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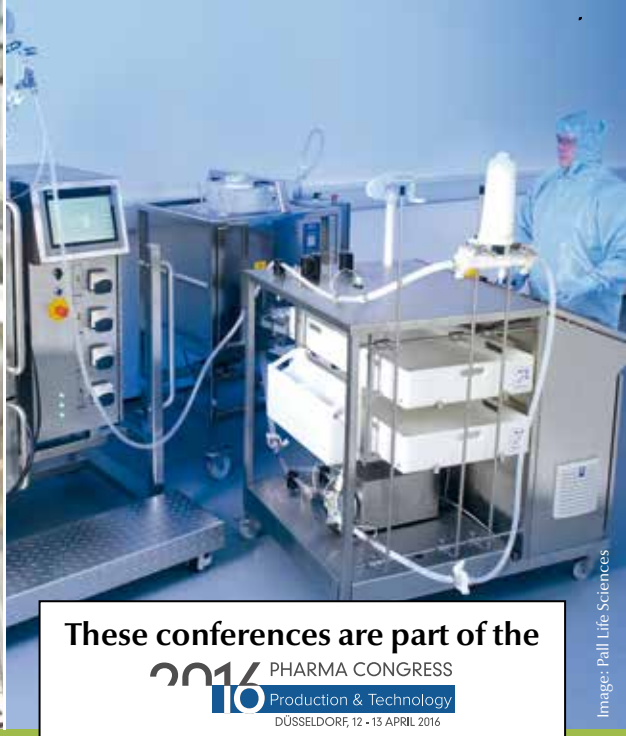

Image: Pall Life Sciences

SPEAKERS

NIELS ALBER
Novartis Pharma

DR THOMAS CENTNER
Sanofi

DR OLIVIER CHANCEL
Merial

PROF REGINE EIBL
Zürich University of Applied Science

PROF DR DIETER EIBL
Zürich University of Applied Science

DR FRIEDRICH HAEFELE
Boehringer Ingelheim Pharma

DR SHAWN D. KINNEY
Berkshire Sterile Manufacturing

DR ANDREAS KÖNIG
Aenonva Group

XAVIER LESAOUT
Merck

DR JEAN-DENIS MALLET
ECA and former head of Afssaps

DR NUNO PEREIRA
GenIbet Biopharmaceuticals

DR BEATE REUTTER
Landesamt für soziale Dienste Schleswig-Holstein

PROF DR SIEGRID SAALER-REINHARDT
Midas Pharma

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10 Production & Technology
DÜSSELDORF, 12 - 13 APRIL 2016
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Current Aseptic Processing

Current Aseptic Technologies
Single-Use Equipment and Applications

Düsseldorf/Neuss, Germany, 12-13 April 2016

HIGHLIGHTS CURRENT ASEPTIC TECHNOLOGIES

- The new EU GMP Guide Annex 1 – current status
- Lessons learned in sterility assurance
- Parameters for an aseptic release
- Isolator based flexible filling system for all containers
- Innovative primary packaging

HIGHLIGHTS SINGLE-USE EQUIPMENT AND APPLICATIONS

- Overview about available Single-Use Technologies
- SU Equipment for Fill & Finish
- Continuous operations in Biopharm Manufacturing
- Virus Production with SU Equipment

Current Aseptic Technologies 12 April 2016

Objectives

Reasons to attend this conference:
- You will be informed on new regulatory and technological developments in sterile / aseptic manufacture
- You learn how current GMP and production requirements have to be implemented technologically in sterile manufacture
- You will get case studies from pharmaceutical companies
- Live Demos will show you how technologies perform

Background

GMP regulations only define general requirements for equipment – it has to be suitable for the intended work process, easy to clean and without any negative influence on the product quality. Questions like 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 in this conference's focus. Speakers from the pharmaceutical industry and from planning and engineering companies deal with pivotal developments in the field of sterile manufacture.

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice. It particularly addresses the departments production, quality assurance and engineering / technology.

Moderator

Gert Moelgaard, *NNE Pharmaplan*

Programme

The upcoming Annex 1 and consequences for industry

DR FRIEDRICH HAEFELE, *Boehringer ingelheim Pharma*

Congress Key Note

Revision of Annex 1 – a short overview

- New structure
- Need for clarification
- More guidance
- Harmonisation

DR BEATTE REUTTER, *Landesamt für soziale Dienste Schleswig-Holstein*

The 99 parameters for an aseptic release

- The future of the aseptic pharmaceutical processes
- Parametric release as a possible way of certification of aseptically produced sterile batches
- "99 parameter" are derived from the "6M" model
  - Media fill results
  - Machine maintenance & operation
  - Materials management
  - Men training
  - Monitoring of the environment
  - Metrology
- Basis for a future parametric release?

DR JEAN-DENIS MALLET, *NNE Pharmaplan*

Ten lessons learned in sterility assurance

- Real life experiences observed on the shop floor over the last year to support various activities of the sterility assurance
- Series of case studies to focus on the practical knowledge, on the "know how" which can be directly applied on daily business by Production, Pharmaceutical Microbiologist and Quality
- Useful insights on various microbiological aspects to detect sources of contaminations for sterile drug products and to prevent them
- Forum for open and practical discussions

DR OLIVIER CHANCEL, *Merial*

Innovative Primary Packaging: Inner barrier coating prevents contamination of drug products with potential impurities from plastic primary packaging, a case study

- Results from an Extractables study conducted with COP vials with and without an inner SiO2 coating
- Results from an ICH stability study (6 month data) and from the associated Leachables study with a small molecule as a basis to apply for a national marketing authorization in Europe.

PROF DR SIEGRID SAALER-REINHARDT, *Midas Pharma*

The Development of an Isolator Based Flexible Filling System for all Containers

- Recent advances and cooperation between primary container suppliers and equipment manufacturers have led to a robust line of primary containers and closures
- This new paradigm reduces the pharmaceutical companies' capital and provides a superior safer packaged drug product
- The advantages and considerations with these systems will be described to allow others to capitalize on these new formats that bring safer and more flexibility to drug development and commercial manufacturing

ALESSANDRO MASSIGNANI, *Nuova Ompi*
DR SHAWN D. KINNEY, *Berkshire Sterile Manufacturing*

Live Demos

In the **practical part** of the conference, suppliers will show you different components and solutions in relation to single use equipment. You will come in contact with the **equipment** and you have the chance to discuss your questions immediately with **technology experts**.

Flooring solutions in a cleanroom environment

- Installation of conductive PVC floor with coves
- Looselay flooring installation without "shut down"
- The right choice of flooring for cleanroom requirements

Gerflor

Functionality and application options of magnetic agitators

- Basic structure of magnet-coupled agitators
- Typical applications
- Special case: Magnetic agitators in bioreactors
- Run-dry properties of bottom-mounted magnetic agitators

This Live Demo will give an overview of the functionalities and application options of magnetic agitators. New stronger magnets are used to lift the impeller off the bearing. This greatly improves the agitator's run-dry performance. The vessel can be completely emptied of liquid with the agitator running – mixing to the last drop.

Zeta Biopharma

Finished product inspection applications for laser-based headspace

Measurements with a benchtop laser-based headspace analyser platform will be demonstrated for a variety of finished product inspection applications. These measurements can also be with an automated machine platform for 100% quality inspection or for statistical process studies

- Container closure integrity testing
- Detection of a contaminated media fill container
- Non-destructive moisture testing of lyo product

Lighthouse Instruments

Specialised Robot for the pharmaceutical and medicinal industries

The demo cell will simulate the handling of blood or chemicals probes in test tubes. For that we will use the 6-axis robot that has been recently certified by the IPA for its use in the pharmaceutical and medical industries. The robot will pick, shake and place the test tubes in a tray. We will use a custom-made gripper from the Italian company GRIMATIC.
The gripper will be attached directly to the robot's flange and protected by a sterilisation-resistant "plastic" cover.

DENSO Robotics Europe

Single-Use Equipment and Applications 13 April 2016

Objectives

Reasons to visit this conference:

- You will get an overview on the current state of single use technologies and a prospect on new developments
- You will get first hand information on how to design and implement a robust and efficient single use technology
- You will get case studies from pharmaceutical companies about the use of single use technology in development and production

Background

The use of single use technology increases in many biotechnological processes as well as in sterile filling processes. There are different reasons for this development, i.e.

- Avoiding cleaning and cleaning validation
- Reducing time to market by omitted construction activities
- Simplified scale-up procedures

On the other side – especially in comparison to stainless steel – new questions arise like

- How to qualify and validate the technology?
- What are the consequences at the GMP-Level?
- How much responsibility can I transfer to the SU supplier?

These questions will be discussed during the conference by experts from pharmaceutical companies and leading suppliers.

Target Audience

The event is directed at decision-makers from pharmaceutical industry and suppliers from

- Production
- Engineering
- Research & Development
- Quality Assurance

who need to be well informed about current developments in the field of single use technology.

Moderator

Prof Dr Dieter Eibl, *Zürcher University of Applied Science*

Programme

How to measure performance in pharmaceutical production – a case study

- Industry Quality Metrics – typical data sets and reports
- How to measure Quality Metrics in daily practice
- Lessons learned from implementation
- Comparison of quality metrics – potential risks and challenges

DR ANDREAS KÖNIG, *Aenova Group*

Single-Use Technology in biopharmaceutical production: An overview from USP to Fill&Finish technologies

- Categorisation of available single-use systems
- Disposables in Upstream-Processing
  - Media preparation
  - Cell expansion and fermentation
- Disposables in Downstream-Processing
  - Filtration and chromatography
  - Buffer preparation and storage
- Disposables in formulation and filling
- Freeze technology
- Hybrid/closed technology platforms

PROF REGINE EIBL, *Zürich University of Applied Science*

Live Demos

In the **practical part** of the conference, suppliers will show you different components and solutions in relation to single use equipment. You will come in contact with the **equipment** and you have the chance to discuss your questions immediately with **technology experts**.

SU equipment for fill/finish focus Multitubing application

For the filling of injection solutions on a laboratory scale, a laboratory device from the FHM 1000 series is shown. The device includes a Human Machine Interface (HMI), a filling and weighing module each, as well as a needle movement for the filling process. The laboratory machine receives the product from the pre-validated, pre-assembled and pre-sterilized single-use filling system PreVAS. Among its key components are bag, tube and filling needles, as well as the Bosch peristaltic pump.
Bosch

Connecting, disconnecting and reconnecting for sterile fluid transfer

One of the most critical step is the sterile connection between disposable fluid paths and the various steps in the filling process.

- In the workshop an easy way of connecting, disconnecting and reconnecting for fluid transfer will be demonstrated, reducing risk of failure and increasing quality of work experience (ergonomics, regulatory).

Merck

Point-of-use leak testing

The workshop demonstrates how to perform a point-of-use leak tests with a Palltronic® Flowstar LGR system.

- Leak testing of any type of single-use systems with a nominal volume of 200 L or less
- Integrity testing of any filters within the single use assembly
- Very short testing time (< 15 minutes)
- Reduced footprint and fully suitable for manufacturing operations; 21 CFR part 11 compliance

Pall BioPharmaceuticals

TBN

SIEMENS

Case Study Sanofi: Bioproduction with SU equipment – Points to consider from End-to-End

DR THOMAS CENTNER, *SANOFI*

Case Study Novartis: Single Use equipment for Fill/Finish

- Challenge of filling low volumes / Rational for the change to a peristaltic pump
- Project timelines
- Cooperation with the supplier: allocation of tasks
- Implementation of the new filling system in the GxP environment
- Pros & Cons of the peristaltic filling technique in combination with SU equipment
- Business Case: what has been the added value of the project

NIELS ALBER, *Novartis Pharma*

Case Study Merck: Continuous operations in Biopharm Manufacturing: Back to the Future

Recently, continuous operations is considered again as a lever to boost process productivity and control product quality. Looking at bioprocess history, this presentation will discuss the reasons of those "back and forth" trends. It will also present results obtained at EMD-Serono using continuous operations in cell-culture and also in purification of biopharmaceuticals. Finally, it will discuss the challenges and opportunities of continuous operations versus current established fed-batch platform.

XAVIER LESAOUT, *Merck*

Case Study GenIbet Biopharmaceuticals: The Challenge of Using Single-Use Materials in Virus Production

- Main reasons for the use of single-use material in biopharmaceutical production
- Single-use materials options for the different steps of a virus production
- Identification of steps where is not possible to use single-use materials. What alternatives?

DR NUNO PEREIRA, *GenIbet Biopharmaceuticals*

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 12 April 2016, 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.

Speakers

NIELS ALBER, *NOVARTIS PHARMA STEIN AG*
Niels Alber is Process Expert PU Vials. He studied pharmaceutical technology and started his career at the Fraunhofer IGB (Institute for Interfacial Engineering and Biotechnology). Later he joined Biologische Heilmittel Heel as Production Engineer. He also worked for Triplan as Technical Project Manager specialized on projects in pharmaceutical environment (solids packaging / semi solids packaging / containment).

DR THOMAS CENTNER, *SANOFI*
Dr Center has been Head of Fermentation at Merckle Biotech and is now Head of Upstream Development at Sanofi in Frankfurt.

DR OLIVIER CHANCEL, *MERIAL, TOULOUSE, FRANCE*
Doctor Pharmacist, graduated in Technological Pharmacy, Quality Control and Management. Currently Sterility Assurance Expert and formerly Head of Performance and Pharmaceutical Support in Merial, a company of Sanofi.

PROF REGINE EIBL, *ZÜRICH UNIVERSITY OF APPLIED SCIENCE*
Regine Eibl is a professor at the Zurich University of Applied Sciences, where she lectures in biotechnology and cell cultivation techniques. She is the platform leader for "Single-use technology" of the Swiss Biotechnet and a member of the DECHEMA (Society for Chemical Engineering and Biotechnology).

PROF DR DIETER EIBL, *ZÜRICH UNIVERSITY OF APPLIED SCIENCE*
Head of the department for Biotechnology and Cell Culture Technology at the Zürcher University of Applied Science. His research focus lies on fermentation and processes based on cell cultures as well as characterization of bio reactions with CFD.

DR FRIEDRICH HAEFELE, *BOEHRINGER INGELHEIM PHARMA GMBH & C. KG*
Vice President BP Fill & Finish Germany.

DR SHAWN D. KINNEY, *BERKSHIRE STERILE MANUFACTURING, LEE, US*
Shawn D. Kinney has been President and CEO of Berkshire Sterile Manufacturing since 2014. Before he was with Wyeth, Anika Therapeutics and Hyaluron Contract Manufacturing.

DR ANDREAS KÖNIG, *AENOVA GROUP, GERMANY*
Dr Andreas Konig is Senior Vice President corporate Quality & HSE. Until 2009 he was Vice President Global Quality Operations Animal Health at Schering Plough. Before that he was head of QC and QA at Fresenius Kabi and later Global Quality Director at Intervet.

XAVIER LESAOUT, *MERCK*
Xavier LeSaout is Associate manager at Merck in the Biopharma Technology and Innovation group. He is supporting downstream process development teams in order to evaluate and facilitate the implementation of new technologies in the purification field.

DR JEAN-DENIS MALLET, *NNE PHARMAPLAN, PARIS, FRANCE*
Currently GMP consultant at NNE Pharmaplan. Jean-Denis Mallet was previously working in the industry at QA and production positions. He also is a former GMP inspector and the Head of pharma inspections at Afssaps (France)

DR NUNO PEREIRA, *GENIBET BIOPHARMACEUTICALS*
Nuno Pereira holds a PhD in Technological Biochemistry and started at GenIbet at 2011 providing support to the operations/production activities. Since the beginning of 2015 he has been Project Manager.

DR BEATE REUTTER, *LANDESAMT FÜR SOZIALE DIENSTE SCHLESWIG-HOLSTEIN, KIEL, GERMANY*
Dr Beate Reutter studied Food Chemistry at Münster University and Pharmacy at Kiel University. After 15 years working for a quality control laboratory, in 2003 she changed to the Drug Supervision Department of Land Schleswig-Holstein. She is now working as a GMDP-Inspector and meanwhile head of the inspectorate. She is member of the German expert circle for sterile manufacturing (EFG 3) at the ZLG, and since 2010 she is leading the group.

PROF DR SIEGRID SAALER-REINHARDT, *MIDAS PHARMA GMBH, GERMANY*
Since 2006 working in different departments of Midas Pharma. Since 2014: Exclusive Representation of SiO2 Medical Products in Europe.

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, 12 April 2016, 09.00 – 17.45 h
Wednesday, 13 April 2016, 08.30 – 17.00 h
(Registration: Monday, 11 April 2016, 19.00 – 20.30 h
Tuesday, 12 April 2016, 08.00 – 09.00 h
Wednesday, 13 April 2016, 07:30 – 08.30 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

Fee
EUR 690.- per delegate and day plus VAT (EUR 1.380,- for both days)

The conference fee is payable in advance after receipt of invoice and includes lunch on that day/both days, beverages during the event and during breaks as well as the Social Event on 12 April. VAT is reclaimable.
Your registration also entitles you to participate in all other Pharma Congress conferences on either day of your registration. For the other conferences on both days please visit www.pharma-kongress.com.

Registration
Via the reservation form below, 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
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 – Current Aseptic Technologies:
Dr Andreas Mangel (Operations Director) at +49-6221/84 44 41, or per e-mail at mangel@concept-heidelberg.de.
For questions regarding content – Single-Use Equipment:
Dr Robert Eicher (Operations Director) at +49-6221/84 44 12, or per e-mail at eicher@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.

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Current Aseptic Processing (12-13 April 2016)
Part of the Pharma Congress Production & Technology 2016
Düsseldorf/Neuss, Germany, 12-13 April 2016

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

I register for:
☐ Current Aseptic Technologies (12 April 2016)
☐ Single-Use Equipment and Applications (13 April 2016)
☐ Both days (12-13 April 2016 – 1.380,- €)

☐ Yes, I would also like to participate in the Social Event on 12 April

☐ Mr ☐ Ms

Title, first name, surname

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