



**2022 PDA Visual Inspection Forum**  
 - *Visual Inspection Process: Driving Continuous Improvement*  
 Berlin/Germany  
 26-27 April 2022

<b>Tuesday, 26 April 2022</b>		<b>09:00 – 18:00 CEST</b>
9:00	Welcome and Introduction	Falk Klar, <i>PDA Europe</i>
9:10	Welcome from the Chairs	John Shabushnig, <i>Insight Pharma Consulting</i> Romain Veillon, <i>GSK</i>
<b>Opening Plenary: Updates from the Regulatory Landscape</b>		<b>Moderator:</b> Romain Veillon, <i>GSK</i> <b>Co-Moderator:</b> Linda Wildling, <i>Takeda</i>
Visual inspection of parenteral is a highly regulated domain, compendial recommendations evolve constantly to adapt to changing environments and technology evolution. This session will cover both European and US perspectives on visual inspection regulation with key speakers from FDA, USP, EDQM, and German inspectorate.		
9:25	Particulates and related Updates in the European Pharmacopeia (Ph.Eur.)	Erika Stippler, <i>EDQM</i> Hanns-Christian Mahler, <i>Ten23 Health</i>
9:50	Inspectors View on Visual Inspection	Daniel Müller, <i>Local Inspectorate Tübingen</i>
<b>10:20</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>	
10:50	USP Particle Chapters: A Summary of Recent Changes and their Implications	John Shabushnig, <i>Insight Pharma Consulting</i>
11:15	Regulatory Aspects of Visible Particulates Testing and Control	Rukman De Silva, <i>U.S. FDA</i>
<b>11:40</b>	<b>Q&amp;A, Discussion</b>	<b>Moderator:</b> Romain Veillon, <i>GSK</i>



**2022 PDA Visual Inspection Forum**  
 - *Visual Inspection Process: Driving Continuous Improvement*  
 Berlin/Germany  
 26-27 April 2022

		<b>Co-Moderator:</b> Linda Wildling, <i>Takeda</i>
<b>12:10</b>	<b>Lunch Break, Poster Session &amp; Exhibition</b>	
<b>Session 1: Particle Characterization and Safety Impact Evaluation</b>		<b>Moderator:</b> Markus Lankers, <i>MIBIC</i>  <b>Co-Moderator:</b> Hanns-Christian Mahler, <i>Ten23 Health</i>
<p>Understanding the source, composition, and health impact of particulate matter provides the necessary information for the development of adequate control strategies and comprehensive risk assessments. A contamination control strategy illustrated by a case study will be highlighted in the first part of the session. The second presentation will discuss the challenges and risk management strategies involving the potential medical impact of particulates.</p>		
13:10	Clinical Considerations: Assessing the Safety Implications of Extrinsic Particles	John Ayres, <i>Pharma Safety Solutions</i>
13:35	Controlling Particulate Contamination at the Source by use of CCS	Subrata Chakraborty, <i>GxPFONT Consulting Group</i>
14:00	<b>Q&amp;A, Discussion</b>	<b>Moderator:</b> Markus Lankers, <i>MIBIC</i>  <b>Co-Moderator:</b> Hanns-Christian Mahler, <i>Ten23 Health</i>
<b>14:20</b>	<b>Exhibition &amp; Poster Session</b>	
<b>Session 2: Artificial Intelligence: from MVI to AVI and into the Future</b>		<b>Moderator:</b> Florian Krickl, <i>Vitronic</i>  <b>Co-Moderator:</b> Djonny Rigot, <i>Syntegon</i>



**2022 PDA Visual Inspection Forum**  
 - *Visual Inspection Process: Driving Continuous Improvement*  
**Berlin/Germany**  
**26-27 April 2022**

<p>Increasing challenges in visual inspection generate demand for new technologies and methods. This session gives a deep understanding of the latest developments in artificial intelligence, automation, and vision technology and its practical application in pharmaceutical inspection processes. In addition, research activities of key industry players and research centers present innovative methods for actual and future inspection needs.</p>		
14:40	Human-like Inspection Robot	Romain Veillon, <i>GSK</i>
15:05	Artificial Intelligence Applied in the Human-Like Automated Vision Inspection	Veronica Ghidotti, <i>Stevanato Group</i>
15:25	Incorporating Deep Learning into Existing Vision Configurations for Cosmetic Defects of Lyophilized Product	Amy Gobel, <i>Johnson &amp; Johnson</i> & Felix Riehn, <i>Körber Pharma Inspection</i>
<b>15:50</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>	
16:20	Interactive Questionnaire: Where is the Industry Now and Where are We Headed: A Status Update	
16:30	Practical Applications, Challenges, and Solutions When Using Deep Learning and Big Data for Automated Visual Inspection	Joseph Straub, <i>MSD</i>
16:55	Integrating Multimodal Sensing and AI for Automated Inspection of Parenteral Products	Denise Tellmann, <i>Massachusetts Institute of Technology</i>
17:20	<b>Q&amp;A, Discussion</b>	<b>Moderator:</b> Florian Krickl, <i>Vitronic</i> <b>Co-Moderator:</b> Djonny Rigot, <i>Syntegon</i>
<b>18:00</b>	<b>End of Conference Day 1 &amp; Networking Event</b>	



**2022 PDA Visual Inspection Forum**  
 - *Visual Inspection Process: Driving Continuous Improvement*  
 Berlin/Germany  
 26-27 April 2022

**Wednesday, 27 April 2022** **09:00 – 16:30 CEST**

9:00	Welcome to Day 2	John Shabushnig, <i>Insight Pharma Consulting</i>  Romain Veillon, <i>GSK</i>
<b>Session 3: Difficult to Inspect Product</b>		<b>Moderator:</b> Andrea Sardella, <i>Stevanato Group</i>  <b>Co-Moderator:</b> Herve Soukiassian, <i>BD</i>
Biotechnology is leading the wave of personalized medicines showing great benefits but also posing new challenges to assess the quality level of bio-manufactured products. Inspection experts are investigating new concepts and technologies to solve these issues as we will see in the following presentations. New drugs require also tailored containers and the third presentation will shed a light on the difficulties and the approach developed to inspect BFS.		
9:05	Visual Inspection of High Viscosity Syringe Containers	Al Goodwin, <i>Amgen</i>  Jan Sende, <i>Syntegon</i>
9:30	Automatic Vision Inspection of Cell Therapy Products: Challenges, Opportunities, Mechanical Approaches, and Technologies	Massimo Frasson, <i>Brevetti CEA</i>  Stefano Baila, <i>ANEMOCYTE S.R.L</i>
9:55	AVI of Difficult to Inspect Blow Fill Seal Container Blocks	Heino Prinz, <i>Rommelag</i>
<b>10:20</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>	
10:50	Challenges during Automatic Inspection of Lyophilized Products: Case Study on Collapsed Cake and Unusual Cake Appearance	Corey Bishop, <i>Amgen Technology Ireland</i>  Massimo Frasson, <i>Brevetti CEA</i>
11:20	Interactive Questionnaire: Addressing Challenges in the Visual Inspection Process Regarding Evolving Medicines	



**2022 PDA Visual Inspection Forum**  
 - *Visual Inspection Process: Driving Continuous Improvement*  
 Berlin/Germany  
 26-27 April 2022

11:30	Q&A, Discussion	<b>Moderator:</b> Andrea Sardella, <i>Stevanato Group</i>  <b>Co-Moderator:</b> Herve Soukiassian, <i>BD</i>
12:15	Lunch Break, Poster Session & Exhibition	
<b>Closing Plenary: Improving the Visual Inspection Life Cycle</b>		<b>Moderator:</b> John Shabushnig, <i>Insight Pharma Consulting</i>  <b>Co-Moderator:</b> Djonny Rigot, <i>Syntegon</i>
<p>This session is organized to share practical experience and lessons learned from a wide range of industry experts. It discusses evolving testing methods for components and expected changes in the European regulations found in EMA Annex 1. Pandemic supply experience provides another valuable lesson, and the session concludes by putting it all together with an example of a life-cycle approach for continuous process improvement.</p>		
13:15	Updates on Recent PDA Activities	<i>Speaker invited</i>
13:30	Practical Implications of the revised Annex 1	Bram Keymolen, <i>eyetec</i>
13:50	Lessons from Visual Inspection	Robert Miller, <i>Pfizer</i>
14:15	How to Establish a Holistic, Company-Wide Visual Inspection & Particle Life-Cycle Management Program	Linda Wildling, <i>Takeda</i>
14:35	Coffee Break, Poster Session & Exhibition	
15:05	Enabling Visual Inspection in Commercial Production during Product Development	Rupert Depner, <i>Körber Pharma Inspection</i>
15:30	<b>Closing Panel Discussion</b>	<b>Moderator:</b> Romain Veillon, <i>GSK</i>  <b>Co-Moderator:</b> Felix Riehn, <i>Körber Pharma Inspection</i>



**2022 PDA Visual Inspection Forum**  
- **Visual Inspection Process: Driving Continuous Improvement**  
**Berlin/Germany**  
**26-27 April 2022**

16:05	Conference Summary and Take-Home Message	John Shabushnig, <i>Insight Pharma Consulting</i> Romain Veillon, <i>GSK</i>
16:20	Closing Remarks & Farewell	Falk Klar, <i>PDA Europe</i>
<b>16:30</b>	<b>End of Conference</b>	

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