

**Tuesday, 24 September 2019**

9:00

**Welcome and Introduction**

Falk Klar, *PDA Europe*

Kerstin Wilken, *PDA Europe*

John Shabushnig,  
*Insight Pharma Consulting, Chair*  
Particles in Injectables

Yves Mayeresse,  
*GSK Vaccines, Chair, Pharmaceutical*  
Freeze Drying Technology

John Ayres,  
*Pharma Safety Solutions, Chair*  
Particles in Injectables

Julian Gitter,  
*University of Munich, Chair, Pharmaceutical*  
Freeze Drying Technology

9:20

**KEYNOTE – Practical Approaches to Patient Safety**

Michael Sasse,  
*Medical School Hannover*

**Joint Opening Plenary: Regulatory Updates**

Moderators: **John Ayres**, *Pharma Safety Solutions*  
**Julian Gitter**, *University of Munich*

9:50

**An Update on USP & the Eur. Pharmacopoeia**

Hanns-Christian Mahler, *LONZA*

John Shabushnig,  
*Insight Pharma Consulting*

10:20

**Regulatory Considerations for Particulate Control in Injectable Products**

Stephen Langille, *ValSource*

10:50

**Q&A, Discussion**

11:15

**Coffee Break, Poster Session & Exhibition**

**TRANSITION TO PARALLEL TRACKS**

**PARTICLES IN INJECTABLES**

**PHARMACEUTICAL FREEZE DRYING TECHNOLOGY**

Session 1:

**In-line Filter Systems**

**Evolution in Lyo-Technologies**

Moderator: Volker Luibl, *PALL*

Moderator: Raf De Dier, *Janssen J&J*

11:45

**In-line Filters, a Way to Limit Particles Exposition to Patients?**

**Aseptic Spray Freeze Drying - Modelling, Application & Scale Up**

Stephanie Genay, *University of Lille*

Bernhard Luy, *Meridion Technologies*

12:15

**In-line Filtration Reduces Postoperative Phlebitis - An Analysis on Effectiveness, Costs and Patients Perspective**

**Controlled vs Spontaneous Nucleation – Comparison of Drying Behavior, Residual Moisture and Cake Appearance**

Gianluca Villa, *Università degli Studi di Firenze*

Benjamin Ledermann, *GEA Lyophil*

12:45

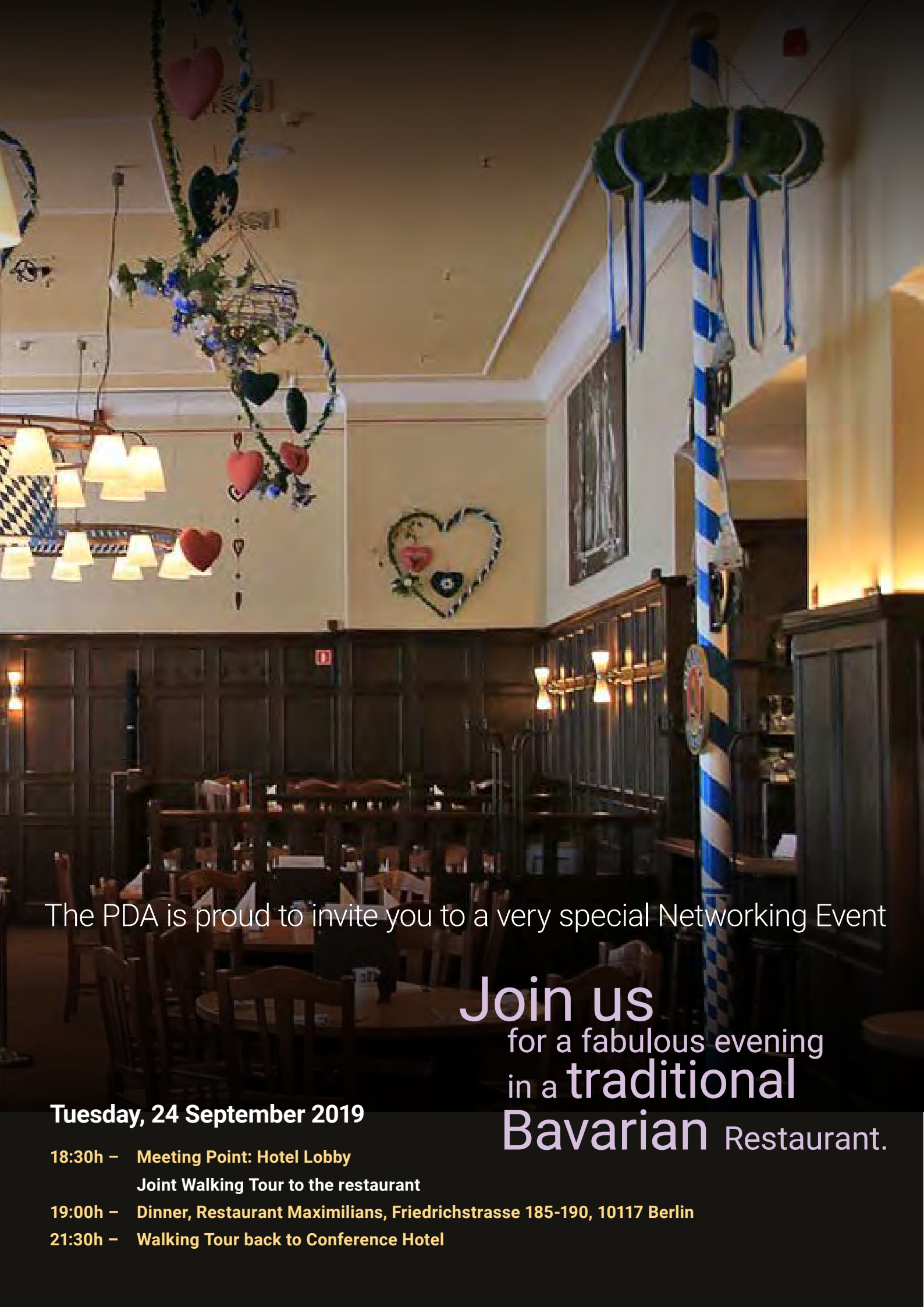
**Q&A, Discussion**

**Q&A, Discussion**

13:15

**Lunch Break, Poster Session & Exhibition**

<b>Session 2:</b>	<b>ATMP &amp; Cell and Gene Therapies</b>  Moderator: Steve Langille, <i>ValSource</i>	<b>Lyo-Considerations: Glass and its Implications on the Freeze Drying Process</b>  Moderator: Anthony Cannon, <i>Merck KGaA</i>
<b>14:15</b>	<b>Addressing the Challenges of Particulates in Cell Therapies</b>  <i>Speaker invited</i>	<b>Applying Innovations in Packaging to Increase Drug Product Quality by Addressing the Root Cause of Issues Associated with Conventional Glass Containers</b>  Carol Flynn, <i>Corning</i>
<b>14:45</b>	<b>Flow Imaging with Rapid Classification of Particles Using Machine Learning for Characterization of Cell Therapies</b>  Amber Fradkin, <i>KBI Biopharma</i>	<b>Investigating Vial Breakage Due to Lyophilization</b>  Raf De Dier, <i>Janssen J&amp;J</i>
<b>15:15</b>	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>
<b>15:45</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>	
<b>Session 3:</b>	<b>Particles Derived from Container Closure Systems</b>  Moderator: John Shabushnig, <i>Insight Pharma Consulting</i>	<b>Changing the Focus: Inspection of Lyophilized Products and Digitalization</b>  Moderator: Yves Mayeresse, <i>GSK Vaccines</i>
<b>16:15</b>	<b>PDA Task Force for Zero Defects for Visible Particles in Injectables</b>  Tia Bush, <i>Amgen</i>	<b>NIR Modelling for Residual Moisture Determination</b>  Matthieu Clauvaud, <i>F. Hoffmann-La Roche</i>
<b>16:40</b>	<b>A Case Study for Mitigation of Visual Particulate in Glass Ready-to-Use Vials</b>  Anthony Vico, <i>Stevanato Group</i> Elizabeth Jane Pavlik, <i>MSD</i>	<b>Workflow of Deep Learning in a Pharmaceutical Environment</b>  Christian Kolic & Patrick Hess, <i>Seidenader</i>
<b>17:05</b>	<b>Method for Quantifying Loose Particles on Elastomeric Components</b>  John Rech, <i>WEST</i> Ravi Patel, <i>WEST</i>	<b>Towards Digitalization of Pharma Industry: Advanced Design of Experiments Approaches to Generate Highly Informative Data for Lyophilization Process Development</b>  Emanuele Tomba, <i>GSK Vaccines</i>
<b>17:30</b>	<b>Q&amp;A, Discussion</b>	<b>Q&amp;A, Discussion</b>
<b>18:00</b>	<b>End of Conference Day 1 &amp; Networking Event</b>	



The PDA is proud to invite you to a very special Networking Event

Join us  
for a fabulous evening  
in a traditional  
**Bavarian** Restaurant.

**Tuesday, 24 September 2019**

**18:30h – Meeting Point: Hotel Lobby**

**Joint Walking Tour to the restaurant**

**19:00h – Dinner, Restaurant Maximilians, Friedrichstrasse 185-190, 10117 Berlin**

**21:30h – Walking Tour back to Conference Hotel**

**Wednesday, 25 September 2019**

	<b>PARTICLES IN INJECTABLES</b>	<b>PHARMACEUTICAL FREEZE DRYING TECHNOLOGY</b>
<b>9:00</b>	<p><b>Welcome</b>                      John Shabushnig, <i>Insight Pharma Consulting</i>                      John Ayres, <i>Pharma Safety Solutions</i></p>	<p><b>Welcome</b>                      Yves Mayeresse, <i>GSK Vaccines</i>                      Julian Gitter, <i>University of Munich</i></p>
<b>Session 4:</b>	<p><b>Clinical Impact of Particles</b>                       Moderator:                      John Ayres, <i>Pharma Safety Solutions</i></p>	<p><b>Formulation and Process Development</b>                       Moderator:                      Joerg Luemkemann, <i>F. Hoffmann – La Roche</i></p>
<b>9:05</b>	<p><b>In Vivo Fate of Nanoparticles - Is It Predictable?</b>                       Cornelia Keck, <i>Philipps-University Marburg</i></p>	<p><b>Effective Stabilization of Viral Vectors by Lyophilized SPS® Formulations Adenovirus Serotype 5 as a Model</b>                       Sabine Hauck, <i>LEUKOCARE</i></p>
<b>9:35</b>	<p><b>A Clinical Perspective on Particulates</b>                       John Ayres, <i>Pharma Safety Solutions</i></p>	<p><b>Process Development Concepts for Freeze-Drying of Highly Potent Agents</b>                       Claudia Kunz, <i>Merck Healthcare KGaA</i></p>
<b>10:05</b>	<p><b>Q&amp;A, Discussion</b></p>	<p><b>Q&amp;A, Discussion</b></p>
<b>10:30</b>	<p><b>Coffee Break, Poster Session &amp; Exhibition</b></p>	
<b>Session 5:</b>	<p><b>Particle Identification</b>                       Moderator: Markus Lankers, <i>MIBIC</i></p>	<p><b>Non-destructive CQA Analysis</b>                       Moderator: Julian Gitter, <i>University of Munich</i></p>
<b>11:00</b>	<p><b>The New VDI 2083 Part 21: Cleanliness of Medical Products in the Manufacturing Process</b>                       Markus Rochowicz, <i>Fraunhofer IPA</i></p>	<p><b>Non-Invasive Methods for Moisture Mapping and Container Closure Integrity</b>                       Kumar Khamar, <i>Sanofi Waterford</i></p>
<b>11:30</b>	<p><b>Particulate Investigations in Injectables</b>                       Pascal Chalus, <i>LONZA</i></p>	<p><b>Assessing Critical Quality Attributes for Freeze-Dried Products</b>                       Jos Corver, <i>Ghent University/Rhea Vita</i></p>
<b>12:00</b>	<p><b>Q&amp;A, Discussion</b></p>	<p><b>Q&amp;A, Discussion</b></p>
<b>12:30</b>	<p><b>Lunch Break, Poster Session &amp; Exhibition</b></p>	

<b>Session 6:</b>	<b>Panel Discussion</b> Moderator: Klaus Wormuth, <i>Sartorius Stedim</i>	<b>Roundtable Discussions</b> Moderator: Kerstin Wilken, <i>PDA Europe</i>
<b>13:30</b>	<ul style="list-style-type: none"> <li>• <b>Compatibility and Interactions of Delivery Systems and Drug Product</b></li> <li>• <b>Evolving Guidance &amp; Regulations and their Implementation</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Product Validation, number of batches needed, batch size, bracketing, matrixing strategies</b></li> <li>• <b>Use of PAT Tools in Commercial Process Control, regulatory filing</b></li> <li>• <b>Implementation of new technologies</b></li> <li>• <b>Robustness of Lyo Cycle</b></li> <li>• <b>Lyo of Novel Therapies</b></li> </ul>
<b>14:30</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>	
<b>Joint Plenary - Closing Keynotes</b>		Moderators: <b>John Shabushnig</b> , <i>Insight Pharma Consulting</i> <b>Yves Mayeresse</b> , <i>GSK Vaccines</i>
<b>15:00</b>	<b>Control Strategy for Visible Particles in Lyophilized Products</b>	Alexis Flaquière, <i>GSK Vaccines</i>
<b>15:00</b>	<b>The Future of Product Differentiation: Increase Patient Safety and Decrease Healthcare Cost When Using Freeze Dried Products</b>	Joerg Luemkemann, <i>F. Hoffmann – La Roche</i>
<b>15:50</b>	<b>Conference Summaries by the Co-Chairs</b>	
	John Shabushnig, <i>Insight Pharma Consulting</i> , <i>Chair Particles in Injectables</i>	Yves Mayeresse, <i>GSK Vaccines</i> , <i>Chair Pharmaceutical Freeze Drying Technology</i>
	John Ayres, <i>Pharma Safety Solutions</i> , <i>Chair Particles in Injectables</i>	Julian Gitter, <i>University of Munich</i> , <i>Chair Pharmaceutical Freeze Drying Technology</i>
<b>16:30</b>	<b>Closing Remarks &amp; Farewell</b>	Falk Klar, <i>PDA Europe</i> Kerstin Wilken, <i>PDA Europe</i>

Agenda is subject to change without notice, all speakers pending confirmation