2020 PDA Visual Inspection Interest Group Workshop

Wednesday, September 23

10:00 a.m. – 11:35 a.m. | **P1: The Changing Regulatory Environment for Visual Inspection**
Moderator: John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

The regulatory environment for pharmaceutical manufacturing constantly evolves. We continue to look at current hot topics in the regulations that govern visual inspection and particle control and recent and proposed revisions to these requirements. EMA Annex 1 and the European Pharmacopoeia (EP) provide this guidance in Europe and Food and Drug Administration (FDA) and The US Pharmacopia (USP) provide this guidance in the United States. Both regions have been actively revising their regulations and guidance on these topics. We will discuss:

- FDA Recalls and Guidance
- USP <1790> *Visual Inspection of Injections*
- EMA Annex 1 *Manufacture of Sterile Products*
- EP 2.9.20 *Particulate Contamination: Visible Particles*
- EP 5.17.2 *Recommendations on testing of particulate contamination: visible particles*

10:00 a.m. – 10:10 a.m. | **Welcome and Introduction of Workshop**
John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

10:10 a.m. – 10:40 a.m. | **Visual Inspection Regulatory and Compendial Update**
John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

10:40 a.m. – 11:35 a.m. | **Group Discussion**

11:35 a.m. – 11:40 a.m. | **Break**

11:40 a.m. – 12:00 p.m. | **P2: 2020 PDA Visual Inspection Forum Preview**
Moderator: John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

This session will highlight topics that will be covered at this year's VI Forum held in Berlin in October. Key topics from this meeting will include:

- Particle identification, reduction and defect prevention
- Experience with difficult to inspect parenteral products (DIP)
- Advances in Automated Inspection
- Application of Artificial Intelligence (AI)/Deep Learning (DL) to automated inspection

11:40 a.m. – 11:50 a.m. | **Forum Highlights**
John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*

11:50 a.m. – 12:00 p.m. | **Group Discussion**

12:00 p.m. – 12:10 p.m. | **Break**

12:10 p.m. – 12:30 p.m. | **P3: Application of Novel Technology in Visual Inspection**
Moderator: Rick Watson, Director, Sterile & Validation CoE, *Merck & Co., Inc.*

This session will discuss novel technologies that are expected to deliver a positive impact on visual inspection processes. The discussion will include examples of current advancements and consideration of likely future direction for application of these new technologies. Topics that will be discussed include:

- Use of Smart Glasses to enhance manual inspection
- Applications for VR technology
- Advances in Artificial Intelligence (AI) in automated inspection
- How you prepare for Artificial Intelligence (AI)/Deep Learning (DL) and how to validate these systems

12:10 p.m. – 12:20 p.m. | **Novel Technology Overview**
Rick Watson, Director, Sterile & Validation CoE, *Merck & Co., Inc.*

12:20 p.m. – 12:30 p.m. | **Q&A**

12:30 p.m. – 12:35 p.m. **| Break**

12:35 p.m. – 2:00 p.m. | **P4: Panel Discussion**
Moderator: Rick Watson, Director, Sterile & Validation CoE, *Merck & Co., Inc.*

This session will provide the opportunity to discuss topics of specific interest to those attending the workshop that were not addressed in the earlier sessions. This will be a good opportunity to:

- Discuss current challenges
- Benchmark with peers
- Discuss current regulatory and compliance environment and experience
- Identify useful references and resources

12:35 p.m. – 12:50 p.m. | **Regulatory Considerations for the Assessment of Visible Particulates**
Rukman S. De Silva, PhD, Chemist/Product Quality Reviewer, CDER, *U.S. FDA*

12:50 p.m. – 1:50 p.m. | **Panel Discussion**
Rukman S. De Silva, PhD, Chemist/Product Quality Reviewer, CDER, *U.S. FDA*
John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*
Romain Veillon, Senior Manager, Vision Inspection & Leak Testing MSAT – Manufacturing Technologies, *GSK Vaccines*
Rick Watson, Director, Sterile & Validation CoE, *Merck & Co., Inc.*

1:50 p.m. – 2:00 p.m. | **Closing Remarks and Final Wrap-up**
John G. Shabushnig, PhD, Principal Consultant, *Insight Pharma Consulting, LLC*