CONTINUOUS MANUFACTURING

Control Strategies and Best Practices for modern OSD Manufacture

27-28 November 2018, Barcelona, Spain

HIGHLIGHTS:
- Regulatory and filing requirements for continuous processes
- FDA’s past, present and future expectations
- Advanced process control with PAT
- Available Equipment & Technology
- Control Strategies in Continuous Processing
- Case Study TEVA
- Case Study GSK
- Case Study Continuus Pharmaceuticals

SPEAKERS

PROF DR THOMAS DE BEER
University of Ghent

DR RANJIT DHENGE
GSK

DR GIUSTINO DI PRETORO
Johnson & Johnson

DR SAU (LARRY) LEE
FDA, Deputy Director; Emerging Technology Team Chair, US FDA

ROGER NOSAL
Pfizer

DR SALVATORE MASCIA
Continuus Pharmaceuticals

NUNO MATOS
Hovione

DR MOHEB NASR
Nasr Pharma Regulatory Consulting & formerly FDA

DR FRANK STREIL
TEVA

This conference is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager“. Please find details at www.gmp-certification.eu
Objectives
It is the aim of this conference to show how a transition from batch to continuous manufacturing for small molecules can look like. Questions regarding technology, process development and GMP/Quality Assurance and Regulatory Affairs 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.

Continuous manufacturing is data driven and by gaining this flood of information two topics become very important: process control and process monitoring. A vast amount of data has to be evaluated in order to control the process and to decide whether material can be collected or has to be rejected.

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 with a continuous mode of operation new and already answered questions raise:

- How should a batch be defined? Is there a difference between lot and batch?
- What risks does a continuous process involve?
- How can a continuous line look like?
- Which concepts are conceivable for continuous processes
- How can a continuous process be kept in a controlled state?
- How is a continuous system validated?
- How to determine the ResidenceTimeDistribution – what about material traceability?
- 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.

Target Audience
This conference is directed at
- Decision makers dealing with the question whether continuous manufacturing should be implemented
- Executives from engineering, production and QA responsible for the implementation of continuous manufacturing

Moderator
Dr Moheb Nasr, NPRC and formerly FDA

Programme
Regulatory considerations of continuous manufacturing

Past, Present and Future for Continuous Manufacturing: FDA/CDER Perspective (remote presentation)
- The progress that FDA has made in CM will be discussed
- The current expectations will from FDA will be highlighted:
  - Submission review
  - Facility evaluation
- The recent trends and future challenges will be described

Global Regulatory Implementation of Continuous Manufacturing
- Impact of current regulatory system on implementation of CM
- Points to consider prior to the implementation of CM
- Filing requirement and expectations – Global perspective
- Remaining regulatory challenges
- Future regulatory guideline – ICH and regional
Programme

Regulatory Experience with Manufacturing Innovation including Continuous Processes
- Innovation can improve, manufacturing capacity, process efficiency & quality assurance. However global regulatory trends have been a barrier to innovation. Global implementation is increasingly confronted by punitive rather than incentive-based regulatory expectations.
- Acceleration only increases the challenge for CMC development & sustainable product commercialization
- This presentation describes regulatory experience, opportunities & challenges, with manufacturing innovations including continuous manufacturing

Development & control of continuous processes

PAT for model based design, optimization, monitoring and control of continuous manufacturing
- Linking a raw material property data-base to the performance of the unit operations of a DC line
- PAT for process understanding & process modeling of continuous manufacturing technologies
- PAT for process monitoring & control of continuous manufacturing
- Model based PAT implementation
- Model based design of continuous manufacturing technologies

Control Strategies in Continuous Processing – taking control to the next level
- Update on the Janssen’s journey to Drug Product Continuous Manufacturing
- Control Strategies in Continuous
- Residence Time Distribution in the control strategy
- How stable is a CM process? – development insights on the first Janssen’s NME in continuous manufacturing

Adapting the Quality System to Continuous Manufacturing and Real Time Release testing
- Batch Definition
- Process Validation
- System dynamics and material traceability
- Material traceability and segregation
- PAT for RTRt and model maintenance
- Batch records and data Review

Technology & Equipment

In this part, practical solutions for continuous manufacturing will be presented and explained by selected suppliers.

In continuous processing various unit operations get seamlessly combined. One of the most critical steps is the preparation of the feed material for the tablet presses. In this chapter/session key vendors explain concepts both for
- Continuous mixing and direct compression
- Continuous granulate drying

Additionally it is discussed how these can be by combination with further up- and downstream processes such as dispensing, compression and coating, further developed
- into fully integrated continuous manufacturing lines

Speakers:
Rainer Lemperle, Director of Sales, Gebrüder Lödige Maschinenbau
Dr Robin Meier, Manager Scientific Operations, L.B. Bohle
Cait Boyd, Sales Manager, Continuous Technology, GEA

Pharmaceutical Case Studies

Case Study TEVA: Continuous manufacturing of direct compression tablets
- Implementation of CM in commercial manufacturing
- Field report - Challenges and Benefits of CM
- Experience gained
Case Study GSK: Continuous Tablet Manufacturing using Wet Granulation
- Introduction to Continuous Tableting Line (CTL): Twin screw granulation
- Design selection considerations for twin screw granulation
- Process development and scale up and operations challenges on CTL
- Considerations for development of platform control strategy
- Current status and challenges for automated testing to enable real time release

Case Study Continus Pharmaceuticals:
Integrated continuous manufacturing with novel technologies
The development of novel manufacturing technologies has the potential for reaping the full benefits of continuous manufacturing. Moreover, their integration into a modular plug-and-play, end-to-end continuous manufacturing process, including both chemical and pharmaceutical operations, i.e. integrated continuous manufacturing (ICM), can open a new manufacturing paradigm for this industry. The development of an integrated control strategy for ICM is crucial to ensure release of pharmaceutical products that conform to specifications. ICM relies on proven principles of quality by design and the use of process analytical technologies to monitor and control the manufacturing operation. ICM will enable “on-demand” manufacturing of pharmaceuticals: high quality medicines will be produced quickly when needed, and a significantly reduced cost.

- Layout motivations for changes in pharmaceutical manufacturing
- Identification of the need for improving quality in pharmaceutical manufacturing
- Presentation of a case study on end-to-end (chemical + formulation) integrated continuous manufacturing

Speakers

PROF DR THOMAS DE BEER | University of Ghent, Professor in PAT at the Faculty of Pharmaceutical Sciences
Thomas De Beer is professor at the University of Ghent. His special fields of interest are: Process Analytical Technology, freeze drying, continuous pharmaceutical manufacturing, process analytics and process modelling.

DR RANJIT DHENGE | GSK, Scientific Investigator
Dr Ranjit Dhenge is Scientific Investigator within R&D Platform Technology & Science at GlaxoSmithKline. He works on product and process development through secondary continuous platforms. Ranjit’s area of expertise is in continuous twin screw wet granulation.

DR GIUSTINO DI PRETORO | Johnson & Johnson, Associate Director Drug Product Development - Continuous Manufacturing
Giustino Di Pretoro is an Associate Director at Janssen Pharmaceutica, a Johnson & Johnson Company. Dr Di Pretoro is a subject matter expert and drug product development lead for continuous manufacturing, and coordinator for a series of academic collaborations within the field of continuous.

DR SAU (LARRY) LEE | FDA, Deputy Director; Emerging Technology Team Chair, US FDA
Sau (Larry) Lee joined FDA in 2005. He is a Senior Biomedical Research Scientist (SBRS). In addition to serving as the Deputy Director in OPQ’s Office of Testing and Research, he is also the chair of the OPQ Emerging Technology Team responsible for facilitating the development and implementation of novel technologies for pharmaceutical applications.

ROGER NOSAL | Pfizer, Vice President and Global CMC Head, Pfizer US
Roger Nosal is Vice President and Head of Global Chemistry, Manufacturing & Controls (GCMC) at Pfizer Inc. He has 37 years of experience in the pharmaceutical industry at G. D. Searle, Monsanto, Pharmacia and Pfizer. During the last 24 years, Roger has been directly accountable for development, preparation and prosecution of regulatory strategies and regulatory CMC submissions.

DR SALVATORE MASCIA | Continus Pharmaceuticals, Founder & CEO Continuous Pharmaceuticals
Dr Salvatore Mascia is the Founder & CEO of CONTINUUS Pharmaceuticals. He was the former Strategic Project Manager at the Novartis-MIT Center for Continuous Manufacturing, where he led the integration of the first end-to-end continuous manufacturing process for pharmaceuticals.

NUNO MATOS | Hovione, Head of Quality Continuous Manufacturing
Nuno Matos is the Head of Quality Continuous Manufacturing, with the responsibility of overseeing all Quality Assurance and Quality Control activities related with Drug Product Continuous Manufacturing. Nuno leads a team of Quality Assurance Specialists and Process Analytical Scientists working on systems and procedures to enable Continuous Manufacturing, Process Analytical Technology enabled control strategies and Real Time Release testing.

DR MOHEB NASR | Principal at Nasr Pharma Regulatory Consulting (NPRC) & formerly FDA
Moheb Nasr managed the CDER Pharmaceutical Analysis Program at the US FDA for four years and had the lead of the CDER/FDA CMC Regulatory Program for more than eight years. He also worked for GSK as VP Global CMC Strategy. In 2018 he started his own consultancy business.

DR FRANK STREIL | TEVA, Director Technical and Scientific Affairs
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.
SOCIAL EVENT
On 27 November you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

WHAT ARE THE ECA FOUNDATION AND THE ECA ACADEMY?
The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

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By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?
During the membership, you enjoy
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- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

GMP/GDP CERTIFICATION PROGRAMME
This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

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- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.
Date
Tuesday, 27 November 2018, 09.30 to approx. 18.00 h
(Registeration and coffee 09.00–09.30 h)
Wednesday, 28 November 2018, 09.00 to approx. 16.00 h

Venue
Barceló Sants Hotel
Plaça dels Països Catalans, s/n
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Fees (per delegate plus VAT)
Non-ECA Members € 1,790
ECA Members € 1,590
APIC Members € 1,690
EU GMP Inspectors € 895
The conference fee is payable in advance after
receipt of invoice and includes conference
documentation, dinner on the first day, lunch
on both days and all refreshments.
VAT is reclaimable.

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CONCEPT HEIDELBERG has reserved a
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with the hotel.
Early reservation is recommended.

Registration
Via the attached reservation form, by
e-mail or by fax message. Or you register
online at www.gmp-compliance.org.

Conference language
The official conference language will be
English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with
the organisation of this event.
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For questions regarding reservation,
hotel, organisation etc. please contact:
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Reservation Form (Please complete in full)
Continuous Manufacturing
27-28 November 2018, Barcelona, Spain

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