Container/Closure Integrity Testing

Current and coming best practice

Including News from the Annex 1 revision

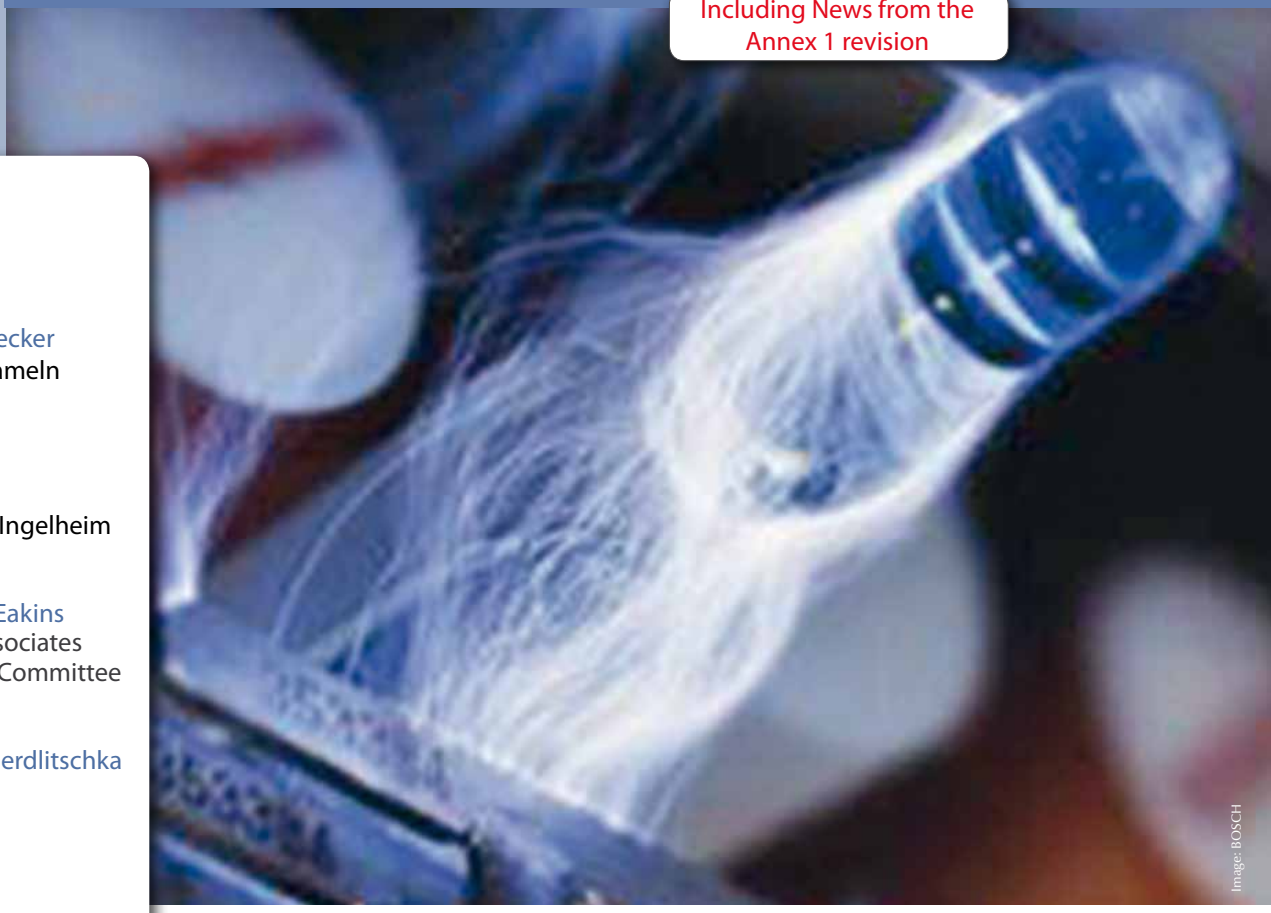

Image: BOSCH

19-20 June 2018, Berlin, Germany

SPEAKERS

Dr Martin Becker
Siegfried Hameln

Klaus Boje
Boehringer Ingelheim

Dr Michael Eakins
Eakins & Associates
USP Expert Committee Member

Christoph Herdlitschka
Wilco

Dr Tobias Posset
Roche

Dr Bernd Renger
ECA & European QP Association

HIGHLIGHTS

- Regulatory and GMP requirements
- USP & Ph.Eur. requirements
- Overview CCI testing technologies
- Online vs. offline testing
- Modern blue dye testing
- 100% testing vs. sampling
- Case Study: CCI testing of prefilled syringes
- Case Study: CCI testing of ampoules
- Case Study: CCI testing of vials
- Impact of the Annex 1 revision on CCI testing

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

Container/Closure Integrity Testing

19-20 June 2018, Berlin, Germany

Objectives

Different products and different container types require different testing methods: this event aims at giving an overview of the different 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 as well as the applicability of inline and offline testing.

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 vapour 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 current and upcoming GMP and compendial requirements in the US / EU / RoW?
- Will container closure integrity testing change to 100% inline testing?
- Modern blue dye 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

Bernd Renger

Image: Seidenader

Programme

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

USP's Approach to Container-Closure Integrity Testing

- Overview of USP chapter <1207>
- CCI definitions and key concepts for sterile drug products
- Leakage concepts
- Regulatory requirements
- Revision of USP chapter <671>: CCI for solid oral dosage forms

Overview of container/closure integrity testing technologies

The presentation gives a complete overview of the different aspects of leak testing to do CCIT in the pharmaceutical production. The systems presented can be used for the CCIT of Vials, Ampoules, Syringes, BFS, IV Bags, Blisters etc.

- Leak, Leak rate and the relevant physical units
- Leak Test Methods
  - Pressure change methods (vacuum, pressure and LFC)
  - Head Space Analysis using TDLAS
  - Helium Leak Test and other Mass Spectroscopy Systems
  - High Voltage Leak Detection (HVLD)
  - Force Sensing Technology
- Capabilities and examples of the different Methods
- How to select the right method
- How to generate positive controls

Modern Blue Dye Testing – still the standard CCI method?

- Regulatory requirements and subsequent test method in industry
- Critical method aspects, e.g. process-monitoring
- Perspective and limits in context of product life cycle

Integrity testing of Prefilled Syringes

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

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
- Validation
- Routine Operation

Programme

Case Study: 100% inline testing of Lyo Vials

- System setup
- Validation
- Routine operation

Impact of the Annex 1 revision on the testing of parenterals

- The final draft for comments of Annex 1
- Contamination Control Strategy
- New requirements on process simulation
- PUPSIT
- Container Closure Integrity requirements
- New expectations on Visual Inspection

Speakers

Dr Martin Becker

Siegfried Hameln, Head of Technical Operations & Head of Production Sterile Operations

Dr Becker studied Chemistry and is actually Head of Technical Operations and Head of Production Sterile Operations at Siegfried Hameln (formerly hameln pharmaceuticals). He previously held different positions in analytical development, quality assurance, and production at IDT in Dessau and Sandoz in Austria.

Klaus Boje

Boehringer Ingelheim, Primary Packaging Scientist

Klaus Boje has been working for Vetter as a supervisor of the Quality Control of packaging material. Since 1999 he is working for Boehringer Ingelheim first in the development and validation of CCIT methods. Since 2014 as Scientist in primary packaging development for early and late stage projects for biopharmaceutical combination products especially pre-filled syringes.

Dr Michael Eakins

Eakins & Associates, USP Expert Committee member

Dr Michael N. Eakins is the Founder and Principal Consultant of Eakins & Associates with over 35 years' experience in pharmaceutical research and development. Michael was Senior Director of Product Internationalization for Bracco S.p.A. responsible for the strategic development of new packaging within R&D and then Senior Director of the Packaging Center for Corporate Worldwide Sales and Marketing. Michael has extensive experience in the packaging of drug products in glass vials and in glass and plastic pre-filled syringes. He is currently a member of the USP Packaging and Distribution Expert Committee for the 2015-2020 cycle.

Christoph Herdlitschka

Wilco, Head of Product Management at Wilco

Christoph is an industrial and economics engineer and has more than 10 years of experience in the field of pharmaceutical fill- and packaging processes. Since 2016 he is heading the Product Management at Wilco in Switzerland.

Dr Tobias Posset

Roche Diagnostics, Head of Production Support & Chairman oft he ECA Visual Inspection Group

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.

Dr Bernd Renger

ECA & European QP Association, Immediate Past Chair of the European QP Association

Dr Bernd Renger is a member of ECA Advisory Board and Immediate Past Chair of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung. He started his career 1977 at Hoechst AG as a R&D chemist. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna.

Social Event

In the evening of the first course day, 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
Tuesday, 19 June 2018, from10.00 to approx. 17.45
(Registration and coffee 9.30 – 10.00 h)
Wednesday, 20 June 2018, from 08.30 to approx. 13.00 h

Venue
InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
10557 Berlin, Germany
Phone 030 288 755 0
Fax 030 288 755 900
Email berlin-hauptbahnhof@intercityhotel.de

Fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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/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
Fax +49 (0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

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:
Ms Marion Weidemaier (Organisation Manager)
at +49-62 21/84 44 46,
or per e-mail at weidemaier@concept-heidelberg.de.

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full) +49 6221 84 44 34

Container/Closure Integrity Testing
19-20 June 2018, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order Number, if applicable**

Street / P.O. Box

City Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

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 %.
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 HEIDELBERGwill 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)! (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

WA1/03052017