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!

Image: Seidenader

SPEAKERS


DR MARTIN BECKER
Siegfried Hameln


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PaxVax Berna


DR HELMUT GAUS
Boehringer Ingelheim


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DR HEINO PRINZ
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DR BERND RENGER
Immediate Past Chair of the European QP Association


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Container/Closure Integrity Testing

27 September 2016, Barcelona, Spain

HIGHLIGHTS

- Regulatory, Pharmacopoeial and GMP requirements
- News from USP regarding CCI testing
- Overview CCI testing technologies
- Case Study Roche: CCI testing of prefilled syringes
- Case Study Siegfried Hameln: CCI testing of ampoules
- Case Study: CCI testing of vials

Particles in Parenterals

28-29 September 2016, Barcelona, Spain

HIGHLIGHTS

- Regulatory and GMP requirements for the inspection of parenterals
- FDA's current expectations on visual inspection
- Inspection of plastic/BFSs containers
- Interaction of production and QA regarding particle testing
- Trending and Monitoring of inspection data
- Japanese requirements regarding injectables
- Reinspection of defect fractions
- Case Study Novartis: Concepts for manual and automated visual inspection
- Case Study MSD: Implementation and operation of an automated inspection system
- Case Study Amgen: Set up of a robust inline inspection system
- Case Study Roche: Particle reduction & identification

With an optional Pre-Conference Course: Fundamentals of Visual Inspection & AQL Testing on 27 September 2016

This conference is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager". Please find details at www.gmp-certification.eu

Container/Closure Integrity Testing

27 September 2016, Barcelona, Spain

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 GMP and compendial requirements?
- Will container closure integrity testing change to 100% inline 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

Key Concepts in the Revised USP Guidance Chapter <1207> Package Integrity Evaluation – Sterile Chapter scope

- New CCI terms and concepts:
  - Maximum allowable leakage limit
  - Inherent Package Integrity
  - Package Integrity Profile
- CCI test method selection and validation guidance

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.

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

Integrity testing of prefilled syringes

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

100% in-line CCI testing of ampoules

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

Case Study Janssen: 100% inline testing of Lyo Vials

- System setup
- Validation
- Routine operation

Particles in Parenterals

28-29 September 2016, Barcelona, Spain

Pre-Conference Course "Fundamentals of Visual Inspection & AQL Testing" on 27 September

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. 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

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 2012, 2013 and 2014 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.

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

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
- Trending and monitoring of visual inspection data
- How to set up a robust vision system
- Re-inspection of defect fractions
- Operation of automated system from qualification to routine
- Reducing the particle load coming from process and packaging materials
- Inspection of plastic/BFS containers

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

Particles in Parenterals

28-29 September 2016,Barcelona, Spain

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

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 life-cycle approach to visible particle inspection and control

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 Barcelona

Re-inspection of defect fractions - statistical evaluation

- Mathematical description of inspection processes
- Strategies for rei-nspection of defect fractions
- Acceptance criteria for re-inspection of defect fractions
- Statistical evaluation
- Design of the re-inspection processes

Particle Testing and the interaction of production and QA

- Monitoring and Trending
- Improvements
- Release process

Novartis concepts for manual and automated visual inspection of injectable products

- General philosophy of visual inspection at Novartis
- AQL testing
- Implementation of automated visual inspection for lyophilizate in vial products
- Qualification and Validation-Philosophy

Case Study MSD: Qualification/Validation of an automated system and routine operation

- Training/Development test set
- Qualification test set
- Daily set up test set for automated system
- Creating defects
- Process Control Limits

In-line automated visual particle inspection of "Blow Fill Seal" containers for injectable drug products

A case study for line integration and validation in combination with related threshold studies

In this presentation a new 100% particle inspection machine at full production speed is presented along with real time case studies for line integration and threshold studies of current pharmaceutical products. It highlights also the benefits of this inspection process in relation to sensitive products like proteins or highly foaming liquids, which usually are disliked by machine vision inspection. Also a validation approach using threshold studies from human inspections based on a Knapp test approach as well as the related pseudo Knapp test results are presented.

Reduction and identification of particles

- Handling of the particle load within the production area
- Projects to reduce visible particles
- Analytics and identification of visible particles
- Example: particles on stoppers - analytic-limits and requirements

Case Study Amgen: How to set up in-line and desktop AVI systems

- Summary of in-line AVI systems with focus on detection capability
- Desktop AVI systems and where they can be used
- Qualification of a desktop AVI system
- One future roadmap for Automatic Visual Inspection

Quality requirements for injections shipped to the Japanese market

- Japanese sensitivity for qualities of general and pharmaceutical products
- General requirements for cosmetic qualities by Japanese medical agencies
- Requirements for direct container suppliers by Japanese pharmaceutical companies
- Requirements for qualities and production/inspection control by Japanese pharmaceutical companies/ authorities/pharmacopeia

Social Event

On 28 September 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.

Speakers

DR MARTIN BECKER,
Siegfried Hameln
Dr Becker studied Chemistry and is actually Head of Technical Operations and Head of Production Sterile Operations at Siegfried Hameln (formerly hameln pharmaceuticals). He previously held different positions in analytical development, quality assurance, and production at IDT in Dessau and Sandoz in Unterach Austria.

MARTIN DEARDEN,
PaxVax Berna GmbH
Martin has 26 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 within the UCB Global Quality Organisation. Now, Martin is Vice President of Quality for PaxVax Berna in Switzerland.

DR HELMUT GAUS,
Boehringer Ingelheim Pharma GmbH & Co KG
Dr Gaus is Director of Quality Control at Boehringer Ingelheim, Biotechnology. He has also been working as Vice President Quality Control and Qualified Person for Novartis Generics, Vetter-Pharma and Rentschler Biotechnolgie were he gained an extensive knowledge in the field of visual inspection.

AL GOODWIN,
Amgen
From the Headquarters of Amgen in California, Al specifies and supports globally all of Amgen's AVI systems for vials, syringes, plastic cartridges and drug delivery devices. Al has 25 years of experience in optical inspection systems. He has worked in Japan for 5 years on optical test measurement systems and at Engineering Director level at inspection design companies based in Europe. In the last 15 years he has worked closely with key International Machine Vision Software design companies and has used this experience in areas of Particle detection, Glass flaw detection and improvements and evaluation of Vision Algorithm Robustness in the pharmaceutical industry.

DR DANA GUAZZO,
USP
Dana Morton Guazzo is a member of the USP Packaging, Storage and Distribution Expert Committee for a second 5-year volunteer cycle where she led the effort to revise the USP guidance chapter <1207>. Dana is the founder and president of RxPax, LLC — a consulting firm committed to providing package development and package integrity testing support to pharmaceutical firms. Additionally, Dr. Guazzo provided collaborative support for the package integrity testing division of Whitehouse Laboratories, from 2008 through 2013. Prior to becoming a consultant, Dana worked for 22 years in pharmaceutical industry R&D.

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.

CHI YUEN LIU,
Janssen Cilag AG
Chi Liu holds a degree in Chemical Engineering He is working as Process Scientist within the Technical Operations Parenterals of the Janssen Supply Chain organization of Johnson & Johnson. Chi is leading and supports projects from a technology perspective. Chi has provided technology support as Subject Matter Expert for fill finish operations by setting up technology standards in the Parenterals Platform.

SUNAO MURAI,
Chugai Pharmaceutical Co., LTD, Japan
Mr Murai is a pharmacist by training with 36 years experience at Chugai Pharmaceutical in Japan. He holds the position of a Senior Specialist at the Quality Assurance Department. He is experienced in formulation technology, design of packaging for solids and injections as well as GMP and QA topics.

DR TOBIAS POSSET,
Roche Diagnostics GmbH
Tobias Posset studied Biochemistry and Chemistry. Actually he is heading the Production Support unit in the Pharma Production at Roche Diagnostics in Mannheim. Herein he is responsible for the in-process control, the particle laboratory, the automated visual inspection machines 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 were 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 the European Compliance Academy (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 in 1977 at Hoechst AG as a research and development chemist. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna.

DR CHRISTOPH STARK,
Novartis Pharma Stein AG
Dr Christoph Stark, since 13 years with Novartis working in the field of Biotech drug product and process development, transfer, launch and commercial production. Currently in TechOps MS&T responsible for scientific support of production, new technologies as well as concepts in visual inspection and implementation of automated visual inspection.

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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Container-/Closure-Integrity Testing Conference
Tuesday, 27 September 2016, 09.00 to 17.30 h
(Registration and coffee 08.30 – 09.00 h)

Pre-conference Course Fundamentals of Visual Inspection
Tuesday, 27 September 2016,
10.00 to approx. 16.30 h
(Registration and coffee 09.30 – 10.00 h)

Particles in Parenterals Conference
Wednesday, 28 September 2016, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 29 September 2016,
08.30 to approx. 15.45 h

Venue of all events

Hotel Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45

Fees (per delegate plus VAT*)

Container-/Closure-Integrity Testing (27 Sept)
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 conference documentation, lunch and all refreshments.

Pre-Conference Course: Fundamentals of visual inspection (27 Sept)
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 conference documentation, lunch and all refreshments.

Particles in Parenterals (28-29 Sept)
ECA Members € 1590
APIC Members € 1690
Non-ECA Members € 1790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, 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. Reservations 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
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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.

Please note that there **will not be any print-outs at the conferences**. Instead you will receive all presentations prior to the event as Downloads as well as after the event, in the case of updates.

* VAT is reclaimable

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Reservation Form (Please complete in full)

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Control of Parenterals, 27 and 28-29 September 2016, Barcelona, Spain

27 September 2016	28-29 September 2016	Please tick
☐ Container/Closure Integrity Testing	☐ Particels in Parenterals	
OR		
☐ Fundamentals of Visual Inspection		

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order Number, if applicable**

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City Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.
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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing.

The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).

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