The Parenteral Drug Association presents:

Visual Inspection Week

An Introduction to Visual Inspection: A Hands-on Course | 11-12 April 2018

Mastering Automated Visual Inspection | 11-12 April 2018

Interest Group Meeting Visual Inspection | 13 April 2018

11-13 April 2018

Courtyard by Marriott Berlin

Berlin | Germany

Welcome to the 2018 Visual Inspection Week

Taking place from **11-13 April 2018 in Berlin**, PDA Europe offers participants an exciting opportunity to develop and refine their practical skills.

Various topics related to visual inspection will be covered by leading industry experts in **two different training courses.**

The week will be concluded by the **Interest Group Meeting Visual Inspection,** providing an additional platform for exchange of experience and expertise with your peers as well as industry professionals in a more personal setting.

Education Program

IG Meeting


Welcome to
Berlin

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.

Wednesday, 11 April 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

Thursday, 12 April 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, *Consultant*

Markus Lankers was one of the co-founders of rap.ID Particle Systems GmbH, a company that develops, manufactures and sells rapid particle identification systems. Within rap.ID Markus was responsible for research and development of specific characterization method of particulate analysis and manages two dedicated particle characterization service labs in Germany and the US. Prior to this position, he worked as scientist in different development departments with Schering AG, Berlin, Germany. He publishes and presents work in the field of particle characterization and spectroscopic analysis. As an active member of the PDA, he has helped establish the PDA Visual Inspection Interest Group in Europe and set up the first company-independent Visual Inspection Trainings Course. He has served as program co-chair for the PDA Visual Inspection Forum 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 continous 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 engineersl
- 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

Romain Veillon, *Senior Manager Visual Inspection & Leak testing, Global MSAT, GlaxoSmithKline Vaccines*

Romain Veillon is Senior Manager Visual Inspection & Leak Testing at GSK Vaccines, in Global MSAT Manufacturing Technologies. Currently Romain focuses on Visual Inspection in a global function to support and advise GSK sites in the fields of Quality Integration Lead, Technology Development, Validation Strategy, Capability, Asset Management, Performance Improvement, and Develop Equipment strategy. Furthermore, he is managing a network of vision experts to develop visual Inspection expertise within GSK Vaccines. During the last 18 years he has worked in the area of parenteral manufacturing and has gained experience at Sanofi Pasteur, Eli Lilly and GSK Vaccines in different functions. Romain has developed innovative vision systems with some academic collaboration and is a frequent speaker at PDA conferences.

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 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.

Wednesday, 11 April 2018 9:00 – 17:30

09:00 **Welcome & Introduction**

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**

Q & A

17:30 **End of Day 1**

Thursday, 12 April 2018 9:00 – 16:30

09:00 **Recap of Day 1**

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**

Visual Inspection

Friday, 13 April 2018 **10:00 – 17:00**

Dear Colleagues,

On 20 December 2017, the long-awaited Annex 1 Revision of the EU GMP Guideline was finally published.

The new requirements issued with this amendment provoke further discussion of the correct understanding and implementation.

We are excited to announce our **2018 Visual Inspection Interest Group Meeting** with the main focus on the impact of the **Annex 1 Revision on Visual Inspection and on Container Closure Integrity.**

The PDA Interest Groups are discussion forums, each with a highly focused topic of interest.
The main idea behind this workshop is to engage in questions raised by attendees and to have a more in-depth discussion compared to the usual presentation-driven meetings. You are invited to contribute and provide your questions to the group, and together develop possible solutions to these challenging issues. Industry experts will be participating to help facilitate the discussion.

As a thematic framework, the IG Leaders have chosen the following topics for this exciting workshop:

- **Container Closure Integrity Testing – The Impact of the Annex 1 Revision**
  - Choosing the right techniques and meeting new standards
  - Which requirements apply for different containers?
- **Visual Inspection – Understanding and Implementing the Annex 1 Revision**
  - Impact of worst case scenarios
  - New implications for semi-automated inspection
  - Accepted Quality Levels

Sincerely,

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

Markus Lankers, *PhD,*
Consultant

Short presentations covering additional information fitting the scope of the Interest Group are very welcome. Please contact schubach@pda.org to submit your topic proposal.

Friday, 13 April 2018		**10:00 – 17:00**
10:00	**Welcome and Introduction** – **Benefits of the PDA Interest Group** – **PDA Connect**	Falk Klar, *PDA Europe* John Shabushnig, *Insight Pharma Consulting* Markus Lankers, *Consultant*
The Annex 1 Revision in Visual Inspection and Container Closure Integrity		
10:15	**What's New in Annex 1?** **Highlights and Comparison to USP**	John Shabushnig, *Insight Pharma Consulting*
Visual Inspection: Understanding and Implementing the Annex 1 Revision		
10:45	**General Requirements for Visual Inspection**	
11:30	**Coffee Break & Exhibition**	
12:00	**Manual Inspection** **Automated Inspection**	
13:00	**Lunch Break & Exhibition**	
14:00	**Trending Inspection Results**	
Container Closure Integrity Testing - Impact of the Annex 1 Revision		
14:30	**Container Closure Integrity Testing –** **The Impact of the Annex 1 Revision**	Derek Duncan, *LIGHTHOUSE*
15:00	**Coffee Break & Exhibition**	
15:30	**Choosing the Right Techniques** **What is Required for Different Containers?**	
16:00	**Summary Remarks**	Falk Klar, *PDA Europe* John Shabushnig, *Insight Pharma Consulting* Markus Lankers, *Consultant*
17:00	**End of IG Meeting and Farewell**	

VENUE

Courtyard by Marriott Berlin City Center
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Berlin 10117
Germany
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https://goo.gl/bJ2oJi

Special Rates
PDA Europe has reserved a limited number of bedrooms until the 16 February 2018. Book your group rate for PDA.
Single Room 135 € per room and night
Double Room 145 € per room and night

Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

DIRECTIONS

© Google For directions click on the picture, scan the QR-code or go to **https://goo.gl/maps/5R3jUubo9LD2**

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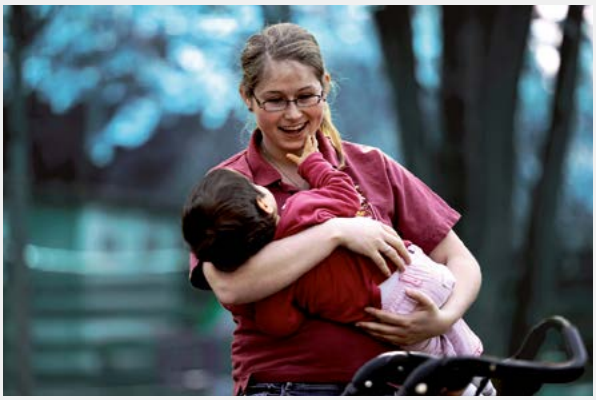
TO EXHIBIT:

PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibition and Sponsorship Opportunities are available. For this event we offer a special 3-for-2 discount: Basic exhibition package for 3 days (Educational Program & IG Meeting) is priced **1.895 € net (table-top).** For more information please contact: **gomez@pda.org**



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**

Björn Schulz
STIFTUNG
Für eine Zeit voller Leben

For contact at PDA Europe
registration-europe@pda.org

3 WAYS TO REGISTER

1. **ONLINE: pda.org**
2. **FAX: +49 30 4365508-66**
3. **EMAIL: registration-europe@pda.org**

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

1 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

☐ Mr. ☐ Ms. ☐ Dr. ☐ Nonmember ☐ **I want to become a PDA Member.** Please send me a subsription form

☐ PDA Member ID Number

Name (Last, First, MI) *

Job Title *

Company*

Department

Mailing Address

City

Postal Code

Country

Email *

Business Phone

Fax

☐ Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

2 Registration

Two-Day Training Course (11-12 April)
An Introduction to Visual Inspection
All Participants ☐ **1495**

Two-Day Training Course (11-12 April)
Mastering Automated Visual Inspection
All Participants ☐ **1495**

IG Meeting (13 April)
Interest Group Meeting Visual Inspection
All Participants ☐ **300**

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

3 Payment Options

☐ **By Credit Card**

☐ American Express ☐ MasterCard ☐ VISA

For your credit card information safety:
Please send your details by fax only (+49 30 4365508-66) or register online.

☐ **By Bank Transfer**
Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDEDBBER
Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

☐ **By Purchase Order** Purchase Order Number

PDA Europe VAT I.D.: DE254459362

Billing Address: ☐ Same as contact information address above. If not, please send your billing address to: **registration-europe@pda.org**

Your Company VAT I.D.:

This number starts by your country code with two characters
(example: PDA Europe's country code starts with: DE | followed by the number)

Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **28 February 2018** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at **registration-europe@pda.org or fax to +49 30 4365508-66. DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

2018 PDA EUROPE EVENTS

13 April	Interest Group Meeting Visual Inspection	IG	**Berlin, Germany**
24-25 April	**Vaccines**		**Málaga, Spain**
8-9 May	**Virus Forum**		**Florence, Italy**
17 May	**Annex 1**		**Dublin, Ireland**
29-30 May	**Pharmacopoeia Conference**		**Vienna, Austria**
5-6 June	**Advanced Therapy Medicinal Products**	*	**Amsterdam, The Netherlands**
25 June	Interest Group Meeting Quality Systems	IG	
25 June	Interest Group Meeting Freeze Drying	IG	
26-27 June	**3rd PDA Europe Annual Meeting**	*	**Berlin, Germany**
15-16 October	**Pharmaceutical Microbiology**	*	**Berlin, Germany**
23-24 October	**Visual Inspection Forum**	*	**Berlin, Germany**
6-7 November	**Outsourcing & Supply Chain - A 360° View**	*	**Seville, Spain**
22 November	**Project Management in the Pharmaceutical Industry – Challenges & Possibilities**	*	**Berlin, Germany**
27-28 November	**Pharmaceutical Freeze Drying Technology**	*	**Seville, Spain**
27-28 November	**11th Workshop on Monoclonal Antibodies**	*	**Seville, Spain**

Subject to change | For latest info: **europe.pda.org** | Shortlist 29 Mar 2018

*** Events with additional Education Program. More information – http://t1p.de/7p9z**

PDA Parenteral Drug Association

Connecting People, Science and Regulation®

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