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Highlight Speakers...

from Authorities & Associations:


James Drinkwater
Chairmann of PHSS (Pharmaceutical and Healthcare Sciences and Society)


Dr. Andreas Grummel
Senior Quality Assessor
BfArM


Dr Beate Reutter
Head of Inspectorate
Landesamt für Soziale Dienste Schleswig-Holstein

from Industry:


Dr Friedrich Haefele
Vice President BP Fill & Finish Germany
Boehringer Ingelheim Pharma


Dr Andreas König
Senior Vice President Corporate Quality & HSE
Aenova Group


Dr Lars Kreye
Director DPM / BP Fill & Finish
Boehringer Ingelheim Pharma


Dr Lorenz Liesum
Head of PAT (Global Pharma Engineering)
Novartis Pharma


Dr Jean-Denis Mallet
GMP Consultant, NNE Pharmaplan, France, and
Former Head of Pharmaceutical Inspection Dpt. AFSSAPS


Gert Moelgaard
Vice President Strategic Development
NNE Pharmaplan


Tobias Schlögl
Head Drug Product Manufacturing
Boehringer Ingelheim Pharma


Tina Sostaric
Senior Director of Sterile Production
Teva Pharmaceuticals


Dr Clemens Stief
Team Leader Product & Process Development
Pfizer Manufacturing


Dr Martin Tuckermann
Technical Manager / Project Manager
Baxter Oncology


Patrick Vanhecke
Senior Manager
GSK Vaccines

and many others...

- **ECA – Trends in Manufacturing**
- **ECA – Current Aseptic Processing**
- **ECA – Barrier Systems**

2016 PHARMA CONGRESS

Production & Technology

DÜSSELDORF, 12 - 13 APRIL 2016

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The Pharma Congress Overview

Under the theme "users report for users" the Pharma Congress 2016 will be conducted for the 18th time. And for the new Congress the programme is again comprised of six conferences in three subject areas in which speakers talk about the challenges in their day-to-day business and about the solution approaches. Therefore, benefit from the experience of your colleagues as well as from the direct information exchange.

Pharma Congress – Overview

Congress Key Note

Key Note 12 April

The upcoming Annex 1 and consequences for industry
Dr Friedrich Haefele, Boehringer Ingelheim Pharma

Key Note 13 April

How to measure performance in pharmaceutical production – a case study
Dr Andreas König, Aenova Group

Conferences (One Day Ticket 690,- EUR)	12 April 9:00–17.45 h	13 April 8:30–17:00 h
ECA - Trends in Manufacturing		
Continuous Manufacturing	✓	
Manufacturing of highly potent Materials		✓
ECA - Aseptic Processing		
Current Aseptic Technologies	✓	
Single-Use Equipment and Applications		✓
ECA - Barrier Systems		
Barrier Systems – Regulations/Technology/New Developments	✓	
Barrier Systems – Case Studies		✓
Trade Fair PharmaTechnica	✓	✓

The exact times for the single conferences as well as updates will be available on the Congress website at www.pharma-kongress.com at a later point in time.

The Steering Committee

Dr Friedrich Haefele, Boehringer Ingelheim
Vice President BP Fill & Finish Germany

Roland Szymoniak, Sanofi
Manager Industrial Engineering & Transfer

Dr Rainer Schmidt, F.Hoffmann-La Roche
Site Manager Kaiseraugst

Gert Moelgaard, NNE Pharmaplan
Vice President Strategy Development

Jörg Zimmermann, Vetter Pharma-Fertigung
Director Process Development and Implementation

Frank Studt, Chemgineering Business Design
General Manager

Dr Johannes Krämer, CSL Behring
Manager Engineering

Günter Körblein
Senior Consultant, Tetragon Consulting

Prof. Franz Maier
Former Manager Technology, Nycomed

The Location

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Emailus@swissotel-duesseldorf.de

The Fees

Charges for the one day tickets are € 690,- plus VAT (due to the special fees for the congress, ECA membership discounts are not applicable). These tickets allow you to attend any conference offered that day (you can also switch between the conferences any time). They include a lunch and beverages during the conferences and in breaks as well as the social event on the evening of the first congress day. Charges are payable after receipt of invoice. *(Please also see the information below)*

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 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.

Contacts

For questions regarding content:
ECA Conferences Continuous Manufacturing / Manufacturing of highly potent Materials / Single-Use Equipment and Applications:
Dr Robert Eicher (Operations Director), Phone +49 (0)6221 84 44 12,
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ECA Conferences Current Aseptic Processing / Barrier Systems – Regulations, Technology, New Developments; Case Studies
Dr Andreas Mangel (Operations Director), Phone +49 (0)6221 84 44 41,
E-Mail: mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation, exhibition etc.:
Detlef Benesch (Organisaton Manager), Phone +49 (0)6221 84 44 45,
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The Organiser

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ECA ACADEMY

PLEASE NOTE !

Exhibition Visit: The exhibition will also be open to visitors on both days who are not attending the Congress. Please be aware, though, that you will need to register in advance of the free of charge visit. The visitor registration will most likely be available on the website starting in March 2016.
The visit of the exhibition does not entitle you to also attend any of the conferences.

Congress Materials: 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.

Room Reservations: 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.

The Exhibition

2016 PHARMA CONGRESS PharmaTechnica DÜSSELDORF, 12 - 13 APRIL 2016

Parallel to the conferences on 12 and 13 April there will be the large exhibition PharmaTechnica.
Take advantage of this opportunity to get to know new technologies, products and services at the stands of the exhibitors. For that purpose there will be Live Demos integrated in some of the conferences again. These Live Demos will be conducted in the exhibition area. That way you will not only be introduced to technology in the conferences, but you will be able to touch and experience it. Get to know new concepts and technology – directly from leading companies. You will find the Live Demos in this programme under the respective conferences as well as on the Congress Website at www.pharma-kongress.com. There you will also find the daily updated exhibitor list.

Company	Stand
AFC Air Filtration & Containment	76
Agidens	54
Andocksysteme G. Untch	6
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ASEPTIC TECHNOLOGIES	64
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Belimed	53
Bilfinger Industrietechnik Salzburg	81
Borer Chemie	34
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Centec	62
Chemgineering	D8

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DEC Deutschland	19
DENSO Robotics	66
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Fedegari	42
F&M Lautenschläger	77

Company	Stand
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Franz Ziel	41
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Letzner Pharmawasseraufbereitung	24
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MK Versuchsanlagen	83
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Company	Stand
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Uhlmann Pac-Systeme	3
ViscoTec Pumpen- und Dosiertechnik	14
Hermann WALDNER	60
Watson-Marlow	80
West Pharmaceutical Services	51
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Speakers from authorities, industry organisations and from industry (as of January 2016)

Niels Alber	**Novartis Pharma Stein AG** Process Expert PU Vials
Deniz Alkanat	**ONKO iLAÇ San. ve Tic. A.S.** Production Group Manager at Onko Pharmaceuticals.
Niko Butscher	**Vetter Pharma-Fertigung GmbH & Co. KG** Head of Production filling dual chamber cartridges.
Marian Cebula	**Ipsen Manufacturing Ireland, Dublin** Chartered chemical engineer with 8+ years experience in API & biologics process development and manufacturing.
Dr Thomas Centner	**Sanofi** Head of Upstream Development at Sanofi in Frankfurt.
Dr Olivier Chancel	**Merial, Toulouse, France** Sterility Assurance Expert.
Prof Dr Thomas De Beer	**University of Ghent** Since 2010 professor in Process Analytics & Technology at the Faculty of Pharmaceutical Sciences at the University of Ghent.
James Drinkwater	**Chairman of PHSS, UK** Head of Aseptic processing technologies and GMP Compliance at F. Ziel, Germany.
Prof Dr Dieter Eibl	**Zürich University of Applied Science** Head of the department for Biotechnology and Cell Culture Technology.
Prof Regine Eibl	**Zürich University of Applied Science** Professor lecturing in biotechnology and cell cultivation techniques.
Dr Andreas Flückiger	**F. Hoffmann-La Roche** Head of the occupational health services of the Roche Group for almost 30 years.
Dr Friedrich Haefele	**Boehringer Ingelheim Pharma GmbH & Co. KG** Seit 2006 bei Boehringer Ingelheim am Standort Biberach Leiter der Biopharma Operations.
Martina Haertwig-Brandt	**Sanofi-Aventis Deutschland GmbH** Senior engineering project manager and responsible for planning and construction of pharmaceutical plants.
Dr Shawn D. Kinney	**Berskhire Sterile Manufacturing** President and CEO of Berkshire Sterile Manufacturing since 2014.
Dr Andreas König	**Aenova Group** Senior Vice President Corporate Quality & HSE.
Günter Körblein	**Tetragon Consulting GmbH** Senior Partner.
Dr Lars Kreye	**Boehringer Ingelheim Pharma GmbH & Co. KG** Director DPM / BP Fill & Finish.
Xavier LeSaout	**Merck** Associate Manager in the Biopharma Technology and Innovation group.
Dr Lorenz Liesum	**Novartis Pharma AG** Head of PAT (Global Pharma Engineering).
Dr Andreas Grummel	**Federal Institute for Drugs and Medical Devices (BfArM)** Senior quality assessor. He is member of the BfArM PAT group and member of the PDCO subgroup for paediatric formulations.
Dr Jean-Denis Mallet	**NNE Pharmaplan, Paris, France** Currently GMP Consultant, former GMP inspector and the Head of pharma inspections at Afssaps (France), Chair of the ECA Validation Working Group.
Gert Moelgaard	**NNE Pharmaplan** Vice President for Strategic Development.
Franck Pavan	**Pierre Fabre, Toulouse, France** Engineer in Biochemistry with more than 15 years experience in injection manufacturing and development for high potent and conventional products.
Dr Nuno Pereira	**GenIbet Biopharmaceuticals** Project Manager.
Dr Peter Pöchlauer	**Patheon** Innovation Manager.
Dr Beate Reutter	**Landesamt für soziale Dienste Schleswig-Holstein, Kiel, Germany** 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** Since 2014: Exclusive Representation of SiO2 Medical Products in Europe.
Tobias Schlögl	**Boehringer Ingelheim Pharma GmbH & Co. KG** Head of Drug Product Manufacturing I, where he is responsible for a vial and a syringe filling line and the central equipment preparation.
Tina Sostaric	**Teva Pharmaceuticals, Zagreb, Croatia** Responsible for sterile production on TEVA Zagreb site.
Dr Harald Stahl	**GEA** Group Director Application & Strategy Management.
Dr Clemens Stief	**Pfizer Manufacturing Deutschland GmbH** QP manufacturing for IMP and commercial products and responsible for the manufacture of solid dosage forms in a high containment area.
Dr Martin Tuckermann	**Baxter Oncology GmbH** Technical manager and senior project manager for the new PPE facility in Halle (Westfalen), Germany.
Patrick Vanhecke	**GlaxoSmithKline Vaccines, Belgium** In charge of Isolator and Aseptic Filling Technologies projects.
Thomas Zinn	**Sandoz AG, Schaftenau, Austria** Plant Head Bioinject in the Business Unit Sandoz Biopharmaceuticals.

Continuous Manufacturing

12 April 2016

Objectives

It is the aim of this conference to show how a transition from batch to continuous manufacturing in the pharmaceutical industry can look like. Questions regarding technology, process development and GMP/Quality Assurance will be discussed.

Background

Solid dosage forms are still the most common dosage form, first and foremost tablets without any pioneering developments in the recent years. But driven by only a few pharmaceutical companies more and more of the global players started to invest in continuous manufacturing. Companies like GSK, Pfizer; Johnson & Johnson and Vertex have been in the news in 2015. The latter one for receiving an FDA approval for it's continuously manufactured Cystic Fibrosis Drug.
A shift from batch to continuous manufacturing could be one of the largest paradigm changes since the system of validation & qualification came up years ago.
Regulating authorities, first of all the FDA, also encourage the transition from batch to continuous production. They expect an increase in product safety while equipment suppliers promote a decrease of production costs. But is this really the case? And, with a continuous mode of operation already answered questions raise again:

- How can batches be defined?
- How is a continuous system validated?
- How should deviations in a continuous process be handled?
- How can a preventive maintenance system look like?

Listen to companies who already did the transition and learn about advantages / disadvantages and how they answered the questions above.

Moderator

Günter Körblein, *Tetragon Consulting*

Target Audience

This conference is directed at decision makers and executives from the areas engineering and production and QA dealing with the question whether or how continuous manufacturing should be implemented.

Programme

09.00 – 10.00	 **Dr. Friedrich Haefele** *Boehringer Ingelheim Pharma*	**The upcoming Annex 1 and consequences for industry**
10.30 – 11.15	 **Günter Körblein** *Tetragon Consulting*	**Continuous Manufacturing of OSDs: What Offers the Market - Now?** ▪ Development Status of Continuous Manufacturing Technologies ▪ State-of-the art Suppliers for Continuous OSD-Technologies ▪ Processing Steps, Suitable Equipment and Missing Links ▪ Seamless System vs. Discrete Components
11.15 – 12.00	 **Dr. Andreas Grummel** *Federal Institute for Drugs and Medical Devices (BfArM)*	**Continuous Manufacturing seen from the viewpoint of a competent authority** ▪ Regulatory background ▪ Process development ▪ Manufacturing process ▪ Summary: pros and cons for continuous manufacturing (from a regulatory point of view)
13.30 – 14.15	 **Dr. Lorenz Liesum** *Novartis Pharma*	**Making PAT fit for Routine Commercial and Continuous Production** ▪ Looking back: 10 Years of QbD and PAT in Global Technical Production at Novartis Pharma ▪ Drivers and prerequisites for PAT highlighted by case examples: Quality, Business and Safety ▪ Differences between PAT applied for batch and continuous processes ▪ Case examples
14.15 – 15.00	 **Prof. Dr. Thomas De Beer** *University of Ghent*	**Investigation of twin screw granulation: integrating experimental and computational approaches** Twin-screw granulation (TSG) has emerged as a promising product design process for continuous wet granulation. A continuous manufacturing line with TSG is followed by a dryer, product control hopper and tabletting machine. A TSG achieves mixing and granulation by a complex interplay between the screw configuration and process settings.
15.45 – 16.30	 **Dr. Clemens Stief** *Pfizer*	**Case Study Pfizer: Established/Projected Continuous Manufacturing Operations for OSD products** ▪ PCMM (Portable Continuous Modular Manufacturing) – Concept (Business Justification) – Design – Manufacturing capabilities (Equipment Components, Process flow) – PAT Applications & Continuous Operation ▪ High Volume Continuous manufacturing @ Freiburg, Germany – Design incl. peripheral systems – Business justification
16.30 – 17.15	 **Dr. Peter Pöchlauer** *Patheon*	**Case Study Patheon: Implementation of continuous flow processes in cGMP environments** ▪ Drivers to implement continuous processes (financial, technical, logistics) ▪ Co-development of process and equipment - a multidisciplinary effort ▪ Integration of continuously operated equipment into existing cGMP equipment ▪ Quality aspects /analytical aspects

Agenda in the back of the programme. Content and times subject to change. Updates on the website at www.pharma-kongress.com.

Manufacturing of highly potent Materials

13 April 2016

Objectives

Main focus of this conference is on the connection of cGMPs with safety aspects, especially on avoiding cross contamination and minimizing exposure.

Background

Due to the increasing number of very potent and toxic ingredients the manufacture of pharmaceutical products is more and more becoming a challenge. In addition to the already well known safety requirements (employee protection) now also the GMP requirements on avoiding cross contamination play an increasing role when processes and facilities are designed. It is safe to say that the meaning of cross-contamination prevention during the handling of highly potent materials in multipurpose facilities gained a complete new dimension. This is especially true for the area of cleaning and cleaning validation.
But on the other hand, scientific data gained in industrial hygiene studies now can be used for GMP reasons for the first time. It is possible to argue that the cross contamination risk is well under control when the industrial hygienist does not find relevant product concentrations in the environment or on the employees.
This is risk management as it is required by the ICH guidelines and the updated chapters 3 and 5 of the EU GMP guide. Also manufactures who have to deal with the situation how to implement a new and potent product in an existing facility will have to use risk management tools to answer the question whether is possible or not.
The handling of highly potent material and the way risks have to be evaluated have changed in the pharmaceutical industry.

Moderator

Dr. Harald Stahl, *GEA*

Target Audience

Managers and technical experts from production, development and occupational health & safety, responsible for the manufacture and handling of highly potent materials. Also engineers who design, install and qualify containment facilities and systems.

Programme

08.30 – 09.30	 **Dr. Andreas König** Aenova Group	**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
10.00 – 11.30	 **Dr. Andreas Flückiger** *F. Hoffman-La Roche*	**Essentials for the manufacture of highly potent drugs** ▪ How worker protection and GMP work hand in hand ▪ Facilities adapted to the potency of the drugs ▪ OELs and OEBs as drivers for the containment ▪ Principles of establishing OELs and OEBs (... and PDEs for cleaning validation) ▪ Using containment monitoring data to help show control of cross-contamination
13.00 – 13.45	 **Deniz Alkanat** *ONKO-KOCSEL Pharmaceuticals*	**Case Study ONKO-KOCSEL Pharmaceuticals: The challenge of building new production capacities for highly potent products** ▪ Building of a new production site for highly potent drugs – Facility Design and selected equipment (isolators, transfer systems etc.) – Process Flows ▪ Case Study details – Preparation and Cleaning and of Equipment before/after working with HighPo substances – Prior opinion of staff for working with HighPo's – Nocebo Effect – Searching for HigPo chemical tracees with blood tests – Measuring exposure levels; methods, risk analysis
13.45 – 14.30	 **Martina Haertwig-Brandt** *Sanofi-Aventis Deutschland*	**Case Study Sanofi-Aventis: Transfer of Oncology Products** ▪ Shut down of a production site and transfer of the production to other sites ▪ Integration of oncology products in an existing pharmaceutical production building ▪ Transfer steps and schedule ▪ Compounding area: Containment technology and explosion hazard area ▪ Handling of wastes and spillages
15.00 – 15.45	 **Dr. Clemens Stief** *Pfizer*	**Case Study Pfizer: Operation of a plant for highly potent OSD products** ▪ Cleaning of equipment and premises ▪ Waste handling (solids, liquids, air, used equipment) ▪ Procedures in case of accidents ▪ Minimising cross contamination: Usage of industrial hygiene data for GMP argumentations
15.45 – 16.30	 **Dr. Martin Tuckermann** *Baxter Oncology*	**Case Study Baxter Oncology: Quality consolidation by standardization of aseptic processing of highly active products with isolator technology** A new facility for processing of highly active products was built in Halle, Westfalen. It combines requirements of aseptic processing, containment of toxic substances and transparent fab design. Baxter own products will be manufactured here as well as a wide variety of aseptically and toxically challenging oncology (anti-cancer) products, which require in the scope of contract manufacturing a high degree of flexibility. The focus of this case study is how quality achievements can be consolidated by a high degree of standardization of aseptic processing in an isolator environment. The core process is kept extremely tight with zero variance at aseptically critical steps, and elsewhere, maximum flexibility is desired to accommodate for a wide set of different requirements.

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.

Moderator

Gert Moelgaard, *NNE Pharmaplan*

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.

Programme

09.00 – 10.00	 **Dr. Friedrich Haefele** *Boehringer Ingelheim Pharma*	**The upcoming Annex 1 and consequences for industry**
10.30 – 11.15	 **Dr. Beate Reutter** *Landesamt für soziale Dienste Schleswig-Holstein*	**Revision of Annex 1 – a short overview** ▪ New structure ▪ Need for clarification ▪ More guidance ▪ harmonisation
11.15 – 12.00	 **Dr. Jean-Denis Mallet** *NNE Pharmaplan*	**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 / Monitoring of the environment – Machine maintenance & operation / Materials management / Metrology – Men training ▪ Basis for a future parametric release?
13.30 – 14.15	 **Dr. Olivier Chancel** *Merial*	**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
14.15 – 15.00	 **Prof. Dr. Siegrid Saaler-Reinhardt** *Midas Pharma*	**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.
15.45 – 16.30	 **Alessandro Massignani** *Nuova Ompi*  **Dr. Shawn D. Kinney** *Berkshire Sterile Manufacturing*	**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
16.30 – 17.15	 **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** *Gerflor* ▪ **Functionality and application options of magnetic agitators** *Zeta Biopharma* ▪ **Specialised Robot for the pharmaceutical and medicinal industries** *DENSO Robotics Europe* ▪ **Finished product inspection applications for laser-based headspace** *Lighthouse Instruments*

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.

Moderator

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

Target Audience

The event is directed at decision-makers from pharmaceutical industry and suppliers from Production, Engineering, Research & Development and Quality Assurance who need to be well informed about current developments in the field of single use technology.

Programme

08.30 – 09.30	 **Dr. Andreas König** Aenova Group	**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
10.00 – 10.45	 **Prof. Regine Eibl** *Zürich University of Applied Science*	**Single-Use Technology in biopharmaceutical production: An overview from USP to Fill&Finish technologies** ▪ Categorisation of available single-use systems ▪ Disposables in Upstream-Processing ▪ Disposables in Downstream-Processing ▪ Disposables in formulation and filling ▪ Freeze technology ▪ Hybrid/closed technology platforms
10.45 – 11.30	 **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** *Bosch* ▪ **Connecting, disconnecting and reconnecting for sterile fluid transfer** *Merck* ▪ **Point-of-use leak testing** *Pall BioPharmaceuticals* ▪ **TBN** *SIEMENS*
13.00 – 13.45	 **Dr. Thomas Centner** *Sanofi*	**Case Study Sanofi: Bioproduction with SU equipment – Points to consider from End-to-End**
13.45 – 14.30	 **Niels Alber** *Novartis Pharma*	**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
15.00 – 15.45	 **Xavier LeSaout** *Merck*	**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 vs. current established fed-batch platform.
15.45 – 16.30	 **Dr. Nuno Pereira** *GenIbet Biopharmaceuticals*	**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?

Regulations / Technology / New Developments

12 April 2016

Objectives

This is why you will benefit from attending this conference:

- 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 get to know first hand the new EU-GMP Annex 1 draft requirements on Barrier Systems
- Experts from pharmaceutical companies will share their knowledge regarding operational experience.

Background

The protection against microbial contamination is the most important point for drugs produced by aseptic processes. The classical clean-room cannot be considered as state of the art any longer, though – especially with regard to new facilities for sterile manufacturing. Today the supervisory authorities require a more strict separation between operators and product in the form of an access barrier.

Two systems are on the market – RABS (Restricted Access Barrier System) and Isolators. But only isolators are referred to by the US FDA as advanced aseptic technology.

This conference will focus on current questions of barrier systems coming from FDA Aseptic Guide requirements as well as from the new EU-GMP Annex 1, and it will specifically address the subject from the perspectives of pharmaceutical operators, planners and engineers.

Moderator

Dr. Friedrich Haefele, *Boehringer Ingelheim Pharma*

Target Audience

This event is directed at decision-makers from pharmaceutical production, development and quality assurance/control. It also addresses engineers and planners who need to be well informed about current developments in the field of barrier systems.

Programme

12. April 2016

09.00 – 10.00	 **Dr. Friedrich Haefele** *Boehringer Ingelheim Pharma*	**The upcoming Annex 1 and consequences for industry**
10.30 – 11.15	 **James Drinkwater** *Chairman of PHSS*	**Different process solutions for Aseptic Filling of multiple products** ▪ Principle requirements of a Control Strategy for manufacture of sterile medicinal products ▪ Balancing the conflicts of GMP with containment ▪ Filling of multiple products considering facility and equipment design – case study example ▪ Principle specification requirement (facility and equipment design) for – Aseptic Filling of non-hazardous sterile products – Aseptic Filling of Toxic sterile products – Aseptic Filling of Bio-hazard sterile products
11.15 – 12.00	 **Niko Butscher** *Vetter Pharma-Fertigung*	**Case study: Improved RABS: Update on implementation of room decontamination using H_2O_2** ▪ Design of the "improved RABS-Concept" ▪ Quality aspects ▪ Implementation into a new clean room ▪ Challenges and advantages ▪ Case Study
13.30 – 14.15	 **Patrick Vanhecke** *GSK Vaccines*	**Case Study: Isolator Technology – New development in H_2O_2 sterilization / decontamination process** ▪ H_2O_2 process Comparison between VHP and nebulization process ▪ Cycle time improvement ▪ Catalytic converter ▪ New VDI guideline for a standardized material assessment
14.15 – 15.00	 **Live Demos**	In the practical part of the conference on 12th April 2016, suppliers will show you different components and solutions in relation to Barrier Systems. You will come in contact with the equipment and you have the chance to discuss your questions immediately with technology experts. ▪ **Glove Integrity Test in Isolators from Inside to Outside for Intermediate Verification During Campaign Filling** *Ziel* ▪ **Glove Management: GITS® LifeCycle Tracking - an industry 4.0 smart factory approach** *MK Versuchsanlagen* ▪ **Standalone H_2O_2 Decontaminations system RG4 C for replacement or retrofitting purpose** *Metall + Plastic*
15.45 – 16.30	 **Dr. Beate Reutter** *Landesamt für soziale Dienste Schleswig-Holstein*	**Barrier Systems – a new standard for aseptic processing?** ▪ Need for change in current EU-GMP-Annex 1 ▪ Inspector's observations and findings ▪ Implementation of risk management ▪ Annex 1 revision status: what to expect

Case Studies

13 April 2016

16.30 – 17.15	 **Patrick Vanhecke** *GSK Vaccines*	**E-beam technology for material transfer in isolator** ▪ Scope of the process ▪ E-beam tunnel design ▪ E-beam tunnel suppliers overview ▪ Case study: E-beam technology in GSK Vaccines ▪ E-beam tunnel validation ▪ Return of experience

Programme 13. April 2016

Congress Key Note 08.30 – 09.30	 **Dr. Andreas König** Aenova Group	**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
10.00 – 10.45	 **Tina Sostaric** *Teva Pharmaceuticals*	**Case study: Fully automated syringe line under isolator** ▪ Description of the key milestones of the project – lesson learned ▪ Isolator concept / zone concept / pressure concept ▪ Transfer of the tub to Isolator and opening ▪ Filling system and use of disposables
10.45 – 11.30	 **Thomas Zinn** *Sandoz*	**Case Study: Filling line for „ready to use syringes“ in Isolator technology** ▪ Factory concept & layout ▪ Sterilisation systems (VHP decontamination, inline CIP/SIP) ▪ Introducing Tubs using eBeam radiation ▪ Denesting the syringes in zone A enabling 100% weight check ▪ Qualification of an Isolator (e.g. smoke studies)
13.00 – 13.45	 **Dr. Lars Kreye** *Boehringer Ingelheim Pharma*	**Case study: Implementing a mid-size isolator filling line** ▪ Approach for setting up the line ▪ Design (rationales) ▪ Features ▪ Regulatory aspects
13.45 – 14.30	 **Franck Pavan** *Pierre Fabre*	**Case study: Handling and manufacturing High Potent products using Isolators** ▪ Constraints in High potent products ▪ Isolator technology innovations ▪ Qualification and monitoring of isolators in high potent liquid or freeze dried products ▪ Investments and fixed costs of isolators
15.00 – 15.45	 **Marian Cebula** *Ipsen Manufacturing*	**Case Study: Use of liquid nitrogen in isolator for flash freeze drying of potent compound** ▪ liquid nitrogen system was retrofitted to an existing freeze dryer equipped with isolator ▪ Number of ergo trials were executed to design the process ▪ KAIZEN study was performed to fine tune the process and improve operator's comfort ▪ Project resulted in successful validation campaign
15.45 – 16.30	 **Tobias Schlögl** *Boehringer Ingelheim Pharma*	**Case Study: Implementation and qualification of a stopper transfer via DPTE-Port** ▪ Design of an aseptic transfer process of RTS-stoppers in Port-Bags ▪ Creation of documents e.g. batch record ▪ Qualification, training of operators, adaption of SOPs and monitoring ▪ Storage and usage in clean room area

Programme

12 April 2016

Time	ECA – Trends in Manufacturing Continuous Manufacturing	ECA – Current Aseptic Processing Current Aseptic Technologies	ECA – Barrier Systems Regulations/Technology/ New Developments	Time
9.00 Uhr 9:15 Uhr 9.30 Uhr 9:45 Uhr	Congress Key Note The upcoming Annex 1 and consequences for industry *Dr Friedrich Haefele, Boehringer Ingelheim Pharma*			9.00 Uhr 9:15 Uhr 9.30 Uhr 9:45 Uhr
10.00 Uhr 10:15 Uhr	Break			10.00 Uhr 10:15 Uhr
10.30 Uhr 10:45 Uhr 11.00 Uhr	Continuous Manufacturing of OSDs: What Offers the Market - Now? *Günter Körblein, Tatragon Consulting*	Revision of Annex 1 – a short overview *Dr Beate Reutter, Landesamt für soaziale Dienste Schleswig-Holstein*	Different process solutions for Aseptic Filling of multiple products *James Drinkwater, Chairman PHSS*	10.30 Uhr 10:45 Uhr 11.00 Uhr
11:15 Uhr 11.30 Uhr 11:45 Uhr	Continuous Manufacturing seen from the viewpoint of a competent authority *Dr Andreas Grummel, Federal Institute for Drugs and Medical Devices (BfArM)*	The 99 parameters for an aseptic release *Dr Jean-Denis Mallet, NNE Pharmaplan*	Case study: Improved RABS: Update on implementation of room decontamination using H_2O_2 *Niko Butscher, Vetter Pharma-Fertigung*	11:15 Uhr 11.30 Uhr 11:45 Uhr
12.00 Uhr 12:15 Uhr 12.30 Uhr 12:45 Uhr 13.00 Uhr 13:15 Uhr	Lunch Break			12.00 Uhr 12:15 Uhr 12.30 Uhr 12:45 Uhr 13.00 Uhr 13:15 Uhr
13.30 Uhr 13:45 Uhr 14.00 Uhr	Making PAT fit for Routine Commercial and Continuous Production *Dr Lorenz Liesum, Novartis Pharma*	Ten lessons learned in sterility assurance *Dr Olivier Chancel, Merial*	Case Study: Isolator Technology - New development in H_2O_2 sterilization / decontamination process *Patrick Vanhecke, GSK Vaccines*	13.30 Uhr 13:45 Uhr 14.00 Uhr
14:15 Uhr 14.30 Uhr 14:45 Uhr	Investigation of twin screw granulation: integrating experimental and computational approaches *Prof Dr Thomas De Beer, University of Ghent*	Innovative Primary Packaging: Inner barrier coating prevents contamination of drug products with potential impurities from plastic primary packaging, a case study *Prof Dr Siegrid Saaler-Reinhardt, Mmidas Pharma*	Live Demos	14:15 Uhr 14.30 Uhr 14:45 Uhr
15.00 Uhr 15:15 Uhr 15.30 Uhr	Break			15.00 Uhr 15:15 Uhr 15.30 Uhr
15:45 Uhr 16.00 Uhr 16:15 Uhr	Case Study Pfizer: Established/Projected Continuous Manufacturing Operations for OSD products *Dr Clemens Stief, Pfizer*	The Development of an Isolator Based Flexible Filling System for all Containers *Alessandro Massignani, Nuova Ompi* *Dr Shawn D. Kinney, Berkshire Sterile Manufacturing*	Barrier Systems – a new standard for aseptic processing? *Dr Beate Reutter, Landesamt für soziale Dienste Schleswig-Holstein*	15:45 Uhr 16.00 Uhr 16:15 Uhr
16.30 Uhr 16:45 Uhr 17.00 Uhr	Case Study Patheon: Implementation of continuous flow processes in cGMP environments *Dr Peter Pöchlauer, Patheon*	Live Demos	E-beam technology for material transfer in isolator *Patrick Vanhecke, GSK Vaccines*	16.30 Uhr 16:45 Uhr 17.00 Uhr
17:15 Uhr 17.30 Uhr	Discussion	Discussion	Discussion	17:15 Uhr 17.30 Uhr
18.00 Uhr	Social Event for Congress Delegates, Speakers and Exhibitors			18.00 Uhr

Programme

13 April 2016

Time	ECA – Trends in Manufacturing Manufacturing of highly potent Materials	ECA – Aseptic Processing Single-Use Equipment and Applications	ECA – Barrier Systems Case Studies	Time
8.30 Uhr 8.45 Uhr 9.00 Uhr 9:15 Uhr	Congress Key Note How to measure performance in pharmaceutical production – a case study *Dr. Andreas König, Aenova Group*			8.30 Uhr 8.45 Uhr 9.00 Uhr 9:15 Uhr
9.30 Uhr 9:45 Uhr	Break			9.30 Uhr 9:45 Uhr
10.00 Uhr 10:15 Uhr 10.30 Uhr	Essentials for the manufacture of highly potent drugs *Dr Andreas Flückiger, F. Hoffmann-La Roche*	Single-Use Technology in biopharmaceutical production: An overview from USP to Fill&Finish technologies *Prof Regine Eibl, Zürich University of Applied Science*	Case study: Fully automated syringe line under isolator *Tina Sostaric, Teva Pharmaceuticals*	10.00 Uhr 10:15 Uhr 10.30 Uhr
10:45 Uhr 11.00 Uhr 11:15 Uhr		Live Demos	Case study: Filling line for „ready to use syringes“ in Isolator technology *Thomas Zinn, Sandoz*	10:45 Uhr 11.00 Uhr 11:15 Uhr
11.30 Uhr 11:45 Uhr 12.00 Uhr 12:15 Uhr 12.30 Uhr 12:45 Uhr	Lunch Break			11.30 Uhr 11:45 Uhr 12.00 Uhr 12:15 Uhr 12.30 Uhr 12:45 Uhr
13.00 Uhr 13:15 Uhr 13.30 Uhr	Case Study ONKO-KOCSEL: The challenge of building new production capacities for highly potent products *Deniz Alkanat, ONKO-KOCSEL Pharmaceuticals*	Case Study Sanofi: Bioproduction with SU equipment – Points to consider from End-to-End *Dr Thomas Centner, Sanofi*	Case study – implementing a mid-size isolator filling line *Dr Lars Kreye, Boehringer Ingelheim Pharma*	13.00 Uhr 13:15 Uhr 13.30 Uhr
13:45 Uhr 14.00 Uhr 14:15 Uhr	Case Study Sanofi-Aventis: Transfer of Oncology Products *Martina Haertwig-Brandt, Sanofi-Aventis*	Case Study Novartis Pharma: Single Use equipment for Fill/Finish *Niels Alber, Novartis Pharma*	Case study: Handling and manufacturing High Potent products using Isolators *Franck Pavan, Pierre Fabre*	13:45 Uhr 14.00 Uhr 14:15 Uhr
14.30 Uhr 14:45 Uhr	Break			14.30 Uhr 14:45 Uhr
15.00 Uhr 15:15 Uhr 15.30 Uhr	Case Study Pfizer: Operation of a plant for highly potent OSD products *Dr Clemens Stief, Pfizer*	Case Study Merck: Continuous operations in Biopharm Manufacturing: Back to the Future *Xavier LeSaout , Merck*	Case Study: Use of liquid nitrogen in isolator for flash freeze drying of potent compound *Marian Cebula, Ipsen Manufacturing*	15.00 Uhr 15:15 Uhr 15.30 Uhr
15:45 Uhr 16.00 Uhr 16:15 Uhr	Case Study Baxter Oncology: Quality consolidation by standardization of aseptic processing of highly active products with isolator technology *Dr Martin Tuckermann, Baxter Oncology*	Case Study GenIbet Biopharmaceuticals: The Challenge of Using Single-Use Materials in Virus Production *Dr Nuno Pereira, GenIbet Biopharmaceuticals*	Case study: Implementation and qualification of a stopper transfer via DPTE-Port *Tobias Schlögl, Boehringer Ingelheim Pharma*	15:45 Uhr 16.00 Uhr 16:15 Uhr
16.30 Uhr 16:45 Uhr	Discussion	Discussion	Discussion	16.30 Uhr 16:45 Uhr
17.00 Uhr				17.00 Uhr

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(Includes participation in any conference on that day and the visit of the exhibition, and, in addition, lunch and beverages during the conferences and in breaks as well as the social event on the evening of the first congress day (one day ticket for the 12 April. Please mark if you would like to attend the Social Event.)

With a one day ticket you can attend any conference offered that day. To be able to prepare the conference rooms, though, we would appreciate it if you marked the conference you are interested in addition to marking the day you plan on attending the Congress. Please mark only one conference per day.

☐ **Day 1 (12 April 2016)**: I would like to attend the Congress on day 1. I'm primarily interested in the conference:

- ☐ ECA – Continuous Manufacturing
- ☐ ECA – Current Aseptic Technologies
- ☐ ECA – Barrier Systems: Regulations / Technology / New Developments

☐ I would also like to take part in the Social Event on the evening of 12 April 2016.

☐ **Day 2 (13 April 2016):** I would like to attend the Congress on day 2. I'm primarily interested in the conference:

- ☐ ECA – Manufacturing of highly potent Materials
- ☐ ECA – Single-Use Equipment and Applications
- ☐ ECA – Barrier Systems: Case Studies

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- 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.

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