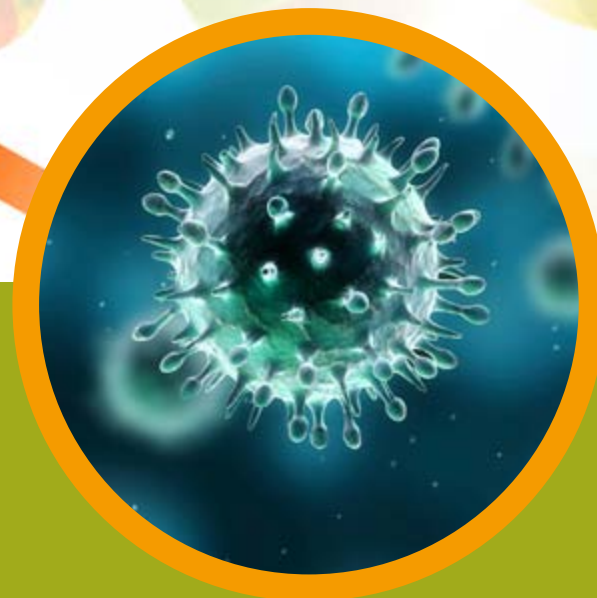




The Parenteral Drug Association presents:

2015 PDA Europe Virus & TSE Safety Forum



Bringing you the latest on Virus Testing, Clearance, and Risk Mitigation from FDA, EMA and Industry Representatives!

Forum, Exhibition 9-11 June

9-11 June 2015

Grande Hotel Real Villa Itália
Lisbon (Cascais) | Portugal

**Register by
11 May 2015
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LETTER FROM THE CO-CHAIRS

Scientific Program Planning Committee

Hannelore Willkommen, *Co-Chair*,
RBS Consulting

Kurt Brorson, *Co-Chair*, *FDA*

Johannes Blümel, *Paul Ehrlich Institute*

Dayue Chen, *Eli Lilly*

Qi Chen, *Genentech*

Houman Dehghani, *Amgen*

Albrecht Gröner, *CSL Behring*

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Michael Ruffing, *Boehringer-Ingelheim*

Sol Ruiz, *AEMPS*

Dorothy Scott, *FDA*

Glenda Silvester, *EMA*

Georg Roessling, *PDA Europe*

Welcome to the 2015 PDA Europe Virus & TSE Safety Forum. This conference was established in 2001 and, held annually since then, alternates between Europe and the U.S.

These truly global meetings are organized under the leadership of PDA in close cooperation with European regulatory agencies and the U.S. FDA. They provide an overview and updates on regulatory expectations and scientific investigations related to virus and TSE safety of biotechnology, plasma-derived and cell-derived medicinal products.

This year's conference follows the same concept.
It will

- illustrate current thinking of regulatory agencies related to the virus safety of medicinal products,
- discuss the role of new technologies for virus detection,
- explore the use of new detergents for virus inactivation especially in the biotech industry, and
- outline the progress achieved in use and development of virus retentive filters.

As in previous years, virus contamination of raw materials as well as emerging viral threats will be discussed. Appropriate risk mitigation strategies consisting of two elements: i.) Testing and processing of raw materials and ii.) Virus removal/inactivation capacity of the processes used for production of medicinal products will be taken into consideration. The last day of the conference will focus on TSE and how much vCJD or BSE currently pose a threat to the safety of medicinal products.

The PDA Europe Virus & TSE Safety Forum always provides attendees a unique opportunity for interactive discussion and benchmarking. Exchange of information between industry and regulators will improve the understanding and acceptance of new techniques, highlight new and emerging risks and explain new regulatory approaches.

Please join us and contribute to this discussion by sharing your experiences and opinions.

You are warmly invited to Lisbon/Portugal next June!



Hannelore Willkommen, *PhD, President, Regulatory Affairs & Biological Safety Consulting*
Conference Co-Chair



Kurt Brorson, *PhD, Senior Investigator, FDA/CDER*
Conference Co-Chair

Tuesday, 9 June 2015

9:00 Welcome & Introduction

Georg Roessling, *PDA Europe*
Hannelore Willkommen, *Co-Chair, RBS Consulting*
Kurt Brorson, *Co-Chair, FDA*

Session 1: Regulatory Update

Moderators: **Glenda Silvester, EMA**
Dorothy Scott, FDA

Virus safety of biopharmaceuticals is an important quality attribute. EMA and FDA will provide updates on their current activities in this field. Experience from the evaluation of clinical trial applications in the EU will be highlighted. The challenges and gaps in assuring viral safety of Ebola convalescent plasma from Western Africa will be presented.

9:15 EMA Update on Plasma-Derived and Urine-Derived Medicinal Products: Workshops on Hepatitis E Virus and Viral Marker Epidemiology, Guideline Urine-Derived Products

Johannes Blümel, *PEI*
Glenda Silvester, *EMA*

9:45 Update FDA

Kurt Brorson, *FDA*

10:15 Update FDA: Plasma Collection in West Africa

Dorothy Scott, *FDA*

10:45 Update on Clinical Trials

Johannes Blümel, *PEI*

11:00 Panel Discussion with Regulators

11:45 Lunch Break, Poster Session & Exhibition

Session 2: Emerging Viruses

Moderator: **Thomas Kreil, Baxter**

The virus safety margins of biological medicinal products have seen significant improvements over time, with contributions from the selection of healthy plasma donors or production cell lines and raw materials, the testing of materials utilized in production, and - most effectively - the introduction of dedicated virus reduction, i.e. removal and inactivation, steps into the manufacturing processes. The result of these interventions, i.e. the safety tripod, are evaluated by risk assessments that compare the potential virus load, as determined by selection and testing strategies, to the virus reduction capacity of the manufacturing process, as determined by studies with a select number of model viruses. Emerging viruses can, however, challenge the basic assumption of such risk assessments. For example, the degree to which an emerging virus is reduced by virus inactivation and removal steps may be unclear based on existing virus reductions studies, and may require verification. Furthermore, a newly developed test technology may reveal the presence of viruses, where absence had been assumed based on limitations of earlier used test systems. Examples of these challenges, and potential mitigation strategies, will be discussed.

12:45 NGS Investigations for Novel Viruses in Insect Cell Substrates

Arifa Khan, *FDA*

13:15 Novel Horse Hepaciviruses: Epidemiological, Clinical and Zoonotic Features

Eike Steinmann, *Twincore*

13:45 Capacity of Plasma-Derived Manufacturing Processes for Inactivation and Removal of HEV: In-vivo Infectivity Studies using a Porcine Model and Partitioning Studies using a Highly Relevant HEV Spike

Nathan Roth, *CSL Behring*

14:15 Q & A, Discussion

14:30 Coffee Break, Poster Session & Exhibition

Session 3: Safety of Starting & Raw Materials

Moderator: **Albrecht Groener**, *Pathoguard*

Virus safety of starting and raw materials of biologicals is of utmost importance in order to prepare virus safe finished products, as the virus inactivation/removal capacity of the manufacturing process has to clearly exceed the potential amount of virus that could enter the production process via starting and raw materials. Different approaches in the detection and the prevention of virus contamination of starting materials will be presented.

15:00	A Case Study of Using Human Cells for Biologic Production: Cell Substrates, Testing, Viral Clearance and Beyond	Dayue Chen, <i>Eli Lilly</i>
15:30	Virus Safety Concepts for Products Derived from Convalescent Plasma	Thomas Kreil, <i>Baxter</i>
16:00	An in-vitro Assay for Detection of Adventitious Viruses of Ovine and Caprine Origin in Raw Materials for the Production of Biopharmaceuticals for Use in Humans	Reginald Clayton, <i>BioReliance</i>
16:30	Coffee Break, Poster Session & Exhibition	
17:00	Identification of a Suitable Positive Control for the Sp2/0 Cells in the Adventitious Virus Assay	Laurence Steegstra-Trannoy, <i>Janssen Biologics</i>
17:30	Evaluation of Growth Properties of Different Strains of MVM in two Different Indicator Cell Test Systems	Houman Dehghani, <i>Amgen</i>
18:00	Panel Discussion	
18:30	End of Day 1 & Networking Event kindly supported by our Diamond Sponsor BioReliance	

Wednesday, 10 June 2015

Session 4: Virus Testing: Risk Mitigation Part I

Moderator: **Qi Chen**, *Genentech*

Since the discovery of circovirus contamination in commercial rotavirus vaccines using next generation sequencing (NGS), this powerful new technology has been considered to evaluate viral safety of biotech products. In this session, an overview of application of this technology as well as case studies will be discussed.

8:30	Current Efforts and Challenges for Using NGS for Adventitious Virus Detection	Arifa Khan, <i>FDA</i>
9:00	NGS-Comparative Study Results	Jens Modrof, <i>Baxter</i>
9:30	Approaches to Improving Product Quality and Safety using NGS	Donna McMutrie, <i>BioReliance</i>
10:00	Q & A, Discussion	
10:15	Coffee Break, Poster Session & Exhibition	

Session 5: Virus Clearance: Risk Mitigation Part II

Moderator: **Dayue Chen**, *Eli Lilly*

The presentations in this session focus on data sharing, practice benchmarking, and out-of-box thinking. The session starts with a comprehensive data set on medium treatment using various technologies to mitigate the potential risk of viral contamination events. The updated version of FDA internal database on viral clearance will be shared, which includes the information from the latest submissions. Finally, intriguing thoughts on log reduction factors (LRF), the standard measurement for the effectiveness of viral clearance, will be presented.

10:45	A Survey of Industry Data on HTST, UV-C and Nanofiltration for Media Treatment and their Efficacy of Removal and Inactivation of Virus	Paul Barone, <i>MIT CAACB</i>
11:15	An Update of the FDA Viral Clearance Database to include Regulatory Submission until 2014	Scott Lute, <i>FDA</i>
11:45	Effective Viral Clearance – a Question of the Reduction Factor?	Horst Ruppach, <i>Charles River</i>
12:15	Q & A, Discussion	
12:45	Lunch Break, Poster Session & Exhibition	

Session 6: Virus Clearance: Inactivation

Moderator: **Kurt Brorson**, *FDA, Co-Chair*

Virus inactivation is a key safety measure for both biotech and plasma derived products. The technology behind this imperative has evolved over the past few years as expectations to use newer and more eco-friendly detergents have arisen. The session will also discuss strategies to minimize virus carry-over in multi-use columns, another application where more robust virus inactivation can lead to a better product safety profile.

13:45	Virus Inactivation by Eco-friendly Detergent	Qi Chen, <i>Genentech</i>
14:15	Evaluation of Virucidal Detergents using a Novel High-Throughput Cell-based Assay Approach	Martina Kopp, <i>Amgen</i>
14:45	Chromatography: Virus Carry-Over and Lifetime Studies	Albrecht Groener, <i>Pathoguard</i>
15:15	Q & A, Discussion	
15:45	Coffee Break, Poster Session & Exhibition	

Session 7: Virus Clearance: Filtration

Moderator: **Hannelore Willkommen**, *Co-Chair*

Virus filters contribute substantially to the virus safety of medicinal products. It is therefore important to understand factors that may affect filter performance. Optimization of virus filtration processes, structure analysis of virus retentive filters, limitation of current filters for retention of small size viruses, effect of flow interruption, comparison of the performance of second generation filter brands and other topics related to the value and the reliability of filters for virus retention will be discussed in this session.

16:15	Optimization of Virus Filtration Studies and Process Parameters	Thomas Kreil, <i>Baxter</i>
16:45	Structure Analysis of Virus Filters via Gold Nanoparticles and liquid-liquid Displacement Porometry	Peter Kosiol, <i>Sartorius-Stedim</i>
17:05	An Evaluation of the Removal of PCV by the Asahi Planova 15Nm 20N, BioEX and Custom-made Filters with a Pore Size of 12.5 nm and 10 nm	Andrew Bailey, <i>Virusure</i>

17:25	Optimization of the Virus Removal Filtration Processes	Tomoko Hongo-Hirasaki, <i>Asahi Kasei</i>
17:45	Effect of Processing Parameters on Parvovirus Retention by Membranes after Flow Interruption	Anne Leahy, <i>EMD Millipore</i>
18:05	High Capacity Virus Filtration	Rachel Specht, <i>Genentech</i>
18:35	Q & A, Discussion	
19:00	End of Day 2	

Thursday, 11 June 2015

Session 8: TSE Risk and Risk Mitigation

Moderator: **Dorothy Scott, FDA**

Existing and emerging TSE's still present potential concerns for safety of biological products. This session provides an update on human and animal TSE epidemiology worldwide, and recent findings related to pathogenesis and dissemination of infectivity in the host. Safety measures to prevent TSE contamination of products will be presented – including current developments in blood testing, TSE clearance studies for a bovine-sourced product, and facility decontamination methods.

9:00	Introduction, Update on US vCJD Donor Deferrals	Dorothy Scott, <i>Principal Investigator Laboratory of Plasma Derivatives CBER/FDA</i>
9:15	Case Study of TSE Clearance in Bovine Heparin Production & Risk of Bovine Materials	Luisa Gregori, <i>Principal Investigator Laboratory of Bacterial and TSE Agents CBER/FDA</i>
9:45	Update on vCJD Epidemiology	Robert Will, <i>National CJD Surveillance Unit and University of Edinburgh</i>
10:15	Update on Blood Testing	Graham Jackson, <i>MRC Prion Unit Department of Neurodegenerative Diseases, UCL Institute of Neurology</i>
10:45	Coffee Break, Poster Session & Exhibition	
11:15	Cell Susceptibility	Peter Kloehn, <i>Program Leader, MRC Prion Unit University College London</i>
11:45	Inactivation of Equipment	Albrecht Groener, <i>Pathoguard</i>
12:15	Q & A, Discussion	
12:45	Farewell Remarks & End of Conference	
13:00	Please join us for a PDA Luncheon	

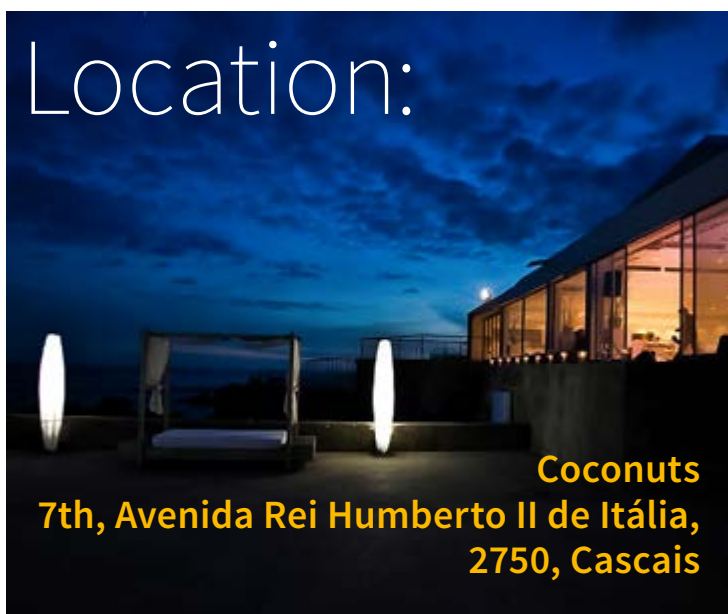


Date:
9 June
2015

Begin:
19.30h

PDA is pleased to invite you to a great evening at **Coconuts** alongside **Cascais Marina**, overlooking the sea and with the **Santa Marta Lighthouse** as a sentinel.

Location:



Coconuts
7th, Avenida Rei Humberto II de Itália,
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Besides the magnificent view and the over the sea outdoor lounge, please join us for a typical atmosphere with barbecue and Fado singers.

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

RSVP REQUIRED, FURTHER INFORMATION UPON CONFERENCE REGISTRATION.

The Networking Event is kindly supported by our Diamond Sponsor BioReliance



Scientific Program Planning Committee

Hannelore Willkommen, *Co-Chair of Conference, RBS Consulting*

Kurt Brorson, *Co-Chair of Conference, FDA*

Johannes Blümel, *Paul Ehrlich Institute*

Dayue Chen, *Eli Lilly*

Qi Chen, *Genentech*

Houman Dehghani, *Amgen*

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Thomas Kreil, *Baxter*

Michael Ruffing, *Boehringer-Ingelheim*

Sol Ruiz, *AEMPS*

Dorothy Scott, *FDA*

Glenda Silvester, *EMA*

Georg Roessling, *PDA Europe*

Contacts

Antje Petzholdt Membership Management petzholdt@pda.org	Membership Management
	Interest Groups
	General Event Information
Sylvia Becker Manager Programs & Events becker@pda.org	Call for Papers
	Speaker Management
	Conference Agenda
Creixell Espilla-Gilart Manager Exhibition & Sponsorship espilla@pda.org	Exhibitor Management
	Sponsorship 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
Adalbertstr. 9
16548 Glienicke/ Berlin, Germany
Tel: +49 (0) 33056 - 23 77 10
Fax: +49 (0) 33056 - 23 77 77



Please note our new address as of 18 May 2015

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin

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

Venue

Grande Hotel Real Villa Itália

Rua Frei Nicolau de Oliveira, 100
2750-319 Cascais-Portugal
T_ (+351)210 966 000
F_ (+351) 210 966 001
E_ realvillaitalia@hoteisreal.com
www.granderealvillaitalia.realhotelsgroup.com/en

Room Reservations

Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

The Hotel is located approximately 30 minutes from Lisbon in Cascais

How to find the venue:



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- 1 **ONLINE:** europe.pda.org/Virus2015
- 2 **FAX:** +49 33056 23 77 77
- 3 **EMAIL:** petzholdt@pda.org
- 4 **MAIL:** PDA Europe, Adalbertstr. 9, 16548 Glienicke/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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<input type="checkbox"/> 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

No PDA membership included

EARLY BIRD DISCOUNT ☐ Book by 11 May to receive
€ 150 off the conference fee only

All fees given in Euro and excluding VAT (23 %) net

Forum(9-11 June)

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☐ 1000

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.

☐ **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

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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.

☐ By Bank Transfer

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☐ 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

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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	8 th 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 28 April 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.
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**For general information
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PDA Europe, Adalbertstr. 9
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Tel: +49 (0) 33056 - 23 77 10
Fax: +49 (0) 33056 - 23 77 77
Email: info-europe@pda.org

**For exhibition information
please contact:**

Creixell Espilla-Gilart
Exhibition & Sponsorship Manager
PDA Europe
Tel: +49 (0) 33056 - 23 77 14
Email: espilla@pda.org

Please note our new address as of 18 May 2015

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin

Tel: +49 (30) 4365508-0

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