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ACADEMY

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SPEAKERS

PATRIZIA ASCANI
Doctors without Borders

DR MARTIN BECKER
hameln pharmaceuticals

MARTIN DEARDEN
PaxVax Berna

DR JEAN-DENIS MALLET
Former Head of Pharmaceutical Inspection Dpt. AFSSAPS

DR DANIEL MÜLLER
GMP Inspector, Germany

DR TOBIAS POSSET
Roche Diagnostics

DR INGO PRESSER
Boehringer Ingelheim

DR HEINO PRINZ
rommelag

DR BERND RENGER
Immediate Past Chair of the European QP Association

DR HARALD STAHL
GEA Pharma Systems

These conferences are part of the
2015 PHARMA CONGRESS
Production & Technology
DÜSSELDORF, 24 - 25 MARCH 2015
www.pharma-kongress.com

Control of Parenterals

Visual Inspection Systems
Container / Closure Integrity Testing

Düsseldorf/Neuss, Germany, 24-25 March 2015

HIGHLIGHTS VISUAL INSPECTION SYSTEMS:

- Requirements from a GMP-Inspector
- From the product requirements to the appropriate inspection system
- Qualification & Validation of a visual inspection system
- Routine Operation: Ejects, Rejects, Re-Inspection
- AQL Testing and "Essentially free of particles"
- Visual Inspection in Third World Countries

HIGHLIGHTS CONTAINER / CLOSURE INTEGRITY TESTING:

- Regulatory, Pharmacopoeial and GMP requirements
- Current CCI testing technologies
- Inline vs Offline CCI testing
- CCI testing of prefilled syringes
- CCI testing of lyo & liquid vials
- CCI testing of ampoules

Visual Inspection Systems — 24 March 2015

Objectives

This event aims at giving an overview of optical inspection systems for the required 100% testing of parenterals. Apart from technical aspects, quality assurance topics 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 set the right inspection parameters in order to run the system GMP-compliance AND economically that is to avoid a high level of rejects. But also during routine process there are new 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 like:

- The compendial requirements concerning particles
- QA aspects of visual inspection, statistics and AQL testing
- Selection of the appropriate inspection system
- The qualification, validation and operation of an automated inspection system

Target Audience

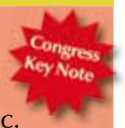
This conference is directed at specialists and executives from the areas engineering and production and QA dealing with the implementation and operation of visual inspection systems for in-process testing of sterile medicinal products.

Moderator

Dr Bernd Renger, *Immediate Past Chair of the European QP Association*

Programme

Towards a renewed or a brand new Annex 1



- The current missing points in the 2008 version
- Expanding the annex to the sterile raw material (mainly API case)
- Detailing the annex to the missing dosage forms : Eye-drops, Implants, LVPS, etc.
- Developing some directions for „sterile failure“ or „aseptic failure“ investigations
- Naming new technologies in the annex : closed vials, single-use, aseptic connections, instant viable counting, etc.
- Adressing the need

DR JEAN DENIS MALLET, *NNE Pharmaplan & ECA Foundation Advisory Board Member*

Current GMP's for visual inspection of parenterals: a GMP inspector's view

- Regulatory framework: EU-GMP-Guide, European Pharmacopoeia
- Manual and semi-automated inspection: personnel, premises and equipment
- GMP requirements for qualification, validation and routine operation of automated systems
- Typical discussion topics: defect classes, warning limits, ejects & rejects handling
- Inspector's experience: recommendations, observations

DR DANIEL MÜLLER, *RP Tübingen*

From the product requirements to the appropriate inspection system: the URS as key to identify the right inspection system

- Compiling product requirements in an URS
- Comparison of products demands and machine properties
- Compilation of product samples for pre-checks at the supplier site
- Conduction of pre-evaluation tests
- Finding the right machine and machine supplier

MARTIN DEARDEN, *PaxVax Berna*

Qualification & validation of an automated inspection system

- Qualification & validation strategy
- Sample sets for qualification purposes
- Generation and Classification of defects and defect libraries
- Performance comparison with the manual inspection
- Definition and handling of ejects and rejects
- Re-qualification & re-validation

DR TOBIAS POSSET, *Roche Diagnostics*

Routine operation of an automated visual inspection system

- Usage of test kits before and after batch inspection (performance kits)
- Classification of defects / defect library
- Handling of ejects and rejects
- Re-inspection? When and how?
- Possibilities of reducing the false reject rate

DR TOBIAS POSSET, *Roche Diagnostics*

AQL testing of visual inspection

- 100% inspection versus AQL testing
- "Essentially free" and AQL limits
- Warning limits, Action limits and Is AQL testing mandatory?
- Organisation of AQL testing
- News from USP and chapter <790>

DR BERND RENGER, *Immediate Past Chair of the European QP Association*

Visual Inspection from the Border of the World

- Medicines sans Frontieres' (MSF; Doctors without Borders) profile
- MSF's policy regarding parenteral: visual inspection and training for staff at end user level
- Constrains in the MSF's field: transport, storage, packaging
- Requirements in third world countries, inspired by BP, USP, EU plus WHO guidelines and the real world
- MSF's case report

PATRIZIA ASCANI, *Doctors without Borders*

Container / Closure Integrity Testing — 25 March 2015

Objectives

Different products and different container types will require different testing methods: this event aims at giving an overview of the different container closure integrity (CCI) testing systems which are applied during production and as part of the quality control system. Apart from technical aspects the regulatory requirements on CCI testing will be highlighted.

Background

An intact container closure system, which is the sum of packaging components that protect the dosage form, is the pre-requisite for a safe and sterile drug product. The CC system protects the product from microbial contamination and also from exposure to gases or water vapor or the loss of solvent. Container Closure integrity testing is therefore a regulatory requirement and it is part of the whole life cycle of a sterile drug product.

Initially this testing was performed as part of the initial development of the packaging system and the system's suitability verified in stability studies including on-going stability. Over the years, the expectation was raised to perform batch by batch verification with latest trends to 100% inline or offline testing wherever possible.

We will discuss and answer questions like:

- What are the GMP- and compendial requirements?
- Will container closure integrity testing change to 100% inline testing?
- Which testing technologies are available and suitable?
- CCI testing of prefilled syringes
- CCI testing of lyo & liquid vials
- CCI testing of ampoules

Target Audience

This conference is directed at specialists and executives from the areas engineering and production and QA dealing with the implementation and operation of systems for the container/closure-integrity testing of sterile medicinal products.

Moderator

Dr Bernd Renger, *Immediate Past Chair of the European QP Association*

Programme

The future of pharmaceutical production – Global developments in OSD manufacture

DR HARALD STAHL, *GEA Pharma Systems*

Container Closure Integrity testing of sterile drug products – requirements, expectations and exaggerations

- Container Closure Integrity during Development, Qualification and Stability Testing
- Regulatory, Pharmacopoeial and GMP requirements
- System integrity versus container damages
- Patient risks – do we need batch by batch testing?
- Industrial best practices

DR BERND RENGER, *Immediate Past Chair of the European QP Association*

Oversight of container/ closure integrity testing technologies

- Physical fundamentals of the different testing methods
  - Pressure / Vacuum Decay
  - LFC (Liquid Filled Container) leak testing
  - TDLAS/ HSA (frequency modulated spectroscopy)
  - High Voltage leak testing
  - 3µm IR and Mass-Spectroscopy
  - Force Detection
- Selection matrix for products including primary container type, product properties (liquid, lyo, etc.)
- Inline versus sample testing
- Limits and false acceptance traps
- Leak sizes and leak rates (false friends and measurable properties?)
- The risk assessment as the first step (or do we need leak detection at all?)

DR HEINO PRINZ, *rommelag*

Integrity testing of Prefilled Syringes

- Sampling plan
- He-leak testing
- Limitations of the He-leakage test
- Cross Validation with mCCI

DR TOBIAS POSSET, *Roche Diagnostics*

100% inline CCI testing of ampoules

- High Voltage inline testing: method description
- Integration in the production process
- Limits of the system
- Qualification of the system
- Routine Operation

DR MARTIN BECKER, *hameln pharmaceuticals*

100% Container Closure Integrity Testing of lyophilized Products in Vials

- Different CCI methods for lyo products - pros and cons
- Application of the laser-based (lyophilized DP) and conductive (liquid DP)test method
- Qualification Strategies for inline testing
- Experience from routine processing

DR TOBIAS POSSET, *Roche Diagnostics*

Inline Container Closure Integrity Testing of liquid Products in Vials

- Ensurance of container/closure tightness for defined stopper-vial combination
  - Oxygen detection with Frequency Modulated Spectroscopy (FMS)
  - Helium leakage test
- 100% control of stopper position of each vial
- Establishment of a Stopper-Position-Control Unit
- Stopper position correlation to vial tightness

DR INGO PRESSER, *Boehringer Ingelheim*

Social Event

The Social Event at the Pharma Congress is already a tradition, and is networking and relaxation at the same time.

On the evening of the first congress day, on 24 March 2015, all congress delegates and speakers are invited to a „Get together" in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

Speakers

PATRIZIA ASCANI, *Doctors without Borders*
In the last 15 years she has been involved in the field as pharmacist in the framework of the of UN, International Red Cross) and MSF (doctors without borders).

DR MARTIN BECKER, *hameln pharmaceuticals GmbH*
Head of Technical Operations and Head of Production Sterile Operations.

MARTIN DEARDEN, *PaxVax Berna GmbH*
Vice President of Quality.

DR JEAN-DENIS MALLET, *NNE Pharmaplan and ECA Foundation Advisory Board Member*
Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS.

DR DANIEL MÜLLER, *Regierungspräsidium Tübingen*
In 2001 he joined a German inspectorate and has since been working as a GMP-Inspector with focus on biotechnological active ingredients and sterile drug products.

DR TOBIAS POSSET, *Roche Diagnostics GmbH*
Head of the Production Support Unit.

DR INGO PRESSER, *Boehringer Ingelheim Pharma GmbH & Co. KG*
Responsible for the clinical trail supply and process transfer unit with the Process Science Department.

DR HEINO PRINZ, *rommelag AG*
Director Inspection Devices.

DR BERND RENGER, *Immediate Past Chair of the European QP Association; Renger Consulting, Germany*
Member of the ECA Foundation Advisory Board and Immediate Past Chair of the European QP Association. Since 2011 he is running his own consultancy business.

DR HARALD STAHL, *GEA Pharma Systems*
Senior Pharmaceutical Technologist.

Easy Registration

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

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.pharma-kongress.com

Date
Tuesday, 24 March 2015, 09.00 – 17.45 h
Wednesday, 25 March 2015, 08.30 – 16.45 h
(Registration Monday, 23 March 2015, 19.00 – 20.30 h
Tuesday, 24 March 2015, 08.00 – 09.00 h
Wednesday, 25 March 2015, 07:30 – 08.30 h)

Venue
Swissôtel Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss, Germany
Tel.: +49 (0) 2131 77 - 00, Fax: +49 (0) 2131 77 - 1367
Emailus@swissotel-duesseldorf.de

Fee
EUR 690.- per delegate and day plus VAT (EUR 1.380,- for both days)

The conference fee is payable in advance after receipt of invoice and includes lunch on that day/both days, beverages during the event and during breaks as well as the Social Event on 24 March. VAT is reclaimable.
Your registration also entitles you to participate in all other Pharma Congress conferences on either day of your registration. For the other conferences on both days please visit www.pharma-kongress.com.

Registration
Via the reservation form below, by e-mail or by fax message. Or you register online at www.pharma-kongress.com

PLEASE NOTE
Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Please further note that there will be no room reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

Organisation & Contact
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For questions regarding reservation, hotel, organisation etc.:
Mr Detlef Benesch (Organisation Manager) at +49-6221/84 44 45, or per e-mail at benesch@concept-heidelberg.de.

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Control of Parenterals (24-25 March 2015)
Part of the Pharma Congress Production & Technology 2015
Düsseldorf/Neuss, Germany, 24-25 March 2015

PLEASE NOTE:
Please book your hotel room directly with the reservation form which you will receive together with your confirmation/ invoice!

I register for:
☐ Visual Inspection Systems (24 March 2015)
☐ Container / Closure Integrity Testing (25 March 2015)
☐ Both days (24-25 March 2015 – 1.380,- €)

☐ Yes, I would also like to participate in the Social Event on 24 March

☐ Mr ☐ Ms

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Title, first name, surname

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