Premium Sponsor

MERCK

With more than 30 Speakers... from Authorities

Dr Daniel Müller
GMP Inspector, Regierungspräsidium Tübingen

Dr Arno Terhechte
GMP Inspector, Bezirksregierung Münster

from Universities and Industry:

Dr Jaya Abraham
Head of Generic Formulation, Packaging and IP Development, Torrent Pharmaceuticals

Lawrence de Belder
Sen. Principal Engineer Continuous Manufacturing, Janssen

Daniel O. Blackwood
Technical Program Lead, PCM&M Development and Manufacturing Initiative for OSD, Pfizer

Dr Norbert Gerling
Head of Pharmaceutical Production, Vetter Pharma-Fertigung

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

Dr Stephen Hilton
UCL School of Pharmacy London

Dr Philip Hörsch
Director QA, Vetter Pharma-Fertigung

Dr Andreas Liebminger
Head Biophysical Science & Mfg Support, Baxalta Innovations

Nuno Matos
Head Continuous Manufacturing, Hovione

Dr Martin Schubert
Senior Director / Head of Drug Delivery Design & Development, UCB Pharma

Dominique Sierakowski
Head of Pharmaceutical Production, Octapharma

Frank Streil
Director Technical and Scientific Affairs, TEVA

Patrick Vanhecke
Expert Isolator and Aseptic Filling Technologies & Room Decontamination, GSK Vaccines

Jörg Zimmermann
Vice President Vetter Development Services, Vetter Pharma-Fertigung

Dr Stephan Zinzen
Head of Research & Development, AqVida

... and many others

CONCEPT HEIDELBERG

Pharmaceutical Quality
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2017 PHARMA CONGRESS

Production & Technology

DÜSSELDORF, 28 - 29 MARCH 2017

network. experience. benefit.

- **ECA – Trends in Manufacturing**
- **ECA – Aseptic Processing**
- **ECA – Regulatory Trends**

Image: Gedeon Richter

The Pharma Congress Overview

The guiding theme of the 19th Pharma Congress on 28/29 March 2017 will be again "users report for users". And speakers will report again about the challenges in their everyday business and about possible solution approaches. As a Congress delegate you will therefore benefit from the experience of your colleagues as well as from the direct information exchange. For that purpose you can choose from presentations in six conferences in three subject areas.

Pharma Congress – Overview

Congress Key Note

Key Note 28 March

The future of Pharmaceutical manufacturing: Flexibility and sustainability through small footprint, modular equipment trains

Daniel O. Blackwood, Technical Program Lead, PCM&M Development and Manufacturing Initiative for OSD, Pfizer

Key Note 29 March

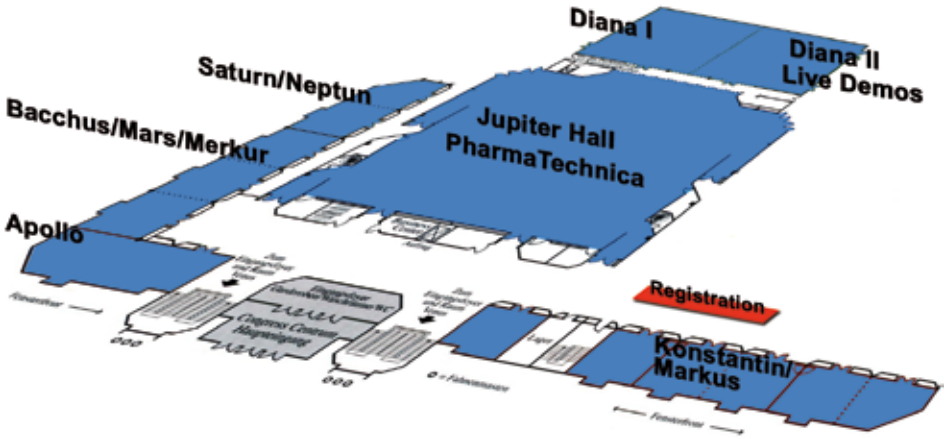
Trends in the pharma market and sterile dosage forms

Jörg Zimmermann, Vice President Vetter Development Service, Vetter Pharma-Fertigung

Conferences (One Day Ticket 690,- EUR)	28 March 9:00–17.45 h	29 March 8:30–17:00 h
ECA - Trends in Manufacturing		
Continuous Manufacturing	✓	
Technology Trends		✓
ECA - Aseptic Processing		
Current Aseptic Technologies	✓	
Barrier Systems		✓
ECA - Regulatory Trends		
Manufacturing Data Integrity	✓	
Revision of EU Annex 1		✓
Exhibition PharmaTechnica	✓	✓

For a complete schedules of the single conferences please see the last pages of this programme. Time schedule updates will be available on the Congress website at www.pharma-kongress.com.

The Room Plan



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, Moelgaard Consulting
Consultant

Jörg Zimmermann, Vetter Pharma-Fertigung
Vice President Vetter Development Service

Frank Studt, Chemgineering Business Design
General Manager

Dr Johannes Krämer, CSL Behring
Manager Engineering

Günter Körblein, Tetragon Consulting
Senior Consultant, Pharmaceutical Technology

Prof. Franz Maier
Former Manager Technology, Nycomed

The Exhibition

2017 PHARMA CONGRESS PharmaTechnica DÜSSELDORF, 28 - 29 MARCH 2017

Parallel to the conferences on 28 and 29 March 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.

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 Location

Swissôtel Congress Centrum Düsseldorf / Neuss
Rheinallee 1
41460 Neuss
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
emailus.neu02@gchhotelgroup.com

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 28 March 2017, 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 Trends in Manufacturing – Continuous Manufacturing / Technology Trends:
Dr Robert Eicher (Operations Director), Phone +49 (0)6221 84 44 12,
E-Mail: eicher@concept-heidelberg.de.

ECA Aseptic Processing – Current Aspetic Technologies / Barrier Systems; ECA Regulatory Trends – Manufacturing Data Integrity / Revision of EU Annex 1:
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,
E-Mail: benesch@concept-heidelberg.de;
Ronny Strohwald (Organisaton Manager), Phone +49 (0)6221 84 44 51,
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The Organiser

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www.gmp-navigator.com

ECA Academy Your GMP/GDP Information Source

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 early March 2017. 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 PharmaTechnica exhibitors – for a daily updated exhibitor list please visit www. pharma-kongress.com.

Company	Stand
AFC Air Filtration & Containment	75
Agidens	38
Albrecht	53
Andocksysteme G. Untch	5
Antares Vision	31
Bausch & Ströbel	1
Beckman Coulter	D4
Belimed	58
Bilfinger Industrietechnik Salzburg	81
BLOCK	19
Borer Chemie	34
castus	62
Chemgineering	77
Chemische Fabrik Dr. Weigert	57
COLANAR	6
COMECER GROUP	30
Concept GMP Engineering	49
Drees & Sommer Carpus & Partner	12
DÜPERTHAL SICHERHEITSTECHNIK	72
Ellab	17
Fette Compacting Glatt Uhlmann Pac-Systeme	3
Fedegari	11
FPS Food and Pharma Systems	66
Franz Ziel	41
GEA Group	16
gempex	D6
GEMÜ Gebr. Müller	35
Gerflor	46
GETINGE La Calhène	27
Groninger	40
Hamilton Bonaduz	4
HAMO / Amsonic Deutschland	76
Harro Höfliger	2
Harter Oberflächen- und Umwelttechnik	18
Hecht Automatisierungs-Systeme	10
HENKEL Beiz- und Elektropoliertechnik	32
Heuft Systemtechnik	78
HOF Sonderanlagenbau	79
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Industrie Montage-Service Ichtershausen	D3
io-consultants	43
Kinetics Germany	23
Letzner Pharmawasseraufbereitung	24

Company	Stand
Lighthouse Instruments	D5
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Mankenberg	13
Martin Christ Gefriertrocknungsanlagen	59
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MERCK	70
Midas Pharma	60
MK Versuchsanlagen	82
MMM Münchner Medizin Mechanik	33
multivac Sepp Haggenmüller	39
M+W Central Europe	8
NARA Machinery	55
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OPTIMA pharma	52
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PMT Partikel-Messtechnik	37
rap.ID Particle Systems	21
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Schneider Electric Systems Germany >EUROTHERM<	63
SCHOTT	45
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Steriline	25
Steris	D2
Sturtevant	64
Telstar Life Sciences	26
Testo Industrial Services	36
ViscoTec Pumpen- u. Dosiertechnik	14
Hermann WALDNER	9
Watson-Marlow	42
West Pharmaceutical Services	51
WILCO	22
WORK Microwave	D1
Zeppelin Power Systems	74
ZETA Biopharma	69

Premium Sponsor

Speakers from authorities, industry organisations and from industry (as of November 2016)

Dr Jaya Abraham	**Torrent Pharmaceuticals** Head of Generic Formulation, Packaging and IP Development.
Lawrence de Belder	**Janssen** Senior Principal Engineer Continuous Manufacturing.
Daniel O. Blackwood	**Pfizer** Technical program lead for Pfizer's Portable, Continuous, Miniature, and Modular (PCM&M) development and manufacturing initiative for Oral Solid Dosage (OSD).
Dr Olivier Chancel	**Merial, Toulouse, France** Sterility Assurance Expert.
Dr Norbert Gerling	**Vetter Pharma-Fertigung** Director of Pharmaceutical Production.
Dr Friedrich Haefele	**Boehringer Ingelheim Pharma GmbH & Co. KG** Vice President BP Fill & Finish Germany.
Robert Hahnraths	**Grünenthal GmbH, Aachen** Since 2013 in Global Computerized Systems Validation QA.
Dr Stefan Henke	**Innovative Injektions-Systeme GmbH & Co.KG** Managing Director.
Dr Stephen Hilton	**UCL School of Pharmacy London** Senior Lecturer.
Dr Philip Hörsch	**Vetter Pharma-Fertigung GmbH & Co. KG** Director Quality Assurance.
Matt Kessler	**MSD Werthenstein BioPharma** Associate Principal Scienties.
Arjan Langen	**MSD, The Netherlands** Pharmaceutical Specialist, responsible for sterile manufacturing of new products in Oss.
Wolfgang Lau	**Roche Diagnostics GmbH** Project manager at the site engineering department.
Dr Andreas Liebminger	**Baxalta Innovations GmbH, Wien** Head of Biophysical Science & Mfg Support within Formulation & Fill/Finish.
Nuno Matos	**Hovione SA** Head of Continuous Manufacturing within R&D.
Dr Norbert Matzanke	**Ferring GmbH, Kiel** Project manager – planning and realizing a new filling line with isolator technique.
Dr Bob McDowall	**R.D.McDowall Limited, Bromley, Kent, UK** Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry.
Didier Meyer	**DMCompliance** Consultant.
Gert Moelgaard	**Moelgaard Consulting, Lyngby, Denmark** Consultant. Chairman of ECA Validation Interest Group.
Henri Motte	**UCB Pharma S.A.** Heading the pilot plant.
Dr Daniel Müller	**Leitstelle Arzneimittelüberwachung Baden-Württemberg, RP Tübingen** Leiter des GMP-Inspektorats. Mitglied der EFG „Biotechnologie und Gewebe" sowie „Qualitätssicherung".
Yves Samson	**Kereon AG, Basel, Switzerland** Chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5.
Hartmut Schaz	**NNE Pharmaplan GmbH** Responsible for planning and commissioning of pharmaceutical fill & finish plants in more than 15 countries.
Dr Martin Schubert	**UCB Pharma S.A.** Senior Director / Head of Drug Delivery Design & Development.
Dr Wolfgang Schumacher	**formerly F. Hoffmann-La Roche Ltd., Switzerland** Chairman of the ECA IT Compliance Interest Group.
Dominique Sierakowski	**Octapharma SAS, Lingolsheim, France** Head of Corporate Pharmaceutical Production.
Alexandra Stärk	**Novartis Pharma AG, Basle, Switzerland** Currently responsible for the microbiological QA and QC.
Dr Harald Stahl	**GEA** Group Director Application & Strategy Management.
Frank Streil	**TEVA** Director Technical and Scientific Affairs.
Dr Arno Terhechte	**Bezirksregierung Münster** Inspector. He is member of the German expert group 11 "computerised systems".
Christian Urban	**Vetter Pharma-Fertigung GmbH & Co. KG** Responsible for the process validation of new products.
Michael Van den Bossche	**NNE Pharmaplan** part of the NNE Pharmaplan process team where he provides consulting services as a process specialist.
Patrick Vanhecke	**GSK Vaccines, Belgium** Expert in Isolator and Aseptic Filling Technologies and Room decontamination process.
Jacqueline Vu	**NNE Pharmaplan** Global Technology Partner OSD.
Dr Ildiko Ziegler	**Gedeon Richter Plc.** Validation expert, specialised in cleaning and process validation as well as in risk analysis.
Jörg Zimmermann	**Vetter Pharma-Fertigung GmbH & Co. KG** Vice President Development Services.
Dr Stephan Zinzen	**AqVida GmbH, Hamburg** Since 2010 managing partner of benavis GmbH and Head of Research & Development at AqVida.

Continuous Manufacturing

28 March 2017

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 lately. 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 does a continuous line look like?
- How can batches be defined?
- What risks does a continuous process involve?
- How is a continuous system validated?
- How should deviations in a continuous process be handled?

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, production and QA dealing with the question whether or how continuous manufacturing should be implemented.

Programme

Complete Key Note

Daniel O. Blackwood
Technical Program Lead PCM&M Development and Manufacturing Initiative for OSD, Pfizer

The future of Pharmaceutical manufacturing: Flexibility and sustainability through small footprint, modular equipment trains

- Current and emerging technologies in primary and secondary manufacturing (focus on non-biologic / small molecules)
- Continuous and semi-continuous (hybrid) operations

Michael Van den Bossche
NNE Pharmaplan

A risk based approach to implement CM for OSD

- Tech transfer: From batch to commercial scale CM (DoE, Registration batches, ...)
- Comparing CM unit operation technologies (dosing, blending, granulation, compression, coating)
- Define control strategy based on RMS (link CPP & CQA's, PAT, track & tracing)
- Examples of CM being implemented & lessons learnt

Lawrence de Belder
Janssen

Case Study Janssen: The Janssen Roadmap to Continuous Manufacturing

- Different designs for different purposes
- The need for Harmonization
- How Harmonization could benefit the complete Industry

Dr Martin Schubert
UCB Pharma

Case Study UCB Pharma

- Concept
- Technology
- Experience
- Outlook

Nuno Matos
Hovione

Case Study Hovione: A Platform Approach to Continuous Manufacturing

- The continuous manufacturing initiative at Hovione
- Built-in flexibility for multi-purpose lines
- Enabling continuous through QbD & PAT

Frank Streil
TEVA

Case Study TEVA: Continuous manufacturing of direct compression tablets

- Process and Equipment Design
- Implementation of CM in commercial manufacturing
- Benefits in commercial operation

Image: TEVA

Technology Trends

29 March 2017

Objectives

This conference aims at giving you an overview of new manufacturing and equipment trends coming up in the pharmaceutical industry, with focus on OSD manufacturing.

Background

The pharmaceutical industry is not known for its high innovativeness. Yet, taking a closer look reveals that there are some interesting trends: Manufacturing processes and technologies have been changing in the past years and will continue to change. Also, although the number of block busters is decreasing, niche busters may not take their place, but are on the rise and receive more and more attention from the industry. These further do not only require much more flexible processes – they already start during process development. Moreover the rise of highly potent molecules coming out of the development is also still a trend in the pharmaceutical industry, which even gained in importance due to the regulatory changes caused by the EMA guide on setting health based exposure limits.

Moderator

Dr. Harald Stahl, *GEA*

Target Audience

Target group of this conference are specialists and executives from pharmaceutical companies and equipment suppliers, dealing with the evaluation, selection and implementation of new equipment, mainly in the field of OSD manufacturing.

Programme

Jörg Zimmermann
VP Development Service, Vetter Pharma-Fertigung

Trends in the pharma market and sterile dosage forms
- Megatrends influencing the pharma market
- Market shares and developments in sterile dosage forms
- Strategies to support patient compliance and convenience
- PENs, Autoinjectors, Safety Devices
- Subcutaneous delivery: patch pumps etc.
- Polymer Syringes
- Needle-less systems
- Conclusions

Dr Harald Stahl
GEA

Nichebusters – Fad or the future?
- Market trend towards smaller volumes?
- Does smaller volume always mean higher value?
- Need for different technologies?
- Case stories

Dr Jaya Abraham
Torrent Pharmaceuticals

Case Study Torrent Pharmaceuticals: Solid Lipid Nano particles
- Intranasal Drug delivery of Solid Lipid Nanoparticles
- Design Rationale & unmet clinical needs
- Design & research methodology
- POC in animals

Dr Stephen Hilton
UCL School of Pharmacy London

3D Printing for the Pharmaceutical Industry: A Novel Platform for Drug Development and Delivery
- Introduction to 3D Printing
- Applications of 3D Printing within a laboratory setting
- Development of New Manufacturing Routes
- Lowering the Development Cost of Novel Plastics for Biomedical Applications
- Novel Methods for Drug Delivery using 3D printing

Dr Stefan Henke
LTS/IIS

New Technologies for Transdermal and Parenteral Drug Delivery
- LTS/IIS
- Situation
- Needlefree Injection of liquids
- Microneedle Systems
- From vision into reality
- Summary

Dr Ildiko Ziegler
Gedeon Richter

Case Study Gedeon Richter: Toxicology-based risk assessment program for the evaluation of possible cross-contamination
- EU GMP: „Cross contamination" guideline, Chapters 3 & 5
- Importance of toxicological concerns
- The role of premises and production in failure modes causing cross contamination
- Case studies:
  - Injection plant
  - Hormonal unit of a Tabletting plant
  - Weighing area for non-hormonal solids

Henri Motte
UCB Pharma

Jacqueline Vu
NNE Pharmaplan

Case study UCB Pharma: Usage of a Containment/Chemical risk assessment tool
- Description of a tool for assessing the containment/chemical risk when handling HPAPI and HP products.

This tool is based on the estimate of the ROI (Real Operator Intake) when operating during process, maintenance, cleaning, etc. It allows to address the risk and to mitigate the risk using appropriate collective protections, administrative controls or PPE (Personal Protective Equipment). It also allows to avoid over-engineering and to justify the containment performance of equipment and the containment strategy.

Current Aseptic Technologies

28 March 2017

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, *Moelgaard Consulting*

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

 **Daniel O. Blackwood** *Technical Program Lead PCM&M Development and Manufacturing Initiative for OSD, Pfizer*	**The future of Pharmaceutical manufacturing: Flexibility and sustainability through small footprint, modular equipment trains** ▪ Current and emerging technologies in primary and secondary manufacturing (focus on non-biologic / small molecules) ▪ Continuous and semi-continuous (hybrid) operations
 **Gert Moelgaard** *Moelgaard Consulting*	**Aseptic Pharma Manufacturing – prepared for the future?** ▪ Current aseptic trends ▪ Manufacturing challenges and opportunities ▪ How do you prepare a strategy for future challenges?
 **Dr Olivier Chancel** *Merial*	**Ten new 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 Andreas Liebminger** *Baxalta Innovations*	**Robust Engineering as guiding principle for filtration process development** ▪ Authority requirements and challenges for filtration processes ▪ Introduction to Robust Engineering ▪ Show Case for development of a sterile filter train used for a plasma derived product solution ▪ Take aways and learning regarding data packages for submission
 **Live Demos**	In the practical part of the conference, suppliers will show you different components and solutions. You will come in contact with the equipment and you have the chance to discuss your questions immediately with technology experts. ▪ **Residual VHP monitoring at the parts-per-billion level for protection of sensitive products** *PICARRO* ▪ **A Flexible Small Scale Filling Machine for Prefilled Syringes in Nest & Tub** *COLONAR* ▪ **Nondestructive lyo moisture determination for statistical moisture mapping** *Lighthouse Instruments* ▪ **Compounding robotic solution in Isolator technology** *Steriline*
 **Dr Stephan Zinzen** *AqVida*	**State of the art facility for robotic manufacturing of cytotoxic injectables – Sharing the experience** ▪ Presentation of a successful greenfield project for a most modern cytotoxic filling facility in Germany ▪ Challenges and solutions for an all-isolator process workflow from compounding to aseptic filling for liquid cytotoxics of OEB 5 category and below ▪ Emphasis on the implementation and validation of a highly flexible and accurate robotic filling line for vial filling from 1 mL to 100 mL ▪ EHS aspects in layout and realization of the facility
 **Christian Urban** *Vetter Pharma-Fertigung*	**Regulatory aspects and challenges during the validation of lyophilised drug products** ▪ Increasing requirements from regulatory bodies ▪ Development strategy of lyophilised products ▪ Recent examples and case studies for authority related questions ▪ Challenges during the validation of lyophilised products

Barrier Systems

29 March 2017

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 issue for drugs produced by aseptic processes. Today the regulators 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 regulations as well as from the revised EU GMP Annex 1, and it will specifically address the subject from the perspectives of pharmaceutical operators, planners and engineers.

Moderator

Didier Meyer, *DMCompliance*

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

Jörg Zimmermann
VP Development Service, Vetter Pharma-Fertigung

Trends in the pharma market and sterile dosage forms

- Megatrends influencing the pharma market
- Market shares and developments in sterile dosage forms
- Strategies to support patient compliance and convenience
- PENs, Autoinjectors, Safety Devices
- Subcutaneous delivery: patch pumps etc.
- Polymer Syringes
- Needle-less systems
- Conclusions

Dr Norbert Gerling
Vetter Pharma-Fertigung

Case study Vetter: Improved RABS-Concept - Advantages Combination of Isolator and RABS

- Comparison of Best Practice concepts
- Decontamination concept
- Monitoring aspects
- OEE-benefits

Patrick Vanhecke
GSK Vaccines

Case study GSK Vaccines: Residual VHP impact on pharmaceutical products

- Potential impact on products
- Residual VHP isolator mapping and absorption kinetic
- How to measure residual VHP?
- Picarro Spectroscopie Technique (Calibration by design, Surrogate gas calibration)
- Development of Calibration method for H_2O_2 sensors (Experimental set-up, Design of experiment, results)

Dominique Sierakowski
Octapharma

Case study Octapharma: Highly automated filling line with isolator for SVP & LVP products

- The first 5 years in the life cycle of the installation – from design to daily routine production
- Installation concept
- Qualification including cycles development studies
- Aseptic processing performance qualification - APS
- Industrialization phase
- Lessons learned

Matt Kessler
MSD Werthenstein BioPharma

Case study MSD: Integrated Sterile Filling in Clinical Manufacturing

Dr Norbert Matzanke
Ferring

Case study Ferring: Isolator filling line for high potent drugs including lyophilisation

- Handling of API for dispensing and compounding
- Classification concept of isolator segments (toxic versus non-toxic)
- Decontamination with dispersed H_2O_2 spray
- How the filters will operate during decontamination / production and WIP mode
- Integration of a catalyst system
- Filing line concept – filling of liquid aseptic products and lyo loading and unloading
- Vial transportation system to assure high yields

Wolfgang Lau
Roche Diagnostics

Hartmut Schaz
NNE Pharmaplan

Case study Roche Diagnostics: High potent fill & finish 2.0

- Introduction
- SHE risk analysis
- General improvements
- Primary & Secondary containment improvements
- First results of FAT / installation phase

Manufacturing Data Integrity

28 March 2017

Objectives

Reasons for attending this conference:

- Understand the current regulatory requirements on data integrity from FDA, EU, WHO and PIC/S
- Learn what is required for a data governance system from senior management to staff in manufacturing
- Understand the data life cycle in manufacturing and how it is linked to business processes

Background

At the moment Data Integrity is one of the hottest topics in the regulatory world. Besides patient safety and quality the integrity of data is another important criterion for drug quality. A lot of findings by inspectors with regard to data integrity issues during the last years draw the regulators' attention to the importance of a GMP compliant data life cycle.

Moderator

Dr. Wolfgang Schumacher, *formerly F. Hoffmann-La Roche*

Target Audience

Managers and staff from Manufacturing and QA from pharmaceutical companies and suppliers who need to understand the current regulatory requirements on Data Integrity.

Programme

 **Daniel O. Blackwood** *Technical Program Lead PCM&M Development and Manufacturing Initiative for OSD, Pfizer*	**The future of Pharmaceutical manufacturing: Flexibility and sustainability through small footprint, modular equipment trains** ▪ Current and emerging technologies in primary and secondary manufacturing (focus on non-biologic / small molecules) ▪ Continuous and semi-continuous (hybrid) operations
 **Dr Arno Terhechte** *Bezirksregierung Münster*	**Manufacturing Data Integrity from the inspector's point of view** ▪ Regulatory Update ▪ Paper Based Systems in Manufacturing – Manufacturing Instruction / - Record – Packaging Instruction / - Record ▪ Computerized Systems in Manufacturing – SPS – Process Control Systems – MES ▪ Data Flow in Production / Hybrid Systems ▪ Remote Access to Production Equipment ▪ Data Integrity during Inspection ▪ Inspection Findings
 **Dr Bob McDowall** *R.D.McDowall*	**What can (Software) Suppliers do to help regulated customers ensure Data Integrity?** ▪ Technical and procedural controls for software in regulated environments ▪ Focus on technical controls for software to ensure data integrity ▪ Database vs. operating systems directories ▪ Networked vs. standalone system ▪ Security and access control ▪ Audit trails and their reviews
 **Dr Philip Hörsch** *Vetter Pharma-Fertigung*	**Handling of data integrity requirements for legacy systems and new acquisition as well as consideration within corporate's policy** ▪ Which requirements on data integrity topics are new and how should they be considered in corporate's policy and written procedures (SOPs)H ▪ How to deal with legacy systems: execution of system analyses, identification of gaps, initiation of measures ▪ Examples from Sterile Manufacturing and Quality Control ▪ Implementation of additional requirements for the acquisition of new computerized systems ▪ Adaption of training concept ▪ Experience from audits and inspections
 **Yves Samson** *Kereon*	**Integrity of manufacturing data** ▪ Reality of the manufacturing field ▪ An approach to secure manufacturing data ▪ Taking advantage of a systematic approach
 **Dr Wolfgang Schumacher** *formerly F.Hoffmann-La Roche*	**How to solve Data Integrity problems in manufacturing** ▪ Training program ▪ Computerised equipment compliance ▪ Audit trail review approach ▪ Audit concept
 **Rob Hahnraths** *Grünenthal*	**Data Integrity „Mind the GAP"** ▪ Building a Data Integrity culture in Manufacturing ▪ Knowing your Manufacturing processes "MES example" ▪ Performing a GAP analysis "where is the meat?" ▪ BPM "Business Process Modell and Notation" ▪ Understanding current regulatory requirements ▪ Electronic Records, what's in it

Revision of EU Annex 1

29 March 2017

Objectives

This is why you may want to attend this conference:

- You get to know the current status of the revision of EU GMP Annex 1
- Inspectors and pharmaceutical operators discuss the consequences of the changes for the operational processes

Background

Since the establishment of the EU GMP Guide the specific requirements for sterile medicinal products have been specified in the Annex 1. After various smaller revisions the pending revision will be quite comprehensive. In early 2015 the European Medicines Agency (EMA) issued a " Concept Paper on the revision of annex 1 of EU-GMP Manufacture of sterile medicinal products EMA/INS/GMP/735037/2014" in which the authority asked the industry to provide proposals for changes and additions. Currently an inspectors working group prepares a first draft for public discussion.

Moderator

Jörg Zimmermann, *Vetter Pharma-Fertigung*

Target Audience

The conference is directed to senior management from the pharmaceutical industry and suppliers who have to deal with the new EU-GMP-Annex 1 revision.

Programme

Jörg Zimmermann
VP Development Service, Vetter Pharma-Fertigung

Trends in the pharma market and sterile dosage forms

- Megatrends influencing the pharma market
- Market shares and developments in sterile dosage forms
- Strategies to support patient compliance and convenience
- PENs, Autoinjectors, Safety Devices
- Subcutaneous delivery: patch pumps etc.
- Polymer Syringes
- Needle-less systems
- Conclusions

Dr. Daniel Müller
GMP-Inspektor, Regierungspräsidium Tübingen

New Technologies – an inspector's point of view

- Existing guidelines on sterile manufacture / aseptic processing
- Current guidelines vs. new developments / trends
- Updating Annex 1: challenges & options

Live Demos

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

- **W-LAN Glove Testing System**

METALL + PLASTIC (Member of OPTIMA)

- **"Simulation of the air flow conditions below laminar flow units by means of air flow calculation and visualization (CFD) already during the product engineering process"**

Bausch + Ströbel Maschinenfabrik Ilshofen

- **Barrier Glove Management Life cycle**

Franz Ziel

- **Glove Tester Next Generation – GITS 4**

MK Versuchsanlagen

Dr. Arno Terhechte
Bezirksregierung Münster

Current Status of Annex 1 – an Update

- Update with regards to the draft recently discussed at 84. GMDP Inspectors WG
- Application of pre-use integrity testing
- Container Closure Integrity Test
- Current Timeline

James Drinkwater
Chairman PHSS

Pharma Industry / PHSS members perspective on the revision of EU GMP Annex

- Overview of key considerations in Annex 1 revision and impact on the Pharma industry.
- GMP compliance for new biological product types, new technologies and new methods of aseptic processing.
- The challenge of aligning risked based initiatives including QRM with real applications.
- A few detail points to consider: EM Process monitoring, Trend Metrics, Training/Knowledge exchange

Dr. Friedrich Haefele
Boehringer Ingelheim Pharma

Alexandra Stärk
Novartis Pharma

James Drinkwater
PHSS

Jörg Zimmermann
Vetter Pharma-Fertigung

Arjan Langen
MSD

Gert Moelgaard
Moelgaard Consulting

Discussion / Workshop: The needs for an Annex 1 revision

- Clean rooms
- Barrier Technologies
- Environmental monitoring
- Process simulation
- Filtration
- Single Use Equipment
- Lyophilisation
- Aseptic process Filling of pre-sterilised containers.
- Assurance of product sterility in aseptic processing via verification the process environment is under control: Process verification, Environmental conditions verification and associated batch record reporting together with trending/ periodic reviews.
- Compatibility of Hydrogen peroxide vapour and biological products and how to manage surface sterility of Stopper Feeder bowls/pathways.

Programme

28 March 2017

Time	ECA – Trends in Manufacturing Continuous Manufacturing	ECA – Aseptic Processing Current Aseptic Technologies	ECA – Regulatory Trends Manufacturing Data Integrity	Time
9:00 h 9:15 h 9:30 h 9:45 h	Congress Key Note The future of Pharmaceutical manufacturing *Daniel O. Blackwood, Pfizer Inc.*			9:00 h 9:15 h 9:30 h 9:45 h
10:00 h 10:15 h	Break			10:00 h 10:15 h
10:30 h 10:45 h 11:00 h	Development of a Q&A Document on Continuous Manufacturing *Efpia invited*	Aseptic Pharma Manufacturing – prepared for the future? *Gert Moelgaard, Moelgaard Consulting*	Manufacturing Data Integrity from the inspector's point of view *Dr. Arno Terhechte, GMP-Inspector, Bezirksregierung Münster*	10:30 h 10:45 h 11:00 h
11:15 h 11:30 h 11:45 h	A risk based approach to implement CM for OSD *Michael Van den Bossche, NNE Pharmaplan*	Ten new lessons learned in sterility assurance *Dr. Olivier Chancel, Merial*	What can (Software) Suppliers do to help regulated customers ensure Data Integrity? *Bob McDowall, R.D. McDowall*	11:15 h 11:30 h 11:45 h
12:00 h 12:15 h 12:30 h 12:45 h 13:00 h 13:15 h	Lunch Break			12:00 h 12:15 h 12:30 h 12:45 h 13:00 h 13:15 h
13:30 h 13:45 h 14:00 h	The Janssen Roadmap to Continuous Manufacturing *Lawrence de Belder, Janssen*	Robust Engineering as guiding principle for filtration process development *Dr. Andreas Liebminger, Baxalta Innovations*	Handling of data integrity requirements for legacy systems and new acquisition as well as consideration within corporate's policy *Dr. Philip Hörsch, Vetter Pharma-Fertigung*	13:30 h 13:45 h 14:00 h
14:15 h 14:30 h 14:45 h	Case Study Continuous Manufacturing at UCB Pharma *Dr. Martin Schubert, UCB Pharma*	Live Demos	Integrity of manufacturing data *Yves Samson, Kereon*	14:15 h 14:30 h 14:45 h
15:00 h 15:15 h 15:30 h	Break			15:00 h 15:15 h 15:30 h
15:45 h 16:00 h 16:15 h	Case Study Hovione: A Platform Approach to Continuous Manufacturing *Nuno Matos, Hovione*	State of the art facility for robotic manufacturing of cytotoxic injectables – Sharing the experience *Dr. Stephan Zinzen, AqVida*	How to solve Data Integrity problems in manufacturing *Dr. Wolfgang Schumacher, form. F.Hoffmann-La Roche*	15:45 h 16:00 h 16:15 h
16:30 h 16:45 h 17:00 h	Continuous manufacturing of direct compression tablets at TEVA *Frank Streil, TEVA*	Regulatory aspects and challenges during the validation of lyophilised drug products *Christian Urban, Vetter Pharma-Fertigung*	Data Integrity „Mind the GAP" *Rob Hahnraths, Grünenthal*	16:30 h 16:45 h 17:00 h
17:15 h 17:30 h	Discussion	Discussion	Discussion	17:15 h 17:30 h
18:00 h	Social Event for Congress Delegates, Speakers and Exhibitors			18:00 h

Programme

29 March 2017

Time	ECA – Trends in Manufacturing Technology Trends	ECA – Aseptic Processing Barrier Systems	ECA – Regulatory Trends Revision of EU Annex 1	Time
8:30 h 8:45 h 9:00 h 9:15 h	Congress Key Note Trends in the pharma market and sterile dosage forms *Jörg Zimmermann, Vetter Pharma-Fertigung*			8:30 h 8:45 h 9:00 h 9:15 h
9:30 h 9:45 h	Break			9:30 h 9:45 h
10:00 h 10:15 h 10:30 h	Nichebusters - Fad or the future? *Dr. Harald Stahl, GEA*	Case study Vetter: Improved RABS-Concept - Advantages Combination of Isolator and RABS *Dr. Norbert Gerling, Vetter Pharma-Fertigung*	New Technologies – an inspector's point of view *Dr Danie Müller, GMP Inspector, Regierungspräsidium Tübingen*	10:00 h 10:15 h 10:30 h
10:45 h 11:00 h 11:15 h	Case Study Torrent Pharmaceuticals: Solid Lipid Nano particles *Dr. Jaya Abraham, Torrent Pharmaceuticals*	Case study GSK Vaccines: Residual VHP impact on pharmaceutical products *Patrick Vanhecke, GSK Vaccines*	Live Demos	10:45 h 11:00 h 11:15 h
11:30 h 11:45 h 12:00 h 12:15 h 12:30 h 12:45 h	Lunch Break			11.30 h 11:45 h 12:00 h 12:15 h 12:30 h 12:45 h
13:00 h 13:15 h 13:30 h	3D Printing for the Pharmaceutical Industry: A Novel Platform for Drug Development and Delivery *Dr. Stephen Hilton, UCL School of Pharmacy London*	Case study Octapharma: Highly automated filling line with isolator for SVP & LVP products *Dominique Sierakowski, Octapharma*	Current Status of Annex 1 – an Update *Dr. Arno Terhechte, GMP-Inspector, Bezirksregierung Münster*	13:00 h 13:15 h 13:30 h
13:45 h 14:00 h 14:15 h	New Technologies for Transdermal and Parenteral Drug Delivery *Dr.Stefan Henke, LTS/IIS*	Case Study Alexion *TBN*	Pharma Industry / PHSS members perspective on the revision of EU GMP Annex *James Drinkwater, PHSS*	13:45 h 14:00 h 14:15 h
14:30 h 14:45 h	Break			14:30 h 14:45 h
15:00 h 15:15 h 15:30 h	Toxicology-based risk assessment program for the evaluation of possible cross-contamination *Dr. Ildiko Ziegler, Gedeon Richter*	Case study Ferring – isolator filling line for high potent drugs including lyophilisation *Dr. Norbert Matzanke, Ferring*	Discussion / Workshop: The needs for an Annex 1 revision *Dr. Friedrich Haefele, Boehringer Ingelheim Pharma* *Alexandra Stärk, Novartis Pharma* *James Drinkwater, PHSS* *Jörg Zimmermann, Vetter Pharma-Fertigung* *Arjan Langen, MSD* *Gert Moelgaard, Moelgaard Consulting*	15:00 h 15:15 h 15:30 h
15:45 h 16:00 h 16:15 h	Usage of a Containment/Chemical risk assessment tool at UCB Pharma *Henri Motte, UCB Pharma* *Jaqueline VU, NNE Pharmaplan*	Case study: High potent fill & finish 2.0 *Wolfgang Lau, Roche Diagnostics* *Hartmut Schaz, NNE Pharmaplan*		15:45 h 16:00 h 16:15 h
16:30 h 16:45 h	Discussion	Discussion		16:30 h 16:45 h
17:00 h				17:00 h

Easy Registration

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Registration Form:
(06221) 84 44 34

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info@concept-heidelberg.de

Internet:
www.pharma-kongress.com

Registration Options

Attending Conferences – One Day Tickets for € 690,- (plus VAT)

(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, the 28 March (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** (28 March 2017): I would like to attend the Congress on day 1. I'm primarily interested in the conference:

- ☐ ECA Trends in Manufacturing – Continuous Manufacturing
- ☐ ECA Aseptic Processing – Current Aseptic Technologies
- ☐ ECA Regulatory Trends – Manufacturing Data Integrity

☐ I would also like to take part in the Social Event on the evening of 28 March 2017.

☐ **Day 2 (29 March 2017):** I would like to attend the Congress on day 2. I'm primarily interested in the conference:

- ☐ ECA Trends in Manufacturing – Technology Trends
- ☐ ECA Aseptic Processing – Barrier Systems
- ☐ ECA Regulatory Trends – Revision of EU Annex 1

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.
- 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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