



# Agenda

PDA Visual Inspection Forum 2025

## Monday, 10 March

07:30 – 08:30

Continental Breakfast

07:30 – 17:30

Registration Open

08:30 – 10:15

P1: Regulatory Perspectives

**Moderator: Rick J. Watson**, Director, *Merck*

08:30 – 08:45

Welcome and Opening Remarks from Forum Co-Chairs

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

**Co-Chair: Rick J. Watson**, Director, *Merck*

08:45 – 09:15

Visual Inspection Regulatory and Compendial Update

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

09:15 – 09:45

Regulatory Expectations for the Assessment of Visible Particulates in Injectable Pharmaceuticals

**Presenter: Rukman S De Silva**, Policy Lead, OPQ, CDER, *U.S. FDA*

09:45 – 10:15

Q&A

10:15 – 11:00

Networking Break in the Exhibit Hall

10:15 – 11:00

Poster Presentations in the Exhibit Hall

10:15 – 11:00



# Agenda

## PDA Visual Inspection Forum 2025

A Comparison of Barrier Film Non-Stick Coated Stoppers vs. Non-Barrier Film Rubber Stoppers in Pharmaceutical Packaging: A Case Study from Historical Data

**Poster Presenter:** Heather Marzolo, Laboratory Technician, *Sartorius*

10:15 – 11:00

Leveraging Deep Learning and AI-Driven Facial Tracking Systems to Enhance Manual Visual Inspection in Pharmaceutical Manufacturing

**Poster Presenter:** Ali Yuksel, Managing Partner | Principal Engineer, *YB*

11:00 – 12:45

### P2: Process Development

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

11:00 – 11:15

Interactive Polling Questionnaire

11:15 – 11:45

Visual Inspection Challenges in Gene and Cell Therapy Production: From Clear Glass and Product to Opaque Plastic and Product

**Presenter:** Ines Bauer, Expert Science & Technology, *Novartis*

11:45 – 12:15

How to Boost Your Manual Visual Inspection: A Case Study of Improving the Efficiency of MVI

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

12:15 – 12:45

Q&A

12:45 – 13:45

### Networking Lunch with Exhibitors

13:45 – 15:15

### A1: New Challenges in Visual Inspection Qualification

**Moderator:** Andrea Sardella, PhD



# Agenda

## PDA Visual Inspection Forum 2025

13:45 – 14:05

Successful Qualification of an AI-Model for a Low-Fill Liquid Vial Particle Inspection

**Presenter:** Christy Eatmon, Global SME Sterile Drug Products, *Thermo Fisher Scientific*

**Co-Presenter:** Bastian Kronenbitter, Head of Data Science, *InspectifAI*

14:05 – 14:25

Qualifying an Automated Visual Inspection Using Recirculation Function

**Presenter:** Jun L. Ordonez, Senior Manager, *Pfizer*

14:25 – 14:45

Development of a Global Standard Operating Procedure Across the Manufacturing Network for Both Liquid and Difficult to Inspect Parenterals Case Study

**Presenter:** Pere Joaquin, Director of Site Quality and QP, *Reig Jofre*

14:45 – 15:15

Q&A

13:45 – 15:15

### B1: Advances in Particle Investigations

**Moderator:** Robert J. Miller, Director, Technical Services, *Pfizer*

13:45 – 14:05

Problem Solving During Trace Foreign Matter Investigations: Points to Consider

**Presenter:** Mary Lee Ciolkowski, PhD, Senior Principal Scientist, *Bausch + Lomb*

14:05 – 14:25

Achieving Particle Reduction via Supplier Contamination Control Strategies and Innovation in RTF Packaging

**Presenter:** Colleen O'Brien, MS, Strategy and Technical Affairs, *Gerresheimer*

14:25 – 14:45

Cellulose – Understanding and Narrowing Down its Sources

**Presenter:** Casey M. Jarvis, Research Scientist, *MVA Scientific Consultants*



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## PDA Visual Inspection Forum 2025

14:45 – 15:15

Q&A

15:15 – 16:00

Networking Break in the Exhibit Hall

15:15 – 16:00

Poster Presentations in the Exhibit Hall

15:15 – 16:00

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**Poster Presenter: Heather Marzolo**, Laboratory Technician, *Sartorius*

15:15 – 16:00

Leveraging Deep Learning and AI-Driven Facial Tracking Systems to Enhance Manual Visual Inspection in Pharmaceutical Manufacturing

**Poster Presenter: Ali Yuksel**, Managing Partner | Principal Engineer, *YB*

16:00 – 17:30

A2: Particle Detection Capability

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

16:00 – 16:20

Beyond Size and Shape: The Role of Color in Particle Detection

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

16:20 – 16:40

3D Printed Protein-Like Model Particles as Particle Standards for Performance Evaluation of Novel Human-Inspired Automated Visual Inspection Instrument

**Presenter: Oliver Germershaus, PhD**, Professor for Pharmaceutical Technology of Macromolecular Drugs, *University of Applied Sciences and Arts Northwestern Switzerland*

16:40 – 17:00

Case Studies: Increasing PoD in Manual Visual Inspection for DIP



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## PDA Visual Inspection Forum 2025

**Presenter: Bram J.J. Keymolen**, Co-Founder, *eyetec*

17:00 – 17:30

Q&A

16:00 – 17:30

### B2: Novel AI-Based Equipment for Difficult-to-Inspect Products

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

16:00 – 16:20

Difference Between Rule-Based and AI Algorithms in the Quality Control of Difficult-to-Inspect Parenterals

**Presenter: Matthias Kahl**, Head of R&D and Lab Services, *WILCO AG*

16:20 – 16:40

Enhancing Image Classification and Reducing False Rejection Rates in BFS DIP Products Using AI on Automated Visual Inspection Systems

**Presenter: Gianmarco Pincelli**, Technical Sales Manager, *Bonfiglioli Engineering*

16:40 – 17:00

Unsupervised Machine Learning Applied to Difficult-to-Inspect Products

**Presenter: Brian Turnquist, PhD**, Chief Technical Officer, *BoonLogic*

17:00 – 17:30

Q&A

17:30 – 18:30

Networking Reception in Exhibit Hall

Tuesday, 11 March

07:30 – 08:30

Continental Breakfast

07:30 – 17:00



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PDA Visual Inspection Forum 2025

Registration Open

08:30 – 10:00

## P3: Visual Inspection Acceptance Sampling and Performance Measurement

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

08:30 – 09:00

Sampling in the Visual Inspection Process: AQL and Defect Trending

**Presenter: Robert J. Miller**, Director, Technical Services, *Pfizer*

09:00 – 09:30

Use of Mathematical Model for Detection Performances Comparison of Manual Visual Inspection vs. Automated Visual Inspection

**Presenter: Mitsutaka Shirasaki**, Principal Engineer, *Genentech Inc.*

09:30 – 10:00

Q&A

10:00 – 10:45

Networking Break in the Exhibit Hall

10:00 – 10:45

## Poster Presentations in the Exhibit Hall

10:00 – 10:45

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**Poster Presenter: Heather Marzolo**, Laboratory Technician, *Sartorius*

10:00 – 10:45

Leveraging Deep Learning and AI-Driven Facial Tracking Systems to Enhance Manual Visual Inspection in Pharmaceutical Manufacturing

**Poster Presenter: Ali Yuksel**, Managing Partner | Principal Engineer, *YB*



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## PDA Visual Inspection Forum 2025

10:45 – 12:15

### A3: Inspection Optimization

**Moderator: Markus Adlberger, MSc**, Product Owner Visual Inspection Software, *Körber Pharma*

10:45 – 11:05

Modernization of an Manual Visual Inspection Program to Improve Defect Detection

**Presenter: David B. Wetherington**, Senior Manager, Operations (Visual Inspection and Packaging), *Thermo Fisher Scientific*

11:05 – 11:25

Revolutionizing Pharmaceutical Inspection: Upgrading to Automated Visual Inspection Systems

**Presenter: Bill Waterstreet**, Principal Validation Engineer, *Performance Validation*

11:25 – 11:45

Manual Visual Inspection and Inspector Training and Qualification

**Presenter: Tracey Sinjen**, Principal Consultant, *Lachman Consultants*

11:45 – 12:15

Q&A

10:45 – 12:15

### B3: Novel Inspection Equipment Design and Application

**Moderator: Rick J. Watson**, Director, *Merck*

10:45 – 11:05

AI-Driven Visual Inspection: Unlocking Data for Smarter Production

**Presenter: Massimo Frasson**, CEO & General Manager, *Brevetti CEA*

11:05 – 11:25

A Semi-Automated IV Bag Inspection System

**Presenter: Neil Jesse Hamilton**, Vice President Technical Services, *AWS Bio-Pharma Technologies*

11:25 – 11:45

The Next Phase in Visual Inspection – Complete Electronic Records



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**Presenter: Gerlad Budd**, President, *Phoenix Imaging Ltd.*

11:45 – 12:15

Q&A

12:15 – 13:15

Networking Lunch with Exhibitors

13:15 – 14:45

**P4: Visual Inspection Process Development and Qualification**

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

13:15 – 13:45

Visual Inspection Validation Considerations for Traditional and New Technology

**Presenter: Rick J. Watson**, Director, *Merck*

13:45 – 14:15

Benefit of Digital Visual Inspection Platform

**Presenter: Romain Veillon**, Director Vision Technology, *GSK*

14:15 – 14:45

Q&A

14:45 – 15:30

Networking Break in the Exhibit Hall

15:00 – 15:45

Poster Presentations in the Exhibit Hall

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**Poster Presenter: Heather Marzolo**, Laboratory Technician, *Sartorius*





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**Poster Presenter:** Ali Yuksel, Managing Partner | Principal Engineer, *YB*

15:30 – 17:00

### P5: Panel Discussion

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

**Moderator:** Rick J. Watson, Director, *Merck*

15:30 – 15:45

Interactive Polling Questionnaire

15:45 – 16:55

Panel Discussion

**Panelist:** Markus Adlberger, MSc, Product Owner Visual Inspection Software, *Körber Pharma*

**Panelist:** Rukman S De Silva, Policy Lead, OPQ, CDER, *U.S. FDA*

**Panelist:** Robert J. Miller, Director, Technical Services, *Pfizer*

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**Panelist:** Rick J. Watson, Director, *Merck*

**Panelist:** Linda Wildling, PhD, Head of Digital Innovation Success Management, *Takeda*

16:55 – 17:00

Closing Remarks from Forum Co-Chairs

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

**Co-Chair:** Rick J. Watson, Director, *Merck*