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 Tobias Posset
Roche


Dr Brian Turnquist
Boon Logic

Désirée Womser
Novartis

Control of Parenterals

Container/Closure Integrity Testing
Visual Inspection Systems

6 - 8 October 2020 | Barcelona, Spain

Highlights

Container-/Closure Integrity Testing, 6 October 2020

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

Visual Inspection Systems, 7/8 October 2020

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

All Participants receive the current Version of ECA's Best Practice Paper on "Visual Inspection" for free!

Container-/Closure-Testing of Parenterals, 6 October 2020

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?
- Is blue dye testing still a standard? And how does modern blue dye testing look like?
- CCI testing of prefilled syringes
- 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

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

Expectations of a GMP-Inspector regarding to Container/Closure Integrity Testing

- Regulatory documents on container / closure integrity testing (an overview)
- Testing methods for CCIT & validation strategies
- Current situation on CCIT in pharmaceutical industry & challenges
- Inspection findings & experience

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

Integrity Testing of Prefilled Syringes

- Sampling plan
- He-leak testing
- Limitations of the He-leakage test
- Cross validation with mCCI

Visual Inspection Systems, 7/8 October 2020

Objective

Main topic of this course is the detection of defetcs 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.

Best-Practice Paper

All participants receive the current version of ECA's Best Practice Paper on "Visual Inspection" for free.

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. But still, lots of questions arise, e.g. concerning 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 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

Dr Tobias Posset, Roche Diagnostics & Chairman of the ECA Visual Inspection Group

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

Expectations of a GMP Inspector regarding Visual Inspection

- Regulatory documents on visual inspection of parenterals (an overview)
- Manual inspection, semi-automated inspection (personnel, working place, equipment, training & qualification)
- Automated inspection (incl. validation strategy)
- Routine operations, AQL testing, handling of (r)ejects
- Inspection findings & experience

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

Handling Inherent Particulate Matter of Biologics in Visual Inspection

- Challenge of inherent particulate matter in drug product solution
- Appearance and characteristics of inherent particulate matter
- Impact on visual inspection
- Handling inherent particulate matter in routine visual inspection
- Establishment of a life-cycle management approach

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.

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 Tobias Posset
Roche Diagnostics

Tobias Posset studied Biochemistry and Chemistry. He is heading the Production Support unit in the Pharma Production at Roche 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 chairman of the ECA Visual Inspection Group.

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.

Désirée Womser
Novartis

Social Event

On 7 October you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

CCI Testing of Parenterals

Date
Tuesday, 6 October 2020, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)

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 and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

Visual Inspection Systems

Date
Wednesday, 7 October 2020, 09.00 – 18.15 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 8 October 2020, 08.30 to approx. 15.30 h

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 and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

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

Venue of both events
Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Email sants@barcelo.com

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

WA/13012020

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

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.

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Reservation Form (Please complete in full)

Visual Inspection Systems, 6-8 October 2020, Barcelona, Spain
☐ *CCI testing of Parenterals, 6 October 2020*
☐ *Visual Inspection Systems, 7-8 October 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)

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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 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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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.

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