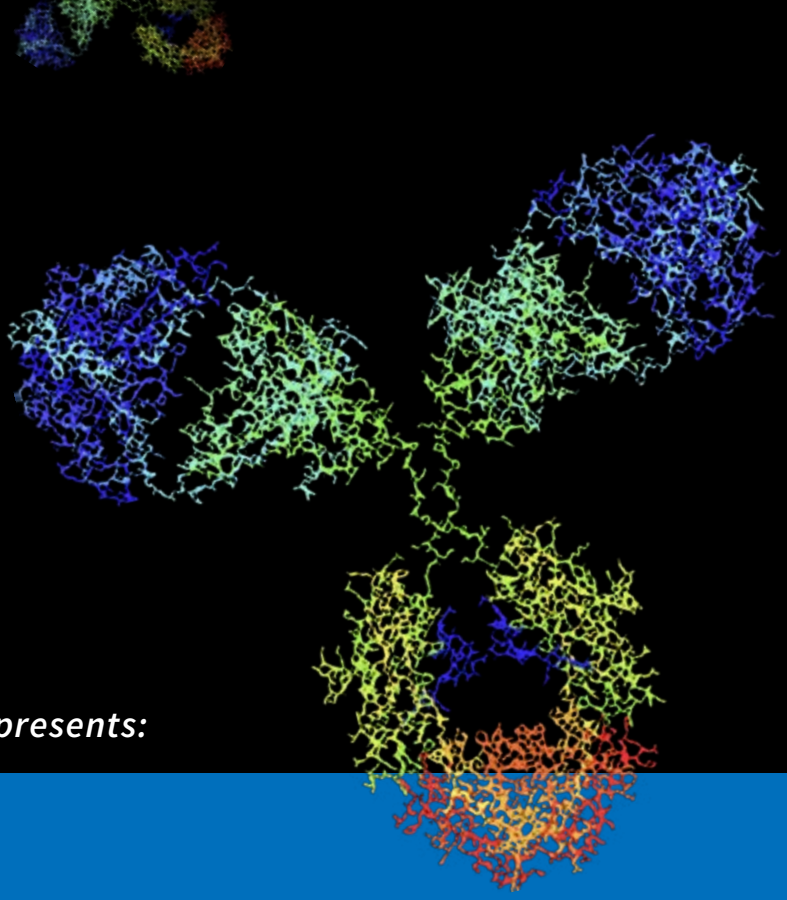
PDA
Parenteral Drug Association



The Parenteral Drug Association presents:

2015 PDA Europe

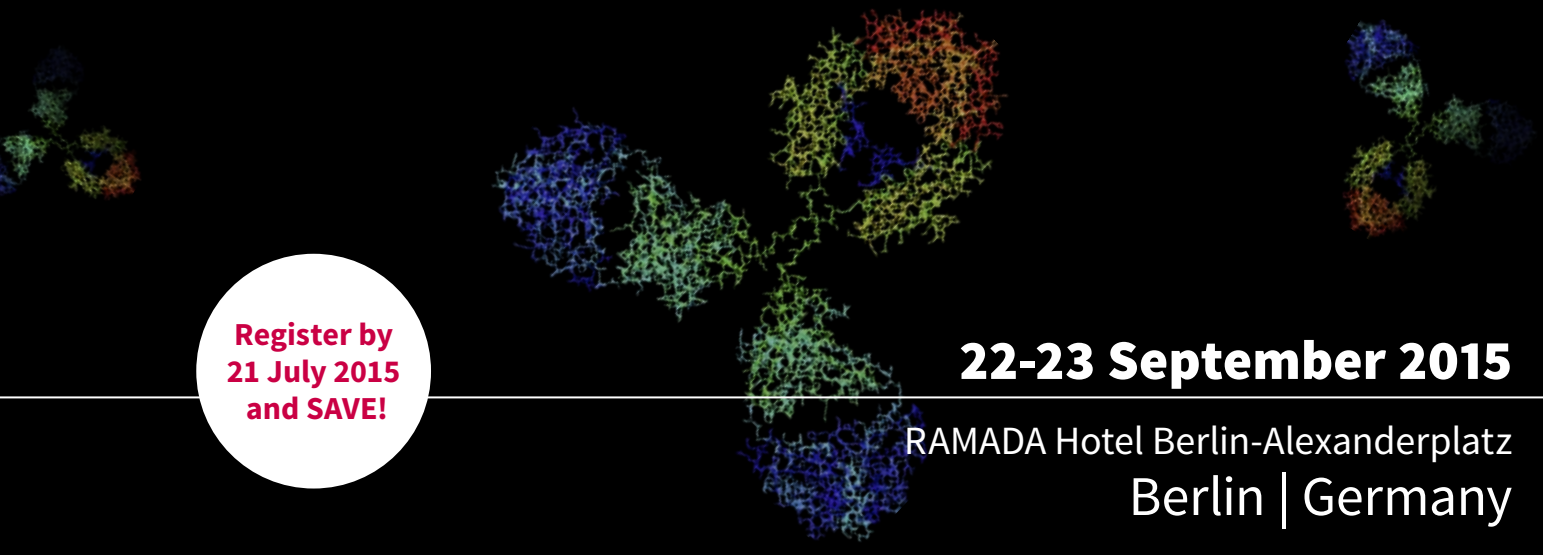
8th Workshop on Monoclonal Antibodies

Current & Future Trends in Process Development

Learn all about State-Of-The-Art and Future Strategies in Process Development. Register Today.

Exhibition 22-23 September | **Education Program** 24-25 September

europe.pda.org/Monoclonals2015



Register by 21 July 2015 and SAVE!

22-23 September 2015

RAMADA Hotel Berlin-Alexanderplatz

Berlin | Germany

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Keep thoroughly informed about our speakers
Post your question even before an event takes place
Have a look at presentations and photos
Have a quick survey of upcoming events

LETTER FROM THE CO-CHAIRS

Scientific Program Planning Committee

Michael DeFelippis, *Co-Chair, Eli Lilly*
Martijn van der Plas, *Co-Chair, Medicines Evaluation Board*
Ilse Blumentals, *GSK*
Ursula Busse, *Novartis*
Mary Cromwell, *Genentech*
Juan Gimenez, *Genentech*
Steffen Gross, *Paul Ehrlich Institute*
Ralf Hess, *PAREXEL*
Li-Hong Malmberg, *AbbVie*
Ilona Reischl, *AGES*
Richard Levy, *PDA*
Georg Roessling, *PDA Europe*
Sylvia Becker, *PDA Europe*

Dear Colleagues,

On behalf of the scientific program planning committee and PDA, we are pleased to invite you to the 8th PDA Europe Monoclonal Antibodies Workshop, to be held 22-23 September 2015 in Berlin, Germany.

Three decades after the licensure of the first monoclonal antibody, interest remains strong in this product class. The top three blockbuster pharmaceuticals of 2013 were monoclonal antibodies; and an estimated 300 compounds are currently in various stages of clinical development for treatment of cancers, inflammatory and autoimmune diseases and other disorders. The intense focus on monoclonal antibodies has in turn driven significant developments in the chemistry, manufacturing and control (CMC) aspects associated with commercial production. Scientific advances in molecular biology have enabled production of fully human monoclonal antibodies. The antibody structure also now serves as a framework to create related molecular entities such as fragments, Fc-fusions, bispecifics and antibody drug conjugates, with the goal of optimizing therapeutic potential. Improvements in expression systems and cell culture have boosted titers, and efficiency gains have been realized in manufacturing by adopting platform processes for upstream and downstream operations. Many manufacturers of monoclonal antibody products were early adopters of QbD-enabled control strategies.

Manufacturers of therapeutic monoclonal antibodies continue to invest in process development in order to accommodate a broader range of product types, and to meet evolving regulatory expectations. Economic factors are strongly fueling efforts to further increase cell culture productivity, optimize operational efficiency and reduce overall manufacturing expenses to reliably produce larger quantities of high quality products at lower cost. Process development clearly remains an area of focus for manufacturers. For this reason, the planning committee has selected this topic as the theme of this year's workshop. The objective of the workshop is to examine the current state-of-the-art for process development of monoclonal antibodies and explore technologies that will influence new CMC approaches.

The workshop program will consist of sessions covering both upstream and downstream process development, control strategy design, antibody related products and technology innovations. In keeping with the format of previous workshops, an entire session will be devoted to regulatory considerations with presentations by regulators involved in dossier review and inspection. Through presentations, case studies and panel discussions, workshop participants will learn the latest trends in process development and understand what approaches will be useful for the next wave of monoclonal antibody and related products. In addition to the planned sessions, the program will provide abundant opportunities for networking and exchange of ideas with friends, colleagues, regulators and industry leaders. We look forward to welcoming you to the 8th PDA Europe Monoclonal Antibody Workshop in Berlin!

The Co-Chairs

Michael DeFelippis,
Eli Lilly

Martijn van der Plas,
Dutch Medicines Evaluation Board, CBG MEB

Featured Conference Topics

Upstream Process Development

- Cell Banking
- New Cell Lines
- Cryo-Preservation
- New Substrates
- Clonality
- Risk Assessment
- Use of Platform Knowledge
- QbD Elements

Downstream Process Development

- Filtration
- Chromatography
- Scale-Down Models
- Alternatives to Protein A
- Virus Removal
- Use of Platform Knowledge
- Risk Assessment
- Experimental Design
- QbD Elements

Regulatory Requirements, Recent Trends

- EU GMP Annex 2 Implementation Challenges
- Global Harmonization of Regulatory Authorities
- Post Approval Life-Cycle Management
- CMC Requirements for Fast-tracked Products (adaptive licensing)

Technological Innovations

- Single-Use System
- PAT
- Continuous Manufacturing
- Other Technological Advances

Antibody-Drug Conjugates

- Starting Materials
- Synthesis
- Requirements

Control Strategy

- Process Monitoring
- Process Capability Analysis
- Host Cell Proteins
- Analytics
- Raw Materials
- Real-time Release Testing
- Validation Requirements
- Life-Cycle Management

Formulation

Fill/Finish

The Parenteral Drug Association presents...

PDA Education Program

24- 25 September 2015

CMC Regulatory Compliance for Biopharmaceuticals

Two-Day Training Course

John Geigert, *PhD, BioPharmaceutical Quality Solutions*

CMC Regulatory Compliance for Biopharmaceuticals

Description

Biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the regulatory requirements for these challenging products. Companies clearly understand the critical importance of their human clinical study strategy, but frequently, the development of a strategy for Chemistry, Manufacturing & Controls (CMC) is an afterthought. Add to this, the frequent lack of CMC regulatory compliance experience in some companies, coupled with the complexity of the biological manufacturing processes and products, and this can be a recipe for disaster.

This course will provide insights and practical guidance for the CMC teams to develop an acceptable cost-effective CMC regulatory compliance strategy for biopharmaceuticals from early clinical stage development through market approval. The course emphasis will include FDA, EMA and ICH guidance.

Who Should Attend

This course is designed specifically for those involved in or interested in the manufacture and control and CMC regulatory issues of biopharmaceuticals, including Senior Management, Directors and Managers/Supervisors, QA/QC, Regulatory Affairs, Manufacturing and Process Development personnel.

Learning Objectives:

Upon completion of this course, you will be able to:

- Explain the importance and underlying principles of an effective CMC regulatory strategy for biopharmaceuticals to move your products through clinical development into the marketplace
- Explain the importance and underlying principles for CMC regulatory compliance of biopharmaceuticals and how this leads regulatory agencies to have different CMC regulatory requirements for biotech products compared to pharmaceuticals of chemical origin.

Faculty

John Geigert, *PhD, BioPharmaceutical Quality*

John Geigert is President of BioPharmaceutical Quality Solutions, which for the last 12 years has specialized in providing CMC regulatory strategy consulting for the biopharmaceutical and biologic industry. He has over 35 years of CMC industrial experience and leadership in the biopharmaceutical industry. He has held senior management positions as Vice President of Quality at both IDEC Pharmaceuticals Corporation in San Diego and Immunex Corporation in Seattle, and he was Director of Product Development at Cetus Corporation in Berkeley. At these companies, he helped lead the CMC efforts to obtain regulatory approvals for 6 biopharmaceutical products now commercially available in the U.S. and in Europe. John Geigert has served on the PDA Board of Directors, current co-chairs the PDA Biotech Advisory Board, and has served as an expert member of the USP Biotechnology Committee. He is the author of the book The Challenge of CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics 2nd Edition, and has written extensively for RAPS Focus (What Senior Management Needs to Know About CMC Regulatory Compliance for Biotech Products (Aug-Nov 2009, 4-part series), Demystifying CMC Regulatory Strategy (Sept 2011-Mar 2012, 4-part series)). John Geigert obtained his B.S. in Chemistry from Washington State University and his Ph.D. degree in Organic/Analytical Chemistry from Colorado State University.

Thursday, 24 September 2015 — 9:00 – 17:00

9:00	Welcome and Introduction
	CMC Regulatory Challenges for Biopharmaceuticals are Different
	Painting the Terminology Landscape: Biologic, specified biologic, biopharmaceutical, biosimilar, CBER, CDER, EMA, ...
10:30	Coffee Break
11:00	Understanding the CMC Differences of Biopharmaceutical Regulation between FDA and EMA
	Biopharmaceuticals are not Chemical Drugs – Regulatory Compliance Consequences of the four Major CMC Differences
12:30	Lunch Break
	How to Develop an Effective Corporate CMC Risk-Managed Control Strategy for Biopharmaceuticals
13:30	Three Major Forces that Shape the CMC Regulatory Compliance Strategy of all Biopharmaceutic
	Five Key Elements of an Effective Corporate CMC Regulatory Compliant Strategy
15:00	Coffee Break
15:30	Impact of the Quality by Design (QbD) on Biopharmaceutical CMC Strategy
	Necessity of a Clinical Phase - Appropriate CMC Regulatory Compliance Strategy
17:00	End of Day 1

Friday, 25 September 2015 — 9:00 – 17:00

	Applying a CMC Risk-Managed Control Strategy to the Biopharmaceutical Manufacturing Process
09:00	Four Myths about Biopharmaceutical Starting Material – the Master Cell Bank
	Necessity of Confirming Clonality and Genetic Stability
10:30	Coffee Break
	Importance and Limitations of small-scale Studies for Biopharmaceuticals
	Clinical Phase - Appropriate Control of the Biopharmaceutical Manufacturing Process
	Formulation and Container-Closure Challenges for Biopharmaceuticals – Impact of Components on the Biopharmaceutical (e.g., protein aggregation) and Impact of the Biopharmaceutical on Components (e.g., glass delamination)
12:30	Lunch Break
	Challenge of Managing Manufacturing Process Changes and Demonstrating Biologic Product Comparability – Not an Easy Task!
13:30	Need for Risk-based, Sequential and Clinical Phase - Appropriate Comparability Studies
	Demonstrating Biologic Product Comparability – Justifying CMC Differences
15:00	Coffee Break
15:30	'Comparability Protocol' and 'Post Approval Change Management Protocol'
	Extreme Comparability of Biosimilars: Limitations of CMC Comparison, Fingerprinting – CMC Biosimilarity Successes and Failures
17:00	End of Training Course

Scientific Program Planning Committee

Michael de Filippis, *Co-Chair, Eli Lilly*
Martijn van der Plas, *Co-Chair, Medicines Evaluation Board*
Ilse Blumentals, *GSK*
Ursula Busse, *Novartis*
Steffen Gross, *Paul Ehrlich Institute*
Mary Cromwell, *Genentech*
Juan Gimenez, *Genentech*
Ralf Hess, *PAREXEL*
Ilona Reischl, *AGES*
Richard Levy, *PDA*
Georg Roessling, *PDA Europe*
Sylvia Becker, *PDA Europe*

Contacts

For additional Workshop information please contact:

Antje Petzholdt Membership Management **petzholdt@pda.org**	**Membership Management** **Interest Group** **General Event Information**
Sylvia Becker Manager Programs & Events **becker@pda.org**	**Call for Papers** **Speaker Management** **Conference Agenda**
Elke von Laufenberg Manager Training & Education **laufenberg@pda.org**	**Education Program** **Faculty Management**
Creixell Espilla-Gilart Manager Exhibition & Sponsorship **espilla@pda.org**	**Exhibitor Management** **Sponsorship Opportunities**

To Exhibit:

Exhibition and Sponsorship Opportunities are available. PDA meetings and Workshops 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

RAMADA Hotel Berlin-Alexanderplatz
Karl-Liebknecht Strasse 32
10178 Berlin, Deutschland
Fon: +49 (30) 3010411-0
Fax: +49 (30) 3010411-550
E-Mail: berlin.alex@h-hotels.com
www.h-hotels.com/en/hotels/ramada-hotel-berlin-alexanderplatz/welcome.html

Special Rates
Double room for single use **€ 129**
Double room: **€ 139**
(including breakfast and WLan, VAT and Servicecharge – Citytax may apply)

Room Reservations
PDA has secured a limited number of rooms at a special group rate until **11 August 2015. Code word: PDA**
Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

How to find the venue:

© Google – For directions click on the picture, scan the QR-code or go to **https://goo.gl/maps/ukf2n**

Lufthansa Austrian brussels airlines germanwings SWISS

Special offer: Discounted travel with Lufthansa Group Airlines

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NOTE: Pop-ups must be enabled otherwise the booking platform window will not open.

These promotional fares are also available through your IATA / ARC travel agent. Travel agents can obtain ticketing instructions by sending an email to **lufthansa.mobility@dlh.de** and providing the access code as a reference.

Your Contact Person is
Antje Petzholdt at PDA Europe
petzholdt@pda.org

4 WAYS TO REGISTER

1. **ONLINE: https://europe.pda.org/Monoclonals2015**
2. **FAX: +49 33056 23 77 77**
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. ☐

☐ Mr. ☐ Ms. ☐ Dr. ☐ Nonmember ☐ **I want to become a PDA Member.** Please send me a subscription form

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Company* Department

Mailing Address

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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.)

* This information will be published in the Workshop 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 21 July to receive € 150 off the conference fee only**

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

	net
Workshop (22-23 September)	
PDA Member	☐ **1495**
Nonmember	☐ **1745**
Govern./Health Authority/Academic	☐ **750**
Two-Day Training Course (24-25 September)	
CMC Regulatory Compliance for Biopharmaceuticals	
All Participants	☐ **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. PDA Europe has secured a limited number of rooms at a special group rate.

Group Registration Discount Register 5 colleagues for the Workshop 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

☐ **Discount for Exhibiting Companies** Please mark here if your company is an exhibitor to this event and you will receive the Workshop 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**

☐ American Express ☐ MasterCard ☐ VISA

For your credit card information safety:
Please send your details by fax only (+49-33056-23 77 77) or register online.

☐ **By Bank Transfer**

Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDEDBBER
Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

☐ **By Purchase Order** Purchase Order Number

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 **24 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 Workshop 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 (33056) 23 77 77. 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 (0)33056 2377-10 **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 (0)33056 2377-10 **Email: petzholdt@pda.org**

THANK YOU FOR YOUR COOPERATION!

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
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 7 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

For general information please contact:

PDA Europe gGmbH
Am Borsigturm 60
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For exhibition information please contact:

Creixell Espilla-Gilart
Exhibition & Sponsorship Manager
PDA Europe
Tel: + 49 (30) 4365508-14
Email: espilla@pda.org

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