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Fundamentals of Visual Inspection

Best Practice for manual and automated Visual Inspection of Parenterals

SPEAKERS



DR HELMUT GAUS
*Winsol, previously
Boehringer Ingelheim*



DR TOBIAS POSSET
Roche

All participants receive:

- **The AQL Inspector's Rule** - A tool for conducting AQL Testing.



- The current version of ECA's Best Practice Guidance on "Visual Inspection"



9 October 2018, Hamburg, Germany

LEARNING GOALS

- Understanding the US/EU Pharmacopeial requirements
- Ensuring GMP compliance in manual inspection
- Categorisation of defects
- Setting up a qualification strategy for automated systems
- Usage of statistical tools
- Assessing and trending of inspection data
- GMP-compliant routine operation of automated systems



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Objectives

The training course on visual inspection gives you an understanding of the fundamentals of visual inspection of injectable products, applicable to manual and automated inspection. You will also learn how to implement an automated system on the basis of manual inspection.

Background

The 100% visual inspection of sterile injectable products is a requirement originating from the Pharmacopoeias, e.g. from the US USP or the European PharmEur. But 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. However, many questions remain, e.g. concerning re-testing, detection capabilities and revalidation of inspection systems.

Furthermore, there has been a recognisable trend towards automated inspection machines in 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 questions also arise during routine processes like, for example re-testing and the usage of test-sets, doing AQL-Testing as well as the adjustment of parameters of the vision systems.

Due to the lack of precise requirements the ECA Visual Inspection Group has developed a Best Practice Guidance. This paper is very helpful during daily business and answers many questions in its chapters:

- Automated inspection
- Manual inspection
- Inspection of lyophilized product
- Defect classes
- Evaluation of defect classes and trending
- Batch release

Therefore, all participants of the Pre-Conference Course receive the ECA Visual Inspection Guidance for free.



The course also includes an AQL training, meaning that you will learn how to use AQL tables to set defect limits and how to evaluate batch inspection data. For that purpose all participants of the Pre-Conference Course receive the **AQL Inspector's Rule as tool for AQL testing for free.**

The rule covers a wide range of AQL's (.065 to 15) with Normal, Tightened and Reduced inspection for both single and double sampling plans according to ISO 2859-1 (1999). The practical usage of this tool will be shown during the course.

Target Audience

This one day course is directed to everybody involved in the 100% inspection of sterile injectables. As the fundamentals are explained in a very comprehensive way, the course is very popular with beginners and medium experienced staff.

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Programme

General requirements

- Requirements of the different Pharmacopeia
- Defect categorisation
- Test kits for training, qualification and routine

Manual Inspection

- Qualification of personnel
- Training of personnel
- Standardisation of working conditions
- AQL in the manual inspection

From Manual to automated inspection

- Usage of the Knapp and the modified Knapp test
- Detection rates
- Cross validation during the PQ phase

Automated inspection

- Importance of particle detection rates
- System-Suitability, Requalification and revalidation
- Defect and reject fractions
- AQL testing as part of the release process
- Trending of inspection data
- Impact of visual inspection data on batch release

Speakers



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 where he gained an extensive knowledge in the field of visual inspection. In 2018 he founded his own company WinSol.



Dr Tobias Posset | Roche Diagnostics GmbH
Tobias Posset studied Biochemistry and Chemistry. He is heading the Production Support unit in the Pharma Production at Roche Diagnostics 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.

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We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!


*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.

Easy Registration

 **Reservation Form:**
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

 **Reservation Form:**
+ 49 6221 84 44 34

 **e-mail:**
info@concept-heidelberg.de

 **Internet:**
www.gmp-compliance.org

Date: Fundamentals of Visual Inspection

Tuesday, 9 October 2018,
10.00 to approx. 17.00 h
(Registration and coffee 09.30 – 10.00 h)

Venue

Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg, Germany
Phone +49 40 22 63 62 0
Email hamburg@barcelo.com

Fees (per delegate plus VAT): Fundamentals of Visual Inspection

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 lunch and all refreshments. VAT is reclaimable.

The course **Fundamentals of Visual Inspection** can be booked together with the conference **Particles in Parenterals (10-11 October, Barceló Hotel Hamburg)** at a reduced price:

Fees (per delegate plus VAT): Fundamentals of Visual Inspection AND Particles in Parenterals (9-11 October)

Non-ECA Members € 2,480
ECA Members € 2,280
APIC Members € 2,280
EU GMP Inspectorates € 1,390
The conference fee is payable in advance after receipt of invoice and includes lunch on all three days and dinner on the second day and all refreshments. VAT is reclaimable.

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
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0)62 21/84 44-0
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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 per e-mail at schopka@concept-heidelberg.de.


Please note that there **will not be any print-outs at the conference**. Instead you will receive all presentations prior to the event as downloads as well as after the event, in case of updates.

If the bill-to-address deviates from the specification to the right, please fill out here:

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Reservation Form (Please complete in full)

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Fundamentals of Visual Inspection
9 October 2018, Hamburg, Germany

I also register for the Conference
 Particles in Parenterals
10-11 October 2018, Hamburg, Germany

Mr Ms

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Important: Please indicate your company's VAT ID Number

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General terms and conditions

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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 %
- until 1 weeks prior to the conference 50 %
- 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.

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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).

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