ECA Academy
Your GMP/GDP Information Source

Isolator Technology Workshop

Engineering - Validation - Operation

Participate in three workshops at Skan AG

SPEAKERS:


Christian Doriath
Skan


Philippe Jérôme
Skan


Theresa Ladwig
Skan


Katharina Schlereth
Labor L+S


Yves Scholler
Skan


Patrick Vanhecke
GSK Vaccines


Christian Vogt
Novartis

28-29 November 2017, Basel, Switzerland

LEARNING OBJECTIVES:

- Isolator and associated technologies
- From the conceptual design to the validated equipment
- Mock-up study
- Process development of isolator decontamination
- Bioindicators
- Troubleshooting in isolator technology
- Glove integrity testing
- Sterility testing in Isolators
- Aseptic / toxic isolators
- Microbiology in filling and sterility isolators
- Regulatory requirements and trends

This education course is recognised for the ECA GMP Certification Programme „Certified Sterile Production Manager“.
Please find details at www.gmp-certification.eu

Isolator Technology Workshop

28-29 November 2017, Basel, Switzerland

Objectives

Why should you attend this event?

- You get an update on isolators for aseptic manufacture and 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 will take 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 use of isolators is increasing both in sterility testing and in the production of sterile medicinal products, particularly in aseptic manufacture. It ensures a greater microbiological safety of the products, but at the same time requires increased inputs as regards the qualification of these systems and the validation of the production processes.

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".

Target Audience

This GMP Education Course addresses those employees from the pharmaceutical industry and from suppliers for aseptic (toxic) manufacture and for sterility testing involved in the engineering, validation and operation of these systems, especially from the areas

- Engineering / Production
- 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 Isolators for Aseptic Use

- Regulatory bodies
- US laws and regulations
- European laws and regulations
- Guidelines

Yves Scholler

Isolator and associated technologies

- Isolator technology in GSK Bio
- Applications for bulk
- Applications for formulation
- Applications for filling processes
- Sterility testing

Patrick Vanhecke

Isolator Application / Projects: From the Conceptual Design to the Validated Equipment (Supplier)

- Key decisions
- What do we need from our customers?
- From URS to engineering – technical details and solutions
- Process challenges and features
- FAT – Installation – Qualification

Philippe Jérôme

Isolator Application / Projects: Mock-up study

- Purpose of mock-up
- What is required before starting a mock-up
- How to document a mock-up
- What simulations need to be included in the mock-up
- Execution of the mock-up itself
- Examples for our mock-up to underline the points above

Philippe Jérôme

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)

Katharina Schlereth

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

Theresa Ladwig

Troubleshooting in isolator technology while understanding

- 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

Christian Doriath

Microbiology in Filling and Sterility Isolators

- Environmental monitoring
- Media Fills
- Sterility tests
- Integrity of gloves and sleeves
- Validation studies
- OOS results in isolators

Dr Christian Vogt

Workshop Session

Workshop 1:
Validation Planning for an Aseptic 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

Yves Scholler / Philippe Jérôme

Workshop Session

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

Theresa Ladwig

Workshop 3:
Isolators in Routine

- Handling in isolators
- Personnel at isolators
- RTP system
- Environmental monitoring in isolators
- Frequency of decontaminations
- Problems in isolators from the point of view of a user

Dr Christian Doriath

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, the train station or the hotel.

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.

Speakers

Christian Doriath, Skan AG, Basel, Switzerland
Christian Doriath joined Eli Lilly & Company (France) in 1991. He joined the H_2O_2 Development Group in 1997 as a Technical Consultant and was involved in the Engineering, Start-up and Qualification of a second filling line under isolator. Since 2012 he is Special Operation Engineer at Skan.

Philippe Jérôme, Skan AG, Basel, Switzerland
Philippe Jérôme joined SKAN AG in 2007. As Head of Sales in Europe, he is in charge of filling line projects and key account manager

Theresa Ladwig, Skan AG, Basel, Switzerland
2007 Theresa Ladwig joined SKAN AG as a Project Engineer in the department Cycle Development and performed Cycle Development and Microbiological Qualifications. Since 2013 she is Head of Process Validation Microbiology and responsible for all aspects of cycle development and qualification.

Katharina Schlereth, Labor L+S AG, Bad Bocklet, Germany
Katharina studied Biology at the University Würzburg. In 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). He joined SKAN AG in 2007 and is now a Sales Manager in the Industrial Division for Isolator Technology, responsible for Germany, Austria, East Europe and Scandinavia.

Patrick Vanhecke, GSK Vaccines, Wavre, Belgium
He joined GSK Bio in 1992 as Aseptic Filing Manager. In 1998 he was transferred to the Wavre site as Aseptic Filling Manager and was in charge of a new project in Aseptic Filling based on Isolator technology. In 2002 he joined the Global Technical Services and today is in charge of Isolator and Aseptic Filling Technologies projects.

Dr Christian Vogt, Novartis Pharma Stein AG, Stein/Basel, Switzerland
Christian Vogt joined Novartis Pharma AG in 2006 and was responsible for sterility testing, in-process controls and microbiological QA Oversight in sterile drug product manufacturing. Since 2011 he is Head of QA/QC Microbiology of Chemical Operations (Basel) and responsible for all aspects of microbiological drug substance testing.

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, 28 November 2017, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 29 November 2017, 08.15 h – 16.15 h

After the workshops on 29 November 2017 at appr. 16.15 h, a bus shuttle service will bring the participants to the airport, the train station or back to the hotel.

Venue

Pullman Basel Europe
Clarastrasse 43
4058 Basel, Switzerland
Phone 0041 61 6908 080
Fax 0041 61 6908 880

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 when you have registered for the event. Please use this form to receive the specially negotiated rate for the duration of your stay. 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
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69007 Heidelberg, Germany
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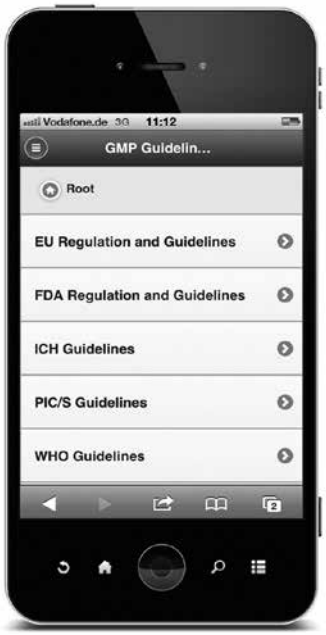
www.concept-heidelberg.de

For questions regarding content:
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.:
Mr Rouwen Schopka (Organisation Manager) at +49-(0)62 21/84 44 13 or per e-mail at schopka@concept-heidelberg.de.



Use the GMP App at no costs!

The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.

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

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Isolator Technology Workshop
28-29 November 2017, Basel, Switzerland

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. 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 HEIDELBERG 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. 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.