Global Quality Operations where he was responsible for providing microbiology and aseptic manufacturing technical support to manu-facturing sites worldwide. He began his career in the pharmaceutical industry as a Research Scientist with The Upjohn Company responsible for development projects in the areas of Process Analytical Technology (PAT) and visual inspection. With the formation of Pharmacia and Upjohn, he became the Director of Technical Support and Engineering with responsibility for sterile and non-sterile technology transfer and process improvement, package engineering, automation and documentation. He was subsequently promoted to the position of Business Unit Director of the Center for Advanced Sterile Technology (CAST), Pharmacia's sterile isolator production facility.

John holds a B.S. in Chemistry from Carroll College and a PhD in Analytical Chemistry from Indiana University. He is an active member of the Parenteral Drug Association (PDA), having served on the Board of Directors (2003-2011) and as Chair (2008-2009) and currently serving as Chair of the Science Advisory Board (SAB) and the leader of the Visual Inspection Interest Group. He is also an instructor at PDA's Training and Research Institute (TRI). John serves on the USP Dosage Forms Expert Committee and Visual Inspection of Parenterals Expert Panel. He is also a member of the American Chemical Society (ACS). He has published and presented numerous papers on the subjects of spectroscopic analysis, process analytical technology (PAT), rapid microbiological test methods and visual inspection of pharmaceutical products.

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 sales rapid particle identification systems. Within rap.ID Markus Lankers is responsible for research and development of specific solution of particulate 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 vis. Inspection trainings course. He served as program cochair for Scientific Conference on Visual Inspection of Partenterals 2001-2007 in Europe and USA.

PDA®
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The Parenteral Drug Association presents:

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Your Contact Person is
Antje Petzholdt at PDA Europe
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4 WAYS TO REGISTER

1. **ONLINE: https://europe.pda.org/Particles2015**
2. **FAX: +49 30 4365508-66**
3. **EMAIL: petzholdt@pda.org**
4. **MAIL: PDA Europe, Am Borsigturm 60, 13507 Berlin, Germany**

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. ☐

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* 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

No PDA membership included

EARLY BIRD DISCOUNT ☐ **Book by 14 August to receive € 150 off the conference fee only**

All fees given in Euro and excluding VAT (7 %)

Conference (10-11 September)		net
PDA Member	☐	**1295**
Nonmember	☐	**1495**
Govern./Health Authority/Academic	☐	**795**
Hospital Staff 1st Conference Day only – no early bird	☐	**350**

Two-Day Training Course (8-9 September)
An Introduction to Visual Inspection

All Participants	☐	**1495**

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 hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

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.

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☐ **Discount for Exhibiting Companies** Please mark here if your company is an exhibitor to this event and you will receive the conference ticket at the **special price of 995 Euro per ticket.** No further discounts are applicable with this option (as PDA Membership Discount or Group Ticket discount). This special rate does not include one-year PDA membership.

3 Payment Options

☐ **By Credit Card** (one week prior to event)

☐ American Express ☐ MasterCard ☐ VISA

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☐ **By Bank Transfer**
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If not, please send your billing address to: **petzholdt@pda.org**

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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 **14 August 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.

Helpful Hints When Registering for PDA Europe Events

MAKING IT EASIER FOR BOTH OF US

1 Please include your member ID number on registration form if available/known

If uncertain about your member ID number and/or your membership status, call or email Ms. Antje Petzholdt.
+49 30 4365508-10 **petzholdt@pda.org**

2 Do not send money in advance

Please wait until we send our invoice to you.
It is helpful to reference our invoice number in your bank transfer details.

3 Complete and sign the event registration form

Please note the registration and cancellation policies at the bottom of the form.

4 Purchase Orders

Registration cannot be completed by sending Purchase Order alone. A Purchase Order is only accepted if a complete registration form is enclosed or follows very soon.

5 Please state VAT ID number if European-based Company

This number starts by your country code
(example: PDA Europe's VAT ID number = DE254459362)

6 Please state the correct billing address on the registration form

This is particularly important if billing address and site address are different. Contact your accounting department for correct address and company name. There could be special requirements for accounting. Changes in the billing address (if induced by participating company) will be charged 25,- € if imposed 3 weeks prior to the start of the event.

7 Confirmation of your registration

Credit card charges are confirmed immediately if successfully approved.
Bank transfers are confirmed upon receipt of full payment.

8 Refund/Credit Notes

Refunds to credit card can be done immediately if payment had been done by credit card and details are available. Refunds to bank accounts can be done if payment had been done by bank transfer and the following details are provided: **a) Name of your bank** **b) IBAN number** **c) Swift/BIC code**

9 Substitutions

If a participant is unable to attend, substitutions are welcome at any time. Changes are free of charge until 3 weeks prior to the start of the event. After this date, there will be a charge of € 50 per name change.

10 For assistance contact: Antje Petzholdt, PDA Europe

Tel: +49 30 4365508-10 **Email: petzholdt@pda.org**

THANK YOU FOR YOUR COOPERATION!

The Parenteral Drug Association presents...

PDA Europe Upcoming Activities and Events

2015

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 21 Jul 2015

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

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