



Participate in three workshops at Skan AG

Photo: Skan

Isolator Technology Workshops

Engineering – Validation - Operation

20-21 March 2012, Basel, Switzerland

SPEAKERS:

Hans-Jürgen Bässler
Skan

André Bösiger
Skan

Angela Gessler
Skan

Timo Krebsbach
Labor L+S

Theresa Ladwig
Skan

Lars Restetzki
F. Hoffmann-La Roche

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



Isolator Technology Workshops

20-21 March 2012, 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 I 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

Hans Jürgen Bässler

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 / Toxic Isolators for clinical manufacturing of 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

Relevance of physical glove integrity testing to microbiological contamination of Isolator systems

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

Angela Gessler

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

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

Hans Jürgen Bässler / André Bösiger

Workshop 2:

Development and Quantification of H₂O₂ 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

Angela Gessler

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 three workshops!

The workshops will take place at SKAN AG in Allschwil. After the workshops at appr. 17.00 h, a bus shuttle service will bring the participants to the airport, the train station or the hotel.

Speakers



Dr Hans-Jürgen Bässler, Skan AG, Basel, Switzerland

The qualified biologist Dr Bässler has been working in different positions of the pharmaceutical industry for more than 35 years. He is responsible for the pharmaceutical isolator technology with Skan AG. He can look back on many years of experience with isolators and their decontamination with gases like hydrogen peroxid or peracetic acid. This topic has also been the subject of several publications that he has written or co-written. In numerous lectures he has managed to direct the attention of experts to the decontamination with H₂O₂.



André Bösiger, Skan AG, Basel, Switzerland

André Bösiger is Technical Sales Manager in the Industrial Division of Skan AG, Switzerland. He studied Mechanical Engineering at the Technical School (TSM) Basel and Economics (HF-NDS) at the Kaderschule Basel. In 2000 he joined the Project Engineering Department of Skan AG where he worked as a Project Manager in the Industrial Division for Isolator Technology. He realised many large Projects for different Customers all over the World as Syringe Filling Line Isolators with E-Beam, Vial Filling Line Isolators with Transfer- and Freeze Dryer Loading Isolators. 2004 he changed into Sales Department - with the main focus to Ireland, UK and Asia.



Angela Gessler, Skan AG, Basel, Switzerland

Angela Gessler studied Hygiene Technology at the Technical University of Albstadt-Sigmaringen and was awarded her degree as Dipl.-Ing. (FH) for her investigation of the glove integrity tests at Novartis Pharma AG and Skan AG. As the Head of Cycle

Development at Skan AG she is now responsible for the cycle development and microbiological qualifications of isolator systems.



Dr Timo Krebsbach, Labor L+S AG, Bad Bocklet, Germany

After completing his studies in biology and obtaining his doctorate at the University of Bonn, Timo joined Labor L+S AG in 2002. He is the head of the sterility testing department at L+S and

responsible for sterility tests performed in a cleanroom as well as in isolators.



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



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 Filling 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 at the Texas A&M University, where he graduated in microbiology. In 2006 he joined the Novartis Pharma AG in Basel and is now

responsible for sterility testing and microbiological QA and QC at the Novartis Pharma site in Stein, Switzerland.

Social Event

On 20 March 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

Tuesday, 20 March 2012, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 21 March 2012, 08.30 h – 17.00 h

After the workshops on 21 March at appr. 17.00 h,
a bus shuttle service will bring the participants to the
airport, the train station or the hotel.

Venue

Mercure Hotel Europe Basel
Clarastraße 43
4005 Basle, Switzerland
Phone +41 61 690 80 80
Fax +41 61 690 88 80

Fees

ECA Members € 1,590.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT
(does not include ECA Membership)
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 re-
freshments. VAT is reclaimable

Accommodation

CONCEPT HEIDELBERG has reserved a limited number
of rooms in the conference hotels. Reservation should
be made directly with the hotels not later than 20 Feb-
ruary 2012. You will receive a room reservation form
when you have registered for the event. Please use this
form for your room reservation or be sure to mention
“ECA Event” to receive the specially negotiated rate (
220,- CHF per night incl. breakfast) for the duration of
your stay. 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.:

Susanne Ludwig (Organisation Manager) at
+49-(0)62 21/84 44 44 or per e-mail at
ludwig@concept-heidelberg.de.

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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 Workshops
20-21 March 2012, 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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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!)