The Parenteral Drug Association presents:

Visual Inspection Forum

On the Path from MVI to AVI - Challenges and Trends

CONFERENCE GUIDE

ATTENDEE NAME

23-24 October 2018
Marriott Hotel
Berlin | Germany
Dear Colleagues,

On behalf of the Scientific Program Planning Committee, we warmly welcome you to the Visual Inspection Forum in Berlin / Germany!

The forum will provide a platform to present and discuss new developments in the field of visual inspection, including a basic understanding of the sampling and inspection process, special aspects of biotech products, practical aspects of manual, semiautomated and automated methods and the regulatory and compendia requirements that govern them.

On 20 December 2017, the long-awaited Annex 1 Revision of the EU GMP Guidelines was finally published. While the currently valid Annex 1 only briefly touches on the important topics of container closure integrity control and visual inspection, this amendment offers a number of innovations. The new requirements encourage further discussion of the correct understanding and implementation in visual inspection and provide only one of this year’s hot topics to be discussed.

Progressing further from manual visual inspection to automated visual inspection, the forum will give insights on the latest trends and the challenges this development entails.

We look forward to exchanging with you at the Visual Inspection Forum 2018!

Welcome to Berlin!

John Shabushnig, PhD, Insight Pharma Consulting, Chair
Markus Lankers, PhD, MIBIC, Chair

Media Partner: Pharmaceutical Technology Europe, EPR

#pdavisual
Welcome to the beautiful city of Berlin!

SCHEDULE AT A GLANCE

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<th>Date</th>
<th>Time</th>
<th>Event</th>
<th>Details</th>
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<tr>
<td>23 October</td>
<td>9:00 – 18:00</td>
<td>Visual Inspection Forum</td>
<td>Conference, Exhibition</td>
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<tr>
<td>23 October</td>
<td>18:30 – 21:30</td>
<td>Networking Event</td>
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<tr>
<td>24 October</td>
<td>9:00 – 16:30</td>
<td>Visual Inspection Forum</td>
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<tr>
<td>25 October</td>
<td>9:00 – 17:30</td>
<td>An Introduction to Visual Inspection:</td>
<td>Training Course</td>
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<tr>
<td>26 October</td>
<td>9:00 – 16:30</td>
<td>A hands-on course</td>
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<tr>
<td>25 October</td>
<td>9:00 – 16:30</td>
<td>Mastering Automated Visual Inspection</td>
<td>Training Course</td>
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For latest information, please visit: [pda.org/EU/VIF2018](http://pda.org/EU/VIF2018)

Join [@PDA_Europe](https://twitter.com/PDA_Europe) on Twitter and post pictures and highlights of this meeting! #pdavisual

Follow us on LinkedIn [http://linkedin.com/company/pda](http://linkedin.com/company/pda)
Tuesday, 23 October 2018

<table>
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<tr>
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<th>Speaker</th>
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<tr>
<td>9:00</td>
<td>Welcome &amp; Introduction</td>
<td>Falk Klar, PDA Europe</td>
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<td>Markus Lankers, MIBIC, Chair</td>
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<td>John Shabushnig, Insight Pharma Consulting, Chair</td>
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<tr>
<td>9:15</td>
<td>Proposed Changes to the EU GMP Guideline Annex 1 and a Comparison with Corresponding USP Chapters</td>
<td>John Shabushnig, Insight Pharma Consulting</td>
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<tr>
<td>9:45</td>
<td>Container Closure Integrity Testing – The Impact of the Annex 1 Revision</td>
<td>Derek Duncan, LIGHTHOUSE</td>
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<tr>
<td>10:15</td>
<td>Coffee Break, Poster Session &amp; Exhibition</td>
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<tr>
<td>10:45</td>
<td>Visible Particle Requirements in the European Pharmacopeia</td>
<td>Hanns-Christian Mahler, LONZA</td>
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<tr>
<td>11:15</td>
<td>Market Recalls and Inspection Trends for Visual Inspection</td>
<td>Romain Veillon, GSK</td>
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<tr>
<td>11:45</td>
<td>Q&amp;A, Discussion</td>
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<tr>
<td>12:30</td>
<td>Lunch Break, Poster Session &amp; Exhibition</td>
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**Session 1  Regulatory Landscape and Updates**

The session will provide regulatory perspectives on visual inspection issues covering USP 790 and 1790. Furthermore, the impact of the long-awaited Annex 1 Revision of the EU GMP guideline on visual inspection and container closure integrity testing will be summarized and discussed.

**Session 2  TRACK A TRACK B**

**Deep Learning and Artificial Intelligence**

**Moderator:** Heino Prinz, Rommelag

Applying Deep Learning algorithms to Automated Visual Inspection has become a terrific opportunity for improved classification and highly precise detection of damages and defective pharmaceutical products lately. In this session, we try to answer the questions about where we stand today and what is at the horizon. Besides this, a stunning question remains to be pursued – how to validate this approach?

**Control Strategies**

**Moderator:** John Ayres, Pharma Safety Solutions

Manufacturing and inspection control strategies are designed to create reliably consistent outcomes. In this session, we will explore the use of statistical methods to evaluate the utility of inspection strategies; considerations to incorporate VI into the overarching product quality control strategy; and one company’s implementation of ‘zero tolerance’ and articulation of their measures to improve quality and pursue the realization of de minimus product defects.
<table>
<thead>
<tr>
<th>Time</th>
<th>Session 3: Particle Identification and Supplemental Testing</th>
<th>Moderator: Renaud Janssen, Datwyler</th>
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<tr>
<td>16:00</td>
<td>Analysis of Particulate Matter in Liquid Finished Dosage</td>
<td>Balazs Havasi, Novartis</td>
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<td>16:30</td>
<td>Introducing the PDA/PMF Zero Visible Particles Project</td>
<td>Maurizio Fantozzi, Stevanato Group</td>
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<td>17:00</td>
<td>Visual Inspection of Single-Use Systems for Biopharmaceutical Processing</td>
<td>Klaus Wormuth, Sartorius Stedim</td>
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<tr>
<td>17:30</td>
<td>Identification of Micro Steel Particles using Energy Dispersive X-ray Spectroscopy coupled with Multivariate Statistics</td>
<td>Jonas Hoeg Thygesen, Novo Nordisk</td>
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</tbody>
</table>

18:00  End of Conference Day 1
18:30  Networking Event

For visual inspection, detectability of particles is of the utmost importance. In order to investigate sources of particulate contamination, it is equally important to identify particles. This session pays attention to visual inspection of Single-Use Systems. It also, in the form of case studies, discusses cases of identification of particles. An introduction is given to the PDA/PMF Zero Visible Particles Project that was initiated in 2017 and that aims to eliminate visible particles using sound scientific and technical approaches.
The PDA is proud to invite you to a very special Networking Event

Tuesday, 23 October 2018

18:30h – Meeting Point: Hotel Lobby
Joint Walking Tour to the restaurant
19:00h – Dinner, Restaurant Maximilians, Friedrichstrasse 185-190, 10117 Berlin
21:30h – Walking Tour back to Conference Hotel

Join us for a fabulous evening in a traditional Bavarian Restaurant.
Wednesday, 24 October 2018

9:00 Welcome
Markus Lankers, MIBIC, Chair
John Shabushnig, Insight Pharma Consulting, Chair

Session 4  Difficult to Inspect Products
Moderator: Romain Veillon, GSK

Due to recent biologic drug developments, increasing numbers of complex formulations and presentations that are more difficult to inspect have entered the market. The emerging concept of Difficult to Inspect Parenterals (DIPs) describes product presentation and formation with limited capability for visual inspection. Recent USP <1790> compendia and PDA Technical Report # 79 released in 2018 now give guidance on how to manage DIP. This session will present some technological innovations to address DIP inspection. Also, it will cover practical examples of DIP control strategy.

9:10 Introducing the New PDA Technical Report TR-79 on Particulate Matter in Difficult to Inspect Parenteral Products
Roy Cherris, Bridge Associates

9:40 An Update on Difficult to Inspect Products, other Physical Characteristics, and Process Related Phenomena Which Equally Influence (Automatic) Inspectability
Søren C. Meyer, InnoScan

10:10 Effect of Visual Inspection Parameters on the Inspection Effectiveness for Flexible Containers
Neal Zupec, Baxter Healthcare

10:40 Coffee Break, Poster Session & Exhibition

11:10 Spectral Coded Illumination for Reliable Differentiation Between Transparent Particles and Air Bubbles.
Christian Scherer, Seidenader Maschinenbau

11:40 Data Driven Control Strategy for Flexible (IV) Containers
Frank Dudzik, Baxter Healthcare

12:10 Q&A, Discussion

12:30 Lunch Break, Poster Session & Exhibition

Session 5  General Inspection Techniques
Moderator: John Shabushnig, Insight Pharma Consulting

This session has been organized to share practical tools and experience for the implementation of a robust visual inspection process. It provides guidance on the analysis of particles that may be found through the visual inspection program either during automated or manual inspection. It continues with discussion on the development of imaging technologies that may be applied to the automated inspection of syringes. The session concludes with information on the development of standards and test sets to aid in assessing inspection performance and qualification of inspection methods and systems.

13:30 Pulsed X-Ray Particles Inspection for Lyophilisates
Stephan Bachmeier, Heuft

14:00 Advanced Technologies for Automated Visual Inspection of Syringes
Jose Zanardi, Bosch Packaging Technology

14:30 Practical Approach to the Preparation of Defect Standards and Test Sets
Jean Malthête, GSK Vaccines

15:00 Coffee Break, Poster Session & Exhibition
## Closing Plenary Manufacturing and its Clinical Relevance

An essential motive for conducting visual inspection is to avoid the unintentional administration of particulate-contaminated drugs to the patient. Understanding the medical hazards particles pose to patients is an important element of a risk assessment when examining inspection methods or inspection failures. This session will also look at the often discussed removal of particles by bedside filtration and its clinical significance.

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<tr>
<th>Time</th>
<th>Session Details</th>
<th>Presenter(s)</th>
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<tr>
<td>15:30</td>
<td>Filtration of IV Drugs</td>
<td>Markus Lankers, MIBIC</td>
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<td>15:55</td>
<td>Medical Impact of Particles</td>
<td>John Ayres, Pharma Safety Solutions</td>
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<tr>
<td>16:20</td>
<td>Q&amp;A, Discussion</td>
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<tr>
<td>16:30</td>
<td>Closing Remarks &amp; Farewell</td>
<td>Markus Lankers, MIBIC, Chair</td>
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<td>John Shabushnig, Insight Pharma Consulting, Chair</td>
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<td>Falk Klar, PDA Europe</td>
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Automated Optical Inspection Finds Even the Smallest Defects That Make a Big Difference

0.2 mm - particles or defects of this size can pose a severe health risk. VINSPEC HEALTHCARE offers a wide range of automated optical inspection systems (AOI) for the pharmaceutical and medical device industries. Through inline inspection we enable improved processes based on fast feedback loops, minimized rejects of high-value pharmaceuticals and 100% quality throughout the entire production. More safety, Better health.

www.vitronic.com
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- **Table Top 2 m x 3 m (6 m²)**
- **Catering**
- **PDA Registration**
- **Poster Presentation**
No trouble with bubbles

Spectral coded illumination for reliable differentiation between transparent particles and air bubbles. The patented BUBBLE-X camera station, integrated into a Seidenader inspection machine, significantly minimizes the false reject rate.
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Stuttgarter Strasse 130
71332 Waiblingen, Germany
Tel: +49 711 811 57 0
info.packaging-cgn@bosch.com
boschpackaging.com


Brevetti CEA S.p.A.
BOOTH 5
Via Del Commercio 28
36050 Sovizzo (VI) - Italy
Tel: +39 0444 551988
info@brevetti-cea.com
www.brevetti-cea.com

Since 1957 Brevetti C.E.A. has been confirming its ability to hit the mark by manufacturing ground-breaking inspection machines for injectable pharmaceutical products. Product innovation, experience and reliability, combined with a full range of Customer pre and after-sales support services highlight Brevetti C.E.A. as the ideal partner for successful investments.

Gateway Analytical
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www.gatewayanalytical.com

Gateway Analytical is the innovative analytical testing laboratory that businesses around the world trust to provide solutions for their most challenging foreign particulate analysis, foreign particulate identification and materials analysis needs. Gateway’s expert scientists, specialized testing techniques and comprehensive analysis methods allow the company to deliver the fast, accurate and reliable results that customers in the pharmaceutical, materials and medical device industries demand. To learn more about Gateway Analytical and how it is making the world healthier and safer, visit http://www.gatewayanalytical.com.

GS Validation / GS Labs. Services, Inc.
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PO Box 143252
00614-3252 Arecibo, Puerto Rico
Tel: +1 787 636 0316
Fax: +1 254 227 6022
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www.gsvalidation.com

Since 2002 our company dedicated its efforts and specialist personnel to the validation field in the biotechnology and pharmaceutical environment. GS Validation consists of a laboratory facility in Puerto Rico to offer services to all our clients in challenge kits creation for particle seeding and cosmetic defects in a controlled environment. Our detailed challenge kits creation consists of four regulatory areas: Training personnel, certification of visual inspection resources, challenge kit for the automatic visual inspection machines, development of new technology for automatic visual inspection and the manual inspection sector. We are specialists in challenge units like: Vials (glass/plastic), syringes (glass/plastic), cartridges (plastic), medical devices example (sure-click devices).

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HEUFT is SYSTEMTECHNIK Quality, safety and efficiency: this is what matters when filling and packaging pharmaceuticals, beverages and food! The modular solutions from HEUFT SYSTEMTECHNIK GMBH put these key factors into practice simply and effectively. They ensure, during maximum productivity, that only perfect products reach the market. Unique camera, X-ray and image processing technologies for a precise empty and full container inspection, trend-setting labelling technology and smart tools for container flow optimisation, production data acquisition and performance analysis safeguard product quality and line efficiency sustainably!
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Tel: +31 6 4226 7380
dduncan@lighthouseinstruments.com
www.lighthouseinstruments.com

Lighthouse is the leading global provider of laser-based, non-destructive headspace inspection systems. Lighthouse introduced the laser-based headspace method into the pharmaceutical industry in 2000 and offers a range of benchtop and in-line platforms with patented laser sensor technology commercialized with the help of funding from the Food and Drug Administration. In addition to delivering equipment, Measurement Services & Support are delivered from laboratory facilities in Amsterdam and Charlottesville, Virginia. A staff of Application Scientists supports customers with outsourced testing services, scientific studies, and lease equipment projects.

Lonza Pharma & Biotech

Sponsor
Booth 9
Hochbergerstrasse 60 A
4057 Basel, Switzerland
Tel: +41 15114846223
marcus.horn@lonza.com
www.lonza.com/drugproduct

At Lonza Pharma & Biotech we provide contract development and manufacturing services that enable pharma and biotech companies to bring medicines to patients in need. From the building blocks of life to the final drug product, our solutions are created to simplify your outsourcing experience and provide a reliable outcome, at the time when you expect it. Our extensive track record includes commercialization of pioneering therapies and manufacturing of a wide variety of biological and chemical drugs. We continuously invest to solve not just the current, but also the future challenges. Together, we can bring your next medicine to life.

Material Analytischer Service M.A.S...

Booth 2
Engesserstr. 4b
79108 Freiburg, Germany
Tel: +49 761 2923477
Fax: +49 761 2923478
mas@ma-service.de
www.ma-service.de

M.A.S... prepares customized reference standard test kits for the visual inspection of parenterals and lyophilisates for the pharmaceutical industry. Each test set is prepared individually according the customer's requirements and demands: Defined defects are added to the finished product.

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https://pharma.stevanatogroup.com/glass-primary-packaging/

Ompi shares the wider Stevanato Group vision: the desire to drive technological innovations that combine products and processes into systems, which then guarantee the integrity of parenteral drugs in a way that is superior to anything that has ever been achieved before. With operations in Italy, Slovakia, Mexico, China and Brazil, Ompi offers the widest range of glass primary packaging, from the traditional ones such as vials and ampoules, as well as the high-value ones such as syringes and cartridges for auto-injectors and pen-injectors. Vials, cartridges and syringes are also available in sterile and ready-to-fill configuration (Ompi EZ-fill®).

Seidenader Maschinenbau GmbH

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Tel: +49 8121 802-0
Fax: +49 8121 802-100
info@seidenader.de
www.seidenader.com

Seidenader is a competent partner to pharmaceutical companies, specialized in inspection solutions for parenterals. We develop and build inspection machines and applications for manufacturers all over the world. State-of-the-art serialization and aggregation solutions for the traceability of products and for the protection from counterfeiting are part of our brand Traxeed. As an innovative and well-established company with more than 120 years of experience in the market Seidenader is now one of the leading suppliers for inspection solutions, worldwide. Seidenader is part of Medipak Systems, the Pharma Systems business area of the international Körber technology group.

Unchained Labs

Sponsor
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California, United States
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Here’s the deal. We’re all about helping biologics researchers break free from tools that just don’t cut it. Unleashing problem-tackling products that make a huge difference in the real science they do every day. That’s our mantra, our promise and we own it.
VITRONIC Dr.-Ing. Stein Bildverarbeitungssysteme GmbH

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VITRONIC is a world leader in industrial machine vision. The owner-managed group of companies develops innovative products and customized solutions in the growth industries of industrial automation, logistics automation and traffic technology.

WILCO AG

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info@wilco.com
www.wilco.com

WILCO AG provides in-line, off-line and laboratory machines with non-destructive testing methods for monitoring the oxygen content and container closure integrity simultaneously. Our patented leak detection methods based on the process analytical technologies (PAT) offers the opportunity for monitoring the finishing processes as well. We have newly implemented Visual Inspection technologies in our portfolio. With CCIT and Visual Inspection WILCO AG now covers all inspection expectations for pharmaceutical products and our customers benefit from WILCO AG’s vast experience in quality inspection.

Finger your suspect particles

Learn more at stand 8
Present your research at the 2019 PDA Visual Inspection Forum!

The 2019 PDA Visual Inspection Forum Program Planning Committee invites you to submit a scientific abstract on all aspects of visual inspection processes as applied to injectable drug products for an oral or poster presentation. Focus topics at this Forum are:

- Inspection lifecycle, including trending, component variabilities, and API raw materials
- Lessons learned from automated inspection: validation strategies and reducing the false reject rate
- New technology trends in visual inspection, including deep learning and robotic applications
- Special considerations for the inspection of biopharmaceuticals, especially with inherent protein particles

To learn more and submit your abstract, please visit [pda.org/2019Visual](http://pda.org/2019Visual)
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PDA Education Program

25-26 October 2018
An Introduction to Visual Inspection
Two-Day Training Course

25-26 October 2018
Mastering Automated Visual Inspection
Two-Day Training Course
An Introduction to Visual Inspection
A hands-on training course

Overview
This training course covers the fundamentals of visual inspection methods and their application to injectable products. The detection and identification of visible particles is a key part of the course content, though container and closure defects are discussed as well. Students combine classroom review of current regulatory requirements and inspection methods with hands-on laboratory exercises to develop and practice practical inspection skills. The skills developed through this combination of classroom and laboratory exercises may be applied to manual human inspection, semi-automated and automated machine inspection methods. This is also an excellent opportunity to discuss your specific inspection questions and challenges with expert instructors.

Who Should Attend:
- Injectable Drug Product Manufacturing Professionals and Management
- Quality Professionals and Management
- Validation and Manufacturing Engineers
- Technical Support Staff
- Product Development Scientists
- Inspection Equipment Manufacturers

Learning Objectives:
Upon completion of this course, the attendee will be familiar with:
- Understand current global regulatory and compendial requirements for visual inspection
- Understand patient risk associated with visible particles in injections
- Implement a technically sound and compliant inspection process
- Assess inspection performance

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

John Shabushnig is the founder of Insight Pharma Consulting, providing expert guidance in all aspects of visual inspection. He has over 30 years of industry experience starting as a Research Scientist at The Upjohn Company and most recently as a member of Pfizer’s Global Quality Operations, where he was responsible for providing microbiology and aseptic manufacturing technical support. John holds a B.S. in Chemistry from Carroll College and a Ph.D. in Analytical Chemistry from Indiana University. He is an active member of the Parenteral Drug Association (PDA), having served on the Board of Directors (2003-2011) and as Chair (2008-2009) and is the founder and leader of the Visual Inspection Interest Group. He serves on the United States Pharmacopeia (USP) Dosage Forms Expert Committee and chairs the Visual Inspection of Parenterals Expert Panel. He has published and presented numerous papers on the subjects of spectroscopic analysis, process analytical technology (PAT), rapid microbiological test methods and the visual inspection of pharmaceutical products.
Thursday, 25 October 2018  9:00 – 18:00

9:00  Welcome and Introduction
• Why We Inspect
• Patient Safety
• Regulatory Requirements
• Compendial Requirements

10:30  Coffee Break

11:00  Inspection Methods and Technologies
• Critical Parameters (lighting, time, contrast and motion)
• Manual Visual Inspection (MVI)
• Semi-Automated Visual Inspection (SAVI)
• Automated Visual Inspection (AVI)

12:30  Lunch Break

13:30  Particle Identification

14:30  Laboratory Exercise: Manual Visual Inspection
• Light Measurement
• Assessment effect of changing critical variables
  - Time (10 sec vs. 20 sec)
  - Lighting (2,500 lux vs. 1,250 lux)
  - Motion/Agitation (with vs. without)

15:30  Coffee Break

16:00  Continue Laboratory Exercise

17:30  Wrap-up Discussion / Q&A

18:00  End of Day 1

Friday, 26 October 2018  9:00 – 16:30

9:00  Inspection Data Review
• From previous day’s laboratory exercise

10:00  Defect Classification Strategies
• Risk classification definitions
• Critical, Major and Minor defects

10:30  Coffee Break

11:00  Acceptance Sampling
• Sampling Plan Variables
  - Sample Size
  - AQL and UQL
• Common Standards
  - ANSI/ASQ Z1.4
  - ISO 2859

12:00  Inspector Selection and Qualification
• Vision Screening
• Initial Training
• Initial Qualification
• Requalification

12:30  Lunch Break

13:30  Inspection Strategies
• Reinspection
• 2-Stage Inspection
• Focused inspection
• Empty Vial Inspection

14:00  Inspection Validation
• Inspection performance Assessment
  - Knapp Method
• Acceptance Criteria

14:30  Coffee Break

15:00  Mythbusting
• Common misperceptions in visual inspection

15:30  Wrap-up Discussion / Q&A

16:30  End of Training Course

Markus Lankers, PhD, MIBIC

Markus is one of the co-founders of MIBIC GmbH that develops rapid bacteria identification systems. Within MIBIC Markus is responsible for research and development of new spectroscopic methods for bacteria analysis. He has 25 years of experience in the field of particle identification. In 2002, he founded rap.ID Particle systems GmbH and served as Managing Director until the sale of the company in 2018. Prior to this position, he worked as a scientist in different development departments at Schering AG, Berlin, Germany. Markus holds a diploma in Chemistry and a Ph.D. in Physical Chemistry from the University of Würzburg. He is an active member of the Parenteral Drug Association (PDA). Since 2003, he has supported the ‘Visual Inspection of Parenterals’ Interest Group in Europe as Interest Group Leader. He has served as program co-chair for the PDA Visual Inspection Forum from 2001 to 2018 in Europe and the USA.
Mastering Automated Visual Inspection

Overview
Visual Inspection mastery is fundamental in parenteral manufacturing in order to guarantee both patient safety and cost effective supply. The capability of Automated Visual Inspection (AVI) has progressed extensively over the years to the point where, when applied appropriately, it can offer significant advantages over manual and semi-automated inspection processes. This has been made possible thanks to major innovations and technology breakthroughs. In line with these technological advances, the regulatory requirements for this challenging process have been reinforced. As a consequence, AVI machines today are complex and require multidisciplinary project teams for successful implementation and to manage continuous improvement.

This course has been devised to support your AVI program development, by addressing critical parameters, key competencies and practical approaches to managing the inherent complexity of AVI. In day 1, after a review of regulatory landscape, key functions of AVI equipment and associated critical parameters will be covered. Then, the participants will look at the interaction between primary packaging component and AVI of the filled drug product. Successful URS development will be covered by a practical workshop in order to address not only user needs but also to produce a comprehensive process flow model. In Day 2, the need for an effective Manual Visual Inspection (MVI) baseline process will be overviewed as a prerequisite to AVI. Then, defect kits and validation strategies will be described. AVI has a scope broader than computer vision alone and the overall control strategy for the process will be covered. ‘Vision Engineering for dummies’ will be explained during a practical workshop using modern vision equipment and genuine examples of production defects.

Who Should Attend:
This course is designed specifically for those who are involved or interested in moving from manual to automated inspection like
• Managers, supervisors and all decision makers in the visual inspection area
• Quality personnel, Project and Qualification engineers
• Prerequisites: Basic understanding and practical experience of manual inspection (as conveyed in the PDA course ‘Introduction to Visual Inspection’)

Learning Objectives:
Upon completion of this course, you will be able to:
• Acquire basics about Regulatory landscape for AVI
• Be ready to design your URS
• Understand Key function of AVI equipment
• Define your defect kits and validation strategy
• Develop your own control strategy around AVI
• Have basic knowledge about computer vision

Fernand Koert, Consultant, Vision Technology, Dresden GlaxoSmithKline Vaccines
Fernand was born in the Hague, Netherlands and started his academic career at the Technical University of Delft to study Electronics. Working in that field, he completed career stages from shift leader to assistant plant manager. After gaining extensive practical experience, he started studying Process Technology at the Maritime Faculty in Amsterdam, graduating Cum Laude and working as a process engineer there after. In 2000, Fernand became a freelancer helping companies to set up practical training programs for operators. At Teva Pharmaceuticals, he did the same and became head of the packaging department in 2003. In 2005, he returned to technical engineering by assuming responsibility for reshaping and automation of packaging lines. Since 2011, Fernand has been specializing in vision technology, improving and sampling for test kits and validation. In 2014, he started with GSK, developing recipes for Seidenader AVI, first in Belgium, and currently for GSK in Dresden, Germany.

Sébastien Koch, Visual Inspection Project and Validation Engineer, Merck Switzerland
Sébastien has over 18 years of field experience in visual Inspection. In 2000 he began his career for Eli Lilly as specialist in Vision technology to carry out Automated Visual Inspection Machines (AVIM) qualification, maintenance and continuous improvement. In 2010, as Green Belt Six Sigma Sébastien became lean manufacturing engineer to drive operational excellence. In 2012, he took over the lead as Responsible Engineer. In 2016, Sébastien joined Merck in Switzerland to support the Aubonne site development as a driver of change and progress. Responsible of the visual Inspection equipment, he leads the strategic roadmap for long term perspectives, the validation strategy and the permanent competitiveness improvements of the manufacturing processes for quality and cost efficiency.
### Thursday, 25 October 2018 9:00 – 17:30

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Welcome &amp; Introduction</td>
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| 09:30 | **Theory 1**: Introduction Into Regulatory Requirements of Visual Inspection  
  • USP 1, USP 788 and 1788, USP 790 and 1790  
  • PhEur e.g. 2.9.20  
  • JP e.g. 6.06  
  • Annex 1  
  • Similarities and differences in compendial methods  
  • 100% inspection and AQL testing  
  • Definitions and practical examples of inherent, intrinsic and extrinsic particles |
| 10:45 | Coffee Break                                                                                                                              |
| 11:15 | **Theory 2**: Introduction Into Technical Principles of Automated Inspection Machines  
  • Functionality of automated inspection machines  
  • Camera systems / light / motion  
  • Image processing and database system  
  • Interlinkage of parameters: Speed, Rotation speed, Inspection parameters, Detection probability, False reject rate  
  • Properties, capabilities and limitations of automated inspection systems  
  • Scope of Automated Visual Inspection |
| 12:15 | Lunch Break                                                                                                                               |
| 13:15 | **Theory 2**: Introduction Into Technical Principles of Automated Inspection Machines (cont.)                                             |
| 14:15 | **Theory 3**: Considerations on Primary Containers and Product Properties  
  • Vials, Ampoules, Syringes, Blow – Fill - Seal, Viscous liquids, Air bubbles / scratches, Refrigerated product containers |
| 14:45 | Exercise 1: Developing an URS Considering the Triangle Cost / Quality / Time                                                               |
| 15:45 | Coffee Break                                                                                                                              |
| 16:15 | **Theory 4**: Selection and Purchasing of an Automated Inspection System  
  • Technical requirements  
  • Integration into existing processes, lines/ machines and systems  
  • Cost and effort considerations  
  • Risk Assessment |
| 17:15 | Exercise 1 (cont.): Presentation of the Results of the Sub-Groups and Discussion of the Results                                           |
| 17:30 | End of Day 1                                                                             |

### Friday, 26 October 2018 9:00 – 16:30

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Recap of Day 1</td>
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</table>
| 09:15 | **Theory 5**: Transition from Manual Inspection to Automated Inspection  
  • Manual inspection as a prerequisite for transition to automated inspection  
  • Interpretation of inspection results and validation data  
  • Considerations on validation program for automated inspection  
  • Performance measurement  
  • Maintaining the manual inspection |
| 10:15 | Exercise 2: Principle Basic Image Processing Using an Open Source Library                                                               |
| 11:00 | Coffee Break                                                                                                                              |
| 11:15 | Exercise 2 (cont.): Presentation of the Results                                                                                           |
| 12:00 | **Theory 6**: Qualification Test Set and Routine Test Set  
  • Statistical considerations on number of objects containing defects  
  • Particle selection, particle size and size uniformity  
  • Labelling of test set objects  
  • Supply/purchase of test sets  
  • Maintaining and lifecycle of test sets  
  • Sampling from rejects  
  • Defect master library  
  • Types of defects  
  • Quality requirements |
| 13:00 | Lunch Break                                                                                                                              |
| 14:00 | **Theory 7**: Visual Inspection Lifecycle and Control Strategy  
  • Integration of visual inspection into overall manufacturing process  
  • Elements of lifecycle  
  • Particle identification/characterization  
  • Defect libraries as dynamic database  
  • AQL and control charting |
| 15:00 | **Theory 8**: Operation and Maintenance of Automated Inspection Systems                                                                     |
| 15:30 | Coffee Break                                                                                                                              |
| 16:00 | Future Trend of Automated Visual Inspection                                                                                                |
| 16:30 | End of Training Course                                                                                                                    |
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Seville | Spain
PDA Europe supports the children's hospice „Sonnenhof”

The Sonnenhof Hospice, located near PDA’s office in Berlin, offers support and assistance to families with children suffering from incurable and/or debilitating diseases. At Sonnenhof, children, together with their families, can spend the time they have left as they wish and find some relief from their suffering. Instead of purchasing expensive gifts for the conference speakers, PDA has decided to donate this amount to the Sonnenhof Hospice. You can also contribute and help us increase the amount, it is easy:

buy a package of chewing gums at the registration desk. THANK YOU!

To know more about the Sonnenhof Hospice, please visit www.bjoern-schulz-stiftung.de
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Pharmaceutical Freeze Drying Technology

Particles in Injectables

24-25 SEPTEMBER 2019
BERLIN, GERMANY

SAVE THE DATE