Agenda

PDA Visual Inspection Forum 2025

13:00 – 18:00 | Registration Open

Monday, 10 March

07:30 – 08:30

Continental Breakfast

07:30 – 17:30

Registration Open

08:30 – 10:15

P1: Regulatory Perspectives and Trends: Foundations and Future Directions in Visual Inspection

Crabtree Ballroom

This opening plenary will explore the compendial and regulatory frameworks that shape visual inspection (VI) process design and control, highlighting recent updates and emerging trends. The session will begin with an overview of current regulatory and compendial requirements, emphasizing their implications for inspection practices, and will be followed by a discussion on regulatory expectations for assessing visible particulates in injectable pharmaceuticals, offering insights into compliance and quality standards. These expert presentations will provide valuable insight into navigating the evolving regulatory landscape for VI in pharmaceutical manufacturing.

Moderator: Rick J. Watson, Director, *Merck & Co., Inc.*

08:30 – 08:45

Welcome and Opening Remarks from Co-Chairs

Co-Chair: Romain Veillon, **PharmD**, Director Platform Lead Visual Inspection, *GSK*

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

08:45 – 09:15

VI 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, **PhD**, Policy Lead, OPQ, CDER, *U.S. FDA*

09:45 – 10:15

Q&A

10:15 – 11:00

Networking Break in the Exhibit Hall (Sponsored by Brevetti C.E.A. SPA)

Agenda

PDA Visual Inspection Forum 2025

10:15 – 11:00

Poster Presentations in the Exhibit Hall

10:15 – 11:00

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, **MS**, 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: Advancing Process Development: Enhancing Manual Visual Inspection for Emerging Challenges

Crabtree Ballroom

Manual visual inspection (MVI) remains the gold standard for establishing baseline performance, yet evolving product modalities present new challenges. This session will explore strategies to enhance MVI processes and address the unique hurdles posed by gene and cell therapy production. After an examination of the complexities of inspecting products ranging from clear glass containers to opaque plastics in gene and cell therapy a case study showcasing practical methods to boost MVI efficiency and effectiveness will be presented. Attendees will leave with actionable insights into optimizing MVI processes to meet the demands of modern biopharmaceutical manufacturing.

Moderator: Romain Veillon, **PharmD**, Director Platform Lead Visual Inspection, *GSK*

11:00 – 11:15

Interactive Polling

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, **MSc**, Expert Science & Technology, *Novartis*

11:45 – 12:15

How to Boost Your MVI: A Case Study to Improve Efficiency

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

12:15 – 12:45

Q&A

Agenda

PDA Visual Inspection Forum 2025

12:45 – 13:45

Networking Lunch with Exhibitors

Glenwood Ballroom

13:45 – 15:15

A1: New Challenges in Visual Inspection Qualification: Navigating Innovation and Global Complexity

City of Oaks Ballroom

Advancements in visual inspection (VI) technologies, the rise of difficult-to-inspect parenteral (DIP) products, and the global reach of pharmaceutical organizations present fresh challenges to the qualification process. This session will examine key aspects of adopting and validating modern technologies, including AI-driven inspection models and automated recirculation functions. Case studies from industry leaders will highlight practical solutions, technical details, and innovative validation strategies. The final presentation will showcase the development of a global standard operating procedure, emphasizing adaptability and continuous training to meet evolving global demands. These insights will encourage critical thinking about the future of VI qualification.

Moderator: Andrea Sardella, **PhD**, Customer Success Manager, *Brevetti CEA*

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, **PhD**, Head of Data Science, *Körber Pharma Inspection GmbH*

14:05 – 14:25

Qualifying an Automated VI Using Recirculation Function

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

14:25 – 14:45

Development of a Global Standard Operating Procedure Development Case Study for Both Liquid and DIP

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 Control and Monitoring: Building a Compliant and Effective Framework

City of Oaks Ballroom

Particle control and monitoring are critical to ensuring compliance and efficiency in parenteral manufacturing. This session will explore the interconnected components of a robust program, including supplier relationships, upstream process monitoring, and visual inspection. The presenters will delve into practical strategies such as solving trace foreign matter investigations, reducing particles through supplier-driven contamination control strategies (CCS), and pinpointing cellulose sources. These advanced concepts will illustrate how a mature particle control program can drive continuous improvement and enhance manufacturing

capabilities, setting new standards for process excellence.

Moderator: Robert J. Miller, **MS**, Independent Consultant, *R. J. Miller and Associates*

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 Ready-toT-Fill 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*

14:45 – 15:15

Q&A

15:15 – 16:00

Networking Break in the Exhibit Hall

Glenwood Ballroom

15:15 – 16:00

Poster Presentations in the Exhibit Hall

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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*

Agenda

PDA Visual Inspection Forum 2025

16:00 – 17:30

A2: Particle Detection Capability: Identifying and Controlling Contaminants

City of Oaks Ballroom

Understanding the source and composition of particles is a crucial part of the visible particle control strategy. This session will discuss issues related to particle detectability under standard inspection conditions. A comprehensive overview of the particle detection capabilities will highlight the complexity of particle sources and approaches for the reduction of the particle contamination in the manufacturing environment. Additionally, the session will feature a manual visual inspection (MVI) case study and introduce an innovative approach to identifying particles in parenteral products.

Moderator: Rukman S. De Silva, **PhD**, 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: Standards for Performance Evaluation of Novel Human-Inspired Automated Visual Inspection Instruments

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 MVI Detection Probability in Difficult-to-Inspect Products

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

17:00 – 17:30

Q&A

16:00 – 17:30

B2: Innovative AI and Machine Learning Solutions for Visual Inspection for Difficult-to-Inspect Parenterals

City of Oaks Ballroom

This session will explore cutting-edge AI and machine learning (ML) techniques that improve quality control for challenging pharmaceutical products. The presentations will cover processes designed to streamline automated visual inspection (AVI), including advanced image classification, deep learning for defect identification, and unsupervised learning methods. These innovations enable precise detection of defects, reduce false rejections, and enhance inspection accuracy across a range of difficult-to-inspect parenteral (DIP) products, underscoring AI's growing impact on quality assurance in the industry.

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

16:00 – 16:20

Rule-Based vs. AI Algorithms in DIP Quality Control

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

16:20 – 16:40

AI-Powered AVI: Image Classification Enhancement and False Rejection Rate Reduction in Blow-Fill-Seal DIPs

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

16:40 – 17:00

Unsupervised ML Applied to DIPs

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

17:00 – 17:30

Q&A

17:30 – 18:30

Networking Reception in the Exhibit Hall

Tuesday, 11 March

07:30 – 08:30

Continental Breakfast

07:30 – 17:00

Registration Open

08:30 – 10:00

P3: Visual Inspection Acceptance Sampling and Performance Metrics: Enhancing Quality and Inspection Validation

Crabtree Ballroom

This session will address critical aspects of acceptance sampling and performance measurement in visual inspection (VI), offering insights into practical considerations and common misconceptions. Subject matter experts will examine the role of acceptance quality limit (AQL) sampling in evaluating batch quality and trending defects following 100% VI as well as introduce mathematical models used to compare the detection performance of manual visual inspection (MVI) versus automated visual inspection (AVI), essential for qualifying and validating alternative inspection methods. Participants will gain a deeper understanding of how sampling and performance metrics enhance inspection reliability and ensure product quality.

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

08:30 – 09:00

Sampling in the VI Process: AQL and Defect Trending

Presenter: Robert J. Miller, **MS**, Independent Consultant, *R. J. Miller and Associates*

Agenda

PDA Visual Inspection Forum 2025

09:00 – 09:30

Mathematical Modeling to Compare Detection Performance: MVI vs. AVI

Presenter: Mark Arsenault, Senior Process Engineer, *Genentech*

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

Glenwood Ballroom

10:00 – 10:45

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

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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*

10:45 – 12:15

A3: Transforming Visual Inspection: Strategies for Modernization and Training

City of Oaks Ballroom

This session will explore how modernizing visual inspection (VI) processes can improve defect detection. Topics will include the revision of manual inspection programs, the transition to automated systems, and the importance of inspector training for ensuring accuracy and compliance. Participants will be provided with practical strategies to improve inspection workflows, implement automated visual inspection (AVI) systems, and foster robust training practices to boost product quality.

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

10:45 – 11:05

Challenges and Considerations in Transitioning from Manual to AVI

Presenter: Andrea Sardella, **PhD**, Customer Success Manager, *Brevetti CEA*

11:05 – 11:25

Revolutionizing Pharmaceutical Inspection: Upgrading to AVI Systems

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

11:25 – 11:45

Manual VI 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: Enhancing Detection and Efficiency

City of Oaks Ballroom

This session will delve into the latest advancements in inspection equipment technology, showcasing innovations that enhance defect detection, streamline processes, and improve data collection. Presentations will include AI-driven visual inspection (VI) systems that leverage data for smarter production, a semi-automated IV bag inspection system (IVBIS), and the integration of complete electronic records in VI processes. These cutting-edge solutions will demonstrate how modern equipment design is driving efficiency and quality in pharmaceutical manufacturing.

Moderator: Rick J. Watson, Director, *Merck & Co., Inc.*

10:45 – 11:05

AI-Driven VI: Unlocking Data for Smarter Production

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

11:05 – 11:25

A Semi-Automated IVBIS

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

11:25 – 11:45

The Next Phase in VI – Complete Electronic Records

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

11:45 – 12:15

Q&A

Agenda

PDA Visual Inspection Forum 2025

12:15 – 13:15

Networking Lunch with Exhibitors

Glenwood Ballroom

13:15 – 14:45

P4: Visual Inspection Process Development and Qualification

Crabtree Ballroom

This session will examine the critical aspects of validating both traditional and advanced visual inspection (VI) technologies while exploring the transformative impact of digital VI platforms. The first presentations will discuss defect set design and validation, addressing the advantages of manufactured versus naturally occurring defects in manual and automated inspections. Following this, a holistic, digitally integrated VI platform that standardizes inspection practices, incorporates human oversight, and enables continuous improvement through advanced defect tracking, digital image libraries, and deep learning infrastructure will be introduced. Together, these subject matter experts will illustrate how both validation and digital innovation are reshaping VI for parenterals.

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

13:15 – 13:45

VI Validation Considerations for Traditional and New Technology

Presenter: Rick J. Watson, Director, *Merck & Co., Inc.*

13:45 – 14:15

Benefits of a Digital VI Platform

Presenter: Romain Veillon, **PharmD**, Director Platform Lead Visual Inspection, *GSK*

14:15 – 14:45

Q&A

14:45 – 15:30

Networking Break in the Exhibit Hall

Glenwood Ballroom

15:00 – 15:45

Poster Presentations in the Exhibit Hall

Glenwood Ballroom

15:00 – 15:45

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15:00 – 15:45

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*

15:30 – 17:00

P5: Panel Discussion: Interactive Insights from Industry Experts

Crabtree Ballroom

This final panel discussion will offer conference attendees a unique opportunity to engage directly with the organizing committee of subject matter experts. Participants will be able to ask questions and discuss various topics, fostering an open dialogue that enhances understanding and collaboration within the field. This interactive session aims to address attendee inquiries and provide valuable insights from experienced professionals.

Moderator: Romain Veillon, **PharmD**, Director Platform Lead Visual Inspection, *GSK*

Moderator: Rick J. Watson, Director, *Merck & Co., Inc.*

15:30 – 15:45

Interactive Polling

15:45 – 16:55

Panel Discussion

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

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

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

Panelist: Robert J. Miller, **MS**, Independent Consultant, *R. J. Miller and Associates*

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Panelist: Romain Veillon, **PharmD**, Director Platform Lead Visual Inspection, *GSK*

Panelist: Rick J. Watson, Director, *Merck & Co., Inc.*

16:55 – 17:00

Closing Remarks from Co-Chairs

Co-Chair: Romain Veillon, **PharmD**, Director Platform Lead Visual Inspection, *GSK*

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