2022 PDA

VISUAL INSPECTION FORUM

VISUAL INSPECTION PROCESS: DRIVING CONTINUOUS IMPROVEMENT

pda.org/EU/VIForum22

26-27 APRIL 2022
BERLIN, GERMANY
EXHIBITION: 26-27 APRIL
TRAINING: 28-29 APRIL

REGISTER BEFORE 27 FEBRUARY AND SAVE UP TO €200!

WELCOME FROM THE CHAIRS

Dear Colleagues,

On behalf of the Scientific Program Planning Committee and PDA Europe, we are looking forward to welcoming you to the **2022 PDA Visual Inspection Forum,** to take place in **Berlin, Germany on 26-27 April 2022!**

We have been hard at work organizing another conference to keep you current with advances in inspection technology and the ever-changing regulatory landscape. We are also excited to return to a live, in-person meeting format.

Visual inspection, and especially the detection of particles, remains at the center of many discussions regarding product manufacturing control, quality assurance, and regulatory compliance. We continue to see product recalls related to visual defects. Inspection methods and technology also continue to advance. The application of artificial intelligence (AI) and deep learning (DL) to automated inspection is an exciting area of recent investigation. These are just a few of the many topics featured at this year's forum.

Since 2000, we have organized the Visual Inspection Forum to discuss new technical and regulatory developments in this field. We are pleased to have experts to discuss new developments in the field of visual inspection, including a basic understanding of the inspection process, special requirements for difficult to inspect products, practical aspects of manual and automated methods, and the regulatory and compendial requirements like those found in the update of Annex 1 or USP <1790> and the new FDA Guidance.

The forum program is intended to initiate and support discussion and professional exchange through the diversity of scientific presentations, training courses, and networking events.

We look forward to you joining us in Berlin!

Sincerely,
The Chairs

John G. Shabushnig, *Ph.D.*
Principal Consultant
Insight Pharma Consulting, LLC

Romain Veillon,
Director Visual Inspection & Leak Testing
GlaxoSmithKline

SCIENTIFIC PROGRAM PLANNING COMMITTEE

John Shabushnig, *Insight Pharma Consulting, Chair*
Romain Veillon, *GSK, Chair*
John Ayres, *Pharma Safety Solutions*
Florian Krickl, *Vitronic*
Markus Lankers, *MIBIC*
Felix Riehn, *Körber Pharma Inspection*
Hanns-Christian Mahler, *ten23 Health*
Andrea Sardella, *Stevanato Group*
Herve Soukassian, *BD*
Linda Wildling, *Takeda*
Jose Zanardi, *Syntegon Technology*
Janie Miller, *PDA*
Falk Klar, *PDA*
Stefanie Nebelin, *Manager Programs & Events, PDA*

WELCOME TO VISUAL INSPECTION FORUM

COVID-19 PERSONAL PRECAUTIONARY MEASURES

PDA is committed to deliver safe and secure in-person events. In conjunction with the venue and vendors supporting our event, PDA strictly adheres to all national, provincial and local government regulations.

CONFERENCE AGENDA

03. Feb 2022

TUESDAY, 26 APRIL 2022 — 09:00 – 18:00 CET

9:00	**Welcome and Introduction**	Falk Klar, *PDA Europe*
	Welcome from the Chairs	John Shabushnig, *Insight Pharma Consulting* Romain Veillon, *GSK*

OPENING PLENARY: Updates from the Regulatory Landscape

Moderator: **Romain Veillon,** *GSK*
Co-Moderator: **Linda Wildling,** *Takeda*

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.

	Particulates and related Updates in the European Pharmacopeia (Ph.Eur.)	*Regulatory Speaker invited* Hanns-Christian Mahler, *Ten23 Health*
	Inspectors View on Visual Inspection	*Speaker invited*
10:20	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	
	USP Particle Chapters: A Summary of Recent Changes and their Implications	John Shabushnig, *Insight Pharma Consulting*
	Regulatory Aspects of Visible Particulates Testing and Control	*U.S. FDA*
	Q&A, Discussion	Romain Veillon, *GSK* Linda Wildling, *Takeda*
12:10	**LUNCH BREAK, POSTER SESSION & EXHIBITION**	

SESSION 1: Particle Characterization and Safety Impact Evaluation

Moderator: **Markus Lankers,** *MIBIC*
Co-Moderator: **Hanns-Christian Mahler,** *Ten23 Health*

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.

	Clinical Considerations: Assessing the Safety Implications of Extrinsic Particles	John Ayres, *Pharma Safety Solutions*
	Controlling Particulate Contamination at the Source by use of CCS	*GxPFONT Consulting Group*
	Q&A, Discussion	Markus Lankers, *MIBIC* Hanns-Christian Mahler, *Ten23 Health*
14:20	**EXHIBITION & POSTER SESSION**	

SESSION 2: Artificial Intelligence: from MVI to AVI and into the Future

Moderator: **Florian Krickl,** *Vitronic*
Co-Moderator: **Jose Zanardi,** *Syntegon*

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.

	Human-like Inspection Robot	Romain Veillon, *GSK*
	Artificial Intelligence Applied in the Human-Like Automated Vision Inspection	*Stevanato Group*
	Incorporating Deep Learning into Existing Vision Configurations for Cosmetic Defects of Lyophilized Product	*Johnson & Johnson* Felix Riehn, *Körber Pharma Inspection*
15:50	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	
	INTERACTIVE QUESTIONNAIRE: Where is the Industry Now and Where are We Headed: A Status Update	
	Practical Applications, Challenges, and Solutions When Using Deep Learning and Big Data for Automated Visual Inspection	*MSD*
	Integrating Multimodal Sensing and AI for Automated Inspection of Parenteral Products	*Massachusetts Institute of Technology*
	Q&A, Discussion	Florian Krickl, *Vitronic* Jose Zanardi, *Syntegon*
18:00	**END OF CONFERENCE DAY 1 & NETWORKING EVENT**	

CONFERENCE AGENDA

WEDNESDAY, 27 APRIL 2022 — 09:00 – 16:30 CET

09:00	**Welcome to Day 2**	John Shabushnig, *Insight Pharma Consulting* Romain Veillon, *GSK*

SESSION 3: Difficult to Inspect Product

Moderator: **Andrea Sardella,** *Stevanato Group*
Co-Moderator: **Jose Zanardi,** *Syntegon*

This session will introduce state of the art inspection technologies developed to tackle the difficulties posed by some of the most challenging products existing in the market. 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. Additionally, new drugs require also tailored containers such as BFS, which pose inspection difficulties of their own. And even with standard formulations and containers, the challenges with lyophilized products and bubbles in liquids are a persisting topic for inspection improvement. Experts are developing new concepts and technologies to solve these issues, as we will see in the following presentations.

	Visual Inspection of High Viscosity Syringe Containers	*Amgen* *Syntegon*
	Automatic Vision Inspection of Cell Therapy Products: Challenges, Opportunities, Mechanical Approaches, and Technologies	*Brevetti CEA* *ANEMOCYTE S.R.L*
	AVI of Difficult to Inspect Blow Fill Seal Container Blocks	*Rommelag*
10:20	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	
	Challenges during Automatic Inspection of Lyophilized Products: Case Study on Collapsed Cake and Unusual Cake Appearance	*Amgen Technology Ireland* *Brevetti CEA*

INTERACTIVE QUESTIONNAIRE: Addressing Challenges in the Visual Inspection Process Regarding Evolving Medicines

	Q&A, Discussion	Romain Veillon, *GSK* Linda Wildling, *Takeda*
12:15	**LUNCH BREAK, POSTER SESSION & EXHIBITION**	

CLOSING PLENARY: Improving the Visual Inspection Life Cycle

Moderator: **John Shabushnig,** *Insight Pharma Con.*
Co-Moderator: **Herve Soukiassian,** *BD*

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.

	Updates on Recent PDA Activities	*Speaker invited*
	Practical Implications of the revised Annex 1	*eyetec*
	Lessons from Visual Inspection	*Pfizer*
	How to Establish a Holistic, Company-Wide Visual Inspection & Particle Life-Cycle Management Program	*Takeda* Linda Wildling, *Takeda*
14:35	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	

CLOSING PLENARY: Improving the Visual Inspection Life Cycle *(continued)*		*Moderator:* **John Shabushnig,** *Insight Pharma Con.* *Co-Moderator:* **Herve Soukiassian,** *BD*
	Enabling Visual Inspection in Commercial Production during Product Development	*Körber Pharma Inspection*
	Closing Panel Discussion	Romain Veillon, *GSK* Felix Riehn, *Körber Pharma Inspection*
	Conference Summary and Take-Home Message	John Shabushnig, *Insight Pharma Con.* Romain Veillon, *GSK*
	Closing Remarks & Farewell	Falk Klar, *PDA Europe*
16:30	**END OF CONFERENCE**	

VENUE

DORINT KURFÜRSTENDAMM BERLIN
Augsburger Strasse 41
10789 Berlin
Germany
Tel: +49 30 800999-0
E-Mail: info.berlin@dorint.com
https://hotel-berlin.dorint.com/de

GENERAL ADDRESS

PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin, Germany
T: + 49 30 436 55 08-0
F: + 49 30 436 55 08-66
info@pda.org

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 info@pda.org.

PDA EUROPE

UPCOMING CONFERENCES AND EVENTS

FOR FURTHER INFORMATION
FOLLOW US ONLINE
www.pda.org

2022

03. Feb 2022

26-27 APR 2022	2022 PDA Visual Inspection Forum	Berlin, Germany
16-17 MAY 2022	2022 PDA Medical Devices and Connected Health Conference	Dublin, Ireland
16-17 MAY 2022	2022 PDA Robotics and Automation Conference	Dublin, Ireland
18-19 MAY 2022	2022 PDA Annex 1 Workshop	Dublin, Ireland
02-03 JUN 2022	2022 PDA Parenteral Packaging Conference	Basel, Switzerland
20-21 JUN 2022	2022 PDA Virus Conference	Brussels, Belgium
22-23 JUN 2022	2022 PDA Advanced Therapy Medicinal Products Conference	Brussels, Belgium
20-21 SEP 2022	2022 PDA BioManufacturing Conference	Amsterdam, The Netherlands
22-23 SEP 2022	2022 PDA Annex 1 Workshop	Amsterdam, The Netherlands
05-06 OCT 2022	2022 PDA Quality and Regulations Conference	Amsterdam, The Netherlands