With FDA and USP Speakers

Particles in Parenterals

Visual Inspection Systems & Root Cause Analysis

7-8 May 2013, Vienna, Austria

Speakers:

Scott Aldrich
USP

Dr Helmut Gaus
Rentschler Biotechnologie

Dr Stephen Langille
FDA

Dr Daniel Müller
Regional Government Tübingen, Germany

Dr Tobias Posset
Roche Diagnostics

Bernd Renger
European QP Association

Highlights

- Regulatory & compendial requirements
  - Pharmacopeias (EU, US, Japan)
  - FDA's expectations
  - GMP requirements in EU & US
- Particle Sources & Root Cause Analysis
  - Sources for visible and sub-visible particles
  - Particle OOS handling
  - Risks associated with particles
- Particle Detection
  - QA aspects of manual, semi-manual and fully automated visual inspection
  - Detection methods for sub-visible particles
  - Classification of defects
  - Qualification and validation of an automated visual inspection system

ECA
European Compliance Academy

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

Particles in Parenterals

7-8 May 2013, Vienna, Austria

Objectives

Main topic of this conference is the detection of particles in parenterals as well as finding their origin. Besides special tests conducted during root cause analysis, routine 100% inspection of products for parenteral use will be addressed. Apart from technical aspects and quality assurance as also the practical operation of inspection systems will be examined, and you will receive guidance on putting them into operation.

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 2012 in the cases of some bigger companies. Responsible staff in charge will have to start root cause analysis to find the source of the particles. There are several origins possible. Particles found can be categorised in extrinsic (not part of the process), intrinsic (part of the process) or inherent (product agglomerates). Nevertheless their source must be found and eliminated.

The testing methodology in the major compendia have been harmonised with regard to subvisible particles, coming for example from agglomeration of biopharmaceutical products. But: the Pharmacopoeias do not address particles smaller than 10 µm in parenteral drugs. Recent publications have emphasised the need to measure these small particles as well, and the FDA wants to further understand possible threats to the health of patients by these particles. New requirements are expected.

Image: Seidenader

Despite the harmonisation of the tests concerning subvisible particles, there is confusion within the global pharmaceutical industry with regard to the requirements for testing on visible particles.

The required 100% visual inspection can be done manually, semi-automated and fully automated. Throughout the last years there has been a recognisable trend towards automated inspection machines. 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 the permission of re-testing and the usage of test-sets and setting AQL-Levels.

We will address those topics during the conference and discuss and answer questions on

- The compendial requirements concerning particles
- The test methodology with respect to particle testing
- The possible origins of particles in sterile products
- The methodology of determining the possible sources
- The GMP requirements for routine testing on particles
- QA aspects of visual inspection and AQL testing
- The qualification and validation of an automated system

Target Audience

This conference is directed at specialists and executives from sterile operations, that is manufacturing, quality control and engineering. But also persons responsible for CAPAs in case of particle OOS and suppliers of primary packaging materials for sterile medicinal products are target group of this conference.

Moderator

Bernd Renger
Chairman of the European QP Association

Regulatory and Compendial Requirements

Compendial requirements for particle testing

- Current requirements for visible particles
- Current requirements for subvisible particles
- Trends and upcoming changes
- FDA proposals & industry response
- Harmonisation and differences in EU and Japan
- Particle Identification
  - The nature of particles and their sources
  - Current trends for compendial guidance

FDA's thinking on particles and particle testing (US)

- FDA regulations relating to particulate matter in injectable drug products
- FDA drug application requirements and trends,
- Recent recall events due to particulate matter contamination
- Clinical concerns regarding particulate matter contamination
- The <10 um particle issue

Regulatory requirements and GMP inspections of visual inspection systems (EU)

- Regulatory Documents (EU-GMP-Guide, Annex 1, others)
- Qualification of premises & equipment
- Requirements for workplace & personnel
- Evaluation of risk / particulate contamination & glass breakage
- Experience for GMP-inspections (observations) & surveillance of quality defects (rapid alert / recall)

Particles – Origin and Root Cause Analysis

Sources of particulate matter in injectables

- External sources
  - Containers & closures
  - Filters, tubing etc.
  - Abrasion form equipment
- Internal sources (product inherent particles, ..)
- Risks associated with particles

Particle OOS - what to do?

- Root Cause Analysis
  - Procedures
  - Tools
  - Analytical methods
- Examples
- Documentation

Particle Detection and Inspection Systems

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 und test samples

Subvisible Particles: the Subvisible Particle Count Test

- What does 'subvisible' mean?
- Compendial Methods
- Comparison of the methods
- Different detection methods
- Validation & Verification of the Particle Count Tests
- Relevance of subvisible particles

Implementation of an automated inspection system

- Qualification program
- Validation program
- Sample sets for qualification purposes
- Generation and Classification of defects and defect libraries
- Performance comparison with the manual inspection
- Ejection of defects & re-inspection
- Routine inspection and system capability

Speakers

Scott Aldrich
USP, Ultramikro LLC, USA
Scott is a biologist and recognized expert in pharmaceutical particulate matter control. He started his career in 1971 working for several pharmaceutical companies in R&D. At Pfizer he led a group for particle identification an contamination control. He now works for Ultramikro, LLC, a consulting firm configured to address projects regarding particulate matter source, control and reduction. Scott is an active member of the 2010-2015 USP Dosage Forms Expert Committee, principally for Injections; USP chapters <1>, <788>, <789> and several others.

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.

Dr Daniel Müller
Regierungspräsidium Tübingen
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).

Dr Stephen Langille
FDA, Center for Drug Evaluation and Research (CDER)
Dr. Langille is a Senior Microbiology Reviewer with the Center for Drug Evaluation and Research. He joined the FDA in 2000 and has served as an FDA liaison to the USP Parenteral Products – Industrial and USP Dosage Forms expert committees. Dr. Langille serves on a number of FDA and USP committees dealing with issues related to particulate matter in injectable drug products.

Dr Tobias Posset
Roche Diagnostics GmbH
Tobias Posset studied Biochemistry and Chemistry. Actually he is heading the Production Support unit in the Pharma Production at Roche Diagnositics in Mannheim. Herein he is responsible for the in-process control, the particle laboratory, the automated visual inspection machines and the coordination of the manual inspection training.

Dr Bernd Renger
Chairman of the European QP Association; Renger Consulting, Germany
Dr Bernd Renger is a member of the ECA Advisory Board and Chairman of the European QP Association. Since 2011, he is running his own consultancy business. Before that he was Director of Quality Control at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several positions at Mundipharma, Altana Pharma and Baxter.

Social EvenT

On 7 May, 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.

Lufthansa is Mobility Partner for all ECA Events
As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

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 – other-wise the booking platform window will not open.

GMP Certification Programme

This Conference is recognised within the GMP Certification Programme for the modules "ECA Certified Technical Operations Manager" ans "ECA Certified Sterile Production Manager". By attending selected seminars, the participant can acquire an additional certificate.
We offer the following certification modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager

On the Internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.

The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a 200 € discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit: The GMP Guidelines Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **http://www.gmp-compliance.org**.

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
Tuesday, 7 May 2013, 10.00 to approx. 17.45 h
(Registration and coffee 09.30 – 10.00 h)
Wednesday, 8 May 2013, 09.00 to approx. 15.00 h

Venue
RENAISSANCE WIEN HOTEL
Linke Wienzeile – Ullmannstrasse 71
1150 Vienna, Austria
Phone + 43 1 89102 0
Fax +43 1 89102 – 300

Conference fees
ECA Members EUR 1,490.- per delegate plus VAT
APIC Members EUR 1,590.- per delegate plus VAT
Non-ECA Members EUR 1,690.- per delegate plus VAT
EU GMP Inspectorates EUR 845.- 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 with all further information when you have registered for the event. Early reservation is recommended.

Registration
Via 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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Germany

Registration form (please complete in full)

Particles in Parenterals
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☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. (if applicable)**

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General Terms of Business
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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)! (As of January 2012)**