2019 Visual Inspection Forum

Preparing for the Future of Visual Inspection

April 23-24, 2019 | Marriott Marquis Washington DC | Washington, DC

As of April 4, 2019

Monday, April 22

3:00 p.m. – 6:00 p.m.
Registration Open

Tuesday, April 23

7:15 a.m. – 6:00 p.m.
Registration Open

7:15 a.m. – 8:15 a.m.
Continental Breakfast

8:15 a.m. – 8:30 a.m.
Welcome and Opening Remarks from Conference Co-Chairs
Markus Lankers, PhD, Consultant, *MIBIC GmbH & Co KG* and
John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

8:30 am. – 10:00 a.m.
P1: Regulatory Overview and Updates
Moderator: Markus Lankers, PhD, Consultant, *MIBIC GmbH & Co KG*

Regulatory requirements are a driving force for the development and implementation of visual inspection. The session will provide regulatory perspectives on visual inspection issues covering USP <790> and <1790>. Furthermore, an overview and analysis about recalls in different countries during the last years will be summarized and discussed.

8:30 a.m. – 8:50 a.m.
Inspection Trends and Market Recall for Visual Inspection
Romain Veillon, Senior Manager, Vision Inspection & Leak Testing MSAT – Manufacturing Technologies, *GSK Vaccines*

8:50 a.m. – 9:10 a.m.
Regulatory and Compendial Update: What's New in Visual Inspection Requirements and Guidance
John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

9:10 a.m. – 9:30 a.m.
Regulatory Perspective on Inspection of Injectable Products for Visible Particulates
Hailin (Sheena) Wang, PhD, Chemist, CDER, *FDA*

9:30 a.m. – 10:00 a.m.
Questions and Answers/Discussion

9:45 a.m. – 6:45 p.m.
Exhibit Hall Open

10:00 a.m. – 10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall

Poster Presentations

The following posters will be presented during refreshment breaks on Tuesday and Wednesday

1. **A Case Study: Investigating the Source of Foreign Particulate Using Multiple Microanalytical Techniques**
   Casey M. Brown, Research Scientist, *MVA Scientific Consultants*
2. **3D Printing for Enhanced Visual Inspection**
   Nicholas K. Coles, Process Engineer, *Genentech, Inc.*
3. **Direct Atomic Emissions Spectroscopy on Lyo Cake to Significantly Reduce Time for Particle Identification**
   Andrew D. Norriss, Principal Engineer, *Genentech, Inc.*
4. **Failures and Triumphs of an Automated Visual Inspection System**
   Neal Zupec, Senior Research Scientist, *Baxter Healthcare*
5. **To Inspect or Not to Inspect – When Should CCI Testing be Part of an Inspection Process?**

Derek I. Duncan, PhD, Director Product Line Europe, *Lighthouse Instruments*

6. **Particle Detection in Printed IV-Bags using Symbol Verification: An New Inspection Method for Difficult to Inspect Products with Printed Flexible Surface**
   Florian Krickl, Product Manager, *VITRONIC*
7. **Determination of the Particulate Matter Contribution to the Pharmaceutical Manufacturing Process from a Widely-used Single-Use-System: Bioprocessing Bags**
   David L. Exline, President, *Gateway Analytical*

10:45 a.m. – 12:15 p.m.
P2: Inspection Control Strategies
Moderator: Rick Watson, Director, Sterile & Validation COE, *Merck & Co., Inc.*

As stated in USP <790>, there is an expectation that parenteral manufacturers establish a "complete program for the control and monitoring of particulate matter". This session covers a wide range control strategies and process design topics that support establishment of a complete and comprehensive inspection program. Presentations in this session will outline key considerations associated with the monitoring of visual inspection reject rates and the establishment of sampling plans. This session will also provide insights into the many product and container related factors that influence particle detection and the design of the container sets used for qualification.

10:45 a.m. – 11:05 a.m.
Defect Trending and Defect Limits: Considerations for the Life Cycle Process and Visual Inspection
Robert J. Miller, Senior Manager Technical Services, *Pfizer Inc.*

11:05 a.m. – 11:25 a.m.
Statistical Sampling Plans to Meet Proposed Annex 1 Revisions Regarding Container Closure Integrity Testing
Jim Veale, PhD, President, *Lighthouse Instruments*

11:25 a.m. – 11:45 a.m.
A Study of Container and Product Factors that Influence the Probability of Rejection (PR) of Containers with Contaminating Particles
Gerald W. Budd, President, *Phoenix Imaging, Ltd.*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. – 1:30 p.m.
Networking Lunch in Exhibit Hall

1:30 p.m. – 3:00 p.m.
P3: Advances in Automated Inspection
Moderator: Romain Veillon, Senior Manager, Vision Inspection & Leak Testing MSAT – Manufacturing Technologies, *GSK Vaccines*

Innovation in Automated Inspection is moving fast forward with emergence of new concepts like Digitalization, Deep Learning and non-visible light inspection. This session will cover 3 cases studies to cover new concept that may reshape automated inspection. First, a case study will focus on enhanced visual inspection for lyophilized vials with non-visible spectrometry. Then, the digitalization concept with image archiving and analysis will be introduced. Finally, advances with Deep-Learning implementation and qualification will be presented.

1:30 p.m. – 1:50 p.m.
Going Beyond the Visible to Provide Enhanced Inspection in Lyophilized Products: A Case Study on the Use of Spectroscopy in 100% AVI
Joanny Salvas, Manager PAT, *Pfizer Inc.*

1:50 p.m. – 2:10 p.m.
Collection, Archival, and Analysis of Images from Automated Vision Inspection: Present Value and Prospective Opportunities
Joseph A. Straub, Associate Director, *Merck & Co., Inc.*

2:10 p.m. – 2:30 p.m.
Deep Learning Development and Qualification in Automated Vision Inspection Technology for Parenteral Pharmaceutical Drug Products
Jorge Delgado, Senior Manger Process Development, *Amgen*

2:30 p.m. – 3:00 p.m.
Questions and Answers/Discussion

3:00 p.m. – 3:45 p.m.
Refreshment Break and Poster Presentations in Exhibit Hall

3:45 p.m. – 5:15 p.m.
P4: Particle Identification, Investigations and Supplemental Testing
Moderator: John D. Ayres, MD, Risk Assessment Clinician, *Pharma Safety Solutions, LLC*

Understanding the source and composition of particulate matter provides the necessary substrate for the development of adequate control strategies and comprehensive risk assessments. This session will discuss the development of analytic methods to further characterize and subsequently classify cellulose fibers—a very common particle in injectables; outline adopting a particulate lifecycle management program utilizing USP <1790> assessment and control considerations; and, reviewing the utilization of forensic microscopy to isolate and characterize trace and ultra-trace amounts of particulate matter in sterile ophthalmic solutions and identify its potential source.

3:45 p.m. – 4:05 p.m.
Towards an Analytical Method for Identification of Cellulose Fibres
Jonas Hoeg Thygesen, PhD Area Specialist, *Microanalysis Centre, R&D, Novo Nordisk Pharmatech A/S*

4:05 p.m. – 4:25 p.m.
Utilization of a Forensic Microscopy (Problem Solving) Approach to the Identification of Subvisible Particles Observed in a Sterile Ophthalmic Solution on Stability
Mary Lee Ciolkowski, PhD, Senior Principal Scientist, *Bausch + Lomb*

4:25 p.m. – 4:45 p.m.
Adopting a Particulate Matter Lifecycle Approach in Harmony with USP <1790>
Antonio J. Scatena, Senior Sales Representative, *Gateway Analytical*

4:45 p.m. – 5:15 p.m.
Questions and Answers/Discussion

5:15 p.m. – 6:45 p.m.
Networking Reception in Exhibit Hall

Wednesday, April 24

7:30 a.m. – 6:00 p.m.
Registration Open

7:30 a.m. – 8:30 a.m.
Continental Breakfast

8:30 a.m. – 10:00 a.m.
P5: Difficult to Inspect Parenterals (DIP)
Moderator: Roy T. Cherris, Managing Partner, *Bridge Associates International & InQuest Science LLC*

Increasing numbers of complex formulations and delivery system presentations that are difficult to inspect have entered the parenteral market. The concept of Difficult to Inspect Parenterals (DIP) describes product container/closure systems and or formations with limited capability for an effective 100% visual inspection. Robust product defect lifecycle management is the key to maintaining product quality with DIPs. The USP<1790> compendial chapter and PDA Technical Report 79 released in 2018 have clarified guidance on how to manage DIP products. This session will present discussions on control strategy approaches to address DIP inspection and supplemental destructive testing.

8:30 a.m. – 8:50 a.m.
Keys to Successful Qualification of Automated Inspection Equipment
Ron Lawson, Director of Operations, *Prime Results (Invited)*

8:50 a.m. – 9:10 a.m.
Rise of the Machines: Can Automated Visual Inspection Reduce Human Error in Difficult to Inspect Products?
Amber H. Fradkin, PhD, Director, Particle Characterization Core Facility, *KBI Biopharma, Inc.*

9:10 a.m. – 9:30 a.m.
Transitioning from Semi-Automated to Automated Inspection: A Case Study for a Difficult to Inspect Product (DIP)
Aaron Shirkey, Senior Specialist, Engineering, *Merck & Co., Inc.* and
Ian T. Jehring, Specialist, Engineering, *Merck & Co., Inc.*

9:30 a.m. – 10:00 a.m.
Questions and Answers/Discussion

9:45 a.m. – 3:30 p.m.
Exhibit Hall Open

10:00 a.m. – 10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall

10:45 a.m. – 12:15 p.m.
P6: Automated and Multi-Stage Inspection Topics
Moderator: Robert J. Miller, Senior Manager Technical Services, *Pfizer Inc.*

This session will provide some real-world problem solving when moving toward automated or multi-stage inspection processes. Learn from those who have "been there before" to reduce false rejects in deployed automated systems, ensure that a new multi-stage inspection process is compliant and robust, and selecting the appropriate technology for your specific product. These case-studies will also highlight contemporary methods for root cause analysis, evaluating inspection effectiveness, and targeted defect detection.

10:45 a.m. – 11:05 a.m.
Case Study: Controlling Interactions Between Packaging Components and Injectable Products that Can Lead to False Rejects
Rick Watson, Director, Sterile & Validation COE, *Merck & Co., Inc.*

11:05 a.m. – 11:25 a.m.
Compliant Approach to Implementation of Multi-Staged Inspection that Combines Automated and Manual Methods Techniques
Nicola Mauriello, GTO ExM Specialist, *MSD International GmbH* and
Andrea Cedrola, Equipment Validation Specialist, *Patheon, part of Thermo Fisher Scientific*

11:25 a.m. – 11:45 a.m.
Use of Automated and Manual Visual Inspection of Container Closure Integrity
Elizabeth Zybczynski, Director, Production and Process Control, *Baxter Healthcare*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. – 1:45 p.m.
Networking Lunch in Exhibit Hall

1:45 p.m. – 2:45 p.m.
P7: Commercial Technical Development
Moderator: John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

Visual inspection systems are constantly evolving to take advantage of new concepts and technology. This session is designed to provide a quick survey of some of the unique technical capabilities in commercially available inspection systems. It should provide a useful benchmark for those considering upgrading existing hardware, assessing how best to meet a new inspection need or preparing for a future transition from manual or semi-automated inspection to automated inspection.

1:45 p.m. – 1:55 a.m.
Reliable Differentiation of Air Bubbles From Transparent Particles
Christain A. Scherer, Head of Sales, *Seidenader Maschinenbau GmbH*

1:55 p.m. – 2:05 p.m.
Particle Detection and Other Challenging Inspections Through a Phased in Machine Learning Approach
Steven Wardell, Director, Imaging, *ATS Automation*

2:05 p.m. – 2:15 p.m.
Deep Learning in Deep: From Research to Real Application
Massimo Frasson, General Manager, *Brevetti C.E.A. Spa*

2:15 p.m. – 2:25 p.m.
Automatic Visual Inspection of Lyophilized Products, Characterizes as Difficult to Inspect Products (DIP), with Very Low False Reject
Søren Christoph Meyer, Mechanical and HW Engineering Manager, *InnoScan*

2:25 p.m. – 2:35 p.m.
Particular Challenges in Automated Visual Inspection of Cartridges for Parenteral Drug Administration
José M. Zanardi Ocampo, PhD, Senior Manager, *Bosch Packaging Technology K.K.*

2:35 p.m. – 2:45 p.m.
Session Wrap-up

2:45 p.m. – 3:30 p.m.
Refreshment Break and Poster Presentations in Exhibit Hall

3:30 p.m. – 5:00 p.m.
P8: Clinical Relevance of Particles in Injectable Products
Moderator: John D. Ayres, MD, Risk Assessment Clinician, *Pharma Safety Solutions, LLC*

Nearing the conclusion of two days discussing the technical and scientific facets of particulate matter control, characterization, and identification this session will explore the question "What does all this mean clinically and what are clinicians saying?" The first speaker will discuss the challenges and risk management strategies involving the potential medical impact of particulates in difficult to inspect products. Next, a review of laboratory and clinical studies will be presented, looking at the potential mitigating impact of bedside in-line filtration in ICU settings. Third, an overview of the potential clinical implications of particles given current manufacturing and inspection capabilities will be presented. The Q&A provides a great opportunity to exploring the interface between capabilities and clinical impact.

3:30 p.m. – 3:50 p.m.
Effect of on In-line Filtration during Infusion of IV Drugs: Clinical and Laboratory Results
Markus Lankers, PhD, Consultant, *MIBIC GmbH & Co KG*

3:50 p.m. – 4:10 p.m.
A Review of the Potential Clinical Implications of Particulate Matter in Injectables
R. Douglas Ross, MD, MBA, Senior Director, *Pfizer Inc.*

4:10 p.m. – 4:30 p.m.
Challenges and Risk Management Strategies for Medical Impact of Particulate Matter in Difficult to Inspect Parenterals
Nathan Cox, Senior Manager, Quality Engineering, *KYMANOX*

4:30 p.m. – 5:00 p.m.
Questions and Answers/ Discussion

5:00 p.m. – 5:15 p.m.
Break

5:15 p.m. – 6:00 p.m.
P9: Panel Discussion with Moderators
Moderator: John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

This is an opportunity to highlight, summarize and discuss the key points from both days of the Forum. Each of the session moderators will provide a brief summary of the highlights from their session during the conference.

5:15 p.m. – 5:45 p.m.
John D. Ayres, MD, Risk Assessment Clinician, *Pharma Safety Solutions, LLC*
Roy T. Cherris, Managing Partner, *Bridge Associates International & InQuest Science LLC*
Markus Lankers, PhD, Consultant, *MIBIC GmbH & Co KG*
Robert J. Miller, Senior Manager Technical Services, *Pfizer Inc.*
Romain Veillon, Senior Manager, Vision Inspection & Leak Testing MSAT – Manufacturing Technologies, *GSK Vaccines*
Rick Watson, Director, Sterile & Validation COE, *Merck & Co., Inc.*

5:45 p.m.
Closing Remarks and Adjournment