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Control of Parenterals

The Participants of the **Particles in Parenterals** Conference receive the current version of ECA's Best Practice Paper on "Visual Inspection" for free!

SPEAKERS



Gabriel Anderson
Novartis



Martin Dearden
PaxVax Berna



Dr Helmut Gaus
Boehringer Ingelheim

Christoph Herdlitschka
Wilco



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Dr Tobias Posset
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Dr Heino Prinz
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Immediate Past Chair of the European QP Association



Marcel Uijlen
MSD



Dr Klaus Wuchner
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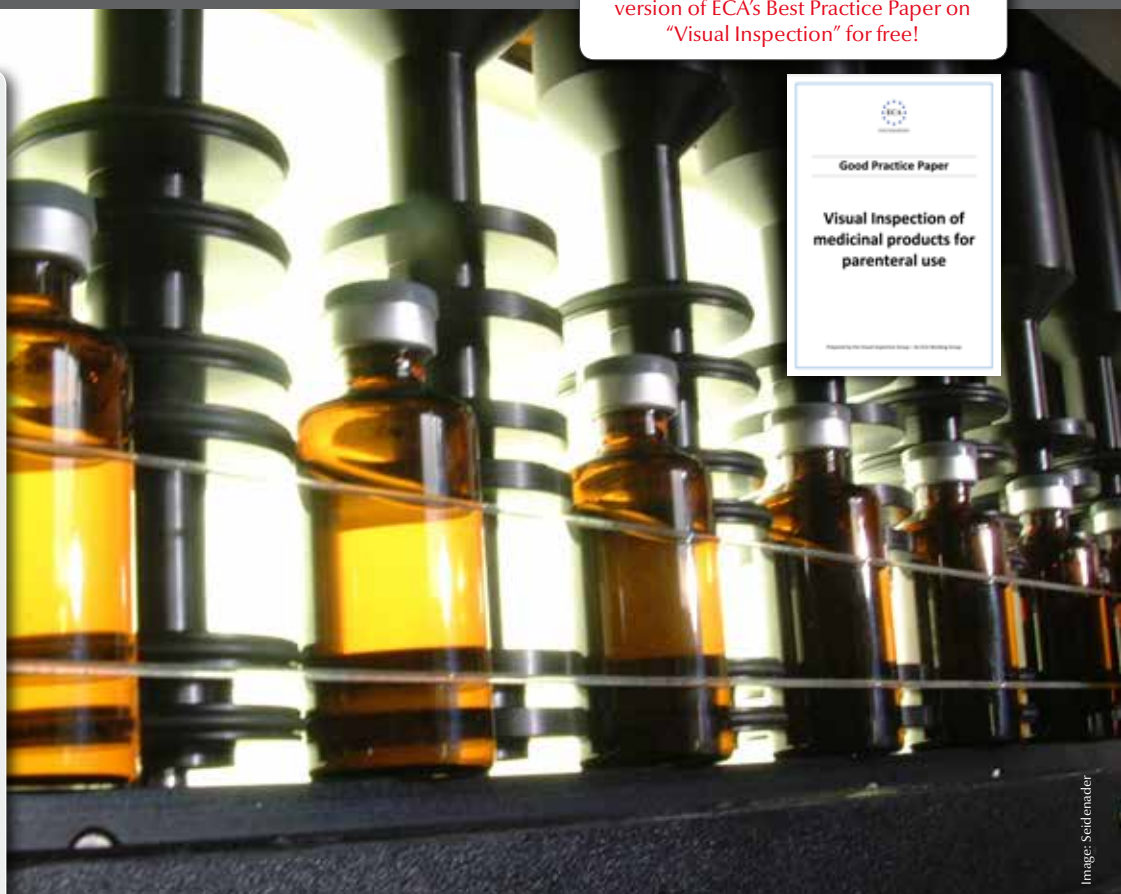


Image: Seidenader



Container/Closure Integrity Testing

10 October 2017, Vienna, Austria

HIGHLIGHTS

- Regulatory, Pharmacopoeial and GMP requirements
- Overview CCI testing technologies
- Modern blue dye testing
- Case Study: CCI testing of prefilled syringes
- Case Study: CCI testing of ampoules
- Case Study: CCI testing of vials

Particles in Parenterals

11-12 October 2017, Vienna, Austria

HIGHLIGHTS

- Regulatory and GMP requirements for the inspection of parenterals
- FDA's current expectations on visual inspection
- Inspection Observations related to visual inspection
- Trending and Monitoring and batch release with respect to inspection data
- Re-inspection of defect fractions
- Alternative approaches for the validation of automated inspection systems
- Subvisible and inherent particles in biological preparations
- Analysis and evaluation of particles during development and deviations
- Particle Threshold studies
- Case Studies from industry: how visual inspection can be carried out

With an optional Pre-Conference Course:
Fundamentals of Visual Inspection &
AQL Testing on 10 October 2017



Container/Closure Integrity Testing

10 October 2017, Vienna, Austria

Objectives

Different products and different container types require different testing methods: this event aims at giving an overview of the different CCI testing systems which are applied during production and as part of the quality control system. Apart from technical aspects the regulatory requirements on CCI testing will be highlighted as well as the applicability of inline and offline testing.

Background

An intact container closure system, which is the sum of packaging components that protect the dosage form, is the pre-requisite for a safe and sterile drug product. The CC system protects the product from microbial contamination and also from exposure to gases or water vapor or the loss of solvent. Container Closure integrity testing is therefore a regulatory requirement and it is part of the whole life cycle of a sterile drug product.

Initially this testing was performed as part of the initial development of the packaging system and the system's suitability verified in stability studies including on-going stability. Over the years, the expectation was raised to perform batch by batch verification with latest trends to 100% inline or offline testing wherever possible.

We will discuss and answer questions like:

- What are the current and upcoming GMP and compendial requirements?
- Will container closure integrity testing change to 100% inline testing?
- Modern blue dye testing
- Which testing technologies are available and suitable?
- CCI testing of prefilled syringes
- CCI testing of lyo & liquid vials
- CCI testing of ampoules

Target Audience

This conference is directed at specialists and executives from the areas engineering and production and QA dealing with the implementation and operation of systems for the container/closure-integrity testing of sterile medicinal products.

Moderator

Bernd Renger,
Immediate Past Chair of the European QP Association



Image: Seidenader

Programme

Container Closure Integrity testing of sterile drug products – requirements, expectations and exaggerations

- Container Closure Integrity during Development, Qualification and Stability Testing
- Regulatory, Pharmacopoeial and GMP requirements
- System integrity versus container damages
- Patient risks – do we need batch by batch testing?
- Industrial best practices

Overview of container/closure integrity testing technologies

The presentation gives a comprehensive overview about current CCI technologies and techniques. It focuses in the first part on physical fundamentals of the different testing methods

- Pressure / Vacuum Decay
- LFC (Liquid Filled Container) leak testing
- TDLAS/ HSA (frequency modulated spectroscopy)
- High Voltage leak testing
- 3µm IR and Mass-Spectroscopy
- Force Detection

In the second part criteria or a selection matrix for test methods related to the product requirements and properties including primary container type, product properties (liquid, lyo, etc.) is presented. The main topics here are as follows.

- Inline versus sample testing
- Limits and false acceptance traps
- Leak sizes and leak rates (false friends and measurable properties?)

Modern Blue Dye Testing – still the standard CCI method?

- Regulatory requirements and subsequent test method in industry
- Critical method aspects, e.g. process monitoring
- Perspective and limits in context of product life cycle

Integrity testing of Prefilled Syringes

- Sampling plan
- He-leak testing
- Limitations of the He-leakage test
- Cross Validation with mCCI

100% inline CCI testing of ampoules

- High Voltage inline testing: method description
- Integration in the production process
- Limits of the system
- Qualification of the system
- Validation
- Routine Operation

Case Study: 100% inline testing of Lyo Vials

- System setup
- Validation
- Routine operation

Pre-Conference Course "Fundamentals of Visual Inspection & AQL Testing" on 10 October

The training course on visual inspection which takes place the day before the Particles Conference gives you an understanding of the fundamentals of visual inspection of injectable products, applicable to manual and automated inspection. You will also learn how to implement an automated system on the basis of the manual inspection. The course also includes an AQL training, that is you will learn how to use AQL tables to set defect limits and how to evaluate batch inspection data.

Skills you will develop through the course:

- Ensuring GMP compliance in manual inspection
- Setting up a qualification strategy for automated systems
- Usage of statistical tools for assessing inspection data
- GMP-compliant routine operation of automated systems



Image: Seidenader

Content of the course in detail:

General requirements

- Requirements of the Pharmacopeia
- Defect categorisation
- Test kits for training, qualification and routine

Manual Inspection

- Qualification and training of personnel
- Standardisation of working conditions
- AQL in the manual inspection

From Manual to automated inspection

- Usage of the Knapp and the modified Knapp test
- Cross validation during the PQ phase

Automated inspection

- Importance of particle detection rates
- System-Suitability, Requalification and revalidation

Course Trainer:

Dr Helmut Gaus, Director Quality Control at Boehringer Ingelheim
Dr Tobias Posset, Head of Production Support Roche Diagnostics

Objectives

Main topic of this conference is the detection of particles in injectables and their evaluation during batch release and continuous process improvement. Besides the current regulatory requirements with regards to particulate matter, routine 100% inspection of injectables will be addressed. Manual inspection as well as automated inspection systems will be covered, including training, AQL testing, trending, inspection equipment and batch release considerations.

Background

All participants receive the current version of ECA's Best Practice Paper on "Visual Inspection" for free

In most cases particles found in parenteral medicines will lead to a quarantined product or even to the recall of the product – as we have seen in the last years in the cases of several pharmaceutical companies. Responsible staff in charge will have to start root cause analysis to find the source of the particles and will have to do an evaluation of batches already shipped.

There is still confusion within the global pharmaceutical industry with regard to the requirements for testing for visible particles. After the USP chapters <790> and <1790> were published, things have become much clearer, at least for the US. But still, lots of questions arise, e.g. concerning re-testing, detection capabilities and revalidation of inspection systems.

Furthermore there has been a recognisable trend towards automated inspection machines throughout the last years. The challenge for pharmaceutical companies is to find a suitable machine for their products and to determine reasonable inspection parameters during qualification and validation. But also during routine process there are questions arising like re-testing and the usage of test-sets, doing AQL Testing as well as the adjustment of parameters of the vision systems.

We will address those topics during the conference and discuss and answer questions on

- The latest compendial requirements concerning particulate matter
- FDA's expectations on visual inspection
- Threshold studies and validation of detection limits
- Training in the manual visual inspection
- Trending and monitoring of visual inspection data
- Limitations of the AQL test
- Re-inspection of defect fractions
- Different validation approaches for automated inspections systems
- Operation of automated system
- Handling of inspection observations & findings
- Particle analysis and identification

Particles in Parenterals

11-12 October 2017, Vienna, Austria

Target Audience

This conference is directed at specialists and executives from sterile operations, that is manufacturing, quality assurance and engineering. But also suppliers of primary packaging materials and inspections technology are target group of this conference.

Moderator

Dr Bernd Renger
Immediate Past Chair of the European QP Association

Programme

Regulatory Requirements for the visual inspection of parenterals

- Compendial Requirements
 - 100% visual inspection & AQL testing
 - PharmEur, USP, JP - similarities and differences
- GMP Expectations
 - Manual inspection
 - Automated Inspection
- Risk Management Considerations

Presentation and discussion of the ECA Best Practice Paper on Visual Inspection

The best practice paper has been originally developed by the advisory board of the ECA Visual Inspection Group. Much rather than a strict requirement document, this paper is intended to be a reference for controversial issues. The first version of this paper has been published in September 2014 in Copenhagen. It has gained a broad acceptance in the industry afterwards. The current version as well as planned updates will be explained and discussed in Vienna.



FDA's current thinking on particles and testing of parenterals

- A summary of recent recall data due to visible particulates
- The FDA's take on AQL testing
- Training and qualification of visual inspection staff
- Automated inspection validation
- A lifecycle approach to visible particle inspection and control

Particles in Parenterals: Methods for the root cause analysis

- Isolation of single particles
- Analysis of particles using FTIR, REM-EDX, and ICP-MS
- Usage of witness-wafers
- Intrinsic particles and their origin
- What can we learn from aerospace research.
- Examples

Qualification in manual visual inspection in a multi-product environment

- Defects and defect categorisation in the manual visual inspection of vials and ampoules
- Composition and qualification of test sets
- Initial qualification of human inspectors
- Bracketing of products in the context of the qualification of human inspectors
- Requalification and continuous evaluation of the inspectors performance
- Maintaining the qualified state of the test sets

Validation of an Automated Inspection System - Alternative Ways for the 5000 Test

- General requirements
 - Requirements of the Pharmacopeia
 - Defect categorisation
 - Test kits for training, qualification and routine
 - Manual Inspection
 - Training and qualification of manual operators
 - Standardisation of working conditions
 - AQL in the manual inspection
- Automated inspection
 - Setup of the vision system
 - Qualification of the machine in 3 steps
 - Detection verification using probabilistic models (i.e. Knapp-Test / Particle-Qualification-Kit)
 - Detection verification using fixed detection rates (i.e. Standard-Defect-Kit)
 - Man-machine-comparison during production run (test of 5000)
 - Alternatives for the test of 5000
- Others
 - System-Suitability-Test, requalification and revalidation

Visual Inspection and Health Authority Expectations & Observations

- Observation at the AIM qualification
- Comments to the 5000 test
- Dealing with particles & complaints

Particle testing and the correlation with trending and Batch release

- Why do we Monitor (What is it all about)
- Data and Measurement
- The AQL trap
- Improvement Process Map
- Investigation and Routine Analysis
- Release Process: "To AQL or not to AQL that is the Question"
- Product Release: "Falling off a log"

Particles in Biotech Parenteral Products

- Particles are a major challenge in the development, manufacture and analysis of Parenteral Products
- The Pharmacopeias and guidances aim towards minimizing visible particulates, yet, the requirements not easy to translate into everyday practice
- Particles can come from different sources and USP has suggested a categorization with particles being extrinsic, intrinsic or inherent, yet, clinical relevance and safety of these would not be necessarily different and identification is often not unambiguous
- This talk aims to discuss approaches and practicality and industry perspective on Visible Particles in Parenteral Products containing active ingredients derived by recombinant manufacture (biologics)

Threshold testing between inspection method development and setup of a qualification set

- Concepts for planning threshold tests
- How to design the test to be representative for routine manufacturing conditions
- Transformation of a threshold test into a qualification set
- Other good use of threshold test (results)

(Re-) inspection of parenteral products

Different scenarios will be covered such as:

- Re-inspection or additional inspection of “grey-channel” units from (semi-) automated inspection
- Re-inspection in case of exceeding alert limits or AQL failures
- Focused re-inspection
- Inspection approaches in case of investigations due to unexpected particles (e.g., to determine frequency of occurrence of visible particles when particles are found during release/stability testing)

Development of a tool for determining the criticality of particles

- Defining the appropriate AQL level for specific particles



Gabriel Anderson, Novartis

Gabriel has a chemical engineering degree and joined Novartis Vaccines in the US in 2011 as a production engineer responsible for setting up the visual inspection program and validating an automated inspection machine. In 2014 he moved to Basel to take on a global role within Novartis as the Technical Steward for visual inspection.



Martin Dearden, PaxVax Berna GmbH

Martin has over 25 years of experience in the Pharmaceutical Industry with over 20 years concerned with the manufacture of sterile products and Biologics. Martin holds Degree level qualifications in Applied Biology and also Immunology and Microbiology. He was Senior Director at UCB S.A. and as the UCB Corporate Microbiologist responsible for microbiological standards, policy and strategy. Now he is Vice President of Quality for PaxVax Berna in Switzerland.



Dr Helmut Gaus, Boehringer Ingelheim Pharma GmbH & Co KG

Dr Gaus is Head of Quality Control Service at Boehringer Ingelheim, Biotechnology. He has also been working as Vice President Quality Control and Qualified Person for Novartis Generics, Vetter-Pharma and Rentschler Biotechnologie where he gained an extensive knowledge in the field of visual inspection.

Christoph Herdlitschka, Wilco



Markus Keller, Fraunhofer IPA

Markus Keller is Senior research engineer and biologist at Fraunhofer IPA in Stuttgart, Germany.



Felix Krumbein, Roche Diagnostics GmbH

Felix Krumbein studied optotechnics and image processing. He worked for Scanware and for Laetus as head of the group identifications systems where he was responsible for the implementation of GMP-compliant imaging tools. Since 2011 he is working for Roche as head of Inspections-Systems-Support. He is responsible for the qualification of visual inspection systems in the GMP environment.



Dr Roman Mathaes, Lonza AG

Roman Mathaes is a Senior Group Leader within the Lonza Drug Product Service organisation. He is leading the Lonza particle lab and the container closure integrity testing. In this role, Roman is responsible for particle analytics in pharmaceutical products (drug products and drug substance). He holds a Ph.D. in pharmaceutical technology from the University of Munich for his work on subvisible particle characterization.

Speakers

**Olivier Métraux, F. Hoffmann-La Roche**

Mr Métraux is a chemist and responsible for the CCI Testing at F. Hoffmann La-Roche (release and stability) since 10 years.

**Dr Stephen Langille, FDA**

Dr Langille is a Branch Chief in the Division of Microbiology Assessment in the Center for Drug Evaluation and Research. He joined the FDA in 2000 and has served as an FDA liaison to the USP Parenteral Products – Industrial and USP Dosage Forms expert committees. Dr Langille serves on a number of FDA and USP committees dealing with issues related to particulate matter in injectable drug products.

**Dr Tobias Posset, Roche Diagnostics GmbH**

Tobias Posset studied Biochemistry and Chemistry. He is heading the Production Support unit in the Pharma Production at Roche Diagnostics in Mannheim. Herein he is responsible for the IPCs, the particle laboratory, the automated visual inspection and the coordination of the manual inspection training. He is also the chairman of the ECA Visual Inspection Group.

**Dr Heino Prinz, Rommelag AG**

Dr Prinz was in charge for research and development at Wilco in Wohlen, Switzerland and changed to Rommelag in 2014 where he has the position of the Director Inspection Devices.

**Dr Bernd Renger, Immediate Past Chair of the European QP Association; Renger Consulting, Germany**

Dr Bernd Renger is a member of ECA Advisory Board and Immediate Past Chair of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung. He started his career 1977 at Hoechst AG as a R&D chemist. Since then, he has held several quality management positions at Mundipharma, Byk Gulen (now Takeda) and Baxter BioScience in Vienna.

**Marcel Uijlen, MSD**

Marcel Uijlen studied Biochemistry and has a postgraduate diploma in Pharmaceutical Validation Technology. He was head of the Sterile Technical Operations group which is responsible for all equipment and process validations. Currently, he is part of the Sterile & Validation Centre of Excellence and in this role supporting different Merck/MSD sites in the network. Within MSD he is the Subject Matter Expert for Visual Inspection.

**Dr Klaus Wuchner, Cilag AG**

Klaus Wuchner is leading a team responsible for particle characterization and container closure integrity testing within the global Pharmaceutical Development and Manufacturing Sciences organization at Janssen R&D. He has over 15 years of experience in the pharmaceutical industry and worked on various products from small molecule APIs to finished biotech products.

Social Event

On 11 October you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



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We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

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What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

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Date

Container-/Closure-Integrity Testing Conference
Tuesday, 10 October 2017, 09.00 to 17.30 h
(Registration and coffee 08.30 – 09.00 h)

Pre-conference Course Fundamentals of Visual Inspection

Tuesday, 10 October 2017, 10.00 to
approx. 16.45 h
(Registration and coffee 09.30 – 10.00 h)

Particles in Parenterals Conference

Wednesday, 11 October 2017, 09.00 – 18.30 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 12 October 2017, 08.30 to
approx. 15.45 h

Venue of all events

Austria Trend Hotel Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43 (1) 891 10-0
email park.royal.palace@austria-trend.at

Fees (per delegate plus VAT*)

Container-/Closure-Integrity Testing (10 Oct)
ECA Members € 790
APIC Members € 890
Non-ECA Members € 990
EU GMP Inspectorates € 495
The conference fee is payable in advance after
receipt of invoice and includes lunch and all
refreshments.

Pre-Conference Course: Fundamentals of visual inspection (10 October)

ECA Members € 590
APIC Members € 690
Non-ECA Members € 790
EU GMP Inspectorates € 395
The conference fee is payable in advance after
receipt of invoice and includes lunch and all
refreshments.

Particles in Parenterals (11-12 October)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after
receipt of invoice and includes dinner on the first
day, lunch on both days and all refreshments.

Saving opportunities

Book two events and save € 300 in total (not
valid for EU GMP Inspectorates).

Accommodation

CONCEPT HEIDELBERG has reserved a limited
number of rooms in the conference hotel. You
will receive a room reservation form when you
have registered for the event. Please use this form
for your room reservation to receive the specially
negotiated rate for the duration of your stay. Reser-
vations should be made directly with the hotel.
Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the
organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0)62 21/84 44-0
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For questions regarding content:

Dr Robert Eicher (Operations Director) at
+49(0)62 21 / 84 44 12, or per e-mail at
eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21 / 84 44 13, or per e-mail at
schopka@concept-heidelberg.de.

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Control of Parenterals, 10 and 11-12 October 2017, Vienna, Austria

Please tick

10 October 2017	11-12 October 2017
☐ Container-/Closure Integrity Testing	☐ Particles in Parenterals
OR	
☐ Fundamentals of Visual Inspection	

☐ Mr ☐ Ms

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