ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Helmut Gaus
WinSol, previously
Boehringer Ingelheim

Dr Tobias Posset
Roche Diagnostics

Fundamentals of Visual Inspection

Best Practice for Manual and Automated Visual Inspection of Parenterals

Live Online Training on 3 December 2020

Highlights

- Understanding the US/EU Pharmacopeial requirements
- Ensuring GMP compliance in manual inspection
- Categorisation of defects
- Handling of Test-Kits
- Setting up a qualification strategy for automated systems
- Assessing and trending of inspection data
- GMP-compliant routine operation of automated systems
- Re-Inspection, Re-Qualification & Re-Validation

Objective

The training course on visual inspection gives you an understanding of the fundamentals of visual inspection of injectable products, applicable to manual and automated inspection. This covers the following aspects of visual inspection: organisation, validation, conduct and evaluation of the results. You will also learn how to implement an automated system on the basis of manual inspection.

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 for visible particles. After the USP chapters <790> and <1790> were published, things have become much clearer, at least for the US. In Europe the new 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 in 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 questions also arise during routine processes like, for example 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
- Compliance with the revised Annex 1 (draft)
- Training and qualification of operators in the manual inspection
- Validation and operation of an automated inspection system
- Setup of test kits for training, qualification and routine inspection
- 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 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

- Qualification of personnel
- 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
- Detection rates
- Cross validation during the PQ phase

Automated Inspection

- Importance of particle detection rates
- System-Suitability, Requalification and revalidation
- Defect and reject fractions
- Routine inspection
- Trending of inspection data
- AQL testing as part of the release process
- Impact of visual inspection data on batch release

Image: Seidenader

Speakers

Dr Helmut Gaus, WinSol, previously Boehringer Ingelheim Former Director Quality Control

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.

Dr Tobias Posset, Roche Diagnostics Head of Production Support & Chairman oft he ECA Visual Inspection Group

Tobias Posset studied Biochemistry and Chemistry. He is heading the Production Support unit in the Pharma Production at Roche Diagnostics in Mannheim. Herein he is responsible for the IPCs, the particle laboratory, the automated visual inspection and the coordination of the manual inspection training. He is also the chairman of the ECA Visual Inspection Group.

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.

Would you like to present your company in an exhibition or as a sponsoring partner?

We offer you the opportunity to present your company, your products and services to your target group. Thus, participants can inform themselves during the breaks and gain additional benefit from the event. Alternatively, you can also become a sponsoring partner, for example by sponsoring lunch/dinner, coffee breaks or a social event. Interested? Then find out more about the possibilities at https://www.gmp-compliance.org/training/exhibitions-and-sponsoring

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.

Why not online? GMP/GDP Training Courses/Conferences, Webinars and E-Learning

Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Fundamentals of Visual Inspection
Live Online Training on 3 December 2020

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
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).
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 http://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, 3 December 2020, 09.30 – 16.30h CET

Technical Requirements
For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 790
APIC Members € 890
Non-ECA Members € 990
EU GMP Inspectorates € 495
The 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 Conferences 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
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 organisation please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or at
schopka@concept-heidelberg.de.