20 YEARS ECA Academy
Your GMP/GDP Information Source

Modern Sterile Operations
100% Control of Parenterals
Sterile Filtration

Image: Pall Life Sciences

This conference is part of the
2019 PHARMA CONGRESS Production & Technology
DÜSSELDORF, 9 - 10 APRIL 2019
www.pharma-congress.com

9/10 April 2019, Düsseldorf/Neuss, Germany

SPEAKERS


GABRIEL ANDERSON
Novartis


KLAUS EICHMÜLLER
Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany


DR MARTIN HAERER
Rommelag CMO


DR MATTHIAS KAHL
Wilco


ALAN KELLY
Genzyme Ireland


FELIX KRUMBEIN
Roche Diagnostics


DR JEAN-DENIS MALLET
ECA Validation Interest Group


DR DANIEL MÜLLER
Local Authority of Baden-Württemberg


THOMAS REINER
Berndt+Partner


DORIS ROTTENBUSCH
Vetter Pharma-Fertigung


MATTHIAS SCHAAR
Novartis Pharma

HIGHLIGHTS – 100% CONTROL OF PARENTERALS:

- Pharmacopeial- and GMP-requirements for visual inspection
- Pharmacopeial- and GMP-requirements for CCI-testing
- Data Integrity & Audit Trail Review for Visual Inspection Systems
- Pharmaceutical Case Study
- Pharmaceutical Case Study

HIGHLIGHTS – STERILE FILTRATION:

- The influence of the Annex 1 revision to sterile filtration
- Case studies from
  - Genzyme
  - Novartis Pharma
  - Vetter Pharma-Fertigung
- Live-Demos from
  - Merck
  - Pall

100% Control of Parenterals — 9 April 2019

Objectives

In this conference an overview is given on GMP- & compendial requirements for the testing of sterile pharmaceutical products concerning container-/Closure-Integrity testing and inspection of particles. It is shown what the actual state-of-the-art in the pharmaceutical industry is and which technologies are available..

Background

The 100% visual inspection of parenteral medicines, irrespective of the container type, is a requirement of the pharmacopeias. The inspection can be done manually or automatically the latter being increasingly used. This is different for the testing of the integrity of the container/closure system. Here a 100% testing is only officially required for containers closed by fusion, e.g. ampoules. But, as the risk of unsterile containers due to cracks or leakages is high for the patient, some pharmaceutical companies also increasingly test the whole batch for integrity. This 100% testing is done with automated systems with different techniques, dependent on the type of container.

In this conference we will discuss:

- What are the actual and future requirements of GMP authorities for the testing of parenterals?
- Which testing techniques are available – with the focus on automated systems?
- What will change due to the revision of EU Annex 1?
- What are the requirements for Data Integrity for the automated testing systems?

Target Audience

This conference is directed at specialists from the areas engineering, production and QA dealing with the implementation and operation of automated systems for the CCI testing or visual inspection of sterile medicinal products.

Moderator

JÖRG ZIMMERMANN, *VETTER PHARMA-FERTIGUNG*

Programme

Congress Key Note

Pharmaceutical industry in digital change

- Changes in the value chains
- Opportunities and risks for production processes
- What can and will change for packaging?
- Strategies to benefit from change

THOMAS REINER, *CEO, Berndt+Partner*

Pharmacopeial- and GMP-requirements for visual inspection

- Manual inspection (training, working place, qualification)
- Automated inspection (system validation and re-validation)
- Test sets (usage, storage, quality aspects)
- AQL testing as part of batch release
- Handling of rejects and ejects

DR DANIEL MÜLLER, *HEAD OF GMP INSPECTORATE BADEN-WÜRTTEMBERG*

Pharmacopeial- and GMP-requirements for Container-/Closure-Integrity Testing

- Test of ampules
- Test of vials and syringes, 100% vs sampling
- test methods: blue dye test and others
- Inspection findings

DR DANIEL MÜLLER, *HEAD OF GMP INSPECTORATE BADEN-WÜRTTEMBERG*

Data Integrity & Audit Trail Review for Visual Inspection Systems

- General regulatory requirements regarding data integrity
- Complete, consistent, and accurate data in the context of Visual Inspection Systems
- Data integrity starts with a proper user access management
- Batch-wise modification of product-related configuration parameters
- Audit Trail review concepts

FELIX KRUMBEIN, *Roche Diagnostics*

Case Study Novartis: Fully automated inspection validation

- New machine qualification
- Operational qualification
  - Particle defect detection
  - Physical defect detection
  - Leak detection equipment
- Performance qualification
  - Running conditions
  - Sampling plan

GABRIEL ANDERSON, *Novartis*

Case Study Rommelag CMO – 100% inline CCIT Testing and Inspection of BFS ampoules

- Technical & regulatory requirements
- Machine concept
- Sample preparation
- Qualification and Validation
- Operation of the inspection system

DR MARTIN HAERER, *Rommelag CMO*
DR MATTHIAS KAHL, *Wilco*

Live Demos

Head Space Analysis for difficult to inspect containers	WILCO
Container-/Closure Integrity Testing with Nitrogen	LIPPOK & WOLF
Pulsed X-ray particle inspection	HEUFT

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 9 April 2019, 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.

Sterile Filtration — 10 April 2019

Objectives

- You will be informed on new regulatory and technological developments in sterile filtration
- You learn the influence of the Annex 1 revision to sterile filtration and how to interpret the requirements to PUPSIT (Pre Use Post Sterilisation Integrity Test)
- You will get case studies from pharmaceutical companies
- Live Demos will show you how technologies perform

Background

Sterile Filtration is especially in the aseptic manufacture of medicinal products still the sterilisation method no 1 choice. The first draft of the Annex 1 revision defines comprehensive requirements wirh regard to the sterilisation. In light of these requirements the conference focuses on their practical implementation in pharmaceutical operations- and will also cover the controversially discussed question on pre-use post sterilisation integrity test.

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as from suppliers who have to deal with sterile filtration technologies in clean in their daily practice.

Moderator

JÖRG ZIMMERMANN, *Vetter Pharma-Fertigung*

Programme

Congress Key Note

EU GMP Inspection in Sterile/ Aseptic Production

- Main focus areas of inspections
- Frequently detected findings
- Data Integrity issues – where are possible weak spots?
- Possible new areas due to the revision of Annex 1 and further regulatory changes

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany – Head of Inspectorate*

Sterile Filtration - GMP inspector's view

- Sterilisation methods & sterile filtration
- Reguatory documents on sterile filtration
- Draft Annex 1: requierements for sterile filtration process
- State of the art equipment & processing
- Experience from GMP inspections

DR DANIEL MÜLLER, *Head of GMP Inspectorate Baden-Württemberg*

Live Demos

Adoption of a Single-Use Sterile Filtration Assembly

Sterile filtration in final filling process is a critical operation. There are multiple options in designing a sterile filtration process to meet regulatory compliance and cost efficiency needs. During this live demo, we will discuss a number of questions to design a sterile filtration process and the benefits using single-use technology to build a ready-to-use filtration set.

- Maximising product recovery
- Filter flushing
- Filter integrity testing (PUPSIT)
- Single stage vs redundant filtration
- Filters in or out of isolator

MERCK CHEMICALS

Sterilizing-grade Filtration in Biopharmaceutical Applications

- Selection Criteria for Sterilizing-grade Filtration
- Sterilizing-grade Filtration versus Bioburden Control
- Filter types (0,2 µm, 0,1 µm)
- Filter Integrity testing
- PUPSIT (Pre-Use Post-Sterilisation Integrity Test)
- Automation (MVP-Technology)

PALL LIFE SCIENCES

Case study: Inline-Filtration using peristaltic pump: Implementation of a pressure control

- Initial request from FDA
- Technical concept phase: market research and laboratory studies
- Implementation of a prototype set-up on a filling line
- Practical experience
- Outlook

DORIS ROTTENBUSCH, *Vetter Pharma Fertigung*

Sterile filtration – microbiological filter validation

- Requirements
- Initiating a scale down study
- How is the correlation to filter integrity testing

MATTHIAS SCHAAR, *Novartis Pharma*

Sterile filtration in aseptic processing using SUT

- Approach to qualification of SUT for Sterile filtration in an aseptic processing environment from design to commercial use.
- Mock-ups
- Location of bacterial retention filters inside or outside the isolator?
- Integrity testing (PUPSIT) with respect to Annex 1
- Handling of SUT sets
- Pre-sterilised – gamma irradiation of SUT sets

ALAN KELLY, *Genzyme*

Some "failing in operation" antimicrobial filtration systems

- Type of products concerned and their relative risks
- Some (sterile) antimicrobial filtration systems
- Position of the filter(s) to the filling equipment
- "Failing in operation" filter(s)
- Investigation: outcome of the product ?

DR JEAN-DENIS MALLET, *ECA Validation Interest Group*

Image: Merck

Image:

Speakers

GABRIEL ANDERSON, *Novartis*
Gabriel Anderson is a chemical engineer and joined Novartis in 2011 as a production engineer responsible for setting up the visual inspection program and validating an automated inspection machine. In 2014 he moved to Basel to take on a global role within Novartis in the manufacturing, science, and technology (MS&T) group and to co-lead Novartis's visual inspection expert network.

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany*
He was Deputy Head of the Central Authority for Supervision of Medicinal Products in Bavaria as long as it existed and has now been Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse since March 2014.

DR MARTIN HAERER, *Rommelag CMO*
Dr Haerer is a pharmacist and works for Rommelag CMO. He currently is responsible for Business Development, Technology Transfer and Research and Development, and is still acting as Qualified Person.

DR MATTHIAS KAHL, *Wilco*
Dr Kahl is a physicist and has been deputy head od development at Boegli-Graavures: Since 2018 he is head of development at Wilco.

ALAN KELLY, *Genzyme Ireland*
Alan Kelly is a mechanical engineer working and currently works in the Technical Development Department at Genzyme.

FELIX KRUMBEIN, *Roche Diagnostics*
Felix Krumbein studied optotechnics. He is working for Roche as Head of Inspections-Systems-Support and is responsible for the qualification of visual inspection systems in the GMP environment.

DR JEAN-DENIS MALLET, *ECA Validation Interest Group and former head of the French Inspection Department AFSSAPS*
He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM). He also used to work in or with the pharmaceutical industry during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. He has also been auditor of the International Red Cross. Now he is member of the ECA advisory board and works for NNE Pharmaplan.

DR DANIEL MÜLLER, *Local Authority of Baden-Württemberg*
Currently Daniel Müller is Head of GMP inspectorate (local competent authority) at Tuebingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA- and overseas inspections. Before joining the authority Dr Müller was working in the pharmaceutical industry, also as qualified person for sterile drug products. He is member of German expert groups 'biotechnology & tissue' and 'quality assurance'.

THOMAS REINER, *Berndt+Partner*
Thomas Reiner is a managing partner and has been with Berndt+Partner for over 25 years. He is also Chairman of the Board of the German Packaging Institute and a member of the Board of the World Packaging Organisation.

DORIS ROTTENBUSCH, *Vetter Pharma-Fertigung*
Doris Rottenbusch is leading a team of experts in Development Service - Technology & Process Transfer at Vetter. Her expertise includes more than eight years of experience in designing and implementing highly efficient, high-quality and very robust manufacturing processes for prefilled injectables. Through her work with biopharmaceutical companies around the globe, she has had experience meeting the requirements of a broad variety of international regulatory authorities. Before transferring to the Development Service - Technology & Process Transfer Department in 2010, Doris Rottenbusch served for five years with Vetter Quality Assurance in Ravensburg and Langenargen, Germany, focusing on process development and process qualification requirements as well as on risk management. She holds a diploma in biology from the Regensburg University.

MATTHIAS SCHAAR, *Novartis Pharma*
Matthias studied at the Beuth University in Berlin. In 2007 he joined Novartis Pharma Stein AG as Specialist Microbiology Quality Assurance (sterile Production). Since 2012 Leading Team Qualification & Infrastructure in Microbiological Department at Novartis Pharma Stein AG.

Easy Registration

Reservation Form:
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Reservation Form:
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e-mail:
info@concept-heidelberg.de

Internet:
www.pharma-congress.com

Date
Tuesday, 9 April 2019, 09.00 – 17.45 h
Wednesday, 10 April 2019, 09.00 – 17.00 h
(Registration: Monday, 8 April 2019, 19.00 – 20.00 h,
Tuesday, 9 April 2019 & Wednesday, 10 April 2019, 08.00 – 09.00 h)

Venue
Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss, Germany
Phone: +49 (0) 2131 77 - 00
E-mail: emailus.neu02@gchhotelgroup.com

Fee
EUR 690.- per delegate and day plus VAT (EUR 1,380.- for both days) (due to the special congress fees, ECA membership discounts are not applicable, and participation does not entail ECA membership).
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 9 April. 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-congress.com.

Registration
Via the reservation form below, by e-mail or by fax message. Or you register online at www.pharma-congress.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
ECA has entrusted Concept Heidelberg with the organisation of this event.
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For questions regarding content:
Dr Robert Elcher (Operations Director) at +49-6221/84 44 12, or per e-mail at eicher@concept-heidelberg.de **(100% Control of Parenterals)**.
Dr Andreas Mangel (Operations Director) at +49-6221/84 44 41, or per e-mail at mangel@concept-heidelberg.de **(Sterile Filtration)**.
For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49-6221/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

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Modern Sterile Operations (9-10 April 2019)
Part of the Pharma Congress Production & Technology 2019
Düsseldorf/Neuss, Germany, 9-10 April 2019

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I register for:
☐ 100% Control of Parenterals (9 April 2019 – € 690)
☐ Sterile Filtration (10 April 2019 – € 690)
☐ Both days (9-10 April 2019 – € 1,380)*

☐ Yes, I would also like to participate in the Social Event on 9 April.

☐ Mr ☐ Ms

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