Participate in three workshops at Skan AG

Photo: Skan

Isolator Technology Workshops

Engineering – Validation - Operation

6-7 November 2013, Basel, Switzerland

SPEAKERS:

André Bösiger
Skan

Christian Doriath
Skan

Timo Krebsbach
Labor L+S

Theresa Ladwig
Skan

Lars Restetzki
F. Hoffmann-La Roche

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
- Troubleshooting in isolator technology
- Glove integrity testing
- Sterility Isolators
- Aseptic / toxic isolators
- Microbiology in filling and sterility isolators
- Regulatory requirements and trends

ECA FOUNDATION

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 Workshops

6-7 November 2013, 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 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

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

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

Challenges in Aseptic Isolators for clinical manufacturing of high potent parenterals

- Regulatory Background
- Aseptic / toxic filling of vials and pre-filled syringes
- Process challenges and features
- Filter units for toxic formulations (Back filters)

Dr Lars Restetzki

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 H2O2 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 / André Bösiger

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 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.

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 H2O2 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.

Dr Timo Krebsbach, Labor L+S AG, Bad Bocklet, Germany
Timo joined Labor L+S AG in 2002. For 10 years he was 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 Developments and Microbiological Qualifications all over the world, especially Europe, Asia and USA.

Dr Lars Restetzki, F. Hoffmann- La Roche AG, Basel, Switzerland
Lars Restetzki is pharmacist and holds a Ph.D. in pharmaceutical technology. He is responsible for the clinical supply of parenteral dosage forms for late-stage clinical studies in the Global Technical Development in Basel.

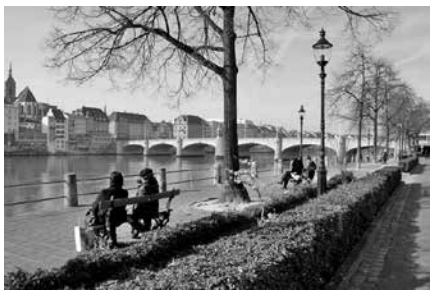
Yves Scholler, Skan AG, Basel, Switzerland
Yves Scholler studied mechatronics at the Trinational Engineering School (FTI) in Muttenz (CH), Mulhouse (F) and Lörrach(D). He joined SKAN AG in 2007 and is now a Sales Manager in the Industrial Division for Isolator Technology, responsible for Germany, Austria, 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 6 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.



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

Wednesday, 6 November 2013, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Thursday, 7 November 2013, 08.30 h – 16.30 h

After the workshops on 7 November 2013 at appr. 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

ECA Members € 1,590.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT
Non-ECA Members € 1,790.- per delegate plus VAT
EU GMP Inspectorates € 895.- per delegate plus VAT
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

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 84
info@concept-heidelberg.de,
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.:
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

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.

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Reservation Form (Please complete in full)

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Isolator Technology Workshops
6-7 November 2013, 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 %.

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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)