Including Workshops at SKAN in Allschwil

Isolator Conference
31 May – 2 June 2016, Basel, Switzerland

SPEAKERS:

Claudio Bechini  
Pharma Integration

Dr Andreas Flückiger  
F. Hoffmann-La Roche

Dr Friedrich Haefele  
Boehringer Ingelheim

Dr Timo Krebsbach  
HHAC Labor Dr. Heusler

Dr. Jörg Lümkearnan  
F. Hoffmann-La Roche

Elodie Muller  
Confarma

Jean-Sébastien Parisse  
Aseptic Technologies

Benoît Ramond  
Sanofi

Lionel Rapin  
GSK Vaccines

Dr Lars Restetzki  
F. Hoffmann-La Roche

Dr Andreas Schreiner  
Novartis Pharma

Thomas Zinn  
Sandoz

HIGHLIGHTS:

- Actual trends in isolator technology
- Future decontamination systems
- High-Potency-API isolators
- Specific requirements for sterility test isolators
- Environmental monitoring of isolators
- Isolators for small scale production
- Robotics in isolators
- Clean requirements for isolators
- Site visits
- Case studies from
  - Aseptic Technologies
  - Boehringer Ingelheim
  - GSK Vaccines
  - Novartis
  - Roche
  - Sandoz
  - Sanofi
Objectives

This is why you will benefit from attending this conference:

- Presentations of the experiences of various specialists working with innovations and state-of-the-art equipment within pharmaceutical industry and microbiology.
- Experts from pharmaceutical companies will share their knowledge regarding operational experience. E.g.:
  - trends in laboratory and environmental monitoring,
  - new decontamination processes and small scale production,
  - market trends, requirements and operation of production isolators.
- Case studies from various pharmaceutical companies deal with the implementation, qualification and operation of isolator and RABS systems.
- You will discuss the current state-of-the-art and new technological developments in Barrier Systems technology.
- You will participate in active workshops based on usual aseptic and aseptic-toxic manipulation.

Target Audience

This event is directed at decision-makers from pharmaceutical production, development and quality assurance/control. It also addresses engineers, technicians, and planners who need to be well informed about current developments in the field of barrier systems. Please understand that, for competitive reasons, not all firms can register their employees for this event.

Moderator

Paul Ruffieux

Workshops at Skan

The workshops will take place at SKAN AG in Allschwil. After lunch on 31 May and 1 June a bus shuttle service will bring the participants to SKAN.

After the workshops at 17.00 h, the bus shuttle will bring the participants to the airport, the train station or back to the venue.

At the end of 2 June a bus will bring the participants to the airport or to the train station.

Programme

Day 1

Laboratory and environmental monitoring
Tuesday, 31 May 2016

History, future and regulatory trends in sterility testing
Elodie Muller, Confarma

Roche containment: High-Potency-API – regulatory requirements
Dr Andreas Flückiger, F. Hoffmann-La Roche

Case study HHAC: Microbiology in isolators
Dr Timo Krebsbach, HHAC Labor Dr. Heusler

Case study Sanofi: Environmental monitoring program: hot topics in microbiology & best practice
Benoît Ramond, Sanofi

Workshops at SKAN

- Sterility testing in an isolator
- Environmental monitoring in an isolator
- Service: qualification of an isolator
- SCADA solution for isolators

Day 2

New decontamination process and small scale production
Wednesday, 1 June 2016

The actual trends in isolator technology
Philippe Jérôme

SKANFOG, the future decontamination system
Volker Sigwart

Case study GSK: Design of isolators for aseptic processes
Lionel Rapin, GSK Vaccines

The isolator solution for flexible small scale production
Frank Lehmann

Different applications for flexible small scale production
Paul Ruffieux, Consultant

Case study Boehringer Ingelheim: Filling of ready-to-use vials in an isolator
Dr Friedrich Haefele, Boehringer Ingelheim

Workshops at SKAN

- E-Beam: Surface decontamination of tubs
- Production filling line isolator
- Flexible small scale filling isolator
- Glove tester for isolators and RABS
- Isolator Academy and bio indicator production
- Containment isolators and innovative safe change filter
Day 3
Production isolators
Thursday, 2 June 2016

Alternative morning session: parallel visits of sterility test laboratories at Roche Kaiseraugst. The number of participants is limited.

Case study: Aseptic, toxic filling line with freeze dryer
Dr. Jörg Lümkemann, F. Hoffmann-La Roche

Case study Roche: Occupational hygiene measurements in isolators for parenteral manufacturing
Dr. Lars Restetzki, F. Hoffmann-La Roche

Pharmaceutical processes with robotics in isolators
Claudio Bechini, Pharma Integration

Case study Sandoz: E-Beam filling line with isolator
Thomas Zinn, Sandoz

Cleaning requirements based on the new EMA guideline
Dr. Andreas Schreiner, Novartis Pharma

Closed vial filling from R+D to market
Jean-Sébastien Parisse, Aseptic Technologies

RABS retrofit for improving aseptic processing quality
Manfred Holzer

Discussion of different current topics

Speakers

Claudio Bechini, Pharma Integration SRL, Italy
Managing Director at Pharma Integration S.r.l with long-term experience in leading positions within pharmaceutical machine manufacturing.

Dr. Andreas Flückiger, F. Hoffmann-La Roche Ltd, Switzerland
An occupational physician by training, Andreas Flückiger has been the head of the occupational health services of the Roche Group for 20 years.

Dr. Friedrich Haefele, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
In May 2006 Dr. Haefele joined Boehringer Ingelheim Pharma where he is responsible for the department Biopharma Fill & Finish Germany.

Social Event

On 31 May you are cordially invited to a dinner and on 1 June you are cordially invited to a social event. These are excellent opportunities to share your experiences with colleagues from other companies in a relaxed atmosphere.
Easy Registration

Registration 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, 31 May 2016, 08.30 h – 17.00 h
(Registration and coffee 08.00 h – 08.30 h)
Wednesday, 1 June 2016, 08.30 h – 17.00 h
(Registration and coffee 08.00 h – 08.30 h)
Thursday, 2 June 2016, 08.30 h – 16.00 h
(Registration and coffee 08.00 h – 08.30 h)

Venue
Congress Center Basel
Messeplatz 21
4058 Basel, Switzerland

The workshops will take place at SKAN AG in Allschwil.
A bus shuttle service will be organised.

Fees (per delegate plus VAT)

<table>
<thead>
<tr>
<th></th>
<th>1 Day</th>
<th>2 Days</th>
<th>3 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECA Members</td>
<td>€ 390</td>
<td>€ 690</td>
<td>€ 890</td>
</tr>
<tr>
<td>APIC Members</td>
<td>€ 490</td>
<td>€ 790</td>
<td>€ 990</td>
</tr>
<tr>
<td>Non-ECA Members</td>
<td>€ 590</td>
<td>€ 890</td>
<td>€ 1090</td>
</tr>
<tr>
<td>EU GMP Inspectorates</td>
<td>€ 295</td>
<td>€ 445</td>
<td>€ 545</td>
</tr>
</tbody>
</table>

The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on all days, dinner on the first and second day and all refreshments. VAT is reclaimable.

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

---

Reserveation Form (Please complete in full)

Isolator Conference, 31 May - 2 June 2016, Basel, Switzerland

Please tick the day(s) you want to register for:

- Laboratory and environmental monitoring, 31 May 2016
- New decontamination process and small scale production, 1 June 2016
- Production isolators, 2 June 2016
- On 2 June, I want to take part in the alternative morning session at Roche Kaiseraugst

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

---

General terms and conditions

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 within 1 week prior to the conference: 100%
   - Cancellation until 1 week prior to the conference: 50%
   - Cancellation until 2 weeks prior to the conference: 10%

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

CONCEPT HEIDELBERG reserves the right to change the programme, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 41, or per e-mail at strohwald@concept-heidelberg.de.
Dr Andreas Mangel (Operations Director) at +49-62 21/84 44 41, or per e-mail at mangel@concept-heidelberg.de.

For questions regarding content:
info@concept-heidelberg.de, www.concept-heidelberg.de

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG, P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-40, Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de, www.concept-heidelberg.de

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/iva/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.