28/29 March 2017, Düsseldorf/Neuss, Germany

HIGHLIGHTS:

- Current Aseptic Technologies
  - Aseptic Pharma Manufacturing – prepared for the future?
  - Ten new lessons learned in sterility assurance
  - Robust Engineering as guiding principle for filtration process development
  - State of the art facility for robotic manufacturing of cytotoxic injectables
  - Regulatory aspects and challenges during the validation of lyophilised drug products
  - Live Demos from PICARRO, COLONAR, Lighthouse Instruments and Sterilne

- Barrier Systems
  - Case study Vetter: Improved RABS-Concept - Advantages
  - Combination of Isolator and RABS
  - Case study Ferring – isolator filling line for high potent drugs including lyophilisation
  - Case study GSK Vaccines: Residual VHP impact on pharmaceutical products
  - Case study MSD: Integrated Sterile Filling in Clinical Manufacturing
  - Case study Roche Diagnostics: High potent fill & finish 2.0
  - Case study Octapharma: Highly automated filling line with isolator for SVP & LVP products
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, Chair ECA Validation Interest Group

Programme

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
- Enhancing process robustness, higher quality and lower cost potential especially at the development/clinical manufacturing/commercial manufacturing interfaces
DANIEL O. BLACKWOOD, Technical Program Lead, PCM&M Development and Manufacturing Initiative for OSD, Pfizer

Aseptic Pharma Manufacturing - prepared for the future?
- Current aseptic trends
- Manufacturing challenges and opportunities
- How do you prepare a strategy for future challenges?
GERT MOELGAARD, Chair ECA Validation Interest Group

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 OLIVIER CHANCEL, Merial

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
DR ANDRéAS LIEBMINGER, Baxalta Innovations

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
Biologics can be sensitive to oxidative damage from residual VHP at 100 ppb or even lower. This workshop demonstrates:
- Easy, automated monitoring of H2O2 levels at ultra-trace levels using Picarro’s G2114 Cavity Ring-Down Spectroscopy (CRDS) system.
- A new method for rapid, in situ analyzer validation using a stable, traceable surrogate gas.
- Analyzer operation in a 21CFR11 compliant manner
PICARRO
A Flexible Small Scale Filling Machine for Prefilled Syringes in Nest & Tub

Specializing in advanced liquid filling and closing systems for small batch processing and laboratory use, COLONAR offers a variety of semi-automatic and automatic solutions for nested syringes, vials and cartridges:
- Improved, isolator-friendly design
- Processing of nested syringes, vials and cartridges in one single unit
- High accuracy filling via rotary piston pumps and/or FSP peristaltic pumps
- Vacuum stoppering
- All movements are servo-driven
- User-friendly operation via touch screen HMI

COLONAR

Nondestructive lyo moisture determination for statistical moisture mapping

An inspection approach based on laser-based headspace analysis will be demonstrated for the moisture determination of lyo product. This approach can be used to support the qualification of freeze dryers through the generation of moisture maps. Statistical moisture mapping also enables lyo cycle optimization resulting in significant savings of lyo production capacity.

Lighthouse Instruments

Compounding robotic solution in Isolator technology

- Isolator technology
- VHP sterilization
- RFID traceability
- Highest throughput on the market
- Advanced vision system

The demo will "virtually" bring you inside of a clean room and you will be able to experience exactly what "delivering automated aseptic compounding solutions" means.

Steriline

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

DR STEPHAN ZINZEN, AqVida

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

CHRISTIAN URBAN, Vetter Pharma-Fertigung

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 point 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.

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.

Moderator

DIDIER MEYER, DMCompliance
Programme

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

JÖRG ZIMMERMANN, Vice President
Development Services,
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

DR NORBERT GERLING, Vetter Pharma-Fertigung

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 Spectroscopic Technique (Calibration by design, Surrogate gas calibration)
- Development of Calibration method for H2O2 sensors (Experimental set-up, Design of experiment, results)

PATRICK VANHECKE, GSK Vaccine

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

DOMINIQUE SIERAKOWSKI, Octapharma

MSD Case Study:
Integrated Sterile Filling in Clinical Manufacturing

MATT KESSLER, MSD Werthenstein BioPharma

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 H2O2 spray
- How the filters will operate during decontamination / production and WIP mode
- Integration of a catalyst system
- Filling line concept – filling of liquid aseptic products and lyo loading and unloading
- Vial transportation system to assure high yields

DR NORBERT MATZANKE, Ferring

Case study Roche Diagnostics:
High potent fill & finish 2.0
- Introduction
- Containment improvements
  - SHE risk analysis
  - General improvements
  - Primary containment improvements
- Secondary containment improvements
- First results of FAT / installation phase

WOLFGANG LAU, Roche Diagnostics
HARTMUT SCHAZ, NNE Pharmaplan
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.

**Speakers**

**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.

**DR NORBERT GERLING**, Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg
He is currently Director of Pharmaceutical Production for Vetter Pharma Fertigung GmbH&Co.KG, Ravensburg, Germany and Site Manager for Vetter’s site in Langenargen at Lake Constance. In this role, he is responsible for the clinical and commercial manufacturing of aseptically prefilled syringe systems, liquid and lyophilized vials and cartridges.

**MATT KESSLER**, MSD Werfenstein BioPharma, Schachen, Switzerland
Associate Principal Scientist leading the Drug Product and Downstream Technology group at MSD outside of Luzern, Switzerland. In this role he is responsible for the sterile filling for clinical biologics material and the implementation of new downstream technologies.

**WOLFGANG LAU**, Roche Diagnostics GmbH, Mannheim
Wolfgang Lau is a master of mechanical engineering. He started to work in 1986 as a project engineer, working on the first fermentation project of Boehringer Mannheim GmbH with mammalian cells. Since 1993 he designed most of the aseptic fill finish facilities at Roche in Mannheim. He is a project manager at the site engineering department.

**DR ANDREAS LIEBINGER**, Baxalta Innovations GmbH, Wien
After his studies in Chemical Engineering he graduated at the Technical University Vienna. Between 2002 and 2015 he had been at Baxter AG in difference management positions, e.g. Head of Pharma Finishing Process within Technical Operations Vienna. Since 2015 he is Head of Biophysical Science & Mfg Support within Formulation & Fill/Finish at Baxalta Innovations.

**DR NORBERT MATZANKE**, Ferring GmbH, Kiel
Mr. Matzanke is an educated pharmacist and made his Ph.D. in pharmaceutical chemistry at the University of Berlin, Germany. In 2004 he joined Ferring GmbH located in Kiel, Germany as a supervisor for a newly installed facility for freeze-dried products. 2014 he changed to the project management team to plan and realize a new filling line with isolator technique.

**GERD MOELGAARD**, Moelgaard Consulting, Lyngby, Denmark
Gert Moelgaard has more than 25 years experience in the pharmaceutical and biotech industry, including several years of experience in process control, automation, computer systems validation and process validation as well as process engineering and consulting. He has previously worked in Novo Nordisk, Novo Nordisk Engineering and NNE Pharmaplan. Since 2015 he is Consultant. He is member of the ECA Validation interest group.

**DOMINIQUE SIERAKOWSKI**, Octapharma SAS, Lingolsheim, France
Head of Corporate Pharmaceutical Production. Before joining Octapharma he held different positions in biopharmaceutical companies in production and in management of industrial strategic programs. Currently responsible for coordinating fill & finish operations as well as Project Manager for implementing new filling lines and freeze dryers within Octapharma manufacturing sites.

**DR CHRISTIAN URBAN**, Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg
Christian Urban holds a diploma of Chemistry and earned his Ph.D. in the area of Organic Chemistry at the University of Wuerzburg, Germany. He joined the Development Service department at Vetter Pharma, Germany in 2011 and is currently working in the area of Technology & Process Transfer.

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Associate Principal Scientist leading the Drug Product and Downstream Technology group at MSD outside of Luzern, Switzerland. In this role he is responsible for the sterile filling for clinical biologics material and the implementation of new downstream technologies.

**DR CHRISTIAN URBAN**, Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg
Christian Urban holds a diploma of Chemistry and earned his Ph.D. in the area of Organic Chemistry at the University of Wuerzburg, Germany. He joined the Development Service department at Vetter Pharma, Germany in 2011 and is currently working in the area of Technology & Process Transfer.

**PATRICK VANHECKE**, GSK Vaccines, Belgium
Patrick Vanhecke joined GSK Bio in 1992 as Aseptic Filling Manager in Rixensart (Belgium). In 2002 he joined the Parenteral Technologies team and since 2015 he joined the Global Manufacturing Science and Technologies - Manufacturing Technologies team as expert in Isolator and Aseptic Filling Technologies and Room decontamination process.

**DR STEPHAN ZINZEN**, AqVida GmbH, Hamburg
Since 2010 managing partner of benavis GmbH and Head of Research & Development at AqVida GmbH.
Date
Tuesday, 28 March 2017, 09.00 – 17.45 h
Wednesday, 29 March 2017, 08.30 – 17.00 h
(Registration: Monday, 27 March 2017, 19.00 – 20.30 h
   Tuesday, 28 March 2017, 08.00 – 09.00 h
   Wednesday, 29 March 2017, 07.30 – 08.30 h)

Venue
Swissôtel Düsseldorf / Neuss
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Fee
EUR 690,- per delegate and day plus VAT (EUR 1.380,- for both days)
due to the special congress fees, ECA membership discounts are
not applicable, and participation does not entail ECA membership.
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 28 March. 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

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Please note that there will be no 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
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Aseptic Processing (28-29 March 2017)
Part of the Pharma Congress Production & Technology 2017
Düsseldorf/Neuss, Germany, 28-29 March 2017

I register for:
☐ Current Aseptic Technologies (28 March 2017)
☐ Barrier Systems (29 March 2017)
☐ Both days (28-29 March 2017 – 1.380, - €)

☐ Yes, I would also like to participate in the Social Event on 28 March
☐ Mr  ☐ Ms

Title, first name, surname

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