ECA
ACADEMY

Image: GEA

These conferences are part of the
2016 PHARMA CONGRESS
IO Production & Technology
DÜSSELDORF, 12 - 13 APRIL 2016
www.pharma-kongress.com
Premium Sponsor: MERCK

Trends in Manufacturing

Continuous Manufacturing

Manufacturing of highly potent Materials

SPEAKERS

DENIZ ALKANAT
ONKO-KOCSEL

PROF DR THOMAS DE BEER
University of Ghent

DR ANDREAS FLÜCKIGER
F. Hoffmann-La Roche

DR ANDREAS GRUMMEL
Federal Institute for Drugs and Medical Devices (BfArM)

DR FRIEDRICH HAEFELE
Boehringer Ingelheim Pharma

MARTINA HAERTWIG-BRANDT
Sanofi-Aventis

DR ANDREAS KÖNIG
Aenova Group

GÜNTER KÖRBLEIN
Tetragon-Consulting

DR LORENZ LIESUM
Novartis Pharma

DR PETER PÖCHLAUER
Patheon

DR HARALD STAHL
GEA

DR CLEMENS STIEF
Pfizer

DR MARTIN TUCKERMANN
Baxter Oncology

Düsseldorf/Neuss, Germany, 12-13 April 2016

HIGHLIGHTS CONTINUOUS MANUFACTURING:

- State-of-the art equipment and suppliers for continuous manufacturing
- Continuous manufacturing seen by a competent authority
- Case Study Novartis: PAT in routine and commercial production
- Case Study Pfizer: Continuous Manufacturing of OSD products
- Case Study Patheon: Continuous flow processes

HIGHLIGHTS MANUFACTURING OF HIGHLY POTENT MATERIALS

- Derivation of OEL, OEB, DEL and PDE values
- Compliance with the EMA Cross-Contamination requirements
- Case Study Onko Kocsel: New Site for highly potent drugs
- Case Study Pfizer: Operation of an HighPo OSD plant
- Case Study Baxter: Aseptic and highly potent drug manufacture
- Case Study Sanofi-Aventis: Transfer of a highly potent Product

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 come up 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.

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.

Moderator

Günter Körblein, *Tetragon Consulting*

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.

Programme

The upcoming Annex 1 and consequences for industry

DR FRIEDRICH HAEFELE, *Boehringer ingelheim Pharma*

Congress Key Note

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

GÜNTER KÖRBLEIN, *Tetragon-Consulting*

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)

DR ANDREAS GRUMMEL, *Federal Institute for Drugs and Medical Devices (BfArM)*

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

DR LORENZ LIESUM, *Novartis Pharma*

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 in continuous solid dosage manufacturing. A continuous manufacturing line with continuous 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 (e.g. feed rate, screw speed, etc.) to produce products with pre-defined end-product specifications in a short time.

PROF DR THOMAS DE BEER, *University of Ghent*

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
  - PAT

DR CLEMENS STIEF, *Pfizer*

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
- Work-up

DR PETER PÖCHLAUER, *Patheon*

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.

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.
Moderator	**Dr Harald Stahl,** *GEA*

Programme

How to measure performance in pharmaceutical production – a case study

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

DR ANDREAS KÖNIG, *Aenova Group*

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 (EMA GMP Guideline ch. 5.21)

DR ANDREAS FLÜCKIGER, *F. Hoffman-La Roche*

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

DENIZ ALKANAT, *ONKO-KOCSEL Pharmaceuticals*

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

MARTINA HAERTWIG-BRANDT, *Sanofi-Aventis Deutschland*

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

DR CLEMENS STIEF, *Pfizer*

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.

DR MARTIN TUCKERMANN, *Baxter Oncology*

Speakers

DENIZ ALKANAT, *ONKO iLAÇ San. ve Tic. A.S.*
Deniz Alkanat is Production Group Manager at Onko Pharmaceuticals. He is responsible for all manufacturing activities from the beginning to end such as dispensing , compounding , filling , freeze drying, packaging. He has a degree in chemical engineering and has over 16 years of experience in the pharmaceutical industry, amongst other in production , building of pharma facilities as well as in qualification/validation.

PROF DR THOMAS DE BEER, *University of Ghent*
Thomas De Beer graduated in pharmaceutical sciences and worked on PAT tools during PHD research and post-doctoral work afterwards. Since 2010 he is professor in Process Analytics & Technology at the Faculty of Pharmaceutical Sciences from the university of Ghent. His research goals include bringing innovation pharmaceutical production processes (freeze-drying, hot-melt extrusion, continuous from-powder-to-tablet processing etc.).

DR ANDREAS FLÜCKIGER, *F. Hoffmann-La Roche*
An occupational physician by training, Andreas Flückiger has been the head of the occupational health services of the Roche Group for almost 30 years. He is active in leading roles in numerous national and international associations such as the International Association for Occupational and Environmental Health in the Chemical Industry (Medichem), in the Scientific Committee of the European Council for Ecotoxicology and Toxicology of Chemicals (ECETOC) and ISPE.

DR ANDREAS GRUMMEL, *Federal Institute for Drugs and Medical Devices (BfArM)*
PhD Pharmacist, over 15 years' experience as senior quality assessor, member of the BfArM PAT group and member of the PDCO subgroup for paediatric formulations.

DR FRIEDRICH HAEFELE, *Boehringer Ingelheim Pharma GmbH & C. KG*
Dr Haefele has been in the pharmaceutical industry for almost 20 years now. In May 2006 Dr Haefele joined Boehringer-Ingelheim Pharma where he is responsible for the department Biopharma Fill & Finish Germany.

MARTINA HAERTWIG-BRANDT, *Sanofi-Aventis Deutschland GmbH*
Martina Haertwig-Brandt is Senior engineering project manager and responsible for Planning and construction of pharmaceutical plants

DR ANDREAS KÖNIG, *Aenova Group*
Senior Vice President Corporate Quality & HSE.

GÜNTER KÖRBLEIN, *Tetragon-Consulting GmbH*
Günter Körblein has a degree in Mechanical Engineering. He started his career at Pharma-Consult Heidelberg, worked later for Sandoz as Head of Engineering Pharma. He joined Boehringer Ingelheim afterwards as Head of Corporate Division Technology and finally worked for Thyssen-Krupp-Uhde where he was Director Marketing for Uhde-Pharma. Having served as Senior Consultant for German Government and United Nations he is now a Senior Partner of Tetragon-Consulting GmbH.

DR LORENZ LIESUM, *Novartis Pharma AG*
As Head of PAT (Global Pharma Engineering) Dr Liesum is responsible for the global coordination of PAT/QbD projects and for the standardization of qualification and PAT method validation and the control strategies.

DR PETER PÖCHLAUER, *Patheon*
Dr Pöchlauer is Innovation Manager at Patheon (fromer DSM FineChemicals). He is responsible for the development and usage of new technologies for the production of fine chemicals especially for the process intensification.

DR HARALD STAHL, *GEA*
Dr Harald Stahl worked for 3 years in the Pharmaceutical Development of Schering AG in Germany. At that time his main interest was the aseptic production of pellets. Since 1995 he served within GEA Process Technology in various positions. Presently he is Group Director Application & Strategy Management. He has published more than 20 papers on various aspects of pharmaceutical production.

DR CLEMENS STIEF, *Pfizer Manufacturing Deutschland GmbH*
Dr Stief studied Pharmacy and gained his PhD in Pharmaceutical Technology in 1994. After several management positions at Gödecke / Parke-Davis Dr Stief became Team Leader Operations of the Product and Process Development at Pfizer Manufacturing Deutschland GmbH in Freiburg. He is the qualified person 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*
Martin Tuckermann is technical manager at Baxter Oncology and senior project manager for the new PPE facility in Halle (Westfalen), Germany. He graduated in the field of atmospheric physics at the University of Heidelberg, Germany, and received his PhD in biophysics / materials science from the Technical University of Dresden. Before joining Baxter Martin held several positions in engineering, marketing and sales in the fields of semiconductor and pharmaceutical industry.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.pharma-kongress.com

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

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

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

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

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

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

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

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

For questions regarding content:
Dr Robert Eicher (Operations Director) at +49-6221/84 44 12, or per e-mail at eicher@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Mr Detlef Benesch (Organisation Manager) at +49-6221/84 44 45, or per e-mail at benesch@concept-heidelberg.de.

If the bill-to-address deviates from the specification to the right, please fill out here:

_____

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

+49 6221 84 44 34

Trends in Manufacturing (12-13 April 2016)
Part of the Pharma Congress Production & Technology 2016
Düsseldorf/Neuss, Germany, 12-13 April 2016

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

I register for:
☐ Continuous Manufacturing (12 April 2016)
☐ Manufacturing of highly potent Materials (13 April 2016)
☐ Both days (12-13 April 2016 – 1.380,- €)

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

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the Purchase Order Number, if applicable

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!
Privacy Policy: By registering for this event, I accept the processing of my Personal Data. CONCEPT HEIDELBERG will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. CONCEPT HEIDELBERG will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

wh/vers.1/110106