HIGHLIGHTS:
- GMP and regulatory background of visual inspections
- QA aspects of manual, semi-manual and fully automated visual inspection
- State of the art fully automated inspection of
  - Prefilled Syringes
  - Ampoules
- Technical evaluation of visual inspection machines
- Qualification and validation of automated visual inspection systems
- Lowering false rejects rates
- Particles, cosmetic deficiencies and Japan Quality
- Identification and Tracking of vials
- Leak detection

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

Technical Evaluation of Visual Inspection Machines
- Contact to inspection machine suppliers
- Compiling product requirements in an URS
- Comparison of products demands and machine properties
- Compilation of product samples for pre-checks at the supplier site
- Finding the right machine and machine supplier

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
- Outlook: Inspection concepts

Fully automated visual inspection of ampoules
- Qualification of the visual inspection system
- Specifics of ampoules in the automated visual inspection
- Overcoming difficulties in the preparation of the test kits
- Typical defects
- Ejection of defects, re-inspection & handling of ampoules with black spots
- Limits of the automated inspection of ampoules
How to cope with the “False Reject Issue” in fully automated visual inspection

The presentation describes practical experiences and points to consider when optimizing false reject rates of automated inspection systems. The focus will be on liquid formulations (vials and syringes) and will show typical root causes and appropriate countermeasures.

- Background: False Rejects in manual and fully automated visual inspection
- Root causes for False Rejects
- Appropriate countermeasures in production process (case studies)

Impact of the Japanese Market on visual inspection
- Specifics to be considered
- Cosmetic defects
- Quality versus cosmetic
- Adaptation of the release process

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.

Leak Detection: 100% Inspection of residual moisture and Oxygen by Laser and NIR
- In-line NIR inspection of freeze dried vials
  - Measurement system
  - Spectra and correlation to moisture content
- Headspace analysis by laser for oxygen content
  - Machine concept
  - Leak detection down to 0.5 µm
- Practical aspects from qualification and implementation

### Speakers

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<thead>
<tr>
<th>Name</th>
<th>Company</th>
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<tr>
<td>Dirk Dickfeld</td>
<td>PCE Pharmacontrol Electronic GmbH</td>
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<tr>
<td>Dr. Helmut Gaus</td>
<td>Rentschler Biotechnologie GmbH</td>
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<tr>
<td>Dr. Bernd Ibscher</td>
<td>Ratiopharm GmbH</td>
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<tr>
<td>Michael Lammel</td>
<td>Roche Diagnostics GmbH</td>
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<tr>
<td>Dr. Daniel Müller</td>
<td>Regierungspräsident Tübingen</td>
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<tr>
<td>Thomas Zinn</td>
<td>Novartis Pharma AG</td>
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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. 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.

Dr. Ibscher is pharmacist, specialised in pharmaceutical technology. After being head of the galenical development and head of quality control he is now head of bulk production for the manufacture of sterile dosage forms at ratiopharm. Moreover he is qualified person at Transpharm Logistik.

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. 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).

Thomas Zinn in an engineer and started his career at Hoffmann-La Roche in the process development of solid dosage forms. He joined the Center of Excellence for sterile dosage forms at Novartis in 2003 and is now responsible for the sterile filling of syringes.

### Social Event

On Tuesday, 24 May 2011 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.
**Date**
Tuesday, 24 May 2011, 13.00 to approx. 18.15 h
(Redemption and coffee 12.30 – 13.00 h)
Wednesday, 25 May 2011, 09.00 to approx. 16.15 h

**Venue**
Hilton Budapest WestEnd
Váci út 1-3.
1062 Budapest, Hungary
Phone  +36 (1) 288 5500
Fax  +36 (1) 288 5588

**Fees**
ECA Members € 1,390- per delegate plus VAT
API Members € 1,490.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,590.- per delegate plus VAT
EU GMP Inspectors € 795.- 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 has reserved a limited number of rooms in the conference hotel. Reservations should be made directly with the hotel. Please use the following link and make your reservation via POG (Personalised Online Group Page) where you also can modify/cancel your reservation until 9 May 2011 without any penalty: http://www.hilton.com/en/bi/groups/personalized/BUDWEHIGECAB-20110523/index.jhtml?WT.mc_id=POG. 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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**Reservation Form (Please complete in full)**

**Visual Inspection Systems**
24-25 May 2011, Budapest, Hungary

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- [ ] Ms

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number

Please indicate the Purchase Order Number, if applicable

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E-Mail (Please fill in)

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**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 3 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. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

**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)!!