## **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 Lümkemann

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



## **Isolator Conference**

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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**



## 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



# 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-touse 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

## **Isolator Conference**

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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 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 icined Rochringer

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 Lümkemann, F. Hoffmann La-Roche Ltd, Switzerland

Jörg Lümkemann 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



Benoît Ramond, Sanofi SA, France

Aseptic Technologies.

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.



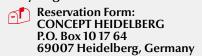
Thomas Zinn, Sandoz AG, Austria

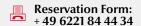
Thomas is Plant Head Bioinject in the Business Unit Sandoz Biopharmaceuticals.

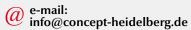
## **Social Event**



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.









#### 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 Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

f the bill-to-address deviates from the	Reservation Form (Please complete in full)	<del>-</del> +49 6221 84 44 34		
specification to the right, please fill out here:	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			
		Title, first name, surname		
	Company			
CONCEPT HEIDELBERG P.O. Box 10 17 64 Fax +49 (0) 6221/84 44 34	Department			
69007 Heidelberg	Important: Please indicate your company's VAT ID Number Purchase	e Order Number, if applicable		
Germany	Street / P.O. Box			
	City Zip Code			
	Country			

#### 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.

any time.

2. If you have to cancel entirely we must charge the follow-

- ing processing fees: Cancellation
  until 2 weeks prior to the conference 10 %,
  until 1 weeks prior to the conference 50 %
- until 1 weeks 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.

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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.