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GMP Certification Programme
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Speakers


Dr Martin Becker
Baxter Oncology


Antonio Burazer
Takeda Manufacturing Austria


Martin Dearden
ECA Visual Inspection Group


Haluk Dönmez
B. Braun


Dr Helmut Gaus
ECA Visual Inspection Group


Felix Krumbein
Head ECA Visual Inspection Group


Christof Langer
OSConsulting


Dr Stephen Langille
formerly FDA


Dr Daniel Müller
GMP-Inspector

NEWS

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Visual Inspection of Parenterals

State-of-the-art Visual 100% Inspection

6/7 November 2024, Berlin, Germany


Image: INSPECTIFAI

With an optional Pre-Conference Course:
Fundamentals of Visual Inspection on 5 November

Highlights

- Current FDA Requirements for Visual Inspection of Injectables
- Compliance with EU Annex 1 and the Pharmacopeias
- Requirements from an EU GMP Inspector's View
- Usage of AI in Automated Visual Inspection
- Semi-Automated Visual Inspection
- Approaches for the Inspection of hard-to-inspect Container-Systems
- Transfer of a Visual Inspection Process
- Case Study Amgen: Usage of AI
- Case Study Takeda: Company-wide Reduction of Particles

Pre-Conference Course: Fundamentals of Visual Inspection

5 November 2024

The training course on visual inspection which takes place 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 and how to qualify it.

Skills you will develop through the course:

- **Ensuring GMP-compliance in manual inspection**
- **Setting up a qualification strategy for automated systems**
- **GMP-compliant routine operation of automated systems**

Content

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
- Evaluation matrices

Automated inspection

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

Evaluation of inspection data & batch release

- Trending of inspection results
- AQL Testing
- Re-inspection – allowed or not?

Course Trainers

Dr Helmut Gaus, *formerly Boehringer Ingelheim*
Felix Krumbein, *Head ECA Visual Inspection Group*

Conference: Visual Inspection of Parenterals

6/7 November 2024

Objective

Main topic of this conference is the detection of defects like 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 validation, training, defect categories, AQL testing and trending.

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 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.
In Europe chapter 5.17.2 of the European Pharmacopoeia now also gives further advice. However, many questions remain, e.g. concerning training, re-testing, detection capabilities and revalidation of inspection systems.

Furthermore, there has been a recognisable trend towards automated inspection machines throughout the last years. High expectations are also placed on the use of artificial intelligence. 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 system.

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

- The latest compendial requirements concerning particulate matter (EU & US)
- How to comply with FDA's new guidance on Visual Inspection
- Compliance with the new EU Annex 1
- Implementation of artificial intelligence in the automated inspection process
- Reduction of false rejects in automated inspection systems
- How to inspect hard-to-inspect containers
- How to set up a company-wide particle reduction programme
- How to transfer a visual inspection process during a site change

The fundamentals, such as training of operators in manual inspection, AQL testing, trending and the validation of an AVI system are content of the Pre-Conference course on November 5th.

Target Audience

This course is directed at staff from sterile operations involved in the 100% inspection process, that is production, quality and engineering. But also suppliers of primary packaging materials and inspections technology are target group of this event.

Moderator

Christof Langer, OSConsulting

Programme

Regulatory Requirements for the Visual Inspection of Parenterals

- Compendial requirements
  - 100% visual inspection & AQL testing
  - PharmEur, USP, JP - similarities and differences
- News from the Annex I
- Risk management considerations

Current FDA Requirements for Visual Inspection of Injectables (remote presentation)

- Difference between current FDA and EU requirements
- Use of quality risk management for the prevention of visible particulate contamination
- FDA Visible Particulate case studies
- Drug-Device combination product considerations

Visual Inspection of Parenterals – a GMP Inspector's View

- Applicable regulations & guidance
- Current requirements for pharmaceutical industry
- Expectations of a GMP-Inspector
- Examples of observations

Presentation of the new Version 4.0 of the ECA Guide

The new version 4.0 of the ECA guide has recently been released. The presentation will introduce the guide itself and the changes in the new version. Among other things a chapter on semi-automated visual inspection has been added. Also, the description of uninterrupted inspection times & breaks in manual visual inspection has been adapted. And the Annex 1 requirement for '**performance checks at regular intervals throughout the batch**' for AV inspection was taken into account.

Semiautomated Inspection – Advantages and Risks

- Regulations for the use of SAVI
- Technical setup of a SAVI system
- Differences manual and semi-automated inspection
- Qualification of inspection personal
- Typical inspection errors and walkarounds

Practical Approaches for the Inspection of hard-to-inspect Container Systems

Part I

- Inspection of Bags
- Single chamber and multi-chamber bags
- Inspection of Blow-Fill-Seal containers
- Inspection of Form-Fill-Seal containers
- Manual, semi-automated and fully-automated approaches
- Two step inspection

Part II

- Use of artificial intelligence
- General approach
- Training and Machine Learning
- Testing and Validation
- Limitations

Establishing a Company-Wide Program for Harmonisation of Visual Inspection and Particle Reduction

This presentation will guide you through a success story of developing and executing a global, company-wide visual inspection and particle life cycle management program at a large pharmaceutical company. Takeda has put a high focus on visual inspection and visible particles since 2020 and has achieved harmonization across their network of 15 sites and 13 CMOs as well as tremendous improvements in particle reduction and life cycle management. This presentation will provide an overview of the strategy, challenges, and achievements as well as learnings from the program.

- Learnings from Takeda's global program
- New challenges for particle LCM in small-scale manufacturing of ATMPs
- Alignment with evolving regulations
- Adaption to other companies

Transfer of a Visual Inspection Process

- Manual inspection
  - Manual process to manual process (same manufacturing location)
  - Manual process to manual process (different manufacturing location)
  - Test set transfer?
  - Create new test set? How, why?
  - What does validation look like?
  - End goals and success (what are we trying to achieve?)
- Automated inspection
  - Automated transfer: same machine (pitfalls)
  - Automated transfer: different machine (pitfalls)
  - End goals and success (what are we trying to achieve?)

Case Study Amgen: Use of AI in Visual inspection

Application, Project Planning and Qualification of AI in fully automated Visual Inspection

- Development of robust, reliable and production-ready models in 4 phases
  - Phase 1: Problem identification & description
  - Phase 2a: Specification of inspection concept
  - Phase 2b: Definition of the sample sets (artificial and production samples), creation of the datasets, clarification of the labelling strategy
  - Phase 3: Model design, training and verification - a risk-based approach
  - Phase 4: Qualification & validation
- Processes & technologies
  - Technologies for efficient image data acquisition, variable model technologies, transfer learning / pre-trained models, labelling application
  - Documentation of model development: traceability, risk minimisation and build-up of confidence

Social Event

On 6 November 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
Baxter Oncology

Martin Becker has many years of experience in the pharmaceutical industry. He worked in analytical development, QA and production at IDT and Sandoz, among others. He was Head of Technical Operations at Siegfried Hameln GmbH and is now Director Manufacturing at Baxter Oncology in Halle.

Antonio Burazer
Takeda Manufacturing Austria

Mr Burazer joined Takeda in 2010 where he has overseen visual inspection and secondary packaging processes at a multi-product manufacturing facility in Vienna, Austria. In 2019 he took over global responsibility for visual inspection and particle life cycle management at Takeda.

Martin Dearden
ECA Visual Inspection Group ,
M&F Pharma Quality Solutions

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 and strategy and for 5 years Vice President of Global Quality for PaxVax Berna in Switzerland. Now he is Director of M&F Pharma Quality Solutions Ltd. Independent Pharmaceutical and Biotechnology sector consultants. He also is member oft he ECA Visual Inspection Board.

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Visual Inspection of Parenterals

6/7 November 2024, Berlin, Germany

☐ Optional Pre-Conference Course “Fundamentals of Visual Inspection”, 5 November 2024

Title, first name, surname

Department | Company

Important: Please indicate your company’s VAT ID Number | Purchase Order Number, if applicable

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German law shall apply. Court of jurisdiction is Heidelberg.

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Speakers (cont.)

Haluk Dönmez, B. Braun

Haluk Dönmez has23 Years work experiences in Life Sciences. His current position is "Head of QM Digital Transformation" in global QM of B.Braun Melsungen AG.

Dr Helmut Gaus, ECA Visual Inspection Group & former Director Quality Control at Boehringer Ingelheim

Dr Gaus was 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. In 2018 he founded his own company WinSol. He is also member of the ECA Visual Inspection Board.

Felix Krumbein, Head ECA Visual Inspection Group, INSPECTIFAI

Mr. Krumbein studied optotechnics and image processing and initially worked on the development of GMP-compliant image processing systems. He was head of Inspections-Systems-Support at Roche Mannheim, where he was responsible for the qualification of visual inspection systems. Since 2022 he is Head of Visual Inspection at INSPECTIFAI / Körber AG, where he is responsible for the development of AI-based solutions for fully automated inspection machines. Mr. Krumbein is Head of the ECA Visual Inspection Group.

Christof Langer, OSConsulting

Christof Langer studied Biotechnology and is certified Risk Manager as well as a Lean Six Sigma Black Belt. He has been working as Managing Director at Baxter BioScience, responsible for Operations. Since 2009 he runs his own consultancy business.

Dr Stephen Langille, ValSource, formerly FDA

Dr Langille is a senior microbiology Consultant at ValSource. He worked for the US FDA for 19 years in the Office of Pharmaceutical Quality's Division of Microbiology Assessment as a reviewer, branch chief and division director. He is a member of the United States Pharmacopeia's expert panel on visual inspection and helped author the FDA's Draft Guidance for Industry on the Inspection of Injectable Products for Visible Particulates.

Dr Daniel Müller, GMP Inspector, Germany

Daniel Müller is head of a local GMP inspectorate in Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA- and overseas inspections. He is member of Germany's expert groups 'biotechnology & tissue' and 'quality assurance'.

Date of the Conference

Wednesday, 6 November 2024, 09.00 to approx. 17.45 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 7 November 2024, 08.30 to approx. 15.00 h

Venue

DoubleTree by Hilton Berlin Ku'damm
Los-Angeles-Platz 1
10789 Berlin

Fees (per delegate, plus VAT)

Conference

ECA Members € 1690
APIC Members € 1790
Non-ECA Members € 1890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes (electronic) conference documentation, dinner on 6 November, lunch on both days and all refreshments. VAT is reclaimable.

Pre-Conference Workshop

Non-ECA Members € 990
ECA Members € 790
APIC Members € 890
The fee is payable in advance after receipt of invoice and includes (electronic) conference documentation, lunch and all refreshments. VAT is reclaimable.

€ **Save € 300** when booking preconference course and conference together.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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