ECA Academy
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GMP Certification Programme
Certified Technical Operations Manager

Continuous Manufacturing of Oral Solid Dosage Forms

Advanced Pharmaceutical Production: GMPs, Development & Technology

16-18 April 2024, Lisbon/Cascais, Portugal

Image: Hovione Site Cascais, Portugal

Speakers

Selma Celikovic
RCPE

Prof Dr Alastair Florence
CMAC

Dr Shashwat Gupta
Eli Lilly

Dr Jim Holman
GEA

Dr Adrian Kape
Glatt

Dr Sau (Larry) Lee
FDA

Prof Dr Jim Litster
University of Sheffield

Dr Rapti Madurawe
FDA

Dr Robert Meyer
MSD

Dr José Luís Santos
Hovione

Wayne Sinclair
TEVA

Jesus Torres
Thermo Fisher Scientific

Jan Verelst
Siemens

Highlights

- FDA's expectations regarding Continuous Manufacturing
- Case Studies from Innovators
  - MSD: PACMPs for Conversions to Continuous Manufacturing
  - Eli Lilly: Expansion of Continuous Manufacturing to Wet Granulation
- Case Studies from Generics and CDMOs
  - TEVA: Continuous Manufacturing of Direct Compression Tablets
  - Hovione: Accelerated Manufacturing by Continuous Tableting
  - Thermo Fisher Scientific: Transitioning to Continuous Manufacturing
- Continuous Manufacturing Technology
  - GEA: Combining Unit Operations for Continuous Tableting
  - Glatt: Modular Continuous Wet Granulation Lines
  - Siemens: PAT data management on continuous pharmaceutical lines
- Latest Research & Development
  - University of Sheffield
  - CMAC
  - Research Center Pharmaceutical Engineering (RCPE)

Incl. Full-day Visit of Hovione's CM Facility

Objective

The objective of this event is to share the practical experience and the potential of continuous manufacturing for oral solid dosage forms, also known as continuous tableting. Through the expertise of leading individuals in academia, industry, and regulation, the following objectives will be achieved:

- **Regulatory Requirements:** The regulatory landscape will be provided by experts, who will discuss Regulatory Processes for New Chemical Entities and Post Approval Change Management Plans (PACMPs).
- **Industry Experience:** In this part of the event, the practical experiences of pharmaceutical manufacturers who are embracing continuous manufacturing are highlighted. Insights will be shared from those with significant experience in the field, including innovators and generic companies that have adopted continuous tablet production, and CDMOs that are developing the expertise and capabilities to provide access to the technology to the entire industry.
- **Technological Opportunities:** The technology providers that synergistically enable the deployment and operationalization of continuous tableting will discuss their efforts and capabilities in detail. This includes the understanding of unit operations and their integration into continuous mode, and process control system enhanced with PAT, to establish an ecosystem of real-time monitoring and advance process control running effective and efficient processes.
- **Latest research:** The event will offer a chance to explore recent research that combines both theoretical and practical aspects of continuous tableting. During this session, it will be shown how the utilization of models, data-driven approaches and seamless integration contribute to improving the effectiveness of continuous tableting development and production.

Background

The pharmaceutical manufacturing landscape is undergoing a significant shift, with continuous manufacturing emerging as a catalyst for change. Historically dominated by batch processes, this transition towards continuous manufacturing holds the promise of improved efficiency, enhanced quality, greater operational flexibility and accelerated development. A select group of pioneering companies alongside leading academic institutions are at the forefront of this transformation and will share their practical experience infusing innovation around continuous tableting into the industry.

Regulatory bodies, namely the FDA, are actively promoting the transition from batch to continuous production. Their primary expectation is an enhancement of product quality, faster development, and reliable, robust, and agile supply. Pharmaceutical companies emphasize the substantial savings in time and materials during development and transfer phases that are a result from the enhancements that continuous manufacturing offers.

The essence of continuous manufacturing lies in data-driven operations. As a flood of information becomes available, two critical areas gain prominence: process control and process monitoring. The residence time of processed materials assumes significance as a quality factor. Notably, time has surpassed equipment volume as the pivotal parameter for scaling up operations. The evaluation of substantial amounts of data is imperative for effective process control and the determination of whether materials meet the required standards or should be discarded. Besides production and technology, the quality unit is decisively affected by these changes, as the entire quality management system must be adapted to include continuous processes.

Target Audience

This conference addresses specialists and executives working in the fields of pharmaceutical development, manufacture and quality assurance, especially those involved in the setup of continuous lines for the manufacture of oral solid dosage forms. Executives from plant construction and engineering companies are also the target group of this event.

Programme

Part I – Regulatory Considerations and Experience in Continuous Manufacturing

CDER Perspective on Advanced Manufacturing (Remote Presentation)

Dr Sau (Larry) Lee, FDA

- The progress that FDA has made in CM will be discussed
- The current expectations from FDA will be highlighted:
  - Submission review
  - Facility evaluation
- The recent trends and future challenges will be described

FDA's Perspective on continuous Manufacturing

Dr Rapti Madurawe, FDA

- Development of ICH Q13 guidance and next steps
- Key concepts of continuous manufacturing
- FDA's experience with CM and ongoing activities
- Future directions

View from Innovators

Post Approval Change Management Plans (PACMPs) for Conversions to Continuous Manufacturing

Dr Bob Meyer, MSD

- Application of ICH Q12 to continuous manufacturing
- What makes a good candidate for conversion to continuous
- Costs and benefits of PACMP
- Case study 1 – legacy high-volume OSD product
- Case study 2 – high-speed low volume OSD product
- Takeaways and future directions

Advancements in the Application of Continuous Manufacturing at Eli Lilly

Dr Shashwat Gupta, Eli Lilly

- Lilly's history and experience with continuous direct compression
- Lilly's expansion of continuous manufacturing to wet granulation platform
- Wet granulation control strategy
- Summary and next steps for continuous manufacturing at Lilly

View from a Generic Manufacturer

Case Study TEVA: Continuous Manufacturing of direct Compression Tablets
Wayne Sinclair, TEVA

- Implementation of CM in commercial manufacturing
- Challenges and Benefits of CM in Generics manufacturing
- Experience gained
- Future outlook

View from CDMOs

Continuous Tableting (CT): Embracing Flexibility to Accelerate Manufacturing
Dr José Luís Santos, Hovione

- The role of a CDMO for the adoption of emerging technologies such as CT
- Need for defining an equipment standard that enables maximum flexibility and efficiency
- Review of the modes of operation and control strategies that current CT equipment can support
- Flexibility as an enabler of the acceleration of drug product manufacturing
- Roadmap to simplification of CT: Hovione's journey

Transitioning to Continuous Manufacturing for OSD within a CDMO
Jesus Torres, Thermo Fisher Scientific

The talk will provide an overview with case studies related to the challenges and successes in introducing continuous manufacturing for OSD including:

- Comparing against batch internally and externally on batch size and price
- Technology selection both initial and ongoing
- Adding technology and capabilities in partnership with clients, Real Time Release, High Potency
- Expanding capabilities across a manufacturing network

Part II – Technology and Technology Providers

Process Understanding of combining Unit Operations for flexible Continuous Tableting (CT) Manufacturing
Dr Jim Holman, GEA

- Overview of CT and flexible manufacturing lines
- Study into the process robustness of the CT line over extended running
- How data from CT lines can be better used for product understanding and process stability using soft sensors and data analysis
- Case studies showing adoption of CT and benefits on commercial products

The Possibilities of modular continuous wet Granulation Lines with regards to exchangeable Unit Operations
Dr Adrian Kape, Glatt

- Introduction of the modular concept of a continuous wet granulation line
- Process possibilities control integration
- Successful product development

Integrated PAT Data Management on Continuous Pharmaceutical Lines
Jan Verelst, Siemens

- 21CFR11 compliant integration of (multiple) PAT tools combined with an (existing) automation environment
- Structured data management of inputs from different data sources
- Real-time CQA monitoring
- Advanced Process Control
- Some use cases

Part III – Latest Research & Development

Right First Time Manufacture of Pharmaceuticals
Prof Dr Jim Litster, University of Sheffield

- Continuous manufacturing of oral solid dosage forms
- Use of models across life cycle from model driven design to real time management and real time release
- Integration across the whole flowsheet rather than a single unit operation
- Emphasis on appropriate use of machine learning (data driven) models
- Validation on two different pilot plants in Sheffield and Purdue

Quality by Digital Design: Bridging Drug Substance and Drug Product Development
Prof Dr Alastair Florence, CMAC

- Overview of our digital CMC vision and Quality by Digital Design Framework for medicines development and manufacturing
- Predictive toolbox development for crystallisation (CCS) and drug product (MCS+)
- Building the data fabric to support product and process development
- Datafactories and automated workflows to accelerate development

Advancing the Design and Application of Digital Twins in Continuous Manufacturing Lines
Selma Celikovic, Research Center Pharmaceutical Engineering

- Process modelling of continuous manufacturing lines
- Design of digital twins in a simulation environment
- Control-oriented digital twin application on industrial equipment
- Digital transformation of the traditional manufacturing lines

18 April 2024: Visit of the Hovione Sites in Lisbon

Hovione Site Visit – Continuous Tableting Facilities

As part of the conference, registered participants will have a unique opportunity to visit Hovione's cutting-edge labs and manufacturing facilities in Lisbon, where research, development, and manufacturing activities take place.

In the labs, participants will gain access to Particle Engineering facilities, explore some of the most advanced analytical PAT tools, and get a close look at the specialized equipment used in continuous tableting development. They will also have the chance to observe analytical and process development operations in an engaging hands-on workshop, guided by Hovione experts.

During the visit to the manufacturing facilities, participants will witness a state-of-the-art facility in action, showcasing a continuous direct compression production unit. Additionally, they will have the opportunity to see and compare with an equivalent batch process.

Please note that availability for this exclusive site visit is limited, so securing your spot early is highly recommended to ensure you don't miss out on this opportunity to experience pharmaceutical innovation at Hovione.

- We provide bus transfer from the conference hotel to the Hovione sites. After the site visit there will be transfers to the airport and back to the conference hotel
- Due to competition reasons, individual participants may be excluded from the site visit
- Participants are required to sign a Confidential Disclosure Agreement (CDA) before entering Hovione sites

Image: Hovione Sete Casas, Portugal

Social Event

On 16 April 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.

Speakers

Selma Celikovic
Research Center Pharmaceutical Engineering (RCPE)

Selma Celikovic is a senior scientist in the 'Next-Generation Manufacturing' area at RCPE with a background in electrical engineering. During the last five years, she has worked on several projects focusing on process modelling & control, optimization and automation of continuous manufacturing lines.

Prof Dr Alastair Florence
CMAC

Professor Alastair Florence is distinguished Professor in Pharmaceutical Sciences at the University of Strathclyde and Director of CMAC, leading a portfolio of collaborative research, training and translational programmes aimed at transforming the way medicines are developed and manufactured.

Dr Shashwat Gupta
Eli Lilly

Dr Shashwat Gupta is an Engineering Advisor in Synthetic Molecule Design & Development at Eli Lilly. He focuses on drug product process design and development via novel CM/semi-CM technologies.

Dr Jim Holman
GEA

Dr Jim Holman is the Senior Director for Technology Management for the Pharmaceutical Solid Dosage business within GEA's Food and Healthcare Division. Jim is responsible for all new product innovations and developments across the continuous, batch, compression and material handling solid dosage business as well as leading industrial and academic collaborations to advanced process understanding in these areas.

Dr Adrian Kape
Glatt

After his PhD in food technologies and material science Dr Adrian Kape worked in the process and equipment development at Glatt. Today as a BD Manager for Key Technologies at Glatt he is responsible for the continuous technologies for pharma customers worldwide.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Continuous Manufacturing of Oral Solid Dosage Forms

16-18 April 2024, Lisbon/Cascais, Portugal

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will 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)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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 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.

Date

Tuesday, 16 April 2024, 14.00 to approx. 18.00 h
(Registration and coffee 13.30 – 14.00 h)
Wednesday 17 April 2024, 08.30 to approx. 17.00 h
Thursday 18 April 2024, 8.30 to approx. 16.00[1]/16.30[2]/17.00[3] h)

[1] approx. end of the site visit
[2] approx. airport arrival
[3] approx. return at the conference hotel

There will be a shuttle after the site visit. This shuttle will arrive at the airport at approx. 16.30 h and approx. at 17.00 h at the hotel.

In certain cases a participation in the site visit may not be possible due to competitive reasons. Participants are required to sign a Confidential Disclosure Agreement (CDA) before entering Hovione sites.

Venue

Pestana Cidadela Cascais
Avenida D. Carlos I
2750-310 Cascais - Portugal

Fees (per delegate, plus VAT)

ECA Members € 2090
APIC Members € 2190
Non-ECA Members € 2290
EU GMP Inspectorates € 1145
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on the second day and a business lunch on the third day as well as all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly 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.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Robert Eicher (Operations Director) at
+49(0)62 21/84 44 12 or per e-mail at
eicher@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Maxillian Bauer (Organisation Manager) at
+49(0)62 21/84 44 25, or per e-mail at
bauer@concept-heidelberg.de

Speakers (cont.)

Dr Sau (Larry) Lee
FDA

Dr Sau (Larry) Lee is the Deputy Super Office Director of Science in the Office of Pharmaceutical Quality. He directs the activities of staff members in OPQ sub-offices responsible for the quality assessment of regulatory submissions. He represents OPQ in programs and activities that impact quality assessments by coordinating with OPQ, CDER, and ORA. He also serves as the point person for the pharmaceutical industry and scientific/academic groups in developing programs to support science- and risk-based application assessment and approval. He developed and established the Emerging Technology Program in CDER. He has been serving as a rapporteur for ICH Q13 on Continuous Manufacturing of Drug Substances and Drug Products.

Prof Dr Jim Litster
University of Sheffield

Jim Litster is Professor of Chemical and Pharmaceutical Engineering at the University of Sheffield. He is principal Investigator in the EPSCR/NSF funded project: Right First Time Manufacture of Pharmaceuticals (RiFTMaP). Jim has been working on continuous manufacture on pharmaceuticals for 16 years as part of the NSF CSOPS centre (2007-2015) and the EPSRC CMAC Hub (2016-present).

Dr Rapti Madurawe
FDA

Rapti Madurawe is a Division Director in the Office of Process and Facilities, Office of Pharmaceutical Quality, FDA. She has extensive regulatory experience in the CMC assessment of new, investigational drug and generic drug applications. She is FDA's topic lead for the ICH Q13 guidance on Continuous Manufacturing.

Dr Robert Meyer
MSD

Dr Robert Meyer is a chemical engineer. He joined MSD in 2002 where he worked in many areas of drug product development with focus on emerging manufacturing platforms such as hot melt extrusion and continuous manufacturing of oral solid doses. As a senior principal scientist, he currently leads a team focused on new technology development and innovation in Global Pharmaceutical Commercialization Development.

Dr José Luís Santos
Hovione

José has a broad experience in spray dried dispersions (SDDs) and CM. Specifically with regards to CM, he was involved in a large capital investment project of a new rig installed at Hovione US. Presently he is involved as a key expert in CM initiatives and new capital projects, and oversees the company's RD efforts around SDDs.

Wayne Sinclair
TEVA

Wayne Sinclair is Associate Director of Process Analytical Technology at Teva Pharmaceuticals. His main interest and experience are in the field of PAT applications in Pharmaceutical R&D and commercial manufacturing. He currently leads the PAT & Continuous Manufacturing initiatives for modernization strategies in Teva's global operations.

Jesus Torres
Thermo Fisher Scientific

With over 8 years of experience in the field of continuous manufacturing, Jesus Torres has been serving as a Staff Scientist within the solid dose Continuous Manufacturing program at Thermo Fisher Scientific since 2019. Throughout his career, Jesus has been actively engaged in various facets of continuous manufacturing, including engineering, automation, PAT and process modeling.

Jan Verelst
Siemens

Jan Verelst is a chemical Engineer with 27 year of experience with CDS, LIMS and PAT Systems. Jan Verelst is currently holding the position of Global Business Development Manager for Digital Quality Management solutions out of the Pharma headquarter division of Siemens.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

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.

GMP/GDP Certification Scheme


John Doe
ECA Certified
Microbiological Laboratory Manager

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org.

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