ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers


Dr Martin Becker
Siegfried Hameln


Martin Dearden
ECA Visual Inspection Group


Dr Helmut Gaus
ECA Visual Inspection Group


Al Goodwin
Amgen


Felix Krumbein
Head ECA Visual Inspection Group


Christof Langer
OSConsulting


Dr Stephen Langille
formerly FDA


Dr Daniel Müller
GMP-Inspector

Visual Inspection of Parenterals

Live Online Conference on 5/6 October 2022

Image: Seidenader

Highlights

- FDA's new guidance on Visual Inspection
- Compliance with EU Annex 1 and the Pharmacopeias
- Requirements from a GMP inspector's view
- Test Sets: Preparation, Handling and Usage
- Manual Inspection
  - Conception
  - Training & Qualification
  - Workplace
- Fully-Automated Inspection
  - Setup of the system
  - Qualification & Validation
  - Minimisation of false rejects
  - Issues during routine
- Re-Inspection of Defect Fractions
- Trending and Monitoring of Inspection Data
- AQL Testing and Batch Release

Visual Inspection of Parenterals, 5/6 October 2022

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, trending and batch release considerations.

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 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 throughout 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 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 systems.

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

- The latest compendial requirements concerning particulate matter
- How to comply with FDA's new guidance on Visual Inspection
- Compliance with the (revised) EU Annex 1
- Training and qualification of operators in the manual inspection
- Validation and operation of an automated inspection system
- Reduction of false rejects in automated inspection systems
- Trending and monitoring of visual inspection data
- Correct AQL testing as part of the batch release
- Re-inspection of defect fractions
- Usage of artificial intelligence in visual inspection

Target Audience

This course is directed at staff from sterile operations, that is production, quality operations 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 1 revison
- Risk Management Considerations

FDA's new Guidance on Visual Inspection

- The reason for the FDA's Visible Particulate Guidance - visual Inspection compendial requirements vs. U.S. current good manufacturing practice
- The use of Quality Risk Management for the prevention of visible particulate contamination
- A lifecycle approach to visible particulate contamination control

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

Manual Visual Inspection – Theory and Practical Aspects

- Probabalistic nature of visual inspection
- Defect categorisation
- Differentiation of test kits for training, qualification and routine
- Qualification and training of personnel
- Standardisation of working conditions in manual inspection
- Usage of the Knapp and the modified Knapp test

Speakers

Requirements, Composition, and Handling of Test-Sets

- Definition of defect categories
- Set-up and composition of a test set
- Test-Sets and their use for Training, Qualification and Routine
- Handling and release of test sets
- Documentation

Automated Visual Inspection – from Setup to Routine Use

- Limitations of automated inspection
- Setting up a qualification strategy for automated systems
- Cross validation during the PQ phase of an automated system
- Importance of particle detection rates
- System-Suitability, Requalification and revalidation
- Inspection of eject fractions
- The Roche Inspection systems: manual, semi-automated and fully automated inspection

Case Study Amgen: Optimisation of Particle Inspection systems – Right First Time

- Inspection of high viscosity syringe products
- How to achieve effectively zero false fail ejects (0.04% false fails on complex particle stations)
- Where to use Mainstream Vision inspection and Deep Learning assisted inspection
- Amgen's procurement and implementation strategy for new AVI systems
- Take home messages for improving visual inspection systems

Re-Inspection of Defect Fractions in Visual Inspection

Different scenarios will be covered such as:

- Re-inspection or additional inspection of "grey-channel" units from (semi-) automated inspection
- Re-inspection in case of exceeding alert limits or AQL-failures
- Focused re-inspection
- Inspection approaches in case of investigations due to unexpected particles (e.g., to determine frequency of occurrence of visible particles when particles are found during release/stability testing

Particle Testing and the Correlation with Trending and Batch Release

- Why do we Monitor (What is it all about?)
- Data and Measurement
- The AQL trap
- Improvement Process Map
- Investigation and Routine Analysis,
- Release Process: "To AQL or not to AQL, that is the Question"
- Product Release: "Falling off a log"

Dr Martin Becker
Siegfried Hameln

Dr Becker is Head of Technical Operations at Siegfried Hameln. Before that he has been Head of Production Sterile Operations. He also worked for IDT and Sandoz where held different positions in analytical development, quality assurance, and production. He is also member of the ECA Visual Inspection Board.

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.

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.

Al Goodwin
Amgen

Al specifies and supports globally Amgen's AVI systems for vials, syringes, plastic cartridges and drug delivery devices. Al has 25 years of experience in optical inspection systems. He has also worked in Japan for 5 years on optical test measurement systems. In the last 15 years he has worked closely with key International Machine Vision Software design companies and has used this experience in areas of Particle detection, Glass flaw detection and improvements and evaluation of Vision Algorithm Robustness in the pharmaceutical industry.

Felix Krumbein
Head ECA Visual Inspection Group, Körber

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 and implementation of AI-based solutions for fully automated inspection machines. Mr. Krumbein is also 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'.

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)

Live Online Conference: Visual Inspection of Parenterals
5/6 October 2022

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 of Live Online Conference

Wednesday, 5 October 2022, 09.00 – 17.45 h CEST
Thursday, 6 October 2022, 09.00 to approx. 16.00 h CEST

Technical Requirements

We use Webex Events 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 € 1590
APIC Members € 1690
Non-ECA Members € 1790
EU GMP Inspectorates € 895
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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

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.

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 seminar in detail and with which you document your training.

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org.

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.

WH/14072022