

# PDA Visual Inspection Forum 2026

## Agenda



**Tuesday, 19 May**

BST Daylight Time (UTC +1:00)

### Welcome and Introduction

09:00 – 09:10

**Committee Member:** Falk Klar PhD, General Manager, Vice President Europe, *Parenteral Drug Association*

### Welcome from the Co-Chairs

09:10 – 09:20

**Co-Chair:** Andrea Sardella PhD, Customer Success Manager, *Brevetti CEA*

**Co-Chair:** Antonio Burazer Global Head Visual Inspection & Particle LCM *Takeda*

### Opening Session: Particle Management from Development to Application

Particle management requires a holistic strategy that spans from the development phase through fill-and-finish operations to final delivery to the patient. Understanding the risk of contamination, whether originating from the manufacturing process, the materials used, or introduced during administration, is essential to ensuring product quality and patient safety. In this session, expert speakers will share their perspectives on the risks associated with each stage of drug development and market deployment.

**Moderator:** Andrea Sardella PhD, Customer Success Manager, *Brevetti CEA*

**Moderator:** Antonio Burazer Global Head Visual Inspection & Particle LCM *Takeda*

09:20 – 09:45

#### Sow In Development to Reap at Commercialization – Tales from the Frontlines of Parenteral Product Development

- **Presenter:** Satish K. Singh PhD, Vice President, Drug Product, *Astria Therapeutics*

09:20 – 11:20

09:45 – 10:10

#### The Top 10 Problems and Solutions Often Observed in Visual Inspection Programs

- **Presenter:** John G. Shabushnig PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

10:10 – 10:35

#### Visible Particles in Injectables: Is Practically Free Essentially Safe?

- **Presenter:** John D. Ayres MD, Risk Assessment Clinician, *Pharma Safety Solutions, LLC*

10:35 – 11:20

#### Q&A and Discussion

- **Moderator:** Andrea Sardella PhD, Customer Success Manager, *Brevetti CEA*
- **Moderator:** Antonio Burazer , Global Head Visual Inspection & Particle LCM , *Takeda*
- **Panelist:** Satish K. Singh PhD, Vice President, Drug Product, *Astria Therapeutics*
- **Panelist:** John G. Shabushnig PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

11:20 – 11:50

### Networking Coffee Break, Poster Session & Exhibition

### Session 1: Advancing Particle Control: Methods, Standards, and Global Strategy

This session will showcase current industry approaches to improving Visual Inspection through advanced methods, harmonized standards, and global strategy alignment. Speakers will share practical insights and case studies that support consistent, high-quality manufacturing across sites and regions.

11:50 – 13:05	11:50 – 12:05	<b>The Knapp Method - misinterpreted and outdated? A consideration from today's industrial perspective and application</b> <ul style="list-style-type: none"> <li>• <b>Presenter: Elisabeth Wagner</b> , Business Process Owner Visual Inspection, <i>CSL Behring</i></li> </ul>
	12:05 – 12:20	<b>Ensuring Pharmaceutical Particle Characterization: Takeda's Multi-Phased Approach to Supporting Particle Investigations</b> <ul style="list-style-type: none"> <li>• <b>Presenter: Ronan Cullen</b> , Particle Lab Specialist, <i>Takeda Manufacturing Austria AG</i></li> </ul>
	12:20 – 12:35	<b>Global Particulate Matter Strategy</b> <ul style="list-style-type: none"> <li>• <b>Presenter: Valerie Rautureau</b> , Global Visual Inspection SME, <i>Eli Lilly</i></li> </ul>
	12:35 – 13:05	<b>Q&amp;A and Discussion</b> <ul style="list-style-type: none"> <li>• <b>Moderator: Atanas Koulov PhD</b>, Chief Scientific Officer, <i>Clear Solutions Laboratories AG</i></li> <li>• <b>Panelist: Elisabeth Wagner</b> , Business Process Owner Visual Inspection, <i>CSL Behring</i></li> <li>• <b>Panelist: Ronan Cullen</b> , Particle Lab Specialist, <i>Takeda Manufacturing Austria AG</i></li> <li>• <b>Panelist: Valerie Rautureau</b> , Global Visual Inspection SME, <i>Eli Lilly</i></li> </ul>
13:05 – 13:35	<b>Guided Poster Walk</b> <b>Moderator: Markus Adlberger MSc</b> , Product Owner Visual Inspection Software, <i>Körber Pharma</i>	
13:35 – 14:20	<b>Networking Lunch Break, Poster Session &amp; Exhibition</b>	
14:20 – 15:55	<b>Session 2: Inspection Process Optimization: Efficiencies and Waste Reduction</b> This session will present a range of opportunities in the visual inspection process to reduce waste and drive efficiency. Waste reduction and process efficiency are key focuses in the effort to manufacture products at a reasonable price for customers. <b>Moderator: Rick J. Watson</b> , Director, <i>Merck &amp; Co., Inc.</i>	
	14:20 – 14:25	<b>Interactive Questionnaire Session</b> <ul style="list-style-type: none"> <li>• <b>Moderator: Rick J. Watson</b> , Director, <i>Merck &amp; Co., Inc.</i></li> </ul>
	14:25 – 14:45	<b>Case Study for Overcoming High False Reject Rate and Trending Analysis From AVI. (Defect Detection Rate &amp; False Reject Rate)</b> <ul style="list-style-type: none"> <li>• <b>Presenter: Wonmin Ricky Kim Safety &amp; industrial engineering</b> , Packaging 2 Part Leader , <i>GC Biopharma</i></li> </ul>
	14:45 – 15:05	<b>A.I. Synthetic Defect Perspectives</b> <ul style="list-style-type: none"> <li>• <b>Presenter: Romain Veillon PharmD</b>, Director Platform Lead Visual Inspection, <i>GSK</i></li> </ul>
	15:05 – 15:25	<b>Technological Advancements for Reduction of False Reject Rate in PFS Automated Inspection</b> <ul style="list-style-type: none"> <li>• <b>Presenter: Matteo Baldini</b> , ,</li> </ul>
	15:25 – 15:55	<b>Q&amp;A and Discussion</b> <ul style="list-style-type: none"> <li>• <b>Moderator: Rick J. Watson</b> , Director, <i>Merck &amp; Co., Inc.</i></li> <li>• <b>Panelist: Wonmin Ricky Kim Safety &amp; industrial engineering</b> , Packaging 2 Part Leader , <i>GC Biopharma</i></li> </ul>

- **Panelist: Romain Veillon PharmD**, Director Platform Lead Visual Inspection, *GSK*
- **Panelist: Matteo Baldini** , ,

15:55 – 16:25    **Networking Coffee Break, Poster Session & Exhibition**

**Session 3: Developing Solutions for Particle Detection and Control**  
This session is about innovative solutions to overcome the limitations of traditional inspection. It focuses on reliable detection of particles and particle control in difficult-to-inspect products.  
**Moderator: Elisabeth Wagner** , Business Process Owner Visual Inspection, *CSL Behring*

16:25 – 17:30	16:25 – 16:45	<b>Ensuring Particle Control in Complex CGT Products: Tailored Visual Inspection Standards for Enhanced Quality and Compliance</b> <ul style="list-style-type: none"><li>• <b>Academic Presenter: Oliver Germershaus PhD</b>, Professor for Pharmaceutical Technology of Macromolecular Drugs / Chief Scientific Officer, <i>University of Applied Sciences and Arts Northwestern Switzerland / Partiris GmbH</i></li></ul>
	16:45 – 17:00	<b>Seeing the Unseen: Innovative Inspection Methods for Challenging, Opaque Products. Overcoming Visibility Barriers in Quality Control of Dark Liquids and Milky Substances</b> <ul style="list-style-type: none"><li>• <b>Presenter: Jan Sende</b> , ,</li></ul>
	17:00 – 17:30	<b>Q&amp;A and Discussion</b> <ul style="list-style-type: none"><li>• <b>Moderator: Elisabeth Wagner</b> , Business Process Owner Visual Inspection, <i>CSL Behring</i></li><li>• <b>Academic Panelist: Oliver Germershaus PhD</b>, Professor for Pharmaceutical Technology of Macromolecular Drugs / Chief Scientific Officer, <i>University of Applied Sciences and Arts Northwestern Switzerland / Partiris GmbH</i></li><li>• <b>Panelist: Jan Sende</b> , ,</li></ul>

17:30 – 21:00    **End of Conference Day 1 & Networking Event**

Wednesday, 20 May

BST Daylight Time (UTC +1:00)

09:00 – 09:05	<b>Welcome to Day 2</b>
	<b>Co-Chair: Andrea Sardella PhD</b> , Customer Success Manager, <i>Brevetti CEA</i> <b>Co-Chair: Antonio Burazer</b> Global Head Visual Inspection & Particle LCM <i>Takeda</i>
<b>Session 4: Overview of Advancements in Visual Inspection</b> This session will highlight recent trends and advances in pharmaceutical visual inspection, with a focus on innovative and risk-based approaches to VI process optimization that drive quality improvements and operational efficiency. <b>Moderator: Romain Veillon PharmD</b> , Director Platform Lead Visual Inspection, <i>GSK</i>	
09:05 – 09:20	<b>Recent Trends and Discussion Topics at the PDA Visual Inspection Interest Group</b> <ul style="list-style-type: none"><li>• <b>Presenter: Rick J. Watson</b> , Director, <i>Merck &amp; Co., Inc.</i></li></ul>
09:20 – 09:35	<b>Risk-Based Design of VI Qualification Test Sets: Data-Driven Justifications for Bracketing Approaches</b> <ul style="list-style-type: none"><li>• <b>Presenter: Atanas Koulov PhD</b>, Chief Scientific Officer, <i>Clear Solutions Laboratories AG</i></li></ul>
<b>Efficient MVI Operator Training: A Structured 4-Week Program</b>	

09:05 – 10:30	09:35 – 09:50	<ul style="list-style-type: none"><li>• <b>Presenter: Barbara Ginda DI (FH)</b>, Process Owner Visual Inspection , <i>Takeda Manufacturing Austria AG</i></li></ul>
	09:50 – 10:00	<p><b>Enhancing Pharmaceutical Visual Inspection: A Case Study on Molded vs Tubular Vials in the Era of AI and Automation</b></p> <ul style="list-style-type: none"><li>• <b>Presenter: Yvan Garnier PhD</b>, SENIOR R&amp;D PROJECT LEADER, <i>SGD PHARMA</i></li></ul>
	10:00 – 10:30	<p><b>Q&amp;A and Discussion</b></p> <ul style="list-style-type: none"><li>• <b>Moderator: Romain Veillon PharmD</b>, Director Platform Lead Visual Inspection, <i>GSK</i></li><li>• <b>Panelist: Atanas Koulov PhD</b>, Chief Scientific Officer, <i>Clear Solutions Laboratories AG</i></li><li>• <b>Panelist: Barbara Ginda DI (FH)</b>, Process Owner Visual Inspection , <i>Takeda Manufacturing Austria AG</i></li><li>• <b>Panelist: Yvan Garnier PhD</b>, SENIOR R&amp;D PROJECT LEADER, <i>SGD PHARMA</i></li></ul>
10:30 – 11:00 <b>Networking Coffee Break, Poster Session &amp; Exhibition</b>		
<p><b>Session 5: Automated and Intelligent Inspection Technologies</b> Recent advances in artificial intelligence (AI) and machine learning (ML) offer software tools to achieve enhanced visual inspection performance. These tools can reduce inspection algorithm development time and incorporate additional inspector knowledge to better accommodate routine product variation. The talks in this session describe projects that utilize these advanced tools.</p> <p><b>Moderator: John G. Shabushnig PhD</b>, Principal Consultant, <i>Insight Pharma Consulting, LLC</i></p>		
11:00 – 12:20	11:00 – 11:25	<p><b>Rethinking Visual Inspection – From Today’s Challenges to a Fully Digital Future</b></p> <ul style="list-style-type: none"><li>• <b>Co-Presenter: Markus Adlberger MSc</b>, Product Owner Visual Inspection Software, <i>Körber Pharma</i></li><li>• <b>Co-Presenter: Steffen Münzer</b> , ,</li></ul>
	11:25 – 11:50	<p><b>Implementation of a Hybrid Semi-Automatic Visual Inspection (H-SAVI) Process Employing Deep Learning for Pre-Filled Syringe Inspection</b></p> <ul style="list-style-type: none"><li>• <b>Presenter: John M. Wadding</b> , Inspection Subject Matter Expert - Technical Lead, Scientific Excellence (Injectables Platform), Manufacturing Sciences, Analytics and Technology (MSAT) , <i>Sanofi</i></li></ul>
	11:50 – 12:20	<p><b>Q&amp;A and Discussion</b></p> <ul style="list-style-type: none"><li>• <b>Moderator: John G. Shabushnig PhD</b>, Principal Consultant, <i>Insight Pharma Consulting, LLC</i></li><li>• <b>Panelist: Markus Adlberger MSc</b>, Product Owner Visual Inspection Software, <i>Körber Pharma</i></li><li>• <b>Panelist: Steffen Münzer</b> , ,</li><li>• <b>Panelist: John M. Wadding</b> , Inspection Subject Matter Expert - Technical Lead, Scientific Excellence (Injectables Platform), Manufacturing Sciences, Analytics and Technology (MSAT) , <i>Sanofi</i></li></ul>
12:20 – 13:20 <b>Networking Lunch Break, Poster Session &amp; Exhibition</b>		
<p><b>Closing Plenary: Managing Risk and Regulatory Expectations</b> This closing plenary focuses on how scientific understanding and regulatory expectations shape particle control strategies for injectable products. The session will cover current thinking on visible particulate control, evolving regulatory perspectives from both US and European authorities, and practical guidance on how particle findings are assessed and managed in development and commercial settings.</p> <p><b>Moderator: Andrea Sardella PhD</b>, Customer Success Manager, <i>Brevetti CEA</i></p>		

13:20 – 15:00	<p>13:20 – 13:35</p> <p><b>Visible Particulate Control for Injectable Pharmaceutical Products – Scientific and Regulatory Considerations</b></p> <ul style="list-style-type: none"> <li>• <b>Regulatory Presenter: Rukman S. De Silva PhD</b>, Policy Lead, OPQ, CDER, <i>U.S. FDA</i></li> </ul>
	<p>13:45 – 14:10</p> <p><b>To be Announced</b></p> <ul style="list-style-type: none"> <li>• <b>Regulatory Presenter: Ciara Turley</b> , ,</li> </ul>
	<p>14:10 – 14:30</p> <p><b>From Detection to Decision: Navigating Particle Risks in Parenteral Development</b></p> <ul style="list-style-type: none"> <li>• <b>Presenter: Felix Nikels</b> , Senior Principal Scientist, <i>Boehringer Ingelheim</i></li> </ul>
	<p>14:30 – 15:00</p> <p><b>Q&amp;A and Discussion</b></p> <ul style="list-style-type: none"> <li>• <b>Moderator: Antonio Burazer</b> , Global Head Visual Inspection &amp; Particle LCM, <i>Takeda</i></li> <li>• <b>Moderator: Andrea Sardella PhD</b>, Customer Success Manager, <i>Brevetti CEA</i></li> <li>• <b>Regulatory Panelist: Rukman S. De Silva PhD</b>, Policy Lead, OPQ, CDER, <i>U.S. FDA</i></li> <li>• <b>Regulatory Panelist: Ciara Turley</b> , ,</li> <li>• <b>Panelist: Felix Nikels</b> , Senior Principal Scientist, <i>Boehringer Ingelheim</i></li> </ul>
15:00 – 15:30	<b>Networking Coffee Break, Poster Session &amp; Exhibition</b>
15:30 – 15:35	<b>Passport Raffle</b>
15:35 – 15:40	<b>Best Poster Presentation</b>
15:40 – 16:40	<p><b>Interactive Session</b></p> <p><b>Moderator: Antonio Burazer</b> , Global Head Visual Inspection &amp; Particle LCM, <i>Takeda</i></p>
16:40 – 16:50	<p><b>Co-Chairs Conference Summary</b></p> <p><b>Co-Chair: Antonio Burazer</b> , Global Head Visual Inspection &amp; Particle LCM, <i>Takeda</i></p> <p><b>Co-Chair: Andrea Sardella PhD</b> Customer Success Manager <i>Brevetti CEA</i></p>
16:50 – 16:55	<p><b>Closing Remarks &amp; Farewell</b></p> <p><b>Presenter: Falk Klar PhD</b>, General Manager, Vice President Europe, <i>Parenteral Drug Association</i></p>
16:55 – 16:55	<b>End of Conference</b>

**PDA How to Handle Test Sets in Visual Inspection Training Course**

21 May - 22 May

**PDA Mastering Automated Visual Inspection Training Course Spring Edition 2026**

21 May - 22 May

**PDA An Introduction to Visual Inspection: A Hands-On Training Course Spring Edition 2026**

21 May - 22 May