

Speakers



Dr Patricia Desmaris
Merck Group



Christian Doriath
SKAN



Theresa Ladwig
SKAN



Benoît Ramond
Sanofi



Ruben Rizzo
SKAN



Yves Scholler
SKAN



Alexandra Stärk
Novartis Pharma Stein



Patrick Vanhecke
GSK Vaccines

Isolator Technology Workshop – Manufacturing Isolator

Engineering – Validation – Operation

24/25 November 2020 | Basel, Switzerland



Image: Skan AG

Highlights

- 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
- Contamination Control Strategy and Isolators
- Microbiology in Filling Isolators
- Case Studies from
 - GSK Vaccines
 - Merck Group
 - Novartis
 - Sanofi
- Regulatory Requirements and Trends
- Workshops on
 - Qualification Tests
 - Development of a H₂O₂ Decontamination Cycle
 - Isolators According to EU Annex 1

Participate in three workshops at SKAN AG

Objective

Why should you attend this event?

- You get an technological update on isolators for aseptic manufacture
- 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 use of isolators is increasing in the manufacturing of sterile medicinal products, particularly in aseptic manufacture, and in the handling of toxic / high potent APIs. 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“ 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 Aseptic (toxic) Manufacturing Isolators, 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
- Basic Isolator definitions

Annex 1 - Risk Analysis and Consideration of Transfer Material and Environmental Monitoring

- Contamination Control Strategy & Quality Risk Management Principles
- Environmental monitoring program
- Gloves/Sleeves management program
- Transfer materials & personnel interventions
- Aseptic processing validation management

Isolator Application / Projects: From the Conceptual Design to the Validated Equipment incl. Mock-Up Study

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

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 H₂O₂ to routine processes

Isolator and Associated Technologies

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

Case Study Merck: New Aseptic Filling Building: A Quality by Design Approach

- Presentation of the project
- Business case construction
- Compliance requirements
- QBD approach and implementation
- Product Tech Transfer strategy
- ASTM E2500 qualification and validation strategy

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

Aseptic Filling Isolators from a Microbiological Point of View

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



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

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

Workshop 3:

Isolators according to EU Annex 1

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

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. (appr. 17.15 h) or the hotel.

Speakers

Dr Patricia Desmaris, Merck Group

Pharmacist specialized in biotechnology, expert in Aseptic Processes, F&F, Isolator Technology and CGMPs Compliance. Currently managing a team in charge of all the equipment (compounding, Aseptic filling, washing and sterilization, stopper processing) for a new aseptic filling building from design to qualification/validation.

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.

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. From 2013 to 2018 she was Head of Process Validation Microbiology. Today she supports the Sales Team for Europe of Skan AG.

Benoît Ramond, Sanofi SA, France

Since 2004 he is microbiology expert in Sanofi group. In his function he has also a leading role in the RMM strategy development within Sanofi group.

Ruben Rizzo, SKAN AG, Basel, Switzerland

Ruben Rizzo studied chemistry and pharma technology. He worked for Novartis Pharma (Stein) as a Production Expert in the R&D before he joined SKAN AG in 2014 as Sales Manager in the Process Solution for Isolator Technology. He is responsible for the area of Switzerland, Spain, Italy and Portugal.

Yves Scholler, SKAN AG, Basel, Switzerland

Yves Scholler studied mechatronics at the Trinational Engineering School (FTI) in Muttens (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.

Alexandra Stärk, Novartis Pharma Stein AG, Basel, Switzerland

Alexandra Stärk has worked since 1995 at Novartis Pharma Stein AG and was heading the microbiological QA/QC department till October 2016. In October 2016 she moved into a new role within Novartis Pharma Stein AG and is now responsible for a team of microbiological experts in the department of Manufacturing, Science & Technology which defines the microbiological control strategies for sterile and non-sterile production on a global and local level.

Patrick Vanhecke, GSK Vaccines, 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.

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

Reservation Form (Please complete in full)

Isolator Technology Workshop – Manufacturing Isolator, 24/25 November 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

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GERMANY

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 week 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 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 can-

cellation 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

Tuesday, 24 November 2020, 09.00 h - 18.00 h
(Registration and coffee 08.30 h – 09.00 h)

Wednesday, 25 November 2020, 08.15 h – 16.15 h

After the workshops on 25 November 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.

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 and the speakers in a relaxed atmosphere.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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