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**, **BS Chem Eng**, 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**, **BS Chem Eng**, 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

11:00 – 12:30

P2: Process Development

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

11:00 – 11:30

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 Pharmaceutical Manufacturing GmbH, Schaftenau*

11:30 – 12:00

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*

12:30 – 13:30

Networking Lunch with Exhibitors

13:30 – 13:45

Interactive Questionnaire Session

13:45 – 15:15

A1: New challenges in Visual Inspection Qualification

Moderator: Andrea Sardella, **PhD**

13:45 – 14:05

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

Presenter: Bastian Kronenbitter, Head of Data Science, *Körber Pharma Inspection GmbH*

Co-Presenter: Bastian Kronenbitter, Head of Data Science, *Körber Pharma Inspection GmbH*

14:05 – 14:25

Qualifying an Automated Visual Inspection (AVI) Using Recirculation Function

Presenter: Jun L. Ordonez, Sr. 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 Inc*

13:45 – 14:05

Problem Solving During Trace Foreign Matter Investigations: Points to Consider

Presenter: Mary Lee Ciolkowski, PhD, Sr. 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*

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

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 AG*

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, Professor, *University of Applied Sciences Northwestern Switzerland*

16:40 – 17:00

Case Studies: Increasing PoD in MVI for DIP

Co-Presenter: Menno Sels, **MSE**, Project Engineer VI & CCIT, *eyetec*

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 Pharmaceuticals International AG*

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 AVI systems

Presenter: GIANMARCO PINCELLI, Technical Sales Manager, *Bonfiglioli Engineering srl*

16:40 – 17:00

Unsupervised Machine Learning Applied to Difficult-to-Inspect Products

Presenter: Brian Turnquist, **PhD**, Chief Technical Officer, *Boon Logic*

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

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 Inc*

09:00 – 09:30

Use of Mathematical Model for Detection Performances Comparison of MVI versus AVI

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

10:45 – 12:15

A3: Inspection Optimization

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

10:45 – 11:05

Modernization of an MVI Program to Improve Defect Detection

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

11:05 – 11:25

Revolutionizing Pharmaceutical Inspection: Upgrading to Automated Visual Inspection Systems

Presenter: Scott Council, North Carolina Division Director, *Performance Validation*

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

11:25 – 11:45

Manual Visual Inspection (MVI) 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, **BS Chem Eng**, Director, *Merck*

10:45 – 11:05

AI-Driven Visual Inspection: Unlocking Data for Smarter Production

Presenter: Massimo Frasson, Ceo & General Manager, *BREVETTI C.E.A. S.p.A.*

11:05 – 11:25

A Semi-Automated IV Bag Inspection System (IVBIS)

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

11:25 – 11:45

The Next Phase in Visual Inspection – Complete Electronic Records

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

11:45 – 12:15

Q&A

12:15 – 13:15

Networking Lunch with Exhibitors

13:15 – 13:30

Interactive Questionnaire Session

13:30 – 15:00

P4: Visual Inspection Process Development and Qualification

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

13:30 – 14:00

Visual Inspection Validation Considerations for Traditional and New Technology

Presenter: Rick J. Watson, **BS Chem Eng**, Director, *Merck*

14:00 – 14:30

Benefit of Digital Visual Inspection Platform

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

14:30 – 15:00

Q&A

15:00 – 15:45

Networking Break in the Exhibit Hall

15:00 – 15:45

Poster Presentations in the Exhibit Hall

15:45 – 17:00

P5: Panel Discussion

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

Moderator: Rick J. Watson, **BS Chem Eng**, Director, *Merck*

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 Inc*

Panelist: Andrea Sardella, **PhD**

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

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

Panelist: Rick J. Watson, **BS Chem Eng**, Director, *Merck*

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

16:55 – 17:00

Closing Remarks from Forum Co-Chairs

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

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