## Tuesday, 9 April

### 09:00 – 09:05

**Welcome and Introduction**

**Committee: Falk Klar PhD PDA Europe**

### 09:05 – 09:15

**Welcome from the Co-Chairs**

- **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**

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

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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>09:15 – 09:45</td>
<td>Visible, Subvisible, and Microparticles in Parenteral Drugs – Facts and Figures in Daily Clinical Practice</td>
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<td><strong>Academic Presenter: Irene Kraemer</strong></td>
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<td>09:45 – 10:15</td>
<td>From Blur to Clarity: Definition of Particle Visibility Threshold in Parenteral Drug Products</td>
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<td><strong>Co-Presenter: Felix Nikels</strong> Senior Principal Scientist <em>Boehringer Ingelheim</em></td>
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<td><strong>Co-Presenter: Atanas Koulov</strong></td>
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<tr>
<td>10:15 – 10:45</td>
<td>Control of Visible Particulates in Injectable Pharmaceutical Products: A Life-Cycle Approach</td>
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<td>Observation of visible particulates continued to be one of the major problems in injectable pharmaceutical products. Visible particulates can form during all the stages of product life-cycle, including manufacture, storage, shipping, and delivery at the patient’s site. If visible particulates are inadvertently administered to patients, they could jeopardize patient safety. In recent years, there have been many recalls associated with visible particulates in injectable pharmaceutical products, and these recalls have led to drug shortages, putting patients at risk. Therefore, regulatory authorities require injectable pharmaceutical products to be essentially free of visible particulates. Manufacturers can achieve these expectations by implementing a life-cycle approach to visible particulate control through understanding the manufacturing process, product, container closure system, and regulatory requirements. This presentation will focus on the life-cycle approach to visible particulates control from a regulatory perspective.</td>
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<td><strong>Regulatory Presenter: Rukman S De Silva PhD</strong> Policy Lead, OPQ, CDER <em>U.S. FDA</em>**</td>
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<td>10:45 – 11:15</td>
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11:15 – 11:45

Coffee Break, Poster Session & Exhibition

11:45 – 13:05

Session 1: Particle Identification and Life Cycle Case Studies

**Moderator: Markus Lankers PhD** Consultant MIBIC GmbH & Co KG

11:45 – 12:00

**Company-Wide Particle Life Cycle Management - A Success Story**

This presentation will guide you through a success story of developing and rolling out a global, company-wide visual inspection and particle life cycle management program. We aim to share how we achieved improvements across multiple disciplines relating to particle LCM and lessons learned from the past 4 years. Furthermore we want to highlight new challenges in regulations and materials which arise with introduction of advanced therapy medicinal products (CGT) and how to effectively implement particle LCM in small-scale manufacturing.

**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**

Loose particles in solution pose a known risk to our patients and currently are a matter of significant regulatory concern. From a cGMP perspective, it is imperative to identify and understand the source and generation of these particles to determine the impact on the quality of our product and to continuously improve our processes. Sites often rely on third-party labs to identify particles, which can be time-consuming and can prevent the ability of the site to quickly react to issues. Baxter Healthcare has developed a particle identification process that provides tools to aid manufacturing sites in the ability to identify particles efficiently and effectively, enabling real-time reactions.

**Presenter: Emily Beattie** Global Quality Operations and Strategy Baxter Healthcare

12:30 – 13:05

Q&A, Discussion

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

Panelist: Irene Kraemer

Panelist: Felix Nikels Senior Principal Scientist Boehringer Ingelheim

Panelist: Atanas Koulov

Regulatory Panelist: Rukman S De Silva PhD Policy Lead, OPQ, CDER U.S. FDA
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13:05 – 14:20

Lunch Break, Poster Session & Exhibition

13:50 – 14:20

Guided Poster Walk

14:20 – 14:35

Interactive Questionnaire Session

**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

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

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14:35 – 14:50

Visual Inspection and Particle Mitigation Approaches for Autologous Cell Therapies

**Co-Presenter:** Pascal Chalus PhD Associate Director Lonza AG

**Co-Presenter:** Mark Tracy

14:50 – 15:05

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

IV bags are manufactured and filled in cleanroom environments to avoid contamination from the outside. Nevertheless, in each processing step up until sealing, there is a slight chance of particles or other defects getting into the bag. Detecting these contaminations in the manufacturing process early and reliably will increase patient safety and save costs for the manufacturer. However, the nature of particles is such that they are not easy to detect:• Different particle categories demand distinct detection methods for reliability. • Particles and contaminations can move freely in the IV bag and could be located in hard to see areas like the seal or ports. • The presence of intricate printing on the IV bag can obstruct particle detection. • Particle sizes can be small, down to 50µm, and need detection in large-volume bags. In this case study, we worked on finding solutions for different contamination classes and various defects on the IV bags. To mitigate the impact of false rejects, caused, for example, by bubbles, methods employing artificial intelligence (AI) have been evaluated. The handling of the IV bags for inspection was one of the major challenges. We will describe the case with a focus on new inspection tools and the achievements in the running manufacturing process.

**Co-Presenter:** Thorsten Daus Product manager VITRONIC Dr.-Ing. Stein Bildverarbeitungssysteme GmbH
Visual Inspection of Small-Volume Parenteral Products

The visual inspection of parenteral drug products presents a challenging yet critical unit operation within pharmaceutical drug product manufacturing. Visual inspection relates to detecting minor, major, and critical defects of the final drug product. These defects can relate to a variety of defects, including defects related to the primary packaging or to the product solution itself, such as particulate contamination, and are thus essential for ensuring product compliance and quality. As a result, parenteral preparations are 100% visually inspected either manually or by means of semi- or fully automated inspection systems with unique advantages and disadvantages typically followed by AQL testing. Several key factors contribute to the complexity of the visual inspection process. First, the nature of the biological formulation, including the presence of proteins and excipients, can lead to inherent coloration, opacity, or turbidity, which further obstructs a clear view of the product. This opacity poses a challenge in detecting particulates, which may differ in size and nature, or critical defects that may be present. Secondly, the primary packaging configuration in relation to the fill volume - typically in the milliliter range, but lately in the 50 to 100 μL-range e.g., for intravitreal products, makes it challenging to find and confirm defects such as visible particulate matter or other contaminants, and training of personnel is essential to ensure appropriate sensitivity of the visual inspection method. Moreover, the high value and limited availability of biological drugs make it imperative to minimize false rejections during inspection, as this can result in significant economic losses. This presentation highlights the challenges for visual inspection especially of small-volume drug products for intravitreal use depending on product configuration and product properties.

Presenter: Ragunath Ananthavettivelu

Q&A, Discussion

Moderator: Andrea A. Sardella PhD Product Development Manager Stevanato Group
Panelist: Pascal Chalus PhD Associate Director Lonza AG
Panelist: Mark Tracy
Panelist: Thorsten Daus Product manager VITRONIC Dr.-Ing. Stein Bildverarbeitungssysteme GmbH
Panelist: Ragunath Ananthavettivelu

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

Sharp knives are safer than blunt knives. If you're in a sinking vehicle, you should wait until water fills it before opening an exit. Accept on zero sampling plans allow more defects to be released to the market than sampling plans with same AQL that accept one or more defects. What do all these things have in common? They're examples of counterintuitive thinking. Explore the math behind AQL Sampling and empower yourself to make better release decisions through colorful explanations of Operating Characteristic (OC) Curves and exciting audience participation games. You’ll be amazed at all the fun you’ve been missing!

Presenter: Elizabeth Zybczynski Senior Director, cGMP Systems Baxter Healthcare
An Innovative Idea to Combine Visual Inspection with Compendial Method Testing

An innovative idea to combine visual inspection with compendial method testing for a faster and material-saving small-batch release. Concept by Stevanato Group and Roche. New drugs with complex formulas or personalized medicine are growing and requiring new guardrails. Small batch sizes combined with small manufacturing capacities result in fewer samples available for analytical testing to release the batch. Therefore, material-saving has become necessary, and new non-destructive technologies with efficient execution of testing are the future state. Stevanato Group and F. Hoffmann-La Roche AG use joint forces to deliver a process innovation driven by platform thoughts and robot systems that improve the release of small batches. In this speech, we will present the concept and idea of a combined visual inspection application (vision robot unit, VRU) with a compendial testing platform (CTP) to allow non-destructive and real-time release testing of small batches of biotech and high-value drugs. We will explain the benefits of a flexible platform solution to enable real-time release, allow for a fleet approach matching the idea of the factory of the future, and serve the manufacturing needs of both clinical trial and industrialization phases.

Co-Presenter: Susanne Gawenda
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, CDER U.S. FDA
Panelist: Elizabeth Zybczynski Senior Director, cGMP Systems Baxter Healthcare
Panelist: Susanne Gawenda
Panelist: Andrea A. Sardella PhD Product Development Manager Stevanato Group

17:45 – 22:00

End of Conference Day 1 & Networking Event

Wednesday, 10 April

09:00 – 09:05

Welcome to Day 2

Co-Chair: John G. Shabunshig 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

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
In our approach, the relevant image regions – region of interest (ROI) – are localized using simple classical image processing tools. A deep neural network is used to classify the extracted image regions. The model is combined with a rule-based classification method that relies on expert knowledge to increase the confidence level of the decision. The combination of the different classifiers allows the strengths of deep learning to be used complimented by the rule-based approaches that support the reduction of false fails. Thereafter, all ROIs of an image sequence which show the same artifact are clustered using their positional information. Finally, a decision function is applied to each detected artifact exploiting its occurrence across all images of the sequence, which increases the reliability of the outcome. It’s especially powerful during analysis of heavy particles sticking on a syringe plunger or classifying air bubbles that lead to costly false fails during the visual inspection process.

**Co-Presenter:** Al Godwin

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

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<td>09:20</td>
<td>Navigating the Black Box: Monitoring and Explaining Deep Learning Models for AVI</td>
<td>Al Godwin, Wolfgang Brandenburger, Ioanna Psylla, Michal Stepień</td>
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<td>09:35</td>
<td>Unlocking Potential: AI-Powered Visual Inspection in Commercial Use</td>
<td>Mario Holl, Alessandra Corbisiero</td>
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<tr>
<td>09:50</td>
<td>Q&amp;A, Discussion</td>
<td>Romain Veillon, AI Godwin, Wolfgang Brandenburger, Ioanna Psylla, Mario Holl</td>
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10:25 – 10:55
Coffee Break, Poster Session & Exhibition

10:55 – 12:15
Session 5: Emerging Technologies for Visual Inspection

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 PhD Candidate Massachusetts Institute of Technology

11:20 – 11:45
Water Proton Nuclear Magnetic Resonance (wNMR) for Noninvasive Pharmaceutical Analysis

Water is the common solvent used in biomanufacturing and biologics formulation. The concentration of water is much higher than that of the API, excipients and adjuvants. Water proton nuclear magnetic resonance (wNMR) measurements can be carried out using benchtop instruments, typically within a minute. Most importantly, wNMR measurements can be carried out in an in situ and contact-free manner. This opens the door for rapid formulation screening, noninvasive product inspection and contact-free in-line processing monitoring. In this presentation, examples of different wNMR applications will be presented.

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 PhD Candidate Massachusetts Institute of Technology

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

12:15 – 13:15
Lunch Break, Poster Session & Exhibition

13:15 – 13:30
Interactive Questionnaire Session

Moderator: Herve Soukiassian Assoc. Director – Product Development BD
13:30 – 14:15

Closing Plenary: Current and Future Perspective Part I

Moderator: Herve Soukiassian  Assoc. Director – Product Development BD

13:30 – 13:50

Highlights from the PDA Visual Inspection Survey 2023

Visual inspection is an important process monitoring and control element for pharmaceutical manufacturing. Inspection practices vary within the industry, and it is informative to review common practices. This comparison is facilitated through benchmarking and the presentation will include highlights from the PDA visual inspection survey completed in 2023. This is an update to past surveys which were completed in 1996, 2003, 2008 and 2014. Comparison to these past surveys helps identify what has changed (and what has not). The survey includes responses from all major pharmaceutical markets and addresses manual, semiautomated and automated inspection methods. Critical inspection parameters, acceptance sampling and inspection results will be discussed. The presentation will conclude with a look at comments received from the survey respondents on future inspection trends.

Co-Chair: 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

Increasing data storing and processing capabilities opens new opportunities for helpful tools to increase the inspection process and monitor upstream equipment. The following use cases indicate what is technically already possible today: - Root analysis of defect creation by upstream equipment - Show how data monitoring can help to increase the yield of inspection equipment - Early, data-driven recognition of machine failure - Particle tracing of a complete image sequence - Defect monitoring with AI.

Co-Presenter: Felix Riehn MSc  Head of Product Management Körber

14:15 – 14:45

Coffee Break, Poster Session & Exhibition

14:45 – 14:50

Passport Raffle

Moderator: Melanie Decker

14:50 – 16:20

Closing Plenary: Current and Future Perspective Part II

Moderator: Herve Soukiassian  Assoc. Director – Product Development BD

14:50 – 15:15

Knowledge Management to Reach Challenging Sustainability Goals

In 2024, working on reducing our environmental footprint has become a standard of the industry. Most healthcare company have now set their sustainability goals. However, there are several challenges to overcome to reach these goals linked to the healthcare industry environment: - How to...
manage the right traceability level to use recycle materials and maintain the value? - How to manage properly re-use &/or refurbish while maintaining the right level of safety and quality? - How to reduce waste generation at the right stage (as early as possible in the value chain)? - How to minimize the energy and materials usage by optimizing the supply chain? To enable that transition, it is critical to have the right data collection in place and the right analysis at the right level. Theses are the first bricks to enable managing traceability, risk management and operational efficiency at the same time. The real challenge remains to engage and change whole organizations altogether towards new ways of working. The unification of human expertise, operational event record, decision-making and traceability is crucial to reach “zero defect” and “zero unnecessary waste” objectives.

In this talk, a concrete example of the semi-conductor industry is going to be shared on how it was leveraged and the actual benefits of a tailor-made knowledge management system. There would be a focus on the preventive maintenance improvement implementation and how the human aspect was considered.

Co-Presenter: Helene Vacelet PhD Sustainability Senior Program Manager Becton Dickinson Pharmaceutical Systems
Co-Presenter: Stephane Hubac

15:15 – 16:00

Closing Panel Discussion

Moderator: Herve Soukiassian Assoc. Director – Product Development BD
Regulatory Panelist: Rukman S De Silva PhD Policy Lead, OPQ, CDER U.S. FDA
Panelist: Irene Kraemer
Panelist: Stephane Hubac
Panelist: Felix Riehn MSc Head of Product Management Körber

16:00 – 16:15

Co-Chairs Conference Summary

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

Presenter: Christian A Scherer Dipl.-Ing. Executive Vice President Sales Körber Pharma Inspection (Seidenader)

16:20 – 16:25

Closing Remarks & Farewell

Committee: Falk Klar PhD PDA Europe