ECA Academy
Your GMP/GDP Information Source

SPEAKERS

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Johnson & Johnson

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Steve Hammond Consulting

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Boehringer Ingelheim Pharma

RICHARD STEINER
GEA

ANTHONY TANTUCCIO
Merck & Co, US

FRANK WITULSKI
Merck & Co, US

JAN VERELST
Siemens

Image: GEA

LIVE ONLINE CONFERENCE | 19/20 OCTOBER 2021

CONTINUOUS MANUFACTURING FROM DEVELOPMENT TO OPERATION

HOW TO DEVELOP, IMPLEMENT AND OPERATE CONTINUOUS OSD MANUFACTURING

HIGHLIGHTS:

- The actual Continuous Manufacturing Landscape
- Technology for Continuous Manufacturing
  - Wet & Dry Granulation
  - Direct compression
- Development of a Continuous Manufacturing Process
  - Prerequisites
  - Usage of DoE
  - How to determine the ResidenceTimeDistribution?
- Set-up of a Control Strategy
- Measurement & Control
  - Usage of PAT
  - Data Management
  - Sensor Interfaces
- Operation of a Continuous Process
  - Handling of non-conforming Material
  - Cleaning
- How to implement Real Time Release?
- Case Studies from MSD and J&J

This conference is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager". Please find details at www.gmp-certification.eu

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Objectives

It is the aim of this event to show how a continuous manufacturing process for oral solid dosage forms can be developed and set into operation. Questions regarding materials, technology, process controls and GMP/ Quality Assurance will be discussed and answered.

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 (CM). Companies like Johnson & Johnson, Vertex, Pfizer and Merck work intensively on the development of continuous processes with some products already approved. This change from batch-to-batch to the continuous mode of operation is one of the largest paradigm changes in the pharmaceutical industry ever.

Continuous manufacturing is data driven and by gaining this flood of information two topics become very important: process control and process monitoring. The residence time of the materials processed becomes another important quality aspect. Time now also is the most important parameter for scale-up, not the volume of the equipment any more.

So a large 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. This fundamental shift is also a major challenge for the Quality Unit. The Quality Management System has to be adapted to also cover continuous processes.

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. Pharmaceutical companies emphasis the savings of time and materials needed during the development and transfer phases.

But with a continuous mode of operation new questions rise:

- How should a batch be defined? Is there a difference between lot and batch?
- What are the prerequisites for the development of a continuous process?
- What new risks does a continuous process involve?
- How can a continuous manufacturing line look like?
- How can a continuous process be kept in a controlled state?
- How is a continuous process validated?
- How to determine the **R**esidence**T**ime**D**istribution – what about material traceability?
- How should deviations in a continuous process be handled?
- How should equipment cleaning and maintenance be scheduled?
- Which documents do the authorities require for approval of continuous processes?

Listen to companies who already did the transition and learn how they answered the questions above.

Target Audience

This conference addresses specialists and executives working in the fields of pharmaceutical development, manufacture and quality assurance as well as technicians, planners and plant designers, especially those involved in the set up of continuous lines for manufacture of oral solid dosage forms.

Programme

The recent Continuous Manufacturing Landscape

- Introduction to Continuous Manufacturing
- From Early ideas to current solutions
- Reasons to go Conti
- A brief market overview- unit operations, suppliers & users...
- Different approaches to CM
  - Direct Compression
  - Roller Compaction &Tableting
  - TSG/Fluidbed Granulation & Tableting

Programme

Prerequisites: how to start with Continuous Manufacturing

- Is a new product suitable for CM?
- What are the business drivers for this product and how can CM meet those goals?
- Evaluation of material properties for CM (e.g. flow, feeding variability, etc.)
- Process modelling
- Control strategy considerations

Using DoE for the development of continuous processes

- Basis of using DoE in process development
- How to start
- Data evaluation
- Limitations
- Example: continuous twin screw granulation (TSG)

Measurement points and sensor interfaces

- Sampling
- PAT techniques
- Mass balance models

Integrated PAT data management on continuous pharmaceutical lines

- Integration of (different) PAT tools into an (existing) automation environment
- Structured data management of data from different data sources
- Real-time monitoring of CQA's
- Product diverting & Advanced Process Control
- Some use cases

Development of a control strategy

- Different approaches
- RTD and its determination
- Material traceability
- Risk analyses

Real time release

- What does this mean?
- Benefits?
- Registered Examples

J&J experience: CM from equipment qualification to regulatory submission

- Overview of the three technologies used at J& J Pharma
  - Wet granulation
  - Dry granulation
  - Direct compression
- SDNV approach for qualification
- Control strategy – practical aspects
  - PAT integration
  - CPPs monitoring
  - RTD
  - Rejection strategy
- Cleaning & Change Over challenge
- Experiences from Regulatory submission

Case Study Merck US: Continuous Manufacturing using Direct Compression

- Experiences with developing, commercializing, and filing Merck's first CM product.
- Use of an RTD Process Model for Rejection in a CDC process.
- Look-ahead towards future innovations with Continuous Manufacturing

SPEAKERS

DOMENICO ANNESE | Johnson & Johnson | Technical Operation Sr. Lead
Domenico has 10 years of experience in J&J in different roles, for example in Quality, Execution Systems, Operations (formulation) and lastly as Technical Operations Sr Lead, responsible for the introduction of new products and Technical Transfers for batch mode and continuous manufacturing mode.

ALESSANDRO CASSETTI | Johnson & Johnson | Operation Manager
Alessandro has 9 years of experience in J&J covering different responsibilities in QC and Technical Operations as scientist on continuous manufacturing as well as Operation Manager responsible for new products (batch and CM mode).

STEVE HAMMOND | Steve Hammond Consulting | Owner
Steve Hammond has more than 30 years of experience in developing and deploying PAT in the Pharmaceutical Industry. He has been working for Pfizer as Director oft he Process Analytical Support Group and led the efforts to develop and deploy PAT within Pfizer Pharmaceuticals Manufacturing division. Now he runs his own consultancy business with focus on Process Analytical Sciences.

DR MARTIN MAUS | Boehringer Ingelheim Pharma | Principal Scientist
Martin is a Principal Scientist at Boehringer Ingelheim in Biberach where is working in late stage product development of solid oral dosage forms.

RICHARD STEINER | GEA | Global Sales Director for Continuous Processing Technologies
Richard Steiner is a mechanical engineer and worked in different management positions during his times at Leistritz. In 2012 he joined GEA and is today Global Sales Director for Continuous Processing Technologies at GEA Pharma Systems.

ANTHONY TANTUCCIO | Merck & Co, US | Senior Scientist
Anthony Tantuccio is a Senior Scientist in the Pharmaceutical Commercialization Technology group at Merck & Co. in the US. He leads the technology development team with the mission to build out processes for the successful adoption of continuous manufacturing. He is the lead designer of Merck's pilot non GMP and clinical GMP continuous manufacturing lines.

FRANK WITULSKI | Merck & Co, US | Director of Engineering
Frank Witulski is a Director of Engineering in Merck's Pharmaceutical Commercialization Technology department and holds a Master of Science in Chemical Engineering. He has over 19 years of experience in process and packaging development and commercialization of OSD products, and has spent the last 4 years leading the group responsible for commercializing Merck's first continuous direct compression process.

JAN VERELST | Siemens | Global Business Development Manager for SIPAT
Jan Verelst is a chemical Engineer with 27 year of experience with CDS, LIMS and PAT Systems. Currently Jan holds the position of Global Business Development Manager for SIPAT, the PAT data management solution of Siemens, focusing on Pharmaceutical Industries.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
- APIs (ICH Q7)
- Medicinal Products
- Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
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- Technical Operations

You will find a time schedule for each training course at www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

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Easy Registration

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Date of Live Online Conference
Tuesday, 19 October 2021;
09.00 to approx. 17.15 h
Wednesday, 20 October 2021,
09.00 to approx.. 16.30 h
All times mentioned are CEST.

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Fees (per delegate plus VAT)
ECA Members EUR 1,490.-
APIC Members EUR 1,590.-
Non-ECA Members EUR 1,690.-
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The conference fee is payable in advance after receipt of invoice.

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

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

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Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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