



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



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Your Benefits

Internationally Acknowledged Certificate from ECA Academy

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.



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Live Online Training: Fundamentals of Manual Visual Inspection 15 May 2025

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date Live Online Training

Thursday, 15 May 2025; 13.30 – 17.00 h CEST

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members EUR 690

APIC Members EUR 740

Non-ECA Members EUR 790

EU GMP Inspectorates EUR 395

The conference fee is payable in advance after receipt of invoice.

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 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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