

SPEAKERS

KLAUS BRAIG
Uhlmann VisioTec

DIRK DICKFELD
PCE Pharmacontrol
Electronic

DR HELMUT GAUS
Rentschler
Biotechnologie

PROF RUDOLF KESSLER
Reutlingen University

MICHAEL LAMMEL
Roche Diagnostics

DR DANIEL MÜLLER
Regional Government
Tübingen

ROBERTO ROSITO
Essex Animal Health
Friesoythe

ALWIN TEPE
Essex Animal Health
Friesoythe



Visual Inspection Systems

100% Inspection of Parenteral Drugs

**Prague, Czech Republic
17-18 March 2010**

HIGHLIGHTS:

- GMP and regulatory background of visual inspections
- QA aspects of manual, semi-manual and fully automated visual inspection
- Particles, cosmetic deficiencies and Japan quality
- State of the art fully automated inspection of
 - Pre-filled Syringes
 - Vials
- Identification, tracking and laser-engraving of vials
- Qualification and validation of visual inspection systems
- Setting of deficiencies and usage of test kits
- Leak detection
- New methods in visual inspections

Objectives This event aims at giving an overview of different optical inspection systems for the required testing of parenterals. Apart from technical aspects, quality assurance as well as the practical operation of these systems are examined, and guidance on putting them into operation is provided.

Background Medicinal products for parenteral application are subject to a large number of tests. An essential aspect is testing for particulate matter and primary packaging deficiencies. Here, the regulations require a 100% inspection. The question of how it is performed is left to the manufacturer's discretion. Next to manual and semi-automatic inspection, fully automatic systems become more and more important. With the help of suitable technologies, qualification and validation, they can ensure an optimum level of safety in an economical way. In this context it is crucial to choose the right settings for the system in order to avoid discarding of too many in-specification products.

However, which form of optical inspection should be chosen? Are there any differences between pre-filled syringes and vials? What has to be taken into account during qualification and validation, what during everyday operation of the system? Which requirements does an inspector have on optical inspection systems? What is important with regard to training or OOS results? What is to be done with rejects? These and further questions are discussed and answered during the conference. Furthermore, new possibilities in optical inspection are presented, e.g. inspecting opaque systems, like plastic containers.

Target Audience This conference is directed at specialists and executives from the areas engineering and production dealing with installation, qualification and operation of visual inspection systems for in-process testing of medicinal products. But it also targets staff from the quality control unit.

Programme

Regulatory Requirements and GMP Inspections of Visual Inspection Systems

- Regulatory framework (EU GMP Guide, European Pharmacopoeia)
- Qualification of premises & equipment
- Requirements for workplace & personnel
- Inspector's experience

Quality Assurance Topics to be considered in Manual and Automatic Visual Inspection

- Defect classes
- Warning limits
- OOS and deviation matrix
- Training of the personnel
- AQL testing, release decision
- Test kits and test samples

Automated Inspection of Parental Solutions in Vials - Implementation and Experiences

a. Engineering

- User requirements
- Products to be inspected
- Inspection stations
- Vision software
- Computer systems
- Maintenance
- Personnel training

b. Qualification/Validation

- Qualification steps
- Categorization of defects
- Test vials
- Knapp test
- Product validation
- Better or equivalent to manual inspection

c. Routine operation

- Functionality verification
- Alert limits
- Product Inspection trends

Validation of an Automated Inspection Line for Syringes

The presentation describes a validation project for a fully automated online 100% visual inspection line for syringes. After being filled in an isolator the syringes are directly transported to the inspection line and inspected by a combination of automated and manual control.

- Basic principles of manual and automated inspection
- The validation program
- Sample sets for qualification purposes
- Performance comparison with the manual inspection
- Practical experiences : inline vs. offline application, how to deal with micro bubbles, reduction of false reject rates
- Trends

Impact of the Japanese Market on Visual Inspection

- Specifics to be considered
- Cosmetic defects
- Quality versus cosmetic
- Adaption of the release process

Programme (cont'd)

Identification and Tracking of Vials

Safeguarding of vial production by serialized imprint of invisible data matrix code. Product, Lot, Serial Number and progression of production are controlled in every stage of production. By using a database the vials can be tracked on site as well as out of site.

Vial Marking by Laser - Glass Engraving

- Glass engraving of large-volume vials, using lasers.
- Entering of data into a glass-surface-onmelted data matrix code.
- Inline tracking of vials for multiple process steps.
- Utilization of provided data matrix information for practical purposes

100% Inspection of Residual Moisture on a Lyophilisation Line with NIR

- Integration of high speed quantitative NIR inspection
- Method development
- Quality Aspects: Reproducibility; Stability
- PAT-based approach

New Concepts in Measuring Particulates: Optics and Spectroscopy in Opaque Systems

- Physical principles of measurements in scattering systems
- State of the art analysis of particles
- Optics and spectroscopy for the separation of scatter (-morphology) from absorption (-chemistry)
- New concepts for inline inspection of particles in liquids and for solids
- Practical realisation

Speakers

KLAUS BRAIG, Uhlmann VisioTec GmbH

Klaus Braig is an industrial electronics technician. He built up the Uhlmann office in UK and was responsible manager for the after sales area. Afterwards he was responsible CR manager for worldwide pharmaceutical key accounts. Since 2008 he is Head of Sales at Uhlmann Visiotec.

DIRK DICKFELD, PCE Pharmacontrol Electronic GmbH

Dirk Dickfeld studied communications engineering. He founded the company Laetus in 1974 and led this company until he founded his new company PCE in 1989, where he still is the managing director.

DR HELMUT GAUS, Rentschler Biotechnologie GmbH

Dr Gaus is Qualified Person and Vice President Quality Control at Rentschler Biotechnologie. Within his various positions in the pharmaceutical industry the incoming inspection of packaging components was always part of his responsibility.

PROF RUDOLF KESSLER, Reutlingen University

Prof Kessler is a chemist and holds a doctoral degree in spectroscopy. He is Professor at Reutlingen University, working on process analytics and chemical imaging. He is chairman of the working group for process-analytics of the GDCh and the Dechema as well as author of the book process analytics.

MICHAEL LAMMEL, Roche Diagnostics GmbH

Michael Lammel holds degrees in chemical engineering and pharmacy. His industrial career started 1990 with the former Boehringer Mannheim GmbH. In his current function he is Head of Production for bulk and packaging operations in the Mannheim site, which is one of Roche's centers of excellence for parenteral production.

DR DANIEL MÜLLER, Regierungspräsidium Tübingen, Germany

Dr Müller studied Pharmacy and started his career in the pharmaceutical industry. Among other positions he served as a Qualified Person of large volume parenterals. In 2001 he joined a German inspectorate and has been working as a GMP Inspector with focus on biotechnological active ingredients and sterile drug products since that time. He is also a member of the German Expert Group 4 (Biotechnology & Tissue).

ROBERTO ROSITO, Essex Animal Health Friesoythe

Roberto Rosito has more than 22 years experience in pharmaceutical production. Since 2003 he has been working as Project Manager at Essex Animal Health Friesoythe a Division of Essex Pharma GmbH, responsible for installation and operational qualification projects, conceptual design of equipment and process optimization.

ALWIN TEPE, Essex Animal Health Friesoythe

Alwin Tepe studied electrical engineering. He started his career as engineer in research and development. Since 2002 he works for Essex Animal Health Friesoythe and is responsible for IQ and OQ in the field of automated Systems and Computer Validation.


Social Event


On Wednesday, 17 March 2010 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.




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

Wednesday, 17 March 2010, 13.00 to approx. 18.15 h
(Registration and coffee 12.30 - 13.00 h)
Thursday, 18 March 2010, 09.00 to approx. 16.15 h

Venue

Dorint Hotel Don Giovanni Prague
Vinohradská 157A
130 20 Prague 3
Czech Republic
Phone +420 2 6703 1111
Fax +420 2 6703 6717

Fees

Non-ECA Members € 1,490.- per delegate plus VAT
ECA Members € 1,341.- per delegate plus VAT
APIC Members € 1,416.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates € 745.- per delegate plus VAT
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.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for

your room reservation or be sure to mention "VA 6277 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 16 February 2010. 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.

Conference language

The official conference language will be English.

Organisation and Contact

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For questions regarding content:

Dr Robert Eicher (Operations Director) at +49-62 21/84 44 12 or per e-mail at eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Marion Grimm (Organisation Manager) at +49-62 21/84 44 18, or per e-mail at grimm@concept-heidelberg.de.

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

Reservation Form (Please complete in full)

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Visual Inspection Systems

17-18 March 2010, Prague, Czech Republic

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the Purchase Order Number, if applicable

Street / P.O. Box

City

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E-Mail (Please fill in)

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Germany

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 %
 - until 1 weeks prior to the conference 50 %
 - within 1 week prior to the conference 100 %.

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