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Speakers


Dr Martin Becker
ECA Visual Inspection Group


Martin Dearden
M&F Pharma Quality Solutions


Haluk Dönmez
B. Braun


Dr Helmut Gaus
ECA Visual Inspection Group


Felix Krumbein
Head ECA Visual Inspection Group


Christof Langer
OSConsulting


Dr Daniel Müller
GMP-Inspector


Ivan Velimirović
Hemofarm

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Visual Inspection of Parenterals

State-of-the-art 100% Visual Inspection

22/23 October 2025, Vienna, Austria


Image: INSPECTIFAI

- With an optional Pre-Conference Course: **Fundamentals of Visual Inspection** on 21 October
- All participants receive the new version of ECA's Guide on "Visual Inspection" for free

Highlights

- 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
- Sources and Assessment of Particulate Matter
- Transfer of a Visual Inspection Process

Fundamentals of Visual Inspection

21 October 2025

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*

ECA Guide on Visual Inspection of Parenterals

All participants receive the new version 5.0 of ECA's Guide on "Visual Inspection of medicinal products for parenteral use" for free.

Visual Inspection of Parenterals

22/23 October 2025

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)
- Compliance with the revised 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 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 21 October.

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

Particulate Matter: Origins and Root Cause Analysis

- External sources (packaging material, filter, abrasion..)
- Internal sources (product and inherent particles)
- Potential risks for patients
- Route cause detection and particle identification
- Avoidance and depletion of particles

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 5.0 of the ECA Guide

The presentation will introduce the guide itself and the changes in the new version 5.0. Among other things a chapter on difficult-to-inspect items 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.

Refining Reject Analysis of Parenteral Containers

In this presentation a method is shown how to estimate precisely the actual defects in production batches. It allows improved trending based of defect severity

- Secondary inspection of rejected containers,
- Grouping defects by detection probability,
- Creating detailed control charts and data trends to better support batch disposition decisions
- Simulating outcomes using Monte Carlo statistical models

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 personnel
- Typical inspection errors and walkarounds

Practical Approaches for the Inspection of hard-to-inspect Container-Systems [Remote Presentation]

Part I

- Inspection of Difficult to Inspect Parenteral Products
- 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 (Excursion)

- Use of artificial intelligence
- General approach machine learning
- Training, validation and testing
- False reject rates
- Limitations

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?)

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 22 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.

Speakers

Dr Martin Becker
ECA Visual Inspection Group

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 Director Manufacturing at Baxter Oncology in Halle.

Martin Dearden
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.

Haluk Dönmez, B. Braun

Haluk Dönmez has23 Years work experience 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

Mr Krumbein studied optotechnics and image processing and was head of Inspections-Systems-Support at Roche for many years. From 2022 he headed the Visual Inspection division at InspectifAI. Mr Krumbein is Head of the ECA Visual Inspection Group. Today, he runs his consultancy STIC consulting.

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.

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GERMANY

Reservation Form (Please complete in full)

Visual Inspection of Parenterals

22/23 October 2025, Vienna, Austria

☐ Optional Pre-Conference Course "Fundamentals of Visual Inspection", 21 October 2025

Title, first name, surname

Department | Company

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

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.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Speakers (cont.)

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'.

Ivan Velimirović, Hemofarm

Ivan Velimirović is a senior pharmaceutical expert with over 20 years of experience in sterile manufacturing and QA, specializing in visual inspection of ampoules and vials. He worked extensively with manual, semi-automatic, and fully automated inspection systems, with a focus on defect characterization and process optimisation.

Date of the Pre-Conference Workshop: Fundamentals of Visual Inspection

Tuesday, 21 October 2025, 09.00 to approx. 17.00 h
(Registration and coffee 08.30 – 09.00 h)

Date of the Conference

Wednesday, 22 October 2025, 09.00 to approx. 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 23 October 2025, 09.00 to approx. 15.00 h

Venue

Doubletree by Hilton Vienna Schönbrunn
Schlossallee 8
1140 Wien
Phone: +43 1 89110
E-Mail: info@doubletree-schonbrunn.at

Fees (per delegate, plus VAT) Conference

ECA Members € 1890
APIC Members € 1990
Non-ECA Members € 2090
EU GMP Inspectorates € 1045
The conference fee is payable in advance after receipt of invoice and includes (electronic) conference documentation, dinner on 22 October, lunch on both days and all refreshments. VAT is reclaimable.

Pre-Conference Workshop: Fundamentals of Visual Inspection

ECA Members € 1090
APIC Members € 1190
Non-ECA Members € 1290
EU GMP Inspectorates € 645
The fee is payable in advance after receipt of invoice and includes (electronic) conference documentation, lunch and all refreshments. VAT is reclaimable.

€ **Save € 400** when booking pre-conference 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 – or search and register directly at www.gmp-compliance.org under the number 21774 (Pre-Conference Workshop & Conference) / 21773 (Pre-Conference Workshop) / 21775 (Conference). To avoid incorrect information, please give us the exact address and full name of the participant.

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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