ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Helmut Gaus
ECA Visual Inspection Group

Fundamentals of Manual Visual Inspection

100 % Inspection of Parenterals

Live Online Training on 15 May 2025

Highlights

- Understanding the US/EU Pharmacopeial requirements
- Ensuring GMP compliance in manual inspection
  - Training of personnel
  - Qualification of personnel
  - Working conditions
- Categorisation of defects
- Setup and handling of test-kits
- AQL testing within the scope of batch release
- Trending of inspection data

Objective

This training course gives you an understanding of the fundamentals of visual inspection applicable to the manual inspection of injectable products. This covers the following aspects of visual inspection: organisation, training, qualification and the inspection process itself. You will also learn about AQL testing and trending of inspection data.

Background

The 100% visual inspection of sterile injectable products is a requirement originating from the Pharmacopoeias, e.g. from the US USP or the European PharmEur. But there is still confusion within the global pharmaceutical industry with regard to the requirements for testing of 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, qualification, detection capabilities and organisation of the visual inspection and the AQL testing.

- We will address those topics during the conference and discuss and answer questions on:
- The latest compendial requirements concerning particulate matter
- Compliance with the revised Annex 1
- Training and qualification of operators in the manual inspection
- Setup of test kits for training and qualification
- Trending and monitoring of visual inspection data
- Correct AQL testing as part of the batch release
- Re-inspection of defect fractions

Target Audience

This one-day training is directed at everybody involved in the manual 100% inspection of sterile injectables. As the fundamentals are explained in a very comprehensive way, the course is very popular with beginners and medium experienced staff.

Programme

General Requirements

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

Manual Inspection

- Organisation of the manual inspection
- Training of personnel
- Qualification of personnel
- Standardisation of working conditions
- AQL testing in the manual inspection
- Trending of inspection data & batch release

Speaker

Dr Helmut Gaus,
ECA Visual Inspection Group

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 were he gained an extensive knowledge in the field of visual inspection. In 2018 he founded his own company WinSol.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

The EU GMP Guide requires: „...All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

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GERMANY

Reservation Form (Please complete in full)

Live Online Training: Fundamentals of Manual Visual Inspection
15 May 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.

Date Live Online Training

Thursday, 15 May 2025; 13.30 – 17.00 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members EUR 890
APIC Members EUR 940
Non-ECA Members EUR 990
EU GMP Inspectorates EUR 445
The conference fee is payable in advance after receipt of invoice.

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 21669. To avoid incorrect information, please give us the exact address and full name of the participant.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. 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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