Agenda

2024 PDA Visual Inspection Forum

15:00 – 18:00 | **Registration Open**

Tuesday, 9 April

08:00 – 17:30

Registration Open
Eventfoyer

09:00 – 09:05

Welcome and Introduction
Room Ludwig-Alois

Committee Member: Falk Klar, **PhD**, *Parenteral Drug Association*

09:05 – 09:15

Welcome from the Co-Chairs
Room Ludwig-Alois

Co-Chair: John G Shabushnig, **PhD**, Principal Consultant, *Insight Pharma Consulting, LLC*

Co-Chair: Romain Veillon, **PharmD**, Director Vision Technology MSAT, *GSK*

09:15 – 11:15

Opening Plenary: Particles: A Pharmacy and Regulatory Perspective
Room Ludwig-Alois

This session focuses on particles in parenteral drugs and how and where they are seen. It will provide both a new understanding of the size and types of particles that can be routinely detected during visible inspection and what is seen by pharmacists in clinical practice. It concludes with an update on current regulatory experience and expectations from the U.S. Food and Drug Administration.

Moderator: John G Shabushnig, **PhD**, Principal Consultant, *Insight Pharma Consulting, LLC*

09:15 – 09:45

Visible, Subvisible, and Microparticles in Parenteral Drugs – Facts and Figures in Daily Clinical Practice

Academic Presenter: Irene Kraemer, **PhD**, Director Department of Pharmacy, *University Medical Center, Johannes Gutenberg-University Mainz*

09:45 – 10:15

From Blur to Clarity: Definition of Particle Visibility Threshold in Parenteral Drug Products

Co-Presenter: Felix Nikels, Senior Principal Scientist, *Boehringer Ingelheim*

Co-Presenter: Atanas Koulov, **PhD**, Chief Scientific Officer, *Clear Solutions Laboratories AG*

10:15 – 10:45

Control of Visible Particulates in Injectable Pharmaceutical Products: A Life-Cycle Approach

Regulatory Presenter: Rukman S De Silva, **PhD**, Policy Lead, OPQ/OPPQ/CDER, *U.S. FDA*

10:45 – 11:15

Q&A, Discussion

Moderator: John G Shabushnig, **PhD**, Principal Consultant, *Insight Pharma Consulting, LLC*

Panelist: Irene Kraemer, **PhD**, Director Department of Pharmacy, *University Medical Center, Johannes Gutenberg-University Mainz*

Panelist: Felix Nikels, Senior Principal Scientist, *Boehringer Ingelheim*

Panelist: Atanas Koulov, **PhD**, Chief Scientific Officer, *Clear Solutions Laboratories AG*

Regulatory Panelist: Rukman S De Silva, **PhD**, Policy Lead, OPQ/OPPQ/CDER, *U.S. FDA*

11:15 – 11:45

Networking Coffee Break, Poster Session & Exhibition

Eventfoyer

11:45 – 13:05

Session 1: Particle Identification and Life Cycle Case Studies

Room Ludwig-Alois

Understanding the source and composition of particulate matter provides the necessary substrate for the development of adequate control strategies and particle life cycle management. This session will discuss the development of analytical methods and tools for particle ID at manufacturing sites as well as a case study of the investigation of intrinsic particulates in early-stage development. Finally, the successful implementation of a visual inspection and particle life cycle management program will be highlighted.

Moderator: Markus Lankers, **PhD**, Managing Director, *MIBIC GmbH & Co KG*

11:45 – 12:00

Company-Wide Particle Life Cycle Management - A Success Story

Presenter: Antonio Burazer, Global Head of Visual Inspection & Particle LCM, *Takeda Pharmaceuticals International AG*

12:00 – 12:15

Investigation of Intrinsic Particulates in Sterile Solution: Case Study on Process vs Product Root Cause

Presenter: Valerie Pritiskutch, Lead Inspection Operator and Technologist, *GSK*

12:15 – 12:30

Identify Me – Particle Analysis at a Site Level

Presenter: Emily Beattie, Quality Technical Consultant- Global Quality Operations and Strategy, *Baxter Healthcare*

12:30 – 13:05

Q&A, Discussion

Moderator: Markus Lankers, **PhD**, Managing Director, *MIBIC GmbH & Co KG*

Panelist: Emily Beattie, Quality Technical Consultant- Global Quality Operations and Strategy, *Baxter Healthcare*

Panelist: Antonio Burazer, Global Head of Visual Inspection & Particle LCM, *Takeda Pharmaceuticals International AG*

Panelist: Valerie Pritiskutch, Lead Inspection Operator and Technologist, *GSK*

13:05 – 14:20

Networking Lunch Break, Poster Session & Exhibition

Eventfoyer

13:50 – 14:20

Guided Poster Walk

Eventfoyer

Moderator: Romain Veillon, **PharmD**, Director Vision Technology MSAT, *GSK*

13:50 – 14:20

Detection of defects in externally coated glass vials with automated visual inspection

Poster Presenter: Nico Spribille, Commercial Director Europe, *Corning Inc.*

13:50 – 14:20

Enhanced Test Methods for Visible Particle Detection & Enumeration on Elastomeric Closures and Glass Containers

Poster Presenter: Jahanvi Miller, **MBA**, Director of Quality, *Amgen Inc.*

13:50 – 14:20

Identify & Eliminate Sources of Visible Particles

Poster Presenter: Clay Foutch, Vice President of Sales, *Foamtec International WCC*

13:50 – 14:20

Probability of Detection Study

Poster Presenter: Menno Sels, **MA**, Process & Project Engineer, *eyetec*

13:50 – 14:20

Visual Inspection Program Development for a Frozen Oncolytic Virus Drug Product: Overcoming Challenges

Poster Presenter: Lynn Ward, **MS**, Senior Engineer, Process Development, *Replimune*

14:20 – 14:35

Interactive Questionnaire Session

Room Ludwig-Alois

Moderator: Hanns-Christian Mahler, **PhD**, CEO (Chief Enablement Officer), *ten23 health AG*

14:35 – 15:55

Session 2: Visual Inspection Challenges for Difficult to Inspect Products

Room Ludwig-Alois

Visual inspection has become a very well-established process that is key to warranty patient safety and product quality but there are still niche products that represent a challenge for implementing it effectively. In this session, we present some very interesting case studies focused on the inspection of difficult products like biologics or where presentation or container creates particular difficulties in the inspection process.

Moderator: Andrea A Sardella, **PhD**, Product Development Manager, *Stevanato Group*

14:35 – 14:50

Visual Inspection and Particle Mitigation Approaches for Autologous Cell Therapies

Presenter: Pascal Chalus, **PhD**, Associate Director, *Lonza AG*

14:50 – 15:05

Attention to Detail – A Case Study on Particle Inspection in IV Bags

Co-Presenter: Thorsten Daus, Product manager, *VITRONIC Dr.-Ing. Stein Bildverarbeitungssysteme GmbH*

Co-Presenter: Rupert Gschwendtner, Head of R&D Medical, *Kiefel GmbH*

15:05 – 15:20

Visual Inspection of Small-Volume Parenteral Products

Presenter: Ragunath Ananthavettivelu, Director Visual Inspection & Device Assembly, *ten23 health*

15:20 – 15:55

Q&A, Discussion

Moderator: Andrea A Sardella, **PhD**, Product Development Manager, *Stevanato Group*

Panelist: Ragunath Ananthavettivelu, Director Visual Inspection & Device Assembly, *ten23 health*

Panelist: Pascal Chalus, **PhD**, Associate Director, *Lonza AG*

Panelist: Thorsten Daus, Product manager, *VITRONIC Dr.-Ing. Stein Bildverarbeitungssysteme GmbH*

Panelist: Rupert Gschwendtner, Head of R&D Medical, *Kiefel GmbH*

15:55 – 16:25

Networking Coffee Break, Poster Session & Exhibition

Eventfoyer

16:25 – 17:45

Session 3: Manual Visual Inspection

Room Ludwig-Alois

The purpose of this session was to discuss practical issues faced by people who work in the field of visual inspection. The discussion will include examples of current considerations for selecting statistical sampling and advancements of future direction for combined visual inspection applications for small drug product batches.

Moderator: Rukman S De Silva, **PhD**, Policy Lead, OPQ/OPPQ/CDER, *U.S. FDA*

16:25 – 16:50

Counterintuitive Thinking: Why Accept on Zero Sampling Plans Allow MORE Defects to be Released

Presenter: Richard Monell, Principal Engineer, *Baxter Healthcare*

16:50 – 17:10

An Innovative Idea to Combine Visual Inspection with Compendial Method Testing

Co-Presenter: Susanne Gawenda, **PhD**, Senior Quality Control Expert, *Analytical Science, Roche Diagnostics GmbH Mannheim*

Co-Presenter: Andrea A Sardella, **PhD**, Product Development Manager, *Stevanato Group*

17:10 – 17:45

Q&A, Discussion

Moderator: Rukman S De Silva, **PhD**, Policy Lead, OPQ/OPPQ/CDER, *U.S. FDA*

Panelist: Susanne Gawenda, **PhD**, Senior Quality Control Expert, *Analytical Science, Roche Diagnostics GmbH Mannheim*

Panelist: Richard Monell, Principal Engineer, *Baxter Healthcare*

Panelist: Andrea A Sardella, **PhD**, Product Development Manager, *Stevanato Group*

17:45 – 22:00

End of Conference Day 1 & Networking Event

Wednesday, 10 April

08:30 – 16:30

Agenda

2024 PDA Visual Inspection Forum

Registration Open
Eventfoyer

09:00 – 09:05

Welcome to Day 2
Room Ludwig-Alois

Co-Chair: John G Shabushnig, **PhD**, Principal Consultant, *Insight Pharma Consulting, LLC*

Co-Chair: Romain Veillon, **PharmD**, Director Vision Technology MSAT, *GSK*

09:05 – 10:25

Session 4: Automation in Visual Inspection & Artificial Intelligence
Room Ludwig-Alois

New Automatic Visual Inspection equipment can deliver Deep Learning capacities that can now reach unmet performances in term of defect detection and false reject management. A.I. validation will require explainability to give transparency and trust to regulators. An example of ongoing deployment to production may inspire your organization.

Moderator: Romain Veillon, **PharmD**, Director Vision Technology MSAT, *GSK*

09:05 – 09:20

Deep Learning for Enhanced AVI Detection Combined with Rule-Based Image Sequence Tracking for False Fail Reduction

Co-Presenter: Al Goodwin, **B.Sc (Eng.) HDip**, PRINCIPAL ENGINEER, *AMGEN*

Co-Presenter: Wolfgang Brandenburger, **Dipl.-Ing.**, Data Scientist Inspection Systems Development, *Körber Pharma*

09:20 – 09:35

Navigating the Black Box: Monitoring and Explaining Deep Learning Models for AVI

Co-Presenter: Ioanna Psylla, **MSc**, Technical Product Owner, *Novo Nordisk*

Co-Presenter: Michal Stepien, **MSc**, OT Data Engineer, *Novo Nordisk*

09:35 – 09:50

Unlocking Potential: AI-Powered Visual Inspection in Commercial Use

Co-Presenter: Mario Holl, **MSc, PhD**, Managing Director, *InspectifAI GmbH*

Co-Presenter: Alessandra Corbisiero, Automation &CSV Manager, *Patheon, by Thermo Fisher Scientific*

09:50 – 10:25

Q&A, Discussion

Moderator: Romain Veillon, **PharmD**, Director Vision Technology MSAT, *GSK*

Panelist: Wolfgang Brandenburger, **Dipl.-Ing.**, Data Scientist Inspection Systems Development, *Körber Pharma*

Panelist: Alessandra Corbisiero, Automation &CSV Manager, *Patheon, by Thermo Fisher Scientific*

Panelist: Al Goodwin, **B.Sc (Eng.) HDip**, PRINCIPAL ENGINEER, *AMGEN*

Panelist: Mario Holl, **MSc, PhD**, Managing Director, *InspectifAI GmbH*

Panelist: Ioanna Psylla, **MSc**, Technical Product Owner, *Novo Nordisk*

Panelist: Michal Stepien, **MSc**, OT Data Engineer, *Novo Nordisk*

10:25 – 10:55

Networking Coffee Break, Poster Session & Exhibition

Eventfoyer

10:55 – 12:15

Session 5: Emerging Technologies for Visual Inspection

Room Ludwig-Alois

As our reliance on technology continues to grow, it plays an increasingly crucial role in enhancing our daily lives and optimizing various operations. This session delves into the realm of emerging technologies, specifically focusing on their applications in visual inspection. Explore two groundbreaking examples that showcase how these innovative approaches are revolutionizing visual inspection within the pharmaceutical industry.

Moderator: Linda Wildling, **PhD**, Head of Digital Innovation Success Management, *Takeda Pharmaceuticals International AG*

10:55 – 11:20

Reducing Inspection Complexity by Introducing Beyond-Human Sensing for Lyophilized Vaccine Inspection

Academic Presenter: Denise Tellbach, **MA**, PhD Candidate, *Massachusetts Institute of Technology*

11:20 – 11:45

Water Proton Nuclear Magnetic Resonance (wNMR) for Noninvasive Pharmaceutical Analysis

Academic Presenter: Bruce Yu, **PhD**, Professor, *University of Maryland School of Pharmacy*

11:45 – 12:15

Q&A, Discussion

Moderator: Linda Wildling, **PhD**, Head of Digital Innovation Success Management, *Takeda Pharmaceuticals International AG*

Panelist: Denise Tellbach, **MA**, PhD Candidate, *Massachusetts Institute of Technology*

Panelist: Bruce Yu, **PhD**, Professor, *University of Maryland School of Pharmacy*

12:15 – 13:15

Networking Lunch Break, Poster Session & Exhibition

Eventfoyer

Agenda

2024 PDA Visual Inspection Forum

13:15 – 13:30

Interactive Questionnaire Session

Room Ludwig-Alois

Moderator: Herve Soukiassian, Assoc. Director – Product Development, *BD*

13:30 – 14:15

Closing Plenary: Current and Future Perspective Part I

Room Ludwig-Alois

This session will try humbly to reconcile the patient, the engineer, and the citizen...should the three be the same person. Starting with the current situation of the strategic Visual Inspection process, we'll then explore two potential forthcoming avenues. The first one will dive into the inevitable topic of data, and how to make sense of them beyond visual inspection itself. At the same time, the latter will share how the ecology of sense-making has contributed to serving sustainability ambitions in the microelectronic sector.

Moderator: Herve Soukiassian, Assoc. Director – Product Development, *BD*

13:30 – 13:50

Highlights from the PDA Visual Inspection Survey 2023

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

13:50 – 14:15

Use Cases on Data Analytics to Increase Inspection Transparency and Machine Availability

Presenter: Felix Riehn, **MSc**, Head of Product Management, *Körber Pharma*

14:15 – 14:45

Networking Coffee Break, Poster Session & Exhibition

Eventfoyer

14:45 – 14:50

Passport Raffle

Room Ludwig-Alois

Moderator: Melanie Decker, *Parenteral Drug Association*

14:50 – 16:20

Closing Plenary: Current and Future Perspective Part II

Room Ludwig-Alois

Moderator: Herve Soukiassian, Assoc. Director – Product Development, *BD*

Agenda

2024 PDA Visual Inspection Forum

14:50 – 15:15

Knowledge Management to Reach Challenging Sustainability Goals

Co-Presenter: Helene Vacelet, **PhD**, Sustainability Senior Program Manager, *Becton Dickinson Pharmaceutical Systems*

Co-Presenter: Stephane Hubac, Manufacturing Science Fellow, *Retired From STMicroelectronics*

15:15 – 16:00

Closing Panel Discussion

Moderator: Herve Soukiassian, Assoc. Director – Product Development, *BD*

Panelist: Antonio Burazer, Global Head of Visual Inspection & Particle LCM, *Takeda Pharmaceuticals International AG*

Regulatory Panelist: Rukman S De Silva, **PhD**, Policy Lead, OPQ/OPPQ/CDER, *U.S. FDA*

Panelist: Stephane Hubac, Manufacturing Science Fellow, *Retired From STMicroelectronics*

Panelist: Irene Kraemer, **PhD**, Director Department of Pharmacy, *University Medical Center, Johannes Gutenberg-University Mainz*

Panelist: Felix Riehn, **MSc**, Head of Product Management, *Körber Pharma*

Panelist: Helene Vacelet, **PhD**, Sustainability Senior Program Manager, *Becton Dickinson Pharmaceutical Systems*

16:00 – 16:15

Co-Chairs Conference Summary

Room Ludwig-Alois

Co-Chair: John G Shabushnig, **PhD**, Principal Consultant, *Insight Pharma Consulting, LLC*

Co-Chair: Romain Veillon, **PharmD**, Director Vision Technology MSAT, *GSK*

16:15 – 16:20

Introduction to Site Visit at the Körber Pharma Facility

Room Ludwig-Alois

Presenter: Rupert Depner, **Dipl Ing**, Area Sales Manager, *Körber Pharma Inspection GmbH*

16:20 – 16:25

Closing Remarks & Farewell

Room Ludwig-Alois

Committee Member: Falk Klar, **PhD**, *Parenteral Drug Association*