ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

Speakers


Dr Michael Daferner
BAYER


Christian Doriath
SKAN


Patrick Graser
SKAN


Theresa Ladwig
SKAN


Elodie Muller
Novartis Pharma


Alain Ribstein
SKAN


Katharina Schlereth
Labor L+S AG


Yves Scholler
SKAN

Isolator Technology Workshop – Sterility Test Isolator

Engineering – Validation - Operation

3/4 June 2020, Basel | Switzerland


Image: Skan AG

Highlights

- Key Decision: Sterility Testing in Isolator vs. Cleanroom
- Process Development of Isolator Decontamination
- Bioindicators
- Troubleshooting in Isolator Technology
- Glove Integrity Testing
- Customer Benefit for Standardized Software
- Case Studies from
  - Bayer
  - Labor L+S
  - Novartis
- Regulatory Requirements and Trends
- Workshops on
  - Qualification Tests
  - Development of a H2O2 Decontamination Cycle
  - Sterility Test isolators in Routine

Participate in three workshops at SKAN AG

Programme

Objective

Why should you attend this event?

- You get an update on isolators for sterility testing
- You get to know the results of recent studies on the validation of isolators
- You have the opportunity to discuss your individual questions personally with experts
- You can translate the theory directly into practice during 3 workshops at the manufacturing site of Skan in Allschwil

Each participant takes part in all 3 workshops. The workshops are held at the plant of SKAN AG, partly including operational isolators. This brings the participants as close to daily practice as possible.

Background

The consequences of a failed sterility test are enormous. The use of Sterility Test Isolators offers a much safer way to avoid false positive results. That's why the use of isolators for sterility testing has become a standard in the pharmaceutical industry and in microbiological contract laboratories. But at the same time Isolator Technology requires an increased input with regard to the qualification of these systems and the validation of the decontamination process.
In 2004, Appendix 1 to the FDA Guidance for Industry „Sterile Drug Products Produced by Aseptic Processing" defined new regulatory requirements on using this technology, as did the PIC/S document PI 014-3 „Isolators used for Aseptic Processing and Sterility Testing" and the expected revision of EU GMP Annex 1.

Target Audience

This GMP Education Course addresses those employees from the pharmaceutical industry and from suppliers / contract organisations involved in the engineering, validation and operation of Sterility Test Isolators, especially from the areas

- Engineering
- Quality Assurance
- Qualification/ Validation
- Microbiology

The number of participants is limited.

Please understand that, for competitive reasons, not all firms can register their employees for this event.

Programme

Regulatory Requirements for Sterility Test Isolators

- Regulatory bodies
- US laws and regulations
- European laws and regulations
- Guidelines
- Basic Isolator definitions

Sterility Test Isolators: Standard Process under Control

- Key decisions: sterility testing in isolator vs. cleanroom
- Cost comparison
- From URS to isolator
- Technical details and solutions
- Airflow and decontamination system

Customer Benefit for Standardized Software

- Define SKAN standards acc. GAMP V
- Integration of customer specific requirements
- Minimizing the engineering costs due to standardization
- Safe internal and external interfaces – Data integrity

Bioindicators / Process Development of Isolator Decontamination

- Overview of current regulations and standards
- Basis and selection of suitable biological indicators as sensor for the inactivation effect
- Development and quantification of decontamination cycles
- Influence of H_2O_2 to routine processes

Isolators Used for Sterility Testing

- Requirements for the isolator
  - Background of the isolator
  - Performance Qualification
  - Qualification of operators
  - Test for gas-tightness of primary packaging materials
- Handling in isolator
  - Capacity
  - Testing the tightness of gloves
- Microbiological Monitoring
  - Sample plan
  - Contamination level
  - Contamination source
  - OOS/CAPA (example)

Troubleshooting in Isolator Technology

- The place of the isolator in a pharmaceutical process
- The influence of critical parameters on the decontamination process
- The reliability and reproducibility of biological indicators
- The expectations of regulators

Gone with the Wind – How Are we Doing with a SkanFog® Sterility Test Isolator?

- From clean room to isolators
- Why SkanFog® for sterility test isolators?
- Our 3 isolators and a bit technology
- Performance Qualification
- The new lab building @ Bayer Berlin
- Double challenge: New lab building and new technology
- Lessons learned

Alternative Sterility Testing Methods: Experience Feedback and Outlook

- Experience feedback regarding alternative method
- Outlook
- Challenges
- Impact on Sterility Test Isolators

Workshop Session

Workshop 1: Validation Planning for an Sterility Test Isolator

- Test master plan (IQ/OQ)
- IQ / OQ test protocols
- Operational qualification - procedures
- Handling of deviations

Performance of Selected Qualification Tests

- Basic SOP for testing
- Execution of tests
- Generate test records
- Drawing up the test report
- Glove testing

Glove Integrity Testing

- Regulatory Background
- Physical methods for glove integrity tests and their boundaries
- Microbiological contamination risk
- Routine program for glove integrity testing

Workshop 2: Development and Quantification of H_2O_2 Decontamination Cycles

- Establish the requirements of a decontamination cycle
- Design a qualification strategy
- Work out the necessary physical and microbiological tests and their chronology
- Interpretation of test results and reaction on deviations
- Write a transparent qualification report
- Workshop including a real isolator system

Workshop 3: Sterility Test Isolators in Routine

- Handling in isolators
- Personnel at isolators
- RTP / airlock system
- Parametric release
- Frequency of decontaminations
- Point of view of a user
- Point of view of regulatory

You will take part in all workshops!
The workshops will take place at SKAN AG in Allschwil. After the workshops, at appr. 16.15 h, a bus shuttle service will bring the participants to the airport (appr. 16.35 h), the German train station (appr. 16.50 h), the Swiss train station (appr. 17.15 h) or the hotel.

Speakers

Dr Michael Daferner, Bayer AG, Berlin

Dr Daferner joined Bayer Healthcare Leverkusen in 2002 as Laboratory Head Microbiology Quality Control. From 2003 to 2009 he worked at Vetter Pharma Ravensburg as Team Manager and Laboratory Head in Microbiology Quality Control. Since 2009 he is Laboratory Head Microbiology Quality Control / Development Products at Bayer Pharma Berlin.

Christian Doriath, SKAN AG, Basel, Switzerland

Christian Doriath joined SKAN in 2012 after more than 20 years spent on isolator technology in the pharmaceutical industry at various positions, maintenance, validation, research, technical services. Since October 2018 he is Head of Process Validation Microbiology at SKAN

Patrick Graser, SKAN AG, Basel, Switzerland

Patric Graser joined SKAN in 2009. Today he is Head Hardware Planning at SKAN AG responsible for electrical engineering.

Theresa Ladwig, SKAN AG, Basel, Switzerland

In 2007 Theresa Ladwig joined SKAN AG as a Project Engineer in the department Cycle Development and performed Cycle Development and Microbiological Qualifications all over the world. From 2013 to 2018 she was Head of Process Validation Microbiology. Today she supports the Sales Team for Europe of Skan AG.

Elodie Muller, Novartis Pharma Stein, Switzerland

Elodie Muller holds a Master's Degree in microbiological quality control and quality assurance. She joined Novartis in 2017 after several years of experience in the microbiological quality control, especially in sterility testing (compendia and rapid method). She is currently team leader of the sterility testing laboratory at Novartis Aseptics Stein.

Alain Ribstein, SKAN AG, Basel, Switzerland

Alain Ribstein studied mechanical engineering at the ESTA school of business and technology in Belfort, France. He joined SKAN AG in 2012 after performing his master thesis in the sales engineering department and is now since 2017 Sales Manager in the Process Solution for Isolator Technology. He is responsible for the area of Austria and East Europe.

Katharina Schlereth, Labor L+S AG, Bad Bocklet, Germany

Katharina studied Biology at the University Würzburg. 2009 she joined Labor L+S AG in Bad Bocklet, Germany, where she is responsible for sterility testing. Her current position is Division Head, Microbiological Testing of Sterile Products.

Yves Scholler, SKAN AG, Basel, Switzerland

Yves Scholler studied mechatronics at the Trinational Engineering School (FTI) in Muttenz (CH), Mulhouse (F) and Lörrach(D). He joined SKAN AG in 2007 and is now Head of Sales Europe in the Process Solution for Isolator Technology.

Social Event

On 3 June you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies and the speakers in a relaxed atmosphere.

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

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Isolator Technology Workshop – Sterility Test Isolator, 3-4 June 2020, Basel, Switzerland

Title, first name, surname

Department | Company

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

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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.

Date
Wednesday, 3 June 2020, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Thursday, 4 June 2020, 08.15 h – 16.15 h

After the workshops on 4 June 2020 at appr. 16.15 h, a bus shuttle service will bring the participants to the airport, the train station or the hotel.

Venue
Pullman Basel Europe
Clarastrasse 43
4058 Basel, Switzerland
Phone 0041 61 6908 080
Email hotel-europe@balehotels.ch

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.

Important Information!
The presentations will be available for download one week before the conference. **Note: there will be no print-outs available during the conference.**

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 course. Reservation should be made directly with the hotel. 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
ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG | P.O.Box 10 17 64
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 Andreas Mangel (Operations Director) at
+49(0)62 21/84 44 41, or per e-mail at
mangel@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or at
schopka@concept-heidelberg.de