28/29 March 2017, Düsseldorf/Neuss, Germany

HIGHLIGHTS:
- Continuous Manufacturing
  - The future of Pharmaceutical manufacturing
  - A risk based approach to continuous manufacturing
  - Janssen: Roadmap to Continuous Manufacturing
  - Teva: Continuous manufacturing of direct compression tablets
  - Hovione: Continuous Manufacturing through QbD & PAT
  - UCB: Continuous Manufacturing

- Technology Trends
  - Trends for sterile dosage forms
  - Technology for Niche Busters
  - 3D Printing for the Pharmaceutical Industry
  - Needle-free injections
  - UCB Pharma: Usage of a Containment risk assessment tool
  - Torrent Pharmaceuticals: Solid Lipid Nano particles
It is the aim of this conference to show how a transition from batch to continuous manufac-
turing in the pharmaceutical industry can look like. Questions regarding technology, process
development and GMP/Quality Assurance will be discussed.

Solid dosage forms are still the most common dosage form, first and foremost tablets with-
out any pioneering developments in the recent years. But driven by only a few pharmaceuti-
cal companies more and more of the global players started to invest in continuous manufac-
turing. 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 con-
tinuous 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 / disadvan-
tages and how they answered the questions above.

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.

Günter Körblein, Tetragon Consulting

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 at-
tmosphere and the entertainment programme.

The future of Pharmaceutical
manufacturing: Flexibility and
sustainability through small
footprint, modular equip-
ment trains

- Current and emerging technologies in primary and secondary manufacturing
  (focus on non-biologic / small molecules)
- Continuous and semi-continuous (hy-
  brid) operations
- Enhancing process robustness, higher
  quality and lower cost potential espe-
  cially at the development/clinical
  manufacturing/commercial manufactur-
  ing interfaces

DANIEL O. BLACKWOOD,
Technical Program Lead, PCM&M Development
and Manufacturing Initiative for OSD, Pfizer
Q&A Document on Continuous Manufacturing

WENDY ZWOLENSKI LAMBERT, Novartis Pharma

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

MICHAEL VAN DEN BOSSCHE, NNE Pharmaplan

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

LAWRENCE DE BELDER, Janssen

Case Study UCB Pharma
- Concept
- Technology
- Experience
- Outlook

DR MARTIN SCHUBERT, UCB Pharma

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

NUNO MATOS, Hovione

Case Study TEVA
Continuous manufacturing of direct compression tablets
- Process and Equipment Design
- Implementation of CM in commercial manufacturing
- Benefits in commercial operation

FRANK STREIL, 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.

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

Moderator
Dr Harald Stahl, GEA

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
Nichebusters- Fad or the future?

- Market trend towards smaller volumes?
- Does smaller volume always mean higher value?
- Need for different technologies?
- Case stories

**DR HARALD STAHL, GEA**

**Case Study Torrent Pharmaceuticals**

**Solid Lipid Nanoparticles**

- Intranasal Drug delivery of Solid Lipid Nanoparticles
- Design Rationale & unmet clinical needs
- Design & research methodology
- POC in animals

**DR JAYA ABRAHAM, Torrent Pharmaceuticals**

**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 STEPHEN HILTON, UCL School of Pharmacy London**

**New Technologies for Transdermal and Parenteral Drug Delivery**

- LTS/IIS
- Situation
- Needle-free Injection of liquids
- Microneedle Systems
- From vision into reality
- Summary

**DR STEFAN HENKE, LTS/IIS**

**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

**DR ILDIKO ZIEGLER, Gedeon Richter**

**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.

**HENRI MOTTE, UCB Pharma**

**JAQUELINE VU, NNE Pharmaplan**
Speakers

**DR JAYA ABRAHAM**, *Torrent Pharmaceuticals*
Head of Generic Formulation, Packaging and IP Development at Torrent Pharmaceuticals in India.

**DANIEL O. BLACKWOOD**, *Pfizer Inc.*
Technical Program Lead, PCM&M Development and Manufacturing Initiative for OSD, Pfizer.

**LAWRENCE DE BELDER**, *JANSSEN*
Senior Principal Engineer Continuous Manufacturing.

**DR STEFAN HENKE**, *Innovative Injektions-Systeme GmbH & Co KG*
Dr Stefan Henke is a pharmacist and he is Managing Director of IIS Innovative Injektions-Systeme GmbH & Co KG, a 100% subsidiary of Lohmann Therapie-Systeme AG. From 1992 to 2008 he has been working in varying positions in the pharmaceutical industry. From 2008 to 2010 he was Managing Director of Merz Consumer Care GmbH, Frankfurt.

**DR STEPHEN HILTON**, *UCL School of Pharmacy London*
Dr Hilton is Senior Lecturer at UCL School of Pharmacy. His research is focused on the applications of 3D printing technology for the synthesis, development and delivery of novel and existing therapeutics.

**NUNO MATOS**, *Hovione SA*
Nuno Matos is the Head of Continuous Manufacturing within R&D, with the responsibility of executing the Company’s strategy for Continuous Manufacturing for both Drug Substance and Drug Product. The mission of the groups he leads is to develop, establish, and deploy to the organization the capabilities and capacity necessary to embrace Continuous Manufacturing.

**HENRI MOTTE**, *UCB Pharma S.A*
Mr Henri Motte is an industrial pharmacist, heading the pilot plant at UCB Braine (Belgium) working in the field of QMS and GxP Compliance of equipment and premises. He has 15 years of experience in the pharmaceutical industry and especially in solid dosage form.

**DR. MARTIN SCHUBERT**, *UCB Pharma S.A.*
Senior Director / Head of Drug Delivery Design & Development.

**DR HARALD STAHL**, *GEA*
Development of Schering AG in Germany. Since 1995 he served within GEA Process Technology. Presently he owns the position of a Group Director Application & Strategy Management of GEA. He has published more than 20 papers on various aspects of pharmaceutical production.

**FRANK STREIL**, *TEVA*
Frank Streil is Director Technical and Scientific Affairs at TEVA / ratiopharm. His main interests and experience is in the field of process development and validation as well as in new technologies, PAT and continuous manufacturing.

**MICHAEL VAN DEN BOOSCHE**, *NNE Pharmaplan*
Michael holds a master in biochemical engineering. Before becoming part of GEA's continuous team, he was a process engineer designing continuous process solutions for the beverage and food industry. Now he is part of the NNE Pharmaplan process team where he provides guidance and consulting services as a process specialist.

**JACQUELINE VU**, *NNE Pharmaplan*
Mrs. Jacqueline Vu is physicist, specialized in pharmaceutical engineering. She has more than 28 years of experience in the pharmaceutical industry and in particular in automated OSD plants and in high potent OSD projects. She is Global Technology Partner OSD at NNE Pharmaplan in Belgium.

**DR ILDIKO ZIEGLER**, *Gedeon Richter Plc.*
Dr Ildiko Ziegler is a chemical engineer and is working for Gedeon Richter for 13 years. She works as an validation expert, specialized in cleaning and process validation as well as in risk analysis.

**JÖRG ZIMMERMANN**, *Vetter Pharma-Fertigung*
Vice President Development Services.

**WENDY ZWOLENSKI LAMBERT**, *Novartis Pharma*
Global Lead, Technology Transfer / Validation Biologics Technical Development and Manufacturing.
### Registration Form

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<td>+49 6221 84 44 34</td>
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<tr>
<td>69007 Heidelberg</td>
<td>Internet: <a href="http://www.pharma-kongress.com">www.pharma-kongress.com</a></td>
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### 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**
- Rheinallee 1
- D-41460 Neuss, Germany
- Tel.: +49 (0) 2131 77 - 00, Fax: +49 (0) 2131 77 - 1367
- e-mail: neu02@gchhotelgroup.com

### 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 per e-mail at benesch@concept-heidelberg.de.

### Terms of payment
- Payable without deductions within 10 days after receipt of invoice.

### Important
- Please indicate your company’s VAT ID Number
- For questions regarding content:
  - Mr Detlef Benesch (Organisation Manager) at +49-6221/84 44 45, or per e-mail at benesch@concept-heidelberg.de.
  - 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.:
  - per e-mail at eicher@concept-heidelberg.de.

### 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
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### Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, having informed us, you will have to pay the full registration fee, 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).

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I register for:
- [ ] Continuous Manufacturing (28 March 2017)
- [ ] Technology Trends (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

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Please indicate the Purchase Order Number, if applicable

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