## Agenda

**2024 PDA Visual Inspection Forum**

### Tuesday, 9 April

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<th>Time</th>
<th>Event</th>
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<tr>
<td>08:00 – 17:30</td>
<td>Registration Open &lt;br&gt;Eventfoyer</td>
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<tr>
<td>09:00 – 09:05</td>
<td>Welcome and Introduction &lt;br&gt;Committee: Falk Klar PhD PDA Europe</td>
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<tr>
<td>09:05 – 09:15</td>
<td>Welcome from the Co-Chairs &lt;br&gt;Co-Chair: John G. Shabushnig PhD Principal Consultant Insight Pharma Consulting, LLC &lt;br&gt;Co-Chair: Romain Veillon PharmD Director Vision Technology MSAT GSK</td>
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<tr>
<td>09:15 – 11:15</td>
<td>Opening Plenary: Particles: A Pharmacy and Regulatory Perspective &lt;br&gt;Moderator: John G. Shabushnig PhD Principal Consultant Insight Pharma Consulting, LLC</td>
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<tr>
<td>09:15 – 09:45</td>
<td>Visible, Subvisible, and Microparticles in Parenteral Drugs – Facts and Figures in Daily Clinical Practice &lt;br&gt;Academic Presenter: Irene Kraemer PhD Director Department of Pharmacy University Medical Center, Johannes Gutenberg-University Mainz</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 &lt;br&gt;Co-Presenter: Felix Nikels Senior Principal Scientist Boehringer Ingelheim &lt;br&gt;Co-Presenter: Atanas Koulov PhD Chief Scientific Officer Clear Solutions Laboratories AG</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 &lt;br&gt;Observation of visible particulates continued to be one of the major problems in injectable pharmaceutical products. Visible particulates can form</td>
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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.

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

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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

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11:15 – 11:45

**Networking Coffee Break, Poster Session & Exhibition**

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11:45 – 13:05

**Session 1: Particle Identification and Life Cycle Case Studies**

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

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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

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

Panelist: Valerie Pritiskutch Lead Inspection Operator and Technologist GSK

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

13:05 – 14:20

Networking Lunch Break, Poster Session & Exhibition

13:50 – 14:20

Guided Poster Walk

Moderator: Romain Veillon PharmD Director Vision Technology MSAT GSK

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

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
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

**Co-Presenter:** Rupert Gschwendtner

15:05 – 15:20

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  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:** Pascal Chalus PhD  Associate Director  Lonza AG

**Panelist:** Mark Tracy

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

**Panelist:** Ragunath Ananthavettivelu  Director Visual Inspection & Device Assembly  ten23 health
15:55 – 16:25

Networking Coffee Break, Poster Session & Exhibition

16:25 – 17:45

Session 3: Manual Visual Inspection

The purpose of this session was to discuss practical issues that 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

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<th>Time</th>
<th>Presentation/Panelist</th>
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<tr>
<td>16:25 – 16:50</td>
<td><strong>Counterintuitive Thinking: Why Accept on Zero Sampling Plans Allow MORE Defects to be Released</strong>&lt;br&gt;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 though colorful explanations of Operating Characteristic (OC) Curves and exciting audience participation games. You'll be amazed at all the fun you've been missing!  &lt;br&gt;<strong>Presenter:</strong> Elizabeth Zybczynski BS Senior Director, cGMP Systems Baxter Healthcare</td>
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<td>16:50 – 17:10</td>
<td><strong>An Innovative Idea to Combine Visual Inspection with Compendial Method Testing</strong>&lt;br&gt;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 RocheNew 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 counterintuitive 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.&lt;br&gt;<strong>Co-Presenter: Susanne Gawenda PhD</strong> Senior Quality Control Expert Analytical Science, Roche Diagnostics GmbH Mannheim  &lt;br&gt;<strong>Co-Presenter: Andrea A. Sardella PhD</strong> Product Development Manager Stevanato Group</td>
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<td>17:10 – 17:45</td>
<td><strong>Q&amp;A, Discussion</strong>&lt;br&gt;<strong>Moderator: Rukman S. De Silva PhD</strong> Policy Lead, OPQ/OPPQ/CDER U.S. FDA  &lt;br&gt;<strong>Panelist: Elizabeth Zybczynski BS</strong> Senior Director, cGMP Systems Baxter Healthcare  &lt;br&gt;<strong>Panelist: Susanne Gawenda PhD</strong> Senior Quality Control Expert Analytical Science, Roche Diagnostics GmbH Mannheim  &lt;br&gt;<strong>Panelist: Andrea A. Sardella PhD</strong> Product Development Manager Stevanato Group</td>
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## 2024 PDA Visual Inspection Forum

### Agenda

**Wednesday, 10 April**

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<th>Time</th>
<th>Event</th>
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<tr>
<td>08:30 – 16:30</td>
<td>Registration Open</td>
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<tr>
<td>09:00 – 09:05</td>
<td>Welcome to Day 2</td>
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<td>Co-Chair: John G. Shabushnig PhD Principal Consultant Insight Pharma Consulting, LLC</td>
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<td>Co-Chair: Romain Veillon PharmD Director Vision Technology MSAT GSK</td>
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<tr>
<td>09:05 – 10:25</td>
<td>Session 4: Automation in Visual Inspection &amp; Artificial Intelligence</td>
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<td>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. Example of ongoing deployment to production may inspire your organization.</td>
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<td>Moderator: Romain Veillon PharmD Director Vision Technology MSAT GSK</td>
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<td>Co-Presenter: Al Goodwin B.Sc (Hons) HDip PRINCIPAL ENGINEER AMGEN</td>
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<td>Co-Presenter: Wolfgang Brandenburger Dipl.-Ing. Data Scientist Inspection Systems Development Koerber Pharma Inspection</td>
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<tr>
<td>09:20 – 09:35</td>
<td>Navigating the Black Box: Monitoring and Explaining Deep Learning Models for AVI</td>
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<td>In the era of deep learning, where models are often regarded as 'black boxes,' understanding and trusting their decisions is crucial, particularly in high-stakes applications. This presentation addresses this challenge by exploring techniques for both explaining and monitoring complex models for Automated Visual Inspection in Drug Manufacturing. We will examine methods for explaining model predictions and delve into strategies for real-time monitoring, encompassing concept drift detection and performance tracking for deployed models. By attending this session, you will gain insights into ensuring reliability and transparency in deep learning models, fostering Responsible AI in critical domains.</td>
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<td>Co-Presenter: Ioanna Psylla Product Owner Novo Nordisk</td>
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Unlocking Potential: AI-Powered Visual Inspection in Commercial Use

Artificial Intelligence (AI) offers huge possibilities to increase Detection Rates (DR), reduce False Reject Rates (FRR) and make overall inspection processes more stable and robust with regards to production variations. The main challenges in applying AI systems within pharmaceutical Automatic Visual Inspection machines (AVIs) involve (i) the provisioning of the required computational power, also for already existing inspection machines, (ii) the proper training and development of generalizing and robust AI models as well as (iii) the end-to-end documentation of the AI model meeting all GxP requirements. In this case study, we present a machine-agnostic solution that solves the above-mentioned challenges by (i) using high-computational edge devices that enable AI empowerment of AVI’s within 2 days (ii) training of robust and reliable AI models that generalize beyond the defect kits due to artificial data generation including the usage of generative AI, (iii) documenting the versioned AI models end-to-end within dedicated Model Change Reports. In our co-presentation with ThermoFisher, we showcase the application of AI to a liquid product in commercial production. The challenges and learnings of (i) the edge device installation and qualification, (ii) the data acquisition, augmentation, artificial data generation and the subsequent AI model training as well as (iii) the corresponding documentation are presented. A special focus is dedicated to the topic of artificial data generation to assure data representativeness and mitigate the common pitfall of overfitted AI models. As a result of the AI model, the inspection system is achieving +20% higher DR while at the same time reducing FRR by ~80%.

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

Q&A, Discussion

Moderator: Romain Veillon PharmD Director Vision Technology MSAT GSK
Panelist: Al Goodwin B.Sc (Hons) HDip PRINCIPAL ENGINEER AMGEN
Panelist: Wolfgang Brandenburger Dipl.-Ing. Data Scientist Inspection Systems Development Koerber Pharma Inspection
Panelist: Ioanna Psylla Product Owner Novo Nordisk
Panelist: Mario Holl MSc, PhD Managing Director InspectifAI GmbH

Networking Coffee Break, Poster Session & Exhibition

Session 5: Emerging Technologies for Visual Inspection

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

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

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 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

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

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, while 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

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.

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

<table>
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<tr>
<th>13:50 – 14:15</th>
<th>Use Cases on Data Analytics to Increase Inspection Transparency and Machine Availability</th>
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<tr>
<td><strong>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:</strong></td>
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<tr>
<td>- Root analysis of defect creation by upstream equipment</td>
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<td>- Show how data monitoring can help to increase the yield of inspection equipment</td>
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<td>- Early, data-driven recognition of machine failure</td>
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<td>- Particle tracing of a complete image sequence</td>
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<td>- Defect monitoring with AI</td>
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<td><strong>Presenter: Felix Riehn MSc Head of Product Management Körber</strong></td>
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| 14:15 – 14:45 | Networking Coffee Break, Poster Session & Exhibition |

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<th>14:45 – 14:50</th>
<th>Passport Raffle</th>
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<td><strong>Moderator: Melanie Decker</strong></td>
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<tr>
<th>14:50 – 16:20</th>
<th>Closing Plenary: Current and Future Perspective Part II</th>
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<tr>
<td><strong>Moderator: Herve Soukiassian Assoc. Director – Product Development BD</strong></td>
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<tr>
<th>14:50 – 15:15</th>
<th>Knowledge Management to Reach Challenging Sustainability Goals</th>
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<td><strong>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:</strong></td>
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<td>- How to manage the right traceability level to use recycle materials and maintain the value?</td>
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<td>- How to manage properly re-use &amp;/or refurbish while maintaining the right level of safety and quality?</td>
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<td>- How to reduce waste generation at the right stage (as early as possible in the value chain)?</td>
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<td>- How to minimize the energy and materials usage by optimizing the supply chain?</td>
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<td>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.**</td>
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<td><strong>Co-Presenter: Helene Vacelet PhD Sustainability Senior Program Manager Becton Dickinson Pharmaceutical Systems</strong></td>
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<td><strong>Co-Presenter: Stephane Hubac Manufacturing Science Fellow Retired From STMicroelectronics</strong></td>
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| 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/OPPQ/CDER U.S. FDA

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

Panelist: Stephane Hubac Manufacturing Science Fellow Retired From STMicroelectronics

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 GmbH

16:20 – 16:25

Closing Remarks & Farewell

Committee: Falk Klar PhD  PDA Europe