PDA Parenteral Drug Association

PIC/S

The Parenteral Drug Association in cooperation with PIC/S presents:

2015 Conference

Quality & Regulations

Presenting the latest on the Revision of Annex 1, Data Integrity, Quality Culture, and much more...

Conference, Exhibition 23-24 June | **Education Program** 25 June

Register by 26 May 2015 and SAVE!

23-24 June 2015

Courtyard by Marriott
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LETTER FROM THE CHAIR

Scientific Program Planning Committee

Veronique Davoust, *Conference Chair, Pfizer*

Ursula Busse, *Novartis*

Jette Christensen, *Novo Nordisk*

Gabriele Gori, *GSK Vaccines*

Frank Hallinan, *Validant Inc.*

Stephan Roenninger, *Amgen Europe*

Georg Roessling, *PDA Europe*

Dear Friends, Colleagues and Peers,

I would like to take this opportunity to personally invite you to the 2015 PDA Europe 'Quality & Regulations' Conference of the Parenteral Drug Association. I know this will prove to be a memorable and important industry conference, which you should not miss.

The Planning Committee and PDA staff have been working tirelessly to plan and organize this major event in Europe, for your benefit. The conference will be held 23-24 June at the Courtyard by Marriott Hotel in Brussels, Belgium. This hotel is an outstanding business conference venue and was selected to provide optimal travel and meeting convenience for you.

The conference will include more than 30 quality and regulations related presentations, several panel discussions and two PDA Interest Group sessions including updates on several of the PDA's recent Technical Report and Points-to-Consider efforts. We are particularly proud to present confirmed regulatory speakers of PIC/S, EMA, MHRA, HPRA and EDQM. The talks in each of the sessions' tracks have been specially designed to encourage interaction and discussion. Moderators include some of the most knowledgeable professionals in their fields and will be on hand to facilitate an exchange of ideas between speakers and the audience. The conference will be attended by the most influential people in our industry and ample opportunity will be provided to network and interact with speakers, regulators and other attendees.

The theme of this year's meeting will be the emerging regulations, guidance and current hot topics in the quality/CMC/GMDP arena - with a special focus on the revision of the GMP Annex 1 on the Manufacture of Sterile Products, and a dialogue on the ways and means how to meet these new and anticipated requirements.

The Opening Plenary will feature presentations on regulatory expectations and challenges in the international globalized environment. Then participants will hear from regulators and industry leaders on current innovative scientific approaches on a variety of subjects, including process validation, post-approval changes/life cycle management, and on controlling impurities in shared facilities. Finally, you will receive an update on the most recent activities in implementing good distribution practices, tackling drug shortage, and preventing data integrity issues. The conference will conclude with an outlook into the future for our industry, putting the emphasis on its quality culture.

In addition to the 2-day conference, PDA Education Courses on Risk-based Prevention of Drug Shortages and on Quality Systems will be held on June 25 and 26.

All of this learning will be complemented by a company exhibition offering you insights into the latest innovations and services that best support your business activities.

A conference of this magnitude on a subject of this significance, combining scientific and technical content with an operational pragmatism, has long been needed. If you are involved in the design, development, validation, registration, manufacture, control, distribution of medicinal products, active substances, vaccines or biological products – you must attend the 2015 PDA Europe 'Quality & Regulations' Conference!

I look forward to seeing you in Brussels in June.
Best regards

Véronique Davoust, *PhD, Pfizer, Global Quality Operations, Quality Strategy, Conference Chair*

Tuesday, 23 June 2015

9:00	**Welcome & Opening Remarks**	Georg Roessling, *PDA Europe* Véronique Davoust, *Pfizer*

Opening Plenary: Regulatory Update & Future Outlook — *Moderator:* **Stephan Roenninger,** *Amgen*

The opening plenary aims to aid in clarifying expectations for innovative, practical implementation and the manufacturing of sterile products. Featured speakers will inform about regulatory expectations and challenges in the international, globalised environment as well as provide future perspectives. For the first time, insights into the enhanced international collaboration by the newly founded International Coalition of Medicinal Regulatory Authorities (ICMRA) will be shared. We will conclude with a regulatory perspective on details about and the need for an update of Annex 1 of the EU and PIC/S GMPs.

9:10	**EU Regulations on Inspections – An Overview Towards Harmonisation**	Brendan Cuddy, *EMA, Head of Manufacturing and Quality Compliance, Compliance & Inspections Department*
9:40	**Keynote: International Challenges and Future Outlook**	Paul Hargreaves, *MHRA, PIC/S*
10:10	**Keynote: Quality Challenges in a Harmonised and Disharmonised World**	Liam Murphy, *Amgen*
10:40	**Coffee Break & Exhibition**	
11:10	**On the International Inspection Collaboration and ICMRA**	Mark Birse, *MHRA, on behalf of ICMRA*
11:40	**Revision Annex 1, Status Update**	Andrew Hopkins, *MHRA , Rapporteur on behalf of EMA & PIC/S*
12:10	**Panel Discussion on Inspections & GMPs**	**All Speakers**
12:40	**Lunch Break & Exhibition**	

PARALLEL TRACKS

Session 1

Track A: Process Validation Life-Cycle Management

This session will deal with the practicalities of the new process validation paradigm with the change from the traditional '3 batch' validation approach to the newer philosophy of the need for continuous process verification, as described in the revised version of Annex 15 (Qualification and Validation) of the EU GMP's that comes into effect by 01 Oct 2015. The speakers in the session will cover the definitions and regulatory landscape behind this new approach; the opportunities it can provide for legacy products and the thoughts from an expert from the regulatory rapporteur on the changes that have been introduced.

Moderator: **Frank Hallinan,** *Validant Inc.*

Track B: Revision of Annex 1

EMA and PIC/S have recently started working on the revision of the GMP Annex 1, as we have heard earlier today directly from the Rapporteur on this topic. This session will provide an industry perspective. We will hear a presentation on the PDA 'Points-to-Consider' document which is being revised to gather current issues in aseptic manufacturing and proposed recommendations, hence providing useful thoughts for consideration when revising Annex 1. Following, a presenter will share his experience of dealing with current requirements on aseptic process simulation, discuss possible, anticipated changes and explore their impact. The third speaker will focus on the many challenges we face with environmental monitoring and how to possibly address them.

Moderator: **Véronique Davoust,** *Pfizer*

13:45	**Definitions and Regulatory Landscape** Stephan Roenninger, *Amgen*
14:15	**Process Validation – Opportunities for Continuous Improvement of Legacy Products** Hal Baseman, *ValSource, PDA Chair and Task Force Leader*
14:45	**Process Validation – Regulators Observations** Catherine Neary, *HPRA*
15:15	**Q&A, Discussion**
15:30	**Coffee Break & Exhibition**

13:45	**New Revision of the PDA Points to Consider in Aseptic Manufacturing** Gabriele Gori, *GSK Vaccines*
14:15	**Process Simulation** Pete Arreola, *Novartis*
14:45	**Environmental Monitoring** Jette Christensen, *Novo Nordisk*
15:15	**Q&A, Discussion**

Session 2 **Track A: Process Validation Life-Cycle Management**

ICH recently started work on a new guideline, ICH Q12, to develop harmonized technical and regulatory approaches for the management of changes during a product's lifecycle. This session will cover the typical hurdles faced during post-approval change management and the current impact on continuous improvement. It will provide the most recent update on progress made for ICH Q12, foreseen opportunities and challenges, and focus on some of the tools that might be used.

Moderator: **Ursula Busse,** *Novartis*

16:00	**Post Approval Changes – A case for Change** Anders Vinther, *Sanofi-Pasteur*
16:30	**ICH Q12 – Life-Cycle Management Concept and Benefits** Graham Cook, *Pfizer*
17:00	**Post Approval Change Management Protocols (PACMP)** Markus Goese, *Roche*
17:30	**Panel Discussion**
18:30	**End of Conference Day 1 & Networking Reception**

Track B: Revision of Annex 1

Critical utilities play an important role in the manufacturing of sterile products. Water for Injection (WFI) is the most common ingredient of sterile medicines and vaccines and Water Systems have been subject to increased attention in the recent years – due to multiple challenges which can potentially compromise water quality (e.g. Biofilms). Also, new requirements in the manufacturing and control of WFI are expected as part of the revision of the corresponding EU Pharmacopoeia monograph and/or of the EU GMP Annex 1. This session will present regulatory perspectives as well as industry, and discuss the foreseen regulatory updates on this matter. Finally, a comprehensive study and discussion of the many challenges of endotoxin detection and how to address it will complete this session.

Moderator: **Gabriele Gori,** *GSK Vaccines*

16:00	**Biofilms & Water Systems** Greg McGurk, *HPRA*
16:30	**Pharmaceutical Water Systems: Industry Perspective and Regulatory Challenges** Paolo Curtò, *DOC*
17:00	**Endotoxin Detection Challenges** Wolfgang Mutter, *Hyglos*
17:30	**Panel Discussion**

Wednesday, 24 June 2015

8:00 **PARALLEL MORNING SESSIONS: PDA INTEREST GROUPS**

Quality Systems & Regulatory Affairs

The regulatory environment is continuously evolving and companies are expected to stay compliant with new and updated regulations. How do companies ensure they stay informed about regulatory changes, and how are changes translated into updates to the Quality Management System? Through interactive discussions, participants will be able to share best practices, address challenges and explore opportunities.

Introduction: **Anette Yan Marcussen,** *Novo Nordisk*

Open Discussion:
How to ensure that your QMS is in compliance with the requirements in all the markets you are present in.

Inspection Trends

This session will be interactive. Discuss with inspectors and industry representatives the challenges they are confronted with during inspections. Current challenges in the GMP/GDP inspection environment will be covered. We will focus on expectations in domestic and foreign inspections and industry's activities towards implementing risk-based approaches and mutual recognition.

Introduction: **Stephan Roenninger,** *Amgen*

With Participation of
Andrea Julsing, *Medicines Control Council, South Africa ,*
on behalf of PIC/S and other Inspectors

PARALLEL TRACKS

Session 3 Track A: Toxicological Aspects in Manufacturing

Toxicological aspects in relation to manufacturing are always of high interest both to the manufacturing organisation and the authorities. In this session you will hear about the regulatory landscape for controlling impurities. Also you will hear a presentation about how to set toxicological limits for cleaning validation when you work in a shared facility, and finally, a risk-based approach for shared facilities will be presented.

Moderator: **Jette Christensen,** *Novo Nordisk*

9:00	**Effective Impurity Management through Effective Design and Control** Andrew Teasdale, *AstraZeneca*
9:30	**Setting Toxicological limits for Cleaning Validation (Shared Facilities)** Andreas Schreiner, *Novartis*
10:00	**Shared Facilities – Acceptance of Risk- based Approaches in Inspections** Nigel Hamilton, *Sanofi*
10:30	**Q&A, Discussion**
10:45	**Coffee Break & Exhibition**

Track B: Drug Shortage

This session will cover the deliverables of an inter-association taskforce which worked together with the EMA Inspectors Working Group and representatives of the National Competent Authorities (NCA) in 2014. The deliverables focused on an overview of communications to regulators about (potential) drug shortages, as well as a risk-based and root-cause-based prevention approach. A seminar following this conference will also allow a deeper look into the PDA TR 68 on this approach.

Moderator: **Stephan Roenninger,** *Amgen*

9:00	**EMA Update on Drug Shortage** Brendan Cuddy, *EMA ,* *Head of Manufacturing and Quality Compliance, Compliance & Inspections Department*
9:15	**Risk-based Prevention** Anders Vinther, *Sanofi-Pasteur*
9:45	**Communication on Drug Shortage** Birgitte Holst, *Novo Nordisk, on behalf of Efpia*
10:15	**Thoughts on Root-Cause-Based Prevention of Drug Shortages** Thomas Zimmer, *ISPE*
10:45	**Q&A, Discussion**

PARALLEL TRACKS

Session 4 — Track A: GDP & Qualified Person

The regulatory environment has considerably changed recently or is bound to change in the very near future with regards to Good Distribution Practices for active substances and medicinal products, as well as regarding the roles and responsibilities of the Qualified Person (GMP Annex 16). This session will present a brief overview of the new or planned requirements, and will discuss the current/anticipated challenges that industry faces with implementation. We will be provided some useful insights into how to address these challenges.

Moderator: **Véronique Davoust,** *Pfizer*

11:00	**Annex 16 – Opportunities and Challenges** Gerd Fischer, *Boehringer-Ingelheim*
11:30	**Challenges in Implementing GDP** Elisabet Sandqvist, *AstraZeneca*
12:00	**Q&A, Discussion**

Track B: Data Integrity

Data and their documentation define the quality, safety and efficacy of pharmaceutical products delivered to patients. Data integrity is therefore of crucial importance to the life science industry. In recent times, significant breaches in data integrity were uncovered through inspections, prompting regulatory action and encouraging companies to review their internal practices. This session will discuss different approaches to detect and prevent data integrity issues, both from a regulator's and industry's perspective.

Moderator: **Ursula Busse,** *Novartis*

11:00	**GMP Compliance and Data Integrity** David Churchward, *MHRA on behalf of PIC/S*
11:30	**A Holistic Approach to Strengthen Data Integrity** Peter Carbone, *Novartis*
12:00	**Q&A, Discussion**

12:30 **Lunch Break & Exhibition**

Closing Plenary: Quality Culture

Moderator: **Véronique Davoust,** *Pfizer*

13:30	**Quality Culture: An EU Regulatory Perspective**	Brendan Cuddy, *EMA ,* *Head of Manufacturing and Quality Compliance, Compliance & Inspections Department*
14:00	**Assuring Quality in a Global and Multicultural Environment**	Gerald W. Heddell, *MHRA ,* *Director, Inspection Enforcement & Standards Division*
14:30	**Quality Culture, Industry Activities**	Steve Mendivil, *Amgen* *PDA Task Force Leader*
15:00	**Panel Discussion**	All Plenary Speakers
15:50	**Closing Remarks**	Georg Roessling, *PDA Europe*
16:00	**End of the Conference & Farewell Coffee**	

Networking Dinner

INVITATION

PDA is pleased to invite you to a great evening at the LA ROSE BLANCHE in the historical heart of Brussels.

Meet with all conference attendees in this original atmosphere and network while you relax.

Location	Date	Meeting Point
LA ROSE BLANCHE Grand Place 11 1000 Brussels	Tuesday 23 June 2015	Conference Hotel Lobby Courtyard Hotel at 18:50 h Bus shuttle from Courtyard Hotel leaving at 19:00 h

We kindly ask you to confirm your attendance directly at the PDA Registration Desk.

PDA Education Program

25 June 2015
One-Day Training Course
Risk Based Approach for Prevention and Management of Drug Shortages

25 June 2015
One-Day Workshop
Effective Quality Systems
How to Ensure that Documentation and Practical Actions are Aligned

Risk Based Approach for Prevention and Management of Drug Shortages

Faculty

Stephan Rönninger, *PhD, Amgen* | **Anders Vinther,** *PhD, Sanofi Pasteur*

Participants will receive the PDA Technical Report # 68

Description

Drug shortages, especially for the supply of critical medicines, have emerged as an important global issue that impacts patients worldwide. Ensuring the uninterrupted supply of safe, efficacious products to patients requires the input of regulators, legislators, healthcare providers and industry together to develop and drive effective and implementable solutions.

To this end, PDA has developed Technical Report 68: Risk-Based Approach for Prevention and Management of Drug Shortages, which describes a risk-based triage of products (i.e., how to establish preventive controls for drug shortage risks in the end-to-end product value chain based on product criticality and patient impact) and the establishment of a Drug Shortage Risk Register and a Drug Shortage Prevention and Response Plan—a holistic framework and simple templates at a product level.

TR 68 has been reviewed by EMA, U.S. FDA and other regulatory agencies and has quickly gained acceptance as globally significant in the effort to reduce drug shortages worldwide. As a result, PDA has developed this new course based on TR 68 designed to raise awareness of the current landscape regarding drug shortages, and increase understanding of the growing Health Authority expectations around ensuring continuity of supply and management of drug shortages.

In this hands-on, interactive course, participants will learn how to apply a proactive risk-based model at a product level to identify drug shortage risks due to manufacturing and quality issues. Attendees will practice how to develop a Drug Shortage Risk Register and a Drug Shortage Prevention and Response Plan using examples and standard templates.

Course participants will explore what controls can be established in the end-to-end product value chain to address drug shortage risks in a manner that will enable them to proactively prevent drug shortages. Attendees will be challenged to think creatively and in a risk-based manner about other practical solutions that can be leveraged beyond conventional solutions, such as collaboration with health authorities to expedite post-approval changes, short-term use of an alternate facility, activating short-term supply from an alternate source to address emergency needs, and more.

To ensure implementation of learned principles, participants will be provided with a practical risk-based triage tool and templates they can use within their companies to proactively identify and manage drug shortage risks.

Who Should Attend

Personnel from Supply Chain, Logistics, Distribution/Agents, Quality, Operations, Regulatory Affairs, Governmental Affairs, Risk Management, CMO Operations, and other functions that may be involved in the management of drug shortages will benefit from taking this course.

Stephan Rönninger, *PhD, Amgen*

Stephan Rönninger provides leadership, support and representation of external activities impacting Amgen's operations functions. He works with associations in the EU, Japan and Emerging markets with focus on Russia and Turkey. He is responsible for advocacy in various external organizations and provides assessment and communication to Amgen. Stephan holds a PhD and engineering degree in organic chemistry. Currently, he represents Amgen in industry trade associations (e.g. EFPIA) and the European industry on GMP/GDP topics as well as at ICH working groups such as Quality Risk Management (ICH Q9), Quality Implementation Working Group (Q-IWG), and the GMP for APIs (ICH Q7) Implementation Working Group. In the Parenteral Drug Association (PDA), he has been elected to the board of directors, was past chair of the Regulatory Affairs and Quality Advisory Board (RAQAB), and leader of the PDA-Europe Inspections Trends Interest group. He also co-chairs several international conferences and training events (e.g. with PIC/S). He is one of the founders and co-chair of the 'Paradigm Change in Manufacturing Operations' (PCMO®) project in PDA, and has received the FDA CDER 'Leveraging & Collaboration Award', and a Certificate of Appreciation / Recognition by PIC/S and Health Canada.

Thursday, 25 June 2015	8:30 – 16:30
8:30	Welcome and Introductions
	Section 1: Current Landscape and Expectations
	Section 2a: Management Responsibilities
	Section 2b: QRM Concepts
10:30	Coffee Break
	Section 3a: The Risk Triage Model
	Section 3b: The Risk Register
	Section 4: Health Authority Interactions & Communications
12:30	Lunch Break
	Section 5: Drug Shortage Prevention and Response Plan
15:30	Coffee Break
	Section 6: Reacting to Drug Shortages
	Key Take-Aways and Wrap-up
16:30	End of Training Course

Effective Quality Systems –
How to Ensure that Documentation and Practical Actions are Aligned

Description

For pharmaceutical companies a Quality Management System (QMS) is a must. ICH Q10 has been implemented since 2008 and regulatory inspections mostly start with the description of the company`s QMS. Mergers and acquisitions, split of product portfolios,etc. cause business changes, and the impacts on the QMS are multiple.

This evolution makes the QMS more and more complex. ICH Q10 intends to promote a business process management-based approach. Some companies are advanced in this implementation, some try but are facing difficulties. We will try to understand how to handle and solve this complexity in this workshop.

First, we will get an overview of the different kinds of remarks related to the QMS companies can have during inspections. Then, we will learn how to measure the efficiency of the documentation from the end-user's point of view with an innovative quality metric called « Overall Documentary Efficiency Rate ». We will then learn more about business process management, the basis of ICH Q10.

Following a brief overview of a company from the energy sector, we will compare our level of maturity for business process management and see how far we are on the route for progress.

At the end, a roundtable discussion with inspectors and industry representatives will discuss the role of the QMS, the limits we have attained, the necessity to deeply change it to enter a world where competitiveness stays compatible with fully adhering to regulations.

Faculty

Olivier Depardieu, *OXO Pharma*
Xavier Duburcq, *Altran*
Lothar Hartmann, *Consultant*
Anette Yan Marcussen, *Novo Nordisk A/S*

Thursday, 25 June 2015 — 9:00 – 17:00

9:00	**Introduction to Pharmaceutical Quality Systems (PQS) according to ICH Q10** – Main key elements of a PQS – Inspection findings	Lothar Hartmann, *Consultant*
10:00	**How to ensure Global Compliance in the QMS** – Process for handling new external requirements – How do you ensure intelligence from all the countries, where you have marketed products? – And how do you ensure that all the global requirements are present in your QMS?	Anette Yan Marcussen, *Novo Nordisk A/S*
10:45	**Coffee Break**	
11:15	**Documentary Efficiency (Practical Approach) Let's Play a Game**	Olivier Depardieu, *OXO Pharma*
11:45	**Back to Theory: Document Efficiency** – Cost of documentation and training – How to measure the documentary efficiency – Benchmark of documentary efficiency in several cases	Olivier Depardieu, *OXO Pharma*
12:45	**Lunch Break**	
13:45	**Management Review** – A key recommendation of a PQS – Guiding the organization – Main elements of a management review – With exercise: Preparing for a management review	Lothar Hartmann, *Consultant*
15:15	**Coffee Break**	
15:45	**Methodology to implement Business Management Process** – Benchmark between energy industry and pharma industry – Maturity level grid for BPM implementation – Stakes and difficulties in BPM implementation	Olivier Depardieu, *OXO Pharma* Xavier Duburcq, *Altran*
16:30	**Round Table, Q&A, Discussion**	
17:00	**End of Workshop**	

Scientific Program Planning Committee

Véronique Davoust, *Conference Chair, Pfizer*
Ursula Busse, *Novartis*
Jette Christensen, *Novo Nordisk*
Gabriele Gori, *GSK Vaccines*
Frank Hallinan, *Validant Inc.*
Stephan Roenninger, *Amgen Europe*
Georg Roessling, *PDA Europe*

Contacts

For additional conference information please contact:

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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**
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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
Tel: +49 (30) 4365508-0
Fax: +49 (30) 4365508-66

Venue

Courtyard by Marriott Brussels
Avenue des Olympiades 6
Brussels, 1140 Belgium
Tel.: +32 2 337 0808
Fax: +32 2 337 0800
Toll Free Room Reservations: 32-0800-18-222

Special Rates
Double room for single use **€159**
Double room: **€179**
(including breakfast, WIFI, VAT and Servicecharge – Citytax apply)

Room Reservations
PDA Europe has reserved a limited number of bedrooms until the **11 May 2015.**
Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.
Book your group rate: **Parenteral Drug Association**

How to find the venue:

© Google – For directions click on the picture, scan the QR-code or go to **https://goo.gl/maps/6jFeI**

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PDA Parenteral Drug Association

2015 PDA Europe Conference, Exhibition, Training Course, Workshop

Quality & Regulations

23-24 June 2015 | Brussels | Belgium

Your Contact Person is
Antje Petzholdt at PDA Europe
petzholdt@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/QuaReg2015**
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. ☐

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(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

No PDA membership included

EARLY BIRD DISCOUNT ☐ **Book by 26 May to receive € 150 off the conference fee only**

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

Conference (23-24 June)

Participants	☐ **1895**
Govern./Health Authority/Academic	☐ **750**

One-Day Training Course (25 June)
Risk-based Prevention of Drug Shortages

All Participants	☐ **695**

One-Day Workshop (25 June)
Effective Quality Systems

All Participants	☐ **695**

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 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

☐ **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

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

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IBAN: DE73 1007 0024 0922 8735 00
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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 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. 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 pre-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 **22 May 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.

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

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
20 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:

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Am Borsigturm 60
13507 Berlin, Germany
Tel: +49 (30) 4365508-0
Fax: +49 (30) 4365508-66
Email: info-europe@pda.org

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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