



EUROPEAN COMPLIANCE  
ACADEMY

**SPEAKERS  
FROM AUTHORITIES  
AND INDUSTRY**

**PHILIPPE CAPPUYNS**  
Janssen Pharmaceutica

**DR HENRY HUANG,**  
AstraZeneca

**ALICIA MOZZACHIO**  
FDA, Office of Manufacturing  
and Product Quality (OMPQ)

**OLIVER PÜTZ**  
A. Nattermann & Cie.

**HARALD RÖMER**  
Notter

**DR HARALD STAHL**  
GEA Group

**DR JÜRGEN WERANI**  
Schuh & Co.  
Komplexitätsmanagement

With  
FDA-Speaker



Image: GEA Pharma Systems

**This conference is part of the  
Pharma Congress 2012**

# Manufacture of Oral Solid Dosage Forms

## Continuous Processing & Increasing Efficiency

Düsseldorf/Neuss, Germany, 25 April 2012

### HIGHLIGHTS:

- Continuous Manufacturing
  - FDA's current thinking
  - Case Story Astra Zeneca
  - Case Story Janssen Pharmaceutica
- Increasing Efficiency
  - Total Productivity Management
  - Increasing the efficiency of tableting processes
  - Tools for achieving operational excellence

## Objectives

This conference aims at informing about recent technologies in the manufacture of oral solid dosage forms and how the efficiency in the manufacturing plant can be increased or costs can be reduced.

## Background

Solid dosage forms are still the most common dosage form, first and foremost tablets with a portion of over 50%. Tablets are the least expensive dosage form, have a good stability and open up adjustable possibilities of drug release.

This conference focuses on two hot topics: **Continuous Processing and Increase of Efficiency**. Both topics are of importance for the question, where future production will take place. Moreover, regulating authorities, first of all the FDA, 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?

Listen to companies who already did this transition and learn about advantages and disadvantages.

The second block of the conference will further deal with how the efficiency of a production plant for oral solid dosage forms can be increased and how production costs can be reduced. These are important points for the discussion about future manufacturing locations and site to site competition.

## Target Audience

This event is designed for all managers and executives from Pharmaceutical Development, Production and Quality Assurance, responsible for development, transfer or manufacture of solid dosage forms.

## Moderator

**Dr Harald Stahl**, *GEA Pharma Systems*

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**Programme**  
**Block**  
**Continuous Processing**

**Regulatory Update on Continuous Processing**

- Validation of continuous processes
- Handling deviations
- Release procedure

**ALICIA MOZZACHIO, FDA, Office of Manufacturing and Product Quality**

**Case Story: Janssen Pharmaceutica**

**Continuous Processing – The Ultimate in Lean Manufacturing**

- Comparison Batch vs Continuous
- Benefits & Pitfalls of Continuous
- Business Case for Continuous
- Continuous & Quality-by-Design
- Continuous Processing Equipment

**PHILIPPE CAPPUYNS, Janssen Pharmaceutica, subsidiary of Johnson & Johnson**

**Case Story: AstraZeneca**

**DR HENRY HUANG, AstraZeneca**

**Block**  
**Increasing Efficiency**

**Increasing the efficiency of tableting processes**

- Technical approaches
  - Multi-tip tools
  - Increased number of punches of the torments
  - process technology
- Quality aspects
- Examples from the field

**HARALD RÖMER, Notter**

**Tools for increasing manufacturing efficiency**

- OPEX Scan: Analyze the Status Quo – Structure the Future
- Outcome of Operational Excellence programmes: experiences from the pharmaceutical industry
- How to save costs and expenses

**DR JÜRGEN WERANI, Schuh & Co. Komplexitätsmanagement**

**Total Productivity Management (TPM) & Change Management**

- Optimization of staffing levels
- Reducing storage space
- Reducing of processing time
- Increase of productivity

**OLIVER PÜTZ, A. Nattermann & Cie. GmbH**

**Speakers**

**PHILIPPE CAPPUYNS, Janssen Pharmaceutica**

Part of Global Technical Services within Janssen Supply Chain responsible for assessment of innovative technologies and the introduction of QbD in development and production.

**DR HENRY HUANG, AstraZeneca**

Senior Formulation Scientist

**ALICIA MOZZACHIO, FDA, Director Regulatory, Office of Manufacturing and Product Quality (OMPQ)**

**OLIVER PÜTZ, A. Nattermann & Cie. GmbH**

Mr Pütz is Head of Maintenance and manages the production and maintenance of strategic TPM projects. This he puts on the production site to the theoretical approach to the practice. Furthermore, the change management falls into his area of responsibility.

**HARALD RÖMER, Notter GmbH**

Mr Römer is an engineer and was Head of Filling in Plastics Division, Tetra Pak and Head of R&D, Engineering at Fette. Today he is a consultant and also working for Notter in the field of application technology.

**DR HARALD STAHL, GEA Pharma Systems**

Dr Stahl worked for the Pharmaceutical Development of Schering AG in Germany. Since 1995 he served within GEA Process Technology in various positions. Presently he owns the position of a Senior Pharmaceutical Technologist of GEA Pharma Systems. He has published more than 20 papers on various aspects of pharmaceutical production.

**DR JÜRGEN WERANI, Schuh & Co. Komplexitätsmanagement AG**

Formerly executive director of Pfizer Deutschland GmbH, Area Leader Europe RFT, Pfizer Global Manufacturing, now member of the executive board of Schuh & Co. Komplexitätsmanagement St. Gallen, Switzerland.

## Easy Registration



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### Date

Wednesday, 25 April 2012, 09.00 – 17.30 h  
(Registration and coffee 08.00 – 09.00 h)

### Venue

Swissôtel Düsseldorf / Neuss  
Rheinallee 1  
D-41460 Neuss  
Germany  
Tel.: +49 (0) 2131 77 - 00  
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### Fees

EUR 490.- per delegate plus VAT

The conference fee is payable in advance after receipt of invoice and includes lunch on that day as well as beverages during the event and during breaks. VAT is reclaimable.

Your registration also entitles you to participate in all other Pharma Congress conferences during that day. If you are also interested in participating in the conferences on 24 April please visit [www.pharma-kongress.com](http://www.pharma-kongress.com) for more information and for your registration.

### Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.pharma-kongress.com](http://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

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### For questions regarding content:

Dr Robert Eicher (Operations Director) at +49-6221/84 44 12, or per e-mail at [eicher@concept-heidelberg.de](mailto: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](mailto:benesch@concept-heidelberg.de).

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### Manufacture of Oral Solid Dosage Forms

Part of the Pharma Congress Production & Technology 2012  
Düsseldorf/Neuss, Germany, 25 April 2012

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