LETTER FROM THE CO-CHAIRS

Dear Colleagues,

The Program Planning Committee and an impressive panel of selected speakers warmly invite you to Dubrovnik / Croatia! We are pleased and grateful to once again come together for the 2017 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, plasmaderived and cell-derived medicinal products.

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.

This 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.

Panel Discussions, luncheons, dinners and a networking event will hopefully complete this impressive program and make it into a worthwhile and well-rounded learning experience for you!

We warmly invite you to join us in Dubrovnik, a World Heritage Site on the Adriatic Sea, rich in history and culture.

Johannes Blümel, PhD, Paul-Ehrlich-Institut, Chair

Thomas R. Kreil, PhD, Shire, Co-Chair
**Welcome to Dubrovnik**

**SCHEDULE AT A GLANCE**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>29 May</td>
<td>9:00 – 17:00</td>
<td><strong>The Principles of Viral Safety for Biologics and Vaccines</strong></td>
<td>Pre-Conference Workshop</td>
</tr>
<tr>
<td>30 May</td>
<td>9:00 – 18:30</td>
<td><strong>Virus &amp; TSE Safety Forum</strong></td>
<td>Conference, Exhibition</td>
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<tr>
<td>31 May</td>
<td>7:30 – 17:00</td>
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<tr>
<td>1 June</td>
<td>9:00 – 13:30</td>
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For latest information, please visit: [pda.org/eu-virus2017](http://pda.org/eu-virus2017)
The Principles of Viral Safety for Biologics and Vaccines

This workshop will provide an overview of two important viral safety barriers – testing and viral clearance approaches. Typically applied testing methods, the benefits and downsides, and some product type specific testing strategies will be presented briefly. The frequently discussed NGS technology and its use in this field will be explained in a simple way. With this background specific applications and testing strategies for critical raw materials, ATMPs, and even medical devices using animal/human derived components will be discussed.

In the second part, important aspects of viral clearance studies like pre-testing, virus assays, viral loads, etc., will be presented and critically reviewed. An overview of the viral removal or inactivation capacity of typically applied process steps will also be given and discussed using case studies. The workshop will consider current best practice including the current regulatory requirements.

It is the intention of the workshop to introduce typical testing strategies and typical viral clearance approaches. The workshop will give much room for discussions and participants are invited to ask questions related to their specific products, their viral safety strategies, or any specific technical or regulatory challenges they have. The speaker panel combines long term regulatory experience, industry experience and contract testing laboratory experience, all to ensure maximal outcome for attendees.

Panel Discussion

Virus Safety Requirements of Raw Materials is one of the topics discussed controversially. PDA aims to collect feedback here and approach the European Medicines Agency to include these in a Q&A of the respective Guidelines.

If you have questions, feedback or topics you would like to see addressed, please e-mail them to programs-europe@pda.org
### Monday, 29 May 2017

#### Welcome and Introduction
9:00  Welcome and Introduction
Georg Roessling, PDA Europe
Horst Ruppach, Charles River, Workshop Chair

#### Plenary 1: Virus Safety Testing

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>9:15</td>
<td>Standard/Compendial Methods</td>
<td>Michael Ruffing, Boehringer Ingelheim</td>
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<td>9:45</td>
<td>Next Generation Sequencing (NGS)</td>
<td>Martin Wisher, BioReliance</td>
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<td>10:15</td>
<td>Coffee Break</td>
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<tr>
<td>11:15</td>
<td>Q&amp;A, Discussion</td>
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<td>12:00</td>
<td>Lunch Break</td>
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#### Plenary 2: Viral Clearance

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<tr>
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<tbody>
<tr>
<td>13:00</td>
<td>Regulatory Background: ICH, FDA, EMA Regulations and their Applicability to Different Products including ATMPs</td>
<td>Johannes Blümel, Paul-Ehrlich-Institut</td>
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<tr>
<td>13:30</td>
<td>Practical Aspects of Viral Clearance Studies: Viral Quantification Assays, Pre-testing, Virus Spike</td>
<td>Johanna Kindermann, Shire</td>
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<td>14:00</td>
<td>The Effectiveness of Typically Applied Process Steps: Chromatography, Virus Retentive Filtration, Inactivation by low pH, Solvent/Detergent, Gamma Irradiation, etc.</td>
<td>Johannes Blümel, Paul-Ehrlich-Institut</td>
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<tr>
<td>14:30</td>
<td>Coffee Break</td>
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<tr>
<td>15:00</td>
<td>Case Study: Viral Clearance Studies for Cell Line Derived Recombinant Products, Raw Materials, ATMPs, Medical Devices</td>
<td>Horst Ruppach, Charles River</td>
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<td>15:30</td>
<td>Panel Discussion &amp; Day’s Conclusion</td>
<td>Panelists: All Speakers, US FDA, Volunteer Attendees</td>
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<tr>
<td>17:00</td>
<td>End of Pre-Conference Workshop</td>
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## Tuesday, 30 May 2017

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<thead>
<tr>
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<tr>
<td>9:00</td>
<td>Welcome and Introduction</td>
<td>Georg Roessling, PDA Europe&lt;br&gt;Johannes Blümel, Co-Chair, Paul-Ehrlich-Institut&lt;br&gt;Thomas R. Kreil, Co-Chair, Shire</td>
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<tr>
<td>9:00</td>
<td>Session 1: Regulatory Developments</td>
<td>Moderator: Houman Dehghani, Amgen</td>
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<td>9:10</td>
<td>Update on European Regulations</td>
<td>Johannes Blümel, Paul-Ehrlich-Institut</td>
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<td>9:40</td>
<td>Convalescent Plasma for Immune Globulins – Viral Safety Issues</td>
<td>Dorothy Scott, US FDA</td>
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<td>10:10</td>
<td>Validation of Virus Reduction at Continuous Processing</td>
<td>Scott Lute, US FDA</td>
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<td>10:40</td>
<td>Panel Discussion</td>
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<td>11:00</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
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<td>11:30</td>
<td>Session 2: Hepatitis E Virus</td>
<td>Moderator: Thomas R. Kreil, Shire</td>
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<td>11:30</td>
<td>Non-enveloped Viruses with a Lipid Envelope: Presence in Plasma and ‘Model’ Virus Preparation for Virus Reduction Studies</td>
<td>Maria Farcet, Shire</td>
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<td>12:00</td>
<td>Hepatitis E Virus Stability Determination in Food – Achievements and Challenges</td>
<td>Reimar Johne, Federal Institute for Risk Assessment</td>
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<td>12:30</td>
<td>Development of a Relevant Model Virus System, Cutthroat Trout Virus, for Hepatitis E Virus Clearance Studies</td>
<td>Nathan Roth, CSL Behring</td>
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<td>13:00</td>
<td>Q &amp; A, Discussion</td>
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### Session 3: Viral Risk Mitigation Strategies

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<tr>
<td>13:30</td>
<td>Moderator: Albrecht Gröner, PathoGuard</td>
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Virus contaminations of biotechnology products derived from carefully tested and selected cell banks may arise from virus contaminated raw materials as cell culture media and by cross contamination of products. Risk mitigation strategies such as appropriate segregation of product intermediates within and between batches and inactivation / removal of adventitious viruses in raw materials will be presented.

The circulation of hepatitis E virus (HEV) as food-borne pathogen has only recently been recognized in industrialized countries. Infections remain mostly asymptomatic, as evidenced by high seroprevalence rates but low numbers of clinical case reports. HEV has, however, also been transmitted by transfusion of labile blood products, and has occasionally been detected in plasma pools for fractionation. It has thus been considered necessary to verify the safety margins of plasma products with respect to HEV, as primarily afforded by virus reduction steps embedded into their manufacturing processes.
14:30  **Industry Approaches to Facility Segregation for Viral Safety**
Paul W. Barone, Massachusetts Institute of Technology, Consortium on Adventitious Agent Contamination in Biomanufacturing (CAACB)

15:00  **New Quantitative, Risk-based Approach to Appropriate Viral Segregation Measures**
Kavita Ramalingam Iyer, Merck Sharp & Dohme

15:30  **Retrospective Evaluation on the Necessity of End of Use Resin Viral Clearance Studies - A Multiple Company Collaboration**
Konstantin Zöller, Novartis Pharma, BioPhorum Development Group Viral Clearance Working Team

16:00  **Mitigation of Risk of Viral Contamination of Media using Upstream Barrier Methods**
Kathryn Martin Remington, BioReliance

16:20  **Coffee Break, Poster Session & Exhibition**

17:00  **Minute Virus of Mice - Non-susceptible CHO Cell Line**
Kevin Kayser, Merck KGaA

17:20  **Defend Your Bioreactor: Using Nanofiltration to Prevent Virus Contamination of Cell Culture Processes**
Christina Carbrello, Merck Group

17:40  **Virus Risk Mitigation in Cell Culture Media – New Solutions**
Anika Manzke, Sartorius Stedim Biotech

18:00  **Q & A, Discussion**

18:30  **End of Day 1**

19:00  **Networking Reception**

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**Wednesday, 31 May 2017**

**MORNING SESSION**

**Interest Group Meeting: Advanced Virus Detection Technologies**  - OPEN TO ALL -  Moderators: Arifa Khan, US FDA  Jean-Pol Cassart, GSK

The Advanced Virus Detection Technologies Interest Group (AVDTIG) is comprised of experts representing industry, academia, government agencies and regulators who discuss the current thinking and planned efforts regarding application of new technologies for virus detection in biologics. The group’s current focus is on next generation sequencing. The session will include brief presentations on the IG history, ongoing activities, and achievements followed by audience participation for Q & A and discussions on additional topics on advanced virus detection technologies for consideration by the IG.

7:30  **Update on IG Activities**
**Open Forum and Discussion, Q&A**

8:45  **Welcome Coffee**
### Session 4: Methods for Virus Detection

**Moderator: Arifa Khan, US FDA**

The “traditional” assays have generally been effective for demonstrating absence of adventitious viruses; however, they may not be sufficiently broad to detect viruses that are distant to known viruses or novel viruses. Virus detection by the routinely used cell culture and molecular methods, and the advanced next generation sequencing technologies will be presented.

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<tr>
<td>9:00</td>
<td>Update on NGS Efforts for Virus Detection</td>
<td>Arifa Khan, US FDA</td>
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<tr>
<td>9:30</td>
<td>Performance of Transcriptomic Analysis by NGS for the Detection of Viral Infection in Cells</td>
<td>Marc Eloit, PathoQuest</td>
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<tr>
<td>10:00</td>
<td>Detection of Different MMV Strains by Cell Culture and PCR Assays, and MMV Permissiveness of Cell Lines used in Biotechnology: How much do we really know?</td>
<td>Thomas R. Kreil, Shire</td>
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<tr>
<td>10:30</td>
<td>Comparing Classical vs New Assays</td>
<td>Siemon Ng, Sanofi</td>
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<td>11:00</td>
<td>Q &amp; A, Discussion</td>
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### Session 5: Virus Filtration

**Moderator: Martin Wisher, BioReliance**

The use of virus filtration in the processing of biological products is considered a robust and well accepted component of a virus clearance strategy. This session will provide new data on a number of topics related to the use of this technology including virus retention mechanisms, effects on virus reduction factors of different model paroviruses, effects of process fluid properties, processing parameters and depressurization/re-pressurization, development of a new nano-cellulose based membrane, and the application of QbD to virus removal by filtration.

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<tbody>
<tr>
<td>13:00</td>
<td>Differential Retention of Animal Parvoviruses during Virus Filtration</td>
<td>Thomas Nowak, CSL Behring</td>
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<tr>
<td>13:20</td>
<td>Retention Mechanisms in Virus Filtration: Membrane Contribution by Size Exclusion and Interactions Between Membrane, Viruses and Solutes under Varied Buffer Conditions</td>
<td>Björn Hansmann, Sartorius Stedim Biotech</td>
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<tr>
<td>13:40</td>
<td>Understanding Virus Filtration and Designing Viral Clearance Studies to Accurately Assess Parvovirus Removal Capability</td>
<td>Daniel Strauss, Asahi Kasei</td>
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<td>14:00</td>
<td>Demonstration of Effective Control of Viral Filtration Unit Operation to Adequately Address the Safety Concern Raised by Health Authorities</td>
<td>Dayue Chen, Eli Lilly</td>
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<tr>
<td>14:30</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
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<td>15:00</td>
<td>Multiple, Deliberate Interruptions of a Virus Removal Filtration Process – Impact on Virus Retention and Throughput</td>
<td>Konstantin Zöller, Novartis Pharma</td>
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<tr>
<td>15:20</td>
<td>Nano-cellulose-based Small-size Virus Retentive Filters</td>
<td>Albert Mihranyan, Uppsala University</td>
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CONFERENCE AGENDA

Thursday, 1 June 2017

Session 6: Virus Clearance

Moderator: Qi Chen, Genentech

Triton X-100 is a widely used detergent for enveloped virus inactivation. Due to environmental concerns of Triton X-100 degradation product, its use in the EU might be restricted through REACh. In this session, the current status and potential impact of the REACh authorization for Triton X-10 on biologics manufacturing in EU, as well as virus inactivation data from eco-friendly detergents will be discussed. Another hot topic in biologics manufacturing is continuous processing. Application of low pH virus inactivation and virus filtration in continuous processing will be presented.

9:00 Advocacy Efforts in Response to Anticipated REACh Regulation on Triton X-100
Marie Murphy, Eli Lilly

9:30 An Alternative “Eco-Friendly” Detergent to Triton X-100
Lenore Norling, Genentech

10:00 Continuous Viral Clearance for the Production of mAbs
Laura Holtmann, INVITE

10:30 Q & A, Discussion

11:00 Coffee Break, Poster Session & Exhibition

Session 7: TSE Safety

Moderator: Dorothy Scott, US FDA

Existing and emerging TSEs still present potential risks to safety of biological products. This session provides an update on human and animal TSE surveillance, including information about atypical BSE. Measures that reduce TSE risk in manufacturing include safe sourcing of raw materials, and use of decontamination methods that are effective against TSE agents. Methods for inactivation of prions exist but are often harsh and not always suitable for laboratory or manufacturing environments. A new chemical method to inactivate prions, as measured by RT-QuIC will be presented and discussed.

11:30 Surveillance (human) Including Appendix Studies, and Confirmed MV Case
Robert Will, University of Edinburgh

12:00 Inactivation of Prions with Hypochlorous Acid (RT-QuIC)
Byron Caughey, NIH

12:30 The Current Risk of Atypical BSE
Torsten Seuberlich, University of Bern

13:00 Q & A, Closing Panel Discussion

13:30 End of Conference, Farewell Lunch
Join us and your colleagues to enjoy drinks and conversation in a relaxing atmosphere.
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.

A basic exhibition package for this event is priced **1.895 Euro net (table-top)**. Sponsorship Packages are available, for more information please contact expo-europe@pda.org
INFORMATION

VENUE
Sheraton Dubrovnik Riviera Hotel
Šetalište Dr. Franje Tudmana 17
Srebreno
Mlini, 20207
Dubrovnik, Croatia
Tel: +385 20 601 500
www.sheratondubrovnikriviera.com

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

DIRECTIONS

© Google  For directions click on the picture, scan the QR-code or go to https://goo.gl/maps/beSC8pHNKcX

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Fax: +49 30 4365508-66

CONFERENCE REGISTRATION HOURS
Monday, 29 May: 7:30 - 10:00
Tuesday, 30 May: 7:30 - 10:00

SPECIAL REQUIREMENTS

If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration-europe@pda.org.

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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.
Virus & TSE Safety Forum
30 May – 1 June 2017 | Dubrovnik | Croatia

3 WAYS TO REGISTER

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.

2 Registration

All fees given in Euro and excluding VAT (25 %)

Conference (30 May–1 June)

PDA Member [ ] 1795
Nonmember ** [ ] 2095
Gover./Health Authority/Academic ** [ ]

*Early Bird 800 € [ ] 900

Poster Presenter please mark here (written approval required, conference fee applies)

Pre-Conference Workshop (29 May)
The Principles of Viral Safety for Biologics and Vaccines

All Participants [ ] 795

**Registration fee includes a one-year PDA membership if no further special discount is granted. If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies).

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. 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 us at registration-europe@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 955 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 30 4365508-66) or register online.

[ ] By Bank Transfer

Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDEBBBER
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 registration-europe@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)

Costs 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. A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. 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 € 200 excl. VAT per name change. REFUNDS: Refund requests must be sent to PDA Europe. If your written request is received on or before 2 April 2017, 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 works 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 registration-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.
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