

Isolator Conference

31 May – 2 June 2016, Basel, Switzerland

Including Workshops at
SKAN in Allschwil



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 Lümekemann

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

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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 Sigwarth

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

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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 Lümekemann, 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.



Dr Timo Krebsbach, HHAC Labor Dr. Heusler GmbH, Germany

Timo Krebsbach has more than 14 years of professional experience in microbiology. Since October 2015 he is Managing Director of HHAC Labor Dr. Heusler.



Dr Jörg Lümekemann, F. Hoffmann La-Roche Ltd, Switzerland

Jörg Lümekemann is leading the Established Product Support Group at F. Hoffmann La Roche in Basel.



Elodie Muller, Conframa France SAS, France

Elodie Muller is Head of Sterility Test Activity, composed of the traditional Sterility Test and Rapid Test.



Jean-Sébastien Parisse, Aseptic Technologies, Les Isnes-Gembloux, Belgium

Jean-Sébastien is Head of Sales Department at Aseptic Technologies.



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.



Lionel Rapin, GSK Vaccines SA, Belgium

Sr Engineer with a ten year expertise in aseptic isolators and vaccine filling process during European and international projects.



Dr Lars Restetzki, F. Hoffmann-La Roche AG, Switzerland

Lars Restetzki is Business Process Manager 'Rocephin' in Kaiseraugst.



Dr Paul Ruffieux, Switzerland

Paul Ruffieux was production director at Cilag and Vice President Industrial Division at Skan AG. Since 2013 he has been consultant



Dr Andreas Schreiner, Novartis Pharma, Switzerland

Since 2013 he works for the Manufacturing Science & Technology Department as Validation Head for Solid Dosage Forms.



Thomas Zinn, Sandoz AG, Austria


Thomas is Plant Head Bioinject in the Business Unit Sandoz Biopharmaceuticals.

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

 **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, 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)

	1 Day	2 Days	3 Days
ECA Members	€ 390	€ 690	€ 890
APIC Members	€ 490	€ 790	€ 990
Non-ECA Members	€ 590	€ 890	€ 1,090
EU GMP Inspectorates	€ 295	€ 445	€ 545

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.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the Dorint Hotel An der Messe Basel, Schönaustr. 10, 4058 Basel, close to the Congress Center. You will receive a room reservation form/POG when you have registered for the conference. 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
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de, www.concept-heidelberg.de

For questions regarding content:


Dr Andreas Mangel (Operations Director) at +49-62 21/84 44 41,
or per e-mail at mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Mr Ronny Strohwalld (Organisation Manager) at +49-62 21/84 44 51,
or per e-mail at strohwalld@concept-heidelberg.de.

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

Reservation Form (Please complete in full)

 +49 6221 84 44 34

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

I want to join the dinner on 31 May

New decontamination process and small scale production, 1 June 2016

I want to join the social event on 1 June

Production isolators, 2 June 2016

On 2 June, I want to take part in the alternative morning session at Roche Kaiseraugst

Mr

Ms

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)

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

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 week prior to the conference 50 %
 - 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 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).

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.