ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers


Dr Martin Becker
IDT Biologika


Martin Dearden
ECA Visual Inspection Group


Dr Helmut Gaus
WinSol, previously Boehringer Ingelheim


Roland Koch
Gasporox


Felix Krumbein
Roche


Christof Langer
OSConsulting

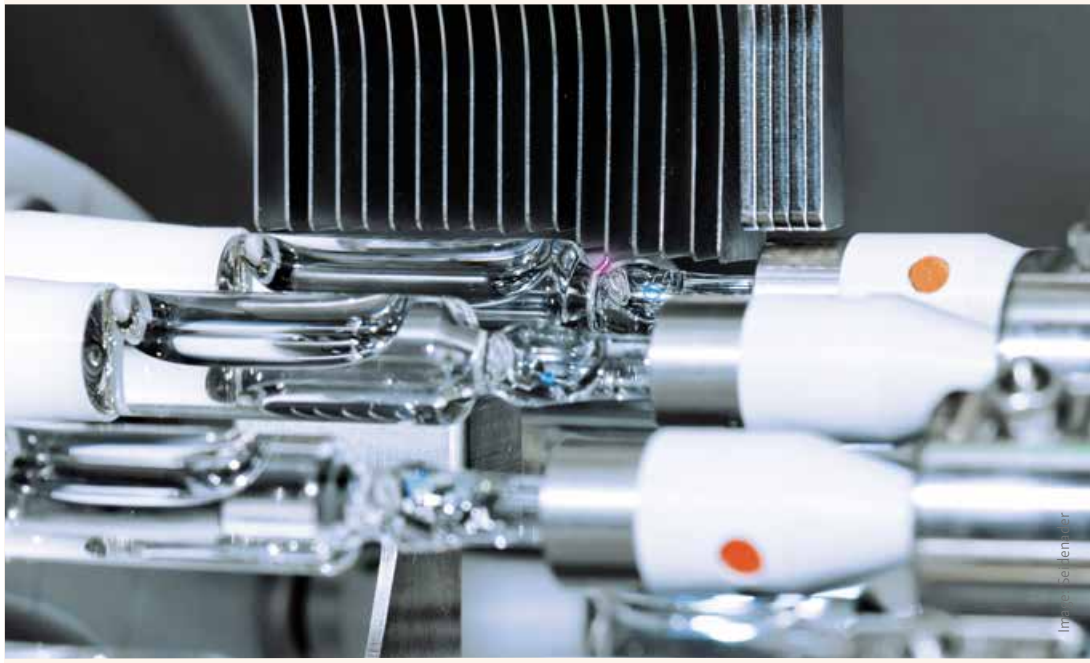

Dr Daniel Müller
GMP-Inspector


Dr Brian Turnquist
Boon Logic

Control of Parenterals

Container/Closure Integrity Testing
Visual Inspection Systems

Live Online Conference from 16-18 November 2021



Highlights

Container-/Closure Integrity Testing, 16 November 2021

- Pharmacopeial Requirements for the CCI testing
- GMP Requirements regarding CCIT
- Overview CCI Testing Technologies
- Online vs. Offline Testing
- Case Study: CCI Testing of Ampoules
- Case Study: CCI Testing of Vials

Visual Inspection Systems, 17/18 November 2021

- Pharmacopeial Requirements for Visual Inspection
- GMP Requirements regarding Visual Inspection
- Manual Inspection
- Fully-Automated Inspection
- Test Sets: Preparation, Handling and Usage
- Re-Inspection of Defect Fractions
- Trending and Monitoring of Inspection Data
- AQL Testing and Batch Release
- Unsupervised Machine Learning: new concept for automated visual inspection

Container-/Closure-Testing of Parenterals, 16 November 2021

Objective

Different products and different container types require different testing methods: this event aims at giving an overview of the different CCI testing systems which are applied during production and as part of the quality control system. Apart from technical aspects the regulatory requirements on CCI testing will be highlighted as well as the applicability of inline and offline testing.

Background

An intact container closure system, which is the sum of packaging components that protect the dosage form, is the pre-requisite for a safe and sterile drug product. The CC system protects the product from microbial contamination and also from exposure to gases or water vapour or the loss of solvent. Container Closure integrity testing is therefore a regulatory requirement and it is part of the whole life cycle of a sterile drug product.

Initially this testing was performed as part of the initial development of the packaging system and the system's suitability verified in stability studies including on-going stability. Over the years, the expectation was raised to perform batch by batch verification with latest trends to 100% inline or offline testing wherever possible.

We will discuss and answer questions like:

- What are the current and upcoming GMP- and compendial requirements in the US / EU / RoW?
- Will container closure integrity testing change to 100% inline testing?
- What does the Annex 1 require?
- How do we have to define 'tight'?
- Which testing technologies are available and suitable?
- CCI testing of lyo & liquid vials
- CCI testing of ampoules

Target Audience

This conference is directed at specialists and executives from the areas engineering and production and QA dealing with the implementation and operation of systems for the container/closure-integrity testing of sterile medicinal products.

Moderator

Christof Langer, OSConsulting

Programme

Container Closure Integrity Testing of Sterile Drug Products – Requirements, Expectations and Exaggerations

- Container Closure Integrity during development, qualification and stability testing
- Regulatory, Pharmacopoeial and GMP requirements
- System integrity versus container damages
- Patient risks – do we need batch by batch testing?
- Industrial best practices

Container Closure Integrity Testing of Parenterals – a GMP inspector's View

- Applicable regulations & guidance
- Implementation of current requirements
- Expectations of a GMP-Inspector in GMP Inspections
- Examples of observations

Overview of Container/Closure Integrity Testing Technologies

The presentation gives a complete overview of the different aspects of leak testing to do CCIT in the pharmaceutical production. The systems presented can be used for the CCIT of vials, ampoules, syringes, BFS, IV bags, blisters etc.

- Leak, leak rate and the relevant physical units
- Leak test methods
  - Pressure change methods (vacuum, pressure and LFC)
  - Head Space Analysis using TDLAS
  - Helium Leak Test and other Mass Spectroscopy Systems
  - High Voltage Leak Detection (HVLD)
  - Force Sensing Technology
- Capabilities and examples of the different methods
- How to select the right method
- How to generate positive controls

Case Study: 100% Testing of Vials

- System setup
- Validation
- Routine operation

100% inline CCI Testing of Ampoules

- High Voltage inline testing: method description
- Integration in the production process
- Limits of the system
- Qualification of the system
- Validation
- Routine Operation

Visual Inspection Systems, 17/18 November 2021

Objective

Main topic of this course is the detection of defects like particles in injectables and their evaluation during batch release. 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
- Compliance with the (revised) EU Annex 1
- Training and qualification of operators in the manual inspection
- Validation and operation of an automated inspection system
- 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 assurance 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

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

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

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

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

Automated Visual Inspection Based on Unsupervised Machine Learning

- Vector segmentation using unsupervised machine learning
- Characterizing variation using computer vision
- Learning normal variation in defect-free bottles
- Visual inspection via anomaly detection

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"

Speakers

Dr Martin Becker
IDT Biologika

Dr Becker is group leader in project management at IDT. Before he has been Head of Technical Operations and Head of Production Sterile Operations at Siegfried Hameln. He previously held also different positions in analytical development, quality assurance, and production at IDT and Sandoz.

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.

Dr Helmut Gaus
WinSol & 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.

Roland Koch
Gasporox

Roland Koch has 25 years' experience in the development and implementation of technologies and systems for the GMP regulated industry (Differential Pressure Measurements, Tunable Laser Absorption Spectroscopy, HVLD, Force Sensor Technology and NDIR). He is at GASPOROX AB in Lund (SE) as a Senior Sales and Application Engineer.

Felix Krumbein
Roche Diagnostics

Felix Krumbein studied optotechnics and image processing and has been responsible for the implementation of GMP-compliant imaging-tools. Now he is head of Inspections-Systems-Support at Roche Mannheim were he is responsible for the qualification of visual inspection systems.

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: Control of Parenterals, 16-18 November 2021
☐ *CCI Testing of Parenterals, 16 November 2021*
☐ *Visual Inspection Systems, 17/18 November 2021*

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.

Speakers

Speakers

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 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'.

Dr Brian Turnquist
Boon Logic

Dr Turnquist has worked in machine learning for the past twenty years developing numerous novel algorithms for automatically clustering biological signals in real-time. Turnquist is CTO of Minneapolis tech start-up, Boon Logic and is a tenured professor at Bethel University.

CCI Testing of Parenterals

Date of Live Online Conference
Tuesday, 16 November 2021, 09.00 – 16.45 h CET

Fees (per delegate, plus VAT)
ECA Members € 790
APIC Members € 890
Non-ECA Members € 990
EU GMP Inspectorates € 495
The conference fee is payable in advance after receipt of invoice.

Visual Inspection Systems

Date of Live Online Conference
Wednesday, 17 November 2021, 09.00 – 17.00 h CET
Thursday, 18 November 2021, 09.00 to approx. 15.30 h CET

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.

Would you like to save money?
Book both courses and save € 300 in total.
(not valid for EU GMP Inspectorates).

Technical Requirements
For our Live Online Training Courses and 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 e-mail 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.

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.

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 Niklaus Thiel (Organisation Manager) at
+49(0)62 21/84 44 43, or at
thiel@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.

WH/03052021