CONTROL OF PARENTERALS
8-10 October 2019, Vienna, Austria

Container/Closure Integrity Testing, 8 October 2019

Learning Objectives:
- Pharmacopeial and GMP requirements for the CCI testing
- Overview CCI testing technologies
- Online vs. offline testing
- Modern blue dye testing
- Case Study: CCI testing of prefilled syringes
- Case Study: CCI testing of ampoules
- Case Study: CCI testing of vials

Visual Inspection Systems, 9/10 October 2019

Learning Objectives:
- Regulatory and GMP requirements for the visual inspection
- Manual Inspection
- Fully-Automated Inspection
- Test Sets: preparation, handling and usage
- Re-inspection of defect fractions
- Particulate Matter: Route Cause Analysis
- Trending and Monitoring of inspection data
- AQL Testing and Batch Release

All participants receive the current version of ECA’s Best Practice Paper on “Visual Inspection” for free.
Objectives
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 CCI 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?
- 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

Modern Blue Dye Testing – still the standard CCI method?
- Regulatory requirements and subsequent test method in industry
- Critical method aspects, e.g. process-monitoring
- Perspective and limits in context of product life cycle

Case Study: 100% inline testing of Lyo Vials
- System setup
- Validation
- Routine operation

CCR Integrity testing of Prefilled Syringes
- Sampling plan
- He-leak testing
- Limitations of the He-leakage test
- Cross Validation with mCCI

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
Objectives
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. 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
- Training in the manual visual inspection
- Qualification 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
- Root cause analysis in case of particulate matter

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.

Best-Practice-Paper
All participants receive the current version of ECA’s Best Practice Paper on “Visual Inspection” for free.

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 revision
- GMP Expectations
  - Manual inspection
  - Automated Inspection
- Risk Management Considerations

Fundamentals of Visual Inspection – Theory and practical aspects
- Probabalistic nature of visual inspection
- Defect categorisation
- Test kits for training, qualification and routine
- Qualification and training of personnel
- Standardisation of working conditions in the manual inspection
- Usage of the Knapp and the modified Knapp test
- AQL testing in the process of visual inspection

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

Particulate Matter: Origins and Root Cause Analysis
- External sources (packaging material, filter, abrasion..)
- Internal sources (product and inherent particles)
- Potential risks for patients
- Route cause detection and particle identification
- Avoidance and depletion of particles
Reinspection 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”

Speakers

**Dr Martin Becker, Siegfried Hameln**
Dr Becker studied Chemistry and is actually Head of Technical Operations and Head of Production Sterile Operations at Siegfried Hameln (formerly hameln pharmaceuticals). He previously held different positions in analytical development, quality assurance, and production at IDT and Sandoz.

**Klaus Boje, Boehringer Ingelheim**
Klaus Boje has been working for Vetter as a supervisor of the QC of packaging material. Since 1999 he is working for Boehringer Ingelheim, first in the development and validation of CCIT methods. Since 2014 as Scientist in primary packaging development for early and late stage projects for biopharmaceutical combination products.

**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, were he gained an extensive knowledge in the field of visual inspection. In 2018 he founded his own company WinSol.
Speakers

**Christoph Herdlitschka, Wilco**
Christoph is an industrial and economics engineer and has more than 10 years of experience in the field of pharmaceutical fill and packaging processes. Since 2016 he is heading the Product Management at Wilco in Switzerland.

**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.

**Felix Krumbein, Roche Diagnostics**
Felix Krumbein studied optotechnics and image processing and has been responsible 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.

**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 the chairman of the ECA Visual Inspection Group.

**Dr Bernd Renger, Immediate Past Chair of the European QP Association; Renger Consulting, Germany**
Dr Bernd Renger is Immediate Past Chair of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung. He has also held several quality management positions at Mundipharma, Byk Gulen (now Takeda) and Baxter BioScience in Vienna.

Social Event

On 9 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, 8 October 2019, 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.

Visual Inspection Systems
Date
Wednesday, 9 October 2019, 09.00 – 17.45 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 10 October 2019, 08.30 to approx. 14.30 h

FEES (per delegate plus VAT*)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
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.

Venue of both events
Radisson Blu Park Royal Palace Hotel Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/891 109 020
Fax +43/1/891 109 050
info.parkroyalpalace.vienna@radissonblu.com

Saving opportunities
Book both courses and save € 300 in total (not valid for EU GMP Inspectorates).

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 event. Reservations should be made directly with the hotel. Early reservation is recommended.

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

For questions regarding reservation, hotel, organisation etc. please contact:
Dr Robert Eicher (Operations Director) at +49(0)62 21 / 84 44 12, or per e-mail at eicher@concept-heidelberg.de.

Reservation Form (Please complete in full)

□ CCI Testing of Parenterals, 8 October 2019, Vienna, Austria
□ Visual Inspection Systems, 9/10 October 2019, Vienna, Austria

□ Mr □ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number

Purchase Order Number, if applicable

Street / P.O. Box

City Zip Code

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E-Mail (Please fill in)

E-Mail (Please fill in)

Special conditions and terms:
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 - within 10 days after receipt of invoice: 100%.

E-mail: info@concept-heidelberg.de

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* VAT is reclaimable