



EUROPEAN COMPLIANCE
ACADEMY

SPEAKERS

SYLVIE ALGARRA

Stäubli Faverge

GERALD BÜRKLE

Vetter Pharma Fertigung

DR OLIVIER CHANCEL

Merial

JENS GEMMECKER

Optima Group Pharma

LEOPOLD GRUBER

SBM Scholler-Bleckmann
Medizintechnik

DR ROLAND GUINET

DR RENAUD JANSSEN

Helvoet Pharma

DR HEINRICH-ANDREAS

KRACKE-HELM

GEA Diessel

JENS KUBISCHIK

Pall

DR JÖRG LÜMKEMANN

F. Hoffmann-La Roche

DR JEAN-DENIS MALLET

SNC-Lavalin

GERT MOELGAARD

NNE Pharmaplan

DR DANIEL MÜLLER

Regierungspräsidium Tübingen

MATTHIAS POSLOVSKI

Optima Group pharma

CHRISTOPH VON STENGLIN

Optima Group pharma

BENOIT VERJANS

Aseptic Technologies

NORM WEICHBRODT

Catalent Pharma Solutions

This conference is part of the
Pharma Congress 2012

Current Aseptic Technologies

Düsseldorf/Neuss, Germany, 24-25 April 2012

HIGHLIGHTS:

- Trends and challenges in aseptic processing
- Regulatory issues today and tomorrow
 - Possible evolutions of Annex 1
 - Interpretation of current regulatory requirements
- Development of new technologies for aseptic manufacturing
 - Single-use technology
 - Closed vial technology
 - Blow, Fill, Seal technology
 - Continuous aseptic processing
 - Robotics in aseptic production areas
- Case studies from pharmaceutical companies

Objectives

Three good reasons to attend this conference:

- You are informed about the latest technological developments in sterile manufacture
- You learn how current GMP and production requirements have to be implemented technologically in sterile manufacture
- You will get the interpretation of new guidelines and requirements from a GMP inspector's point of view

Background

GMP regulations only define general requirements on equipment – it has to be suitable for the intended work process, easy to clean and without any negative influence on the product quality. The questions of how these general requirements have to be fulfilled concretely in sterile manufacture, which points call for special attention and which new technologies will be used in the future are the focus of this event. Speakers from the pharmaceutical industry, from planning and engineering companies as well as from Inspectorates deal with pivotal developments in the field of sterile manufacture.



Image: groningen & co.

Target Audience

The event is directed at specialists from the pharmaceutical industry, at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice. It particularly aims at the departments:

- Production
- Quality assurance
- Engineering / technology

Moderator

Gert Moelgaard, *NNE Pharmaplan*

The Social Event



The Social Event at the Pharma Congress is already a tradition, and is networking and relaxation at the same time.

On the evening of the first congress day, on 24 April 2012, all congress delegates and speakers are invited to a „Get together“ in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

Special offer from Lufthansa – discounted travel for Pharma Congress attendees

Lufthansa is the mobility partner for all ECA events. This means, that, as an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.



And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the „Access to Event Booking“ area you will also receive. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

Programme 24 April

Aseptic Pharmaceutical Manufacturing – where are we going?

- Trends and challenges in aseptic processing
- Manufacturing opportunities in a business perspective
- Regulatory issues today and tomorrow
- Operating efficiency in aseptic processing

GERT MOELGAARD, *NNE Pharmaplan*

Mediafill Readout by Tunable Diode Laser Spectroscopy

- Detection of bacterial grow in Mediafill units
- Automated and fast detection method differing from visual control of Mediafill units
- Detection of oxygen consumption of microbial species
- Workload reduction and detection safety enhancement for Mediafill control

DR JÖRG LÜMKEMANN, *F. Hoffmann-La Roche*

Case Study: Turn Key Cytotoxic Line

- Washing
- Sterilizing
- Filling / Stoppering
- Lyophilization with automatic loading
- Capping
- Isolator / Decontamination

MATTHIAS POSLOVSKI / JENS GEMMECKER / CHRISTOPH VON STENGLIN, *OPTIMA GROUP pharma*

Current regulatory requirements: interpretation, main differences and technological implementation

- General comments on the PIC/S document
- Aseptic process validation interpretation
- Requalification frequencies
- Alternatives for Grade A capping
- Issues related to RTU components
- Some deviations observed in inspections

DR ROLAND GUINET

Possible evolutions of the annex 1: what's next ?

- Introduction: history of the successive versions of annex 1
- Parallel evolution of EU annex 1 and US-FDA guidance
- Some missing points in the current version
- Possible additional points to come

JEAN-DENIS MALLET, *SNC-Lavalin*

Robotics provides high efficiency and reliability in aseptic production areas

- Robot system safety in aseptic drug manufacturing,
- Robotics ensures patient and personnel safety
- Increase of product quality
- Sterile drug manufacturing
- Stäubli TX robot series Stericlean
- Cleanroom and sterile environment

SYLVIE ALGARRA, *Stäubli Faverges*

Application possibilities of continuous aseptic processing in liquid pharma

- Advantages of continuous processes compared to batch and fed batch processes
- Examples for possible fields of applications
- Process parameters for continuous processes compared to batch processes
- Design criteria and requirements for components in continuous sterile processes
- Concepts / examples for continuous processes based on current continuous applications in non pharma

DR HEINRICH-ANDREAS KRACKE-HELM, *GEA Diessel*

Advanced Aseptic Processing using Blow, Fill, Seal Technology

- Overview of blow, fill, seal process (BFS)
- Current applications of BFS
- Engineering controls of automated aseptic process vs. traditional filling process administrative controls
- Flexibility of BFS forms
- BFS Benefits vs. glass
- Case Study – Microbial performance of BFS

NORM WEICHBRODT, *Catalent Pharma Solutions*

Programme 25 April

Case study on Container closure integrity; from design to stabilities

- Design: microbial ingress testing to validate both the stopper / bottle association and the crimping parameters
 - In process parameters and stability studies; experience of a vacuum test to confirm container and closure system integrity as a part of an IPC program on stability protocol
- OLIVIER CHANCEL, *Merial, Toulouse*

Ready - To - Use aluminium / plastic caps in view of new capping requirements

- What are 'EU GMP Annex 1' capping requirements about ?
- Learn on how Ready-To-Use aluminium/plastic caps are defined
- Get a detailed insight into the validation package for RTU caps :
 - Product Validation
 - Process Validation
 - Packaging Validation

DR RENAUD JANSSEN, *Helvoet Pharma*

Implementation of Single-Use Downstream Technologies for GMP Processing

- Single-Use-Systems (SUS) for Fluid Management
- Single-Use Key Technologies for Downstream Processing (Single-Use TFF, Single-Use Mixing etc.)
- Sterile processing with SUS
- Validation approach for process specific SUS

JENS KUBISCHIK, *Pall GmbH*

Single use technology in pharmaceutical manufacturing - an inspector's point of view

- Guidelines & regulatory framework
- Pharmaceutical applications for disposable systems
- Single-use - versus multi-use systems
- Importance of supplier management
- Future prospects

DR DANIEL MÜLLER, *Regierungspräsidium Tübingen*

The Closed Vial technology reduces risk of contamination

- Presence of living particle is possible in Grade A environment
- Risk of contamination is proportional to exposed surface and exposed time
- 5 different technologies have been assessed: open glass vials, PFS, open ampoules, BFS and closed vials
- The results show a difference factor for the risk of contamination over than 2 logs between closed vials and BFS versus open vials

BENOIT VERJANS, *Aseptic Technologies*

Capacity extension through a high performance line for pre-sterilized syringes

- Current facts regarding the youngest Vetter production site RVS
- Presentation of the high performance filling line for pre-sterilized syringes RVS3
- Spray Tunnel regarding tub disinfection
- Waste logistics out of the Cleanroom
- Process video

GERALD BÜRKLE, *Vetter Pharma-Fertigung*

Sterilisation of pre-filled Syringes

- Suitable packaging
- Arrangement
- Process-oriented parameters
- Sterilisation method in the test bench

LEOPOLD GRUBER, *SBM Schoeller Bleckmann Medizintechnik*



Image: groninger & co.

Speakers

SYLVIE ALGARRA, *Stäubli Faverges SCA, Faverges, France*

Mrs Algarra is Activity Manager responsible for worldwide Life Science.

GERALD BÜRKLE, *Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany*

Since 2005 „Director Pharmaceutical Production“ at Vetter Pharma Fertigung - Ravensburg.

DR OLIVIER CHANCEL, *Merial, Toulouse, France*

Currently Head of Pharmaceutical Support in Merial.

JENS GEMMECKER, *OPTIMA GROUP pharma GmbH, Mornshausen, Germany*

Sales manager at OPTIMA GROUP pharma, facility Mornshausen.

LEOPOLD GRUBER, *SBM Schoeller Bleckmann Medizintechnik Ges.m.B., Ternitz, Austria*

Mr. Gruber was active from 1974 till the end of 2010 for the Company SBM in the area of the design and sales in leading functions.

DR ROLAND GUINET

Consultant Regulatory Compliance Sites and Processes. From 2002-2011 GMP Inspector at AFSSaPS (French Agency for the Safety of Health Products)

DR RENAUD JANSSEN, *Helvoet Pharma Belgium, Alken, Belgium*

He currently is Global Director of Scientific Affairs for Helvoet Pharma worldwide.

DR HEINRICH-ANDREAS KRACKE-HELM, *GEA Diessel GmbH, Hildesheim*

Active since 1989 as Sales Manager and Engineer for Biotech Plants, since 2011 for GEA Diessel.

JENS KUBISCHIK, *Pall GmbH, Dreieich, Germany*

Since 2007, he is projectmanager for single-use-disposables in Europe.

DR JÖRG LÜMKEMANN, *F. Hoffmann-La Roche AG, Basel, Switzerland*

Since 2001 in the development of parenterals and in charge of the implementation of new technologies in this area.

DR JEAN-DENIS MALLET, *SNC Lavalin, Ivry-sur-Seine, France*

Director Pharma Europe, formerly Head of the French Pharmaceutical Inspection Department (AFSSAPS).

GERT MOELGAARD, *NNE Pharmaplan, Søborg, Denmark*

Gert Moelgaard is Vice President for Innovation & Business Development in NNE Pharmaplan.

DR DANIEL MÜLLER, *Regierungspräsidium Tübingen, Germany*

In 2001 he joined a German inspectorate and has been working as a GMP-Inspector with focus on biotechnological active ingredients and sterile drug products since that time.

MATTHIAS POSLOVSKI, *OPTIMA GROUP pharma GmbH, Schwäbisch Hall, Germany*

Director Technical Sales of the OPTIMA GROUP pharma GmbH responsible for US and South American markets.

BENOÎT VERJANS, *Aseptic Technologies S.A., Les Isnes, Belgium*

He is currently Commercial Director of Aseptic Technologies, responsible of developing the sales of the closed vial technology worldwide.

CHRISTOPH VON STENGLIN, *OPTIMA GROUP pharma GmbH, Radolfzell, Germany*

Managing director of Metall + Plastic, Radolfzell.


NORM WEICHBRODT, *Catalent Pharma Solutions, Woodstock, IL, USA*

R&D Strategic Account Manager with >30 years pharmaceutical experience in sterile injectables, lyophilization, and blow, fill, seal technology platforms.

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.pharma-kongress.com

Date

Tuesday, 24 April 2012, 08.45 – 18.00 h
(Registration Monday, 23 April 19.00 – 20.30 h and
Tuesday, 24 April, 08.00 – 08.45 h)
Wednesday, 25 April 2012, 09.00 – 17.00 h

Venue

Swissôtel Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss
Germany
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
Emailus@swissotel-duesseldorf.de

Fees

EUR 980.- per delegate plus VAT

The conference fee is payable in advance after receipt of invoice and includes lunch on that day as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day (24 April 2012) VAT is reclaimable.

Your registration also entitles you to participate in all other Pharma Congress conferences during the two days. For further information please visit www.pharma-kongress.com.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.pharma-kongress.com

PLEASE NOTE

Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Please further note that there will be no room reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

Organisation & Contact

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

For questions regarding content:


Dr Andreas Mangel (Operations Director) at +49-6221/84 44 41, or per e-mail at mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Mr Detlef Benesch (Organisation Manager) at +49-6221/84 44 45, or per e-mail at benesch@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

Current Aseptic Technologies

Part of the Pharma Congress Production & Technology 2012
Düsseldorf/Neuss, Germany, 24-25 April 2012

PLEASE NOTE: Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice!

- Yes, I would like to participate in the Social Event.
 Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the 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 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. 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)!