Isolator Technology Workshops

Engineering - Validation - Operation

4-5 November 2014, Basel, Switzerland

SPEAKERS:

André Bösiger
Skan

Christian Doriath
Skan

Etienne Hembert
Lilly France

Timo Krebsbach
Labor L+S

Theresa Ladwig
Skan

Yves Scholler
Skan

Patrick Vanhecke
GSK Biologicals

Christian Vogt
Novartis

LEARNING OBJECTIVES:

- 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 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
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 of isolators 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

Programme

Regulatory Requirements for Isolators for Aseptic Use
- Regulatory bodies
- US laws and regulations
- European laws and regulations
- Guidelines
  Yves Scholler

Filling Isolator 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
  André Bösiger

Filling Isolator 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
  André Bösiger

Isolator Technology: From the Conceptual Design to the Validated Equipment
- Isolator technology in GSK Bio
- Isolator and associated development
- Conceptual design for a new process under isolator
- Validation challenges
- Manufacturing advantages
  Patrick Vanhecke

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
  - Movie
  - Capacity
  - Testing the tightness of gloves
- Microbiological Monitoring
  - Sample plan
  - Contamination level
  - Contamination source
  - OOS/CAPA (example)
- Comparison Isolator vs. Cleanroom
  - Practicability
  - Reliability
  - Costs
  Timo Krebsbach
**Bioindicators**
Etienne Hembert

**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$_2$O$_2$ 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

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**Workshop Session**

**Workshop 2:**
**Development and Quantification of H$_2$O$_2$ 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 Vogt

**You will take part in all workshops!**

The workshops will take place at SKAN AG in Allschwil. After the workshops at appr. 16.30 h, a bus shuttle service will bring the participants to the airport, the train station or the hotel.

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**Speakers**

**André Bösiger, Skan AG, Basel, Switzerland**
André Bösiger studied Mechanical Engineering at the Technical School (TSM) Basel and Economics (HF-NDS) at the Kaderschule Basel. In 2000 he joined Skan AG where he worked as a Project Manager in the Industrial Division for Isolator Technology. 2004 he changed into Sales Department – with the main focus to Ireland, UK and Asia.

**Christian Doriath, Skan AG, Basel, Switzerland**
Christian Doriath joined Eli Lilly & Company (France) in 1991. He joined the H$_2$O$_2$ 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.

**Etienne Hembert, Lilly France SAS, Illkirch Cedex, France**
From 2002 until 2011 Site Qualification Manager, involved in the start-up and qualification of new facilities using barrier technology. Since 2011 he is the Filling & Isolator Technology Responsible Engineer of the site.
Dr Timo Krebsbach, Labor L+S AG, Bad Bocklet, Germany
Timo joined Labor L+S AG in 2002. For 10 years he has been division manager of the sterility testing department with responsibility for sterility tests performed in a cleanroom as well as in isolators and is now division manager marketing & sales.

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 all over the world. Since 2013 she is Head of Process Validation Microbiology and responsible for all aspects of cycle development, qualification, improvement and optimization of the H2O2 decontamination process, in house (Quality Lab, Internal testing) and on customer site.

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 a Sales Manager in the Industrial Division for Isolator Technology, responsible for Germany, Austria, East Europe and Scandinavia.

Patrick Vanhecke, GlaxoSmithKline Biologicals SA, Wavre, Belgium
Patrick Vanhecke studied Organic Chemistry at the University of Brussels (ULB). He joined GSK Bio in 1992 as Aseptic Filing Manager in Rixensart (Belgium). In 1998 he was transferred to the Wavre site (Belgium) 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 studied Biology at the University of Constance and Texas A&M University. He 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.

Social Event
On 4 November 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.
Date

Tuesday, 4 November 2014, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 5 November 2014, 08.30 h – 16.30 h

After the workshops on 5 November 2014 at approx. 16.30 h, a bus shuttle service will bring the participants to the airport, the train station or the hotel.

Venue

Hotel Bildungszentrum 21 Basel
Missionsstrasse 21
4003 Basel, Switzerland
Phone 0041 61 260 2121
Fax 0041 61 260 2122

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
P.O. Box 10 17 64
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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.:
Ms Susanne Ludwig (Organisation Manager) at +49-(0)62 21/84 44 44 or per e-mail at ludwig@concept-heidelberg.de.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.
Reservation Form (Please complete in full)

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4-5 November 2014, Basel, Switzerland

☐ Mr    ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number

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

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GERMANY

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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 %
   - within 1 week prior to the conference 100 %.

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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).

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