**Learning Objectives:**

- Regulatory and GMP Requirements for the Visual Inspection
- Manual Inspection
  - Training
  - Qualification
  - Premises
- Semi-Automated Inspection
- Fully-Automated Inspection
  - Validation
  - Routine Use
- Categorisation of Defects & Test Sets
- 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.

*This conference is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager“. Please find details at www.gmp-certification.eu*
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.

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
- 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.

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
- Probabilistic 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”

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.

Speakers

Dr Martin Becker, Siegfried Hamln
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.

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.

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 heis 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 Gulden (now Takeda) and Baxter BioScience in Vienna.
Visual Inspection Systems
9/10 October 2019, Vienna, Austria

Optional pre-course session: CCI Testing of Parenterals, 8 October 2019, Vienna, Austria

Title, first name, surname

Company

Department

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2. If you have to cancel entirely we must charge the following processing fees: Cancellation - within 1 week prior to the conference 100 %.
   - until 1 weeks prior to the conference 50 %
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(As of January 2012).

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