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January 30 – February 1, 2018 | Boston, USA

2nd Annual

CCP Summit 2018

Commercializing Continuous Processing in Pharma

Accelerate the Transition with Tightened Control to Ensure Drug Quality

20+ Speakers Include:

Yanxi Tan Cain
Executive Director, Global Quality Assurance, Global Head, Quality Management System
Merck

Aleksandar Cvetkovic
Head of Continuous Manufacturing Skill Center
Sanofi Genzyme

Giustino Di Pretoro
Associate Director – Continuous Manufacturing
Johnson & Johnson

Jon Coffman
Global Head of Innovation, Technology Biopharm
Boehringer-Inghelheim

Jorgen Magnus
Head of Bioprocess Technology
Bayer AG

"Great opportunity to exchange directly with the industry on case studies, suppliers and regulators. Very good organization!"
Scientific Director, Ypso-Facto

Innovation Partner

LEWA
Creating Fluid Solutions

Media Partner

Pharmaceutical Manufacturing

www.continuous-processing-pharma.com
Tel: +1 212 537 5898 **Email:** info@hansonwade.com

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Revitalize Your Manufacturing Approach

The **Commercializing Continuous Processing in Pharma Summit** returns to Boston as the only commercial pharmaceutical conference dedicated to continuous processing, helping you accelerate the switch from batch to CM.

With the recent success of Janssen in Europe and Vertex in the US, followed by the establishments of a two UK- and Singapore-led CM consortiums - the benefits of transitioning are widely being recognized and the industry has shown no signs of slowing down.

The **2nd annual CCP Summit 2018** is designed to help you fast track your switch with exclusive insights into engaging regional regulatory agencies for smooth approval, confronting technical challenges in both biologics and small molecules, and adopting quality control systems to drive reliability and drug quality.

Join your peers at this must-attend forum to access **practical case studies providing actionable insights** to keep you up to date with the rapidly changing landscape of continuous processing.

Hear what previous CCP Summit attendees have to say:

"This conference exceeded all of my expectations. The topics, speakers and suppliers were very relevant to my interests. I was able to walk away with many ideas and contacts to benchmark with!"
GSK

"It was very useful to hear about and interact with others regarding their challenges and achievements in continuous processing."
Momenta Pharmaceuticals

Key Case Studies Include:

1. **Sanofi Genzyme** demonstrates how to debottleneck downstream processing to accelerate CM advancement

2. **Vertex** shares tips on CP validation and control strategy – and how they have come so far with 2nd CM rig commercialization

3. **GSK** shares formulation considerations and QbD application for smooth CM implementation

4. **Pfizer** and **Biogen** unveil the possibility of end-to-end CM

5. **Johnson & Johnson** and **Eli Lilly** present their CM journeys so far, and how to execute tech transfer to CMO

Expert Speakers

Aleksandar Cvetkovic
Head of Continuous Manufacturing Skill Center
Sanofi Genzyme

Yanxi Tan Cain
Executive Director, Global Quality Assurance, Global Head, Quality Management System
Merck

Nathan Collins
Vice President, Applied Research & Technology Development
SRI Biosciences

Jon Coffman
Global Head of Innovation, Technology Biopharm
Boehringer-Inghelheim

Robert Fahrner
Senior Principal Scientist & Group Leader, Bioprocess R&D
Pfizer, Inc.

Giustino Di Pretoro,
Associate Director – Continuous Manufacturing
Johnson & Johnson

Kevin Cole
Principal Research Scientist, Small Molecules Design & Development
Eli Lilly & Co.

Michelle Bailey
Associate Director, GMP Validation, Continuous Manufacturing & Automation
Vertex

Indrajeetsinh Yadav
Investigator (Secondary Continuous), Drug Product Development
GSK

Jorgen Magnus
Head of Bioprocess Technology
Bayer AG

Engin Ayturk
Senior Manager, Technical Development
Biogen

Ding Ming
VP, Research & Innovation
US Pharmacopeia

Sanjeev Kothari
Senior Director of Pharmaceutical Chemistry and Formulations
Ardelyx, Inc.

Gerard Gach
Chief Marketing Officer
LEWA-Nikkiso America, Inc.

Roger-Marc Nicoud
Founder & CEO
Ypso-Facto

David Pfister
Project Manager
Ypso-Facto

Terry Seanard
Principal Engineer
New England Controls, Inc.

Morten Munk
Global Technology Partner
NNE

Antonio Lima Grillo
Researcher, Biological Systems Engineering Group
Imperial College

Jeffery Odum
Global Technology Partner, Strategic Manufacturing Concept Group
NNE

Jana Spes
Former Vice President, Technical Operations
Apotex

Niels Guldager
Global Technology Partner
NNE

"I enjoyed the discussions and meeting our colleagues at the conference!"
Bristol-Myers Squibb

PRE-CONFERENCE WORKSHOP DAY
TUESDAY, JANUARY 30, 2018

Workshop A - Going Continuous for Sure, but Why & How?

08:00 – 11:00

Despite the current infatuation for continuous manufacturing technologies, some interrogations remain about the real gain brought when turning continuous.

This workshop will enable you to thoroughly compare batch and continuous processes from a chemical engineering perspective, and see in which circumstances and why CM can be a real game changer. Through various case studies we will investigate scenarios where the choice between batch and continuous is not as easy as it may seem.

Moreover, this workshop will demonstrate **how process modeling can be used as an efficient tool for a smooth implementation of CM.** Modeling can really be a powerful asset to understand, compare and design your processes.

This workshop will help you:

- Rationalize your decision when investigating continuous technology
- Make sound choices and investigate various scenarios with the help of process modeling
- Gain confidence when implementing a new continuous process

Workshop Leader
Roger-Marc Nicoud
Founder & CEO
Ypso-Facto

Workshop Leader
David Pfister
Project Manager
Ypso-Facto

Roger-Marc Nicoud, founder and CEO of Ypso-Facto, has forged a successful career as an entrepreneur in the life sciences industry.

Roger-Marc Nicoud founded Ypso-Facto in 2014 as a service company offering assistance to industrial firms to develop, optimize and secure their chemical and bioprocesses.

David is a chemical and biochemical engineer with expertise in chromatography and in process modeling He holds a PhD in Chemical Engineering from Eidgenössische Technische Hochschule Zürich (EHT Zürich, Switzerland) with post-doctoral experience. He has worked on improving the production process of PEGylated proteins with the support of modeling and simulation, including the integration of the reaction and separation steps

Workshop B - Do's & Dont's in Continuous Manufacturing Biotech Facility Design

11:30 – 14:30

The advantages of continuous bioprocessing include increased productivity, flexibility of operations and decreased facility footprint. That being said, a detailed thought process needs to be incorporated during facility design and ancillary support services.

This workshop will provide you with a step-by-step guide of how to optimize facility suitable for continuous bioprocessing in a cost-efficient way.

Key takeaways:

- Benefit from hands-on experience with the design and operation of CM facilities
- Explore a holistic approach to establishing a CM facility from design to operations, and other logistical considerations
- Gain insight into the regulatory expectations
- Address real time process control, strategy and requirements for successful CM operations

Workshop Leader
Morten Munk
Global Technology Partner
NNE

Workshop Leader
Jeffery Odum
Global Technology Partner, Strategic Manufacturing Concept Group
NNE

Workshop Leader
Niels Guldager
Global Technology Partner
NNE

PRE-CONFERENCE WORKSHOP DAY
TUESDAY, JANUARY 30, 2018

Workshop C - Realizing Robust Process Control for Continuous Manufacturing

15:00 – 18:00

Traditional batch processing consists of distinct unit operations with sufficient time for verifying forward processing conditions based on critical quality attributes before progressing to the next unit operations.

In a Continuous Manufacturing (CM) process, quality attributes must be verified real time to prevent exposing downstream units with out-of-specification material. While batch processing can usually be scaled by discrete steps (batches per year), CM provides the opportunity to scale throughput by modulating flow rates through the system and provides additional degrees of freedom in operational flexibility.

A tightly integrated Process Control System and Real Time Dynamic Model provides the ability **to manage the complexity of interlinked material transport, reaction rates, and equilibrium conditions.** A well designed control and real time modeling strategy can enable process options which are otherwise not possible by expanding design space constraints and improving process understanding.

This workshop will enable you to:

- Understand the components of an integrated control strategy and real time modeling and how they interact during each phase of the project lifecycle, from process design through scale up, validation, and operation
- Assess the considerations and benefits of integrating control strategy design and real time modeling with the design of the overall process
- Understand what to include and what to ask when preparing a bid package or project plan for a CM process with a tightly integrated control and modeling strategy

Workshop Leader
Terry Seanard
Principal Engineer
New England Controls, Inc.

Terry is currently a Principal Engineer and the Continuous Manufacturing Program Technical Lead at New England Controls. His formal education in Chemical Engineering and Bioengineering is supplemented by almost 15 years of experience supporting many of the large scale biotech manufacturers in the Boston area. His experience ranges across design, management, implementation, site startup, and life cycle support of complex process control systems and manufacturing operational enhancement projects, primarily in the life sciences industry.

"This was one of the best conferences I've been to in years. Specific to the business needs, applicable to current situations facing pharma!"
Sanofi

Conference Day One | Wednesday, January 31, 2018

8.30 Coffee & Registration

9.00 Chair's Opening Remarks

Continuous Manufacturing Regulatory Updates

Ding Ming
VP, Research & Innovation
US Pharmacopeia

9.10 The Need to Define & Standardize Global CM Guidance

- Hear USP's perspective on continuous processing, and a comparison between US, EMEA and APAC
- Learn how to successfully interact and engage with regulatory agencies
- Address the challenges of defining quality standard globally
- What's next? Assess quality and risk management guidelines

Moderated by:

Sanjeev Kothari
Senior Director of Pharmaceutical Chemistry and Formulations
Ardelyx, Inc.

9.40 Roundtable Discussion: Establishing a Winning Business Case for Investment

- Weighing your options: highly automated batch processing vs. continuous manufacturing
- Discussing upfront investment costs against long-term benefits
- Defining your risk framework and laying out a mitigation strategy
- From feasibility study to evaluation to phase 1 - how do you convince your organization to switch?
- Accelerating time to market with commercial CM

10.20 Speed Networking & Coffee Break

Where Are We? Biologics CM Advancements

Robert Fahrner
Senior Principal Scientist & Group Leader, Bioprocess R&D
Pfizer, Inc.

11.40 End-to-End Integrated Processing Using Continuous/Batch Hybrid Systems

- Integrating upstream and downstream operations
- Analyzing results from pilot scale operations and options for scaling up
- Exploring pathways to implementation

Aleksandar Cvetkovic
Head of Continuous Manufacturing Skill Center
Sanofi Genzyme

12.10 Strategy for Continuous Capturing of Antibodies from Perfusion Processes

- Translating the upstream success of continuous processing into downstream units – perfusion and chromatography
- Is scaling down the way to go?
- What equipment and analytical tools are required to breakthrough continuous DSP?

12.40 Tech-Show in the Exhibition Hall!

Live demos from our technology partners: find out how continuous manufacturing can be made possible!

Delegates will get the chance to ask questions during this interactive sessions.

12.55 Lunch & Networking

Where Are We? Biologics CM Advancements

Gerard Gach
Chief Marketing Officer
LEWA-Nikkiso America, Inc.

13.55 SPOTLIGHT: Pioneering Technologies – Advanced Multi-Column Chromatography Platform

- Evaluating continuous 2 column capture; details and data
- Assessing sequential column operation with in-line buffer adjust between columns
- Exploring the impact of integrated buffer in-line dilution from concentrates
- Demonstrating three unit modes all on the same skid to manage nearly any production scenario

Engin Ayturk
Senior Manager, Technical Development
Biogen

14.10 Progress & Challenges in Bridging the Gap – End-to-End Continuous Processing

- Addressing implementation challenges for end-to-end automated continuous processing
- Evaluating early success in lab and pilot scale continuous biomanufacturing
- Reality check: Feasibility and operability – considerations and modifications to different technologies

Nathan Collins
Vice President, Applied Research & Technology Development
SRI Biosciences

14.40 Get it Right First Time – Designing Your Synthetic Process for CM at the Drug Discovery Stage

- Laying a good foundation for success at early drug discovery stage to ensure selected molecule can fit with CP
- Developing the recipe for CP during synthesis design using advanced lab based multistep continuous flow automation
- Pilot project data and next steps: Modeling scale-up to accelerate drug development and processing program

15.10 Tech-Show in the Exhibition Hall!

Live demos from our technology partners: find out how continuous manufacturing can be made possible!

Delegates will get the chance to ask questions during this interactive sessions.

15.30 Afternoon Refreshments & Networking

Enhancing Quality Control & Validation Strategy

Michelle Bailey
Associate Director, GMP Validation, Continuous Manufacturing & Automation
Vertex

16.00 Project Update: One Year On & Launch of Second Commercial CM Rig

- Discussing the lessons learnt in the first launch of CM at Vertex and challenges in the second commercial rig
- Collaborating with suppliers and CMOs for CM program build out
- Understanding regulatory inspection concentration areas for CM
- Looking beyond – what's next?

Antonio Lima Grillo
Researcher, Biological Systems Engineering Group
Imperial College

16.30 Poster Session: Towards Model-Based Bioprocess Design: An Upstream In-Silico Model of Cell Cycle, Metabolism & Apoptosis

- Modeling of bioprocess systems: providing a powerful tool to cope with the current QbD paradigm, the challenges imposed to the biologicals market by biosimilars and the move towards continuous biomanufacturing, and the need for time-to-market reduction
- Developing and validating an in-silico model of upstream mammalian cells biomanufacturing
- Addressing the potential of the model for process optimization, bioreactor heterogeneity description and reduction of experimental-based process development

16.45 Chair's Closing Remarks

16.50 Close of Day One

Conference Day Two | Thursday, February 1, 2018

8.30 **Coffee & Refreshments**

9.00 **Chair's Opening Remarks**

Commerciality of CM

Giustino Di Pretoro
Associate Director – Continuous Manufacturing
Johnson & Johnson

9.10 **Opening Address: Manufacturing the Future: The Journey from Batch to Continuous Manufacturing from an Industry Perspective**

- Janssen's historic FDA approval – gaining key insights into the successful change from batch to continuous manufacturing of Prezista®
- Understanding the vision and strategy for deployment of continuous manufacturing at Janssen
- Challenges and path forward – addressing the implementation of CM in development
  - API needs
  - Tech transfer

Kevin Cole
Principal Research Scientist, Small Molecules Design & Development
Eli Lilly & Co.

9.40 **Continuous Small Molecule API Manufacturing: Development & Technology Transfer to a CMO**

- Discover the case for and status of small molecule continuous processing at Eli Lilly
- Developing a multi-step fully continuous process
- Assessing the selection criteria and transfer of key elements of the continuous process to a CMO

10.10 **Tech-Show in the Exhibition Hall!**

Live demos from our technology partners: find out how continuous manufacturing can be made possible!

Delegates will get the chance to ask questions during this interactive sessions.

10.25 **Morning Refreshments and Networking**

Moderated by:

Jorgen Magnus
Head of Bioprocess Technology
Bayer AG

10.55 **Mastermind: Redefining Continuous Manufacturing Workflow**

In this session, delegates will be split into groups of 10 to brainstorm and share ideas and challenges in the following areas for transitioning to CM:

- Continuous operation as a post approval change: Can we switch to continuous operation for a product that has been developed and launched as a batch process without repeating the clinical trials? What needs to be demonstrated? What are the requirements for the continuous setup?
- How do we define a batch and release the product? How do we correlate the drug substance to the raw materials and process data?
- What is the sensible campaign length? What are the limitations? How do we validate very long production campaigns? What is the flexibility of continuous processing regarding amount of product per campaign?

The audience will choose one topic to discuss for 30 minutes and come back with a key takeaway, which we will share with the rest of the attendees at the end of this session.

The Supporting Act – Technology Advancements to Enable CM

Jon Coffman
Global Head of Innovation, Technology Biopharm
Boehringer-Inghelheim

11.35 Bridging Continuous, Integrated & Batch Processing as a Path to Implementation

- Discussing how the largest issue in continuous and integrated processing is not technology -it's stakeholders
- Understanding how Boehringer Ingelheim's continuous and integrated technology was developed to satisfy stakeholders to achieve implementation
- Evaluating targeted hybrid systems to bridge the gap between a batch culture and a continuous processing future

Indrajeetsinh Yadav
Investigator (Secondary Continuous), Drug Product Development
GSK

12.05 The Roll Out – Smooth Implementation of Continuous Manufacture of Small Molecules

- Applying QbD throughout product development to ensure absolute control over the quality of end products
- Formulation considerations for continuous manufacture
- Why collaborate? Collective approach to tackle common challenges and accelerate implementation

12.35 Lunch & Networking

Yanxi Tan Cain
Executive Director, Global Quality Assurance, Global Head, Quality Management System
Merck

13.55 Quality Management System to Facilitate CM Implementation

- Define a good quality assurance and risk management framework for continuous manufacturing
- How to test and validate? Fitting with the global GMP requirements and expectations
- Develop industry standard guidelines – challenges ahead

Jana Spes
Former Vice President, Technical Operations
Apotex

14.25 Continuous Process Development & Monitoring

- Maintenance and update of models correlating process signals to CQAs
- What are the requirements from FDA and ICH?
- Advantages of CP in generics and biosimilars market and how it can address challenges with existing capacity

14.55 Chair's Closing Remarks

15.00 Close of Conference

For the latest meeting updates and content, **visit our website.**

PARTNERSHIP OPPORTUNITIES

Innovation Partner

LEWA Bioprocess Technologies

LEWA Bioprocess Technologies create advanced downstream processing systems for GMP environments across the world. Our standard systems do the work of up to three conventional units in a smaller footprint. We have industry leading solutions for batch and continuous chromatography and buffer in-line dilution. Our deep expertise in fluid dynamics, combined with industry-leading pump technology, allows us to provide precise batch to continuous processing solutions with the perfect balance of accuracy, repeatability and capacity. Our design, fabrication and automation services assure single point, vertical supply benefits getting you on-line faster.

www.lewapt.com

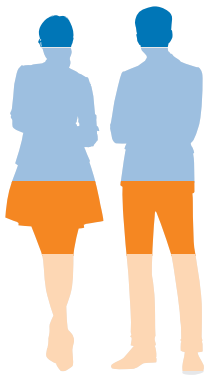
Are you front of mind for our CP community as they look externally for assistance in CM commercialization?

The **2nd annual CCP Summit** will bring together key decision makers from industry-leading pharma and biotech companies who are part of the continuous manufacturing transformation journey.

This summit provides a unique opportunity to get in front of the CP community to:

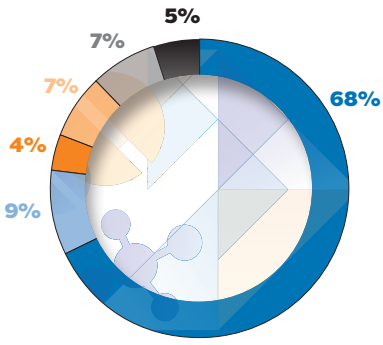
- **Showcase Your Solution**
  Through tech demos and content-driven talks, you can educate our community about your innovative products and solutions, and demonstrate why CP is not as difficult as they think
- **Engage with Industry Thought Leaders**
  This niche meeting will allow you to engage directly with the pioneering pharma and biotechs at this crucial time to start fostering relationships and grow with this community
- **Be the Influencer**
  Raise your profile and share your experiences with our audience – who are still 'explorers' in CM field. Position yourself as the go-to solution leader in this rapidly evolving space today

SENIORITY OF ATTENDEES*



- VP & C-Level: 7%
- Director & Head: 46%
- Manager & Project Lead: 27%
- Scientist: 20%

ATTENDEES' BY SECTOR



Based on 2017 attendees' profile

DROP US A LINE TO FIND OUT WHO ATTENDED IN 2017!

GET INVOLVED

Peter Trebelev
Partnership Director
T.+1 212 537 5898
E. Sponsor@hansonwade.com

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3 EASY WAYS TO BOOK

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Special 40% off for academics available upon request

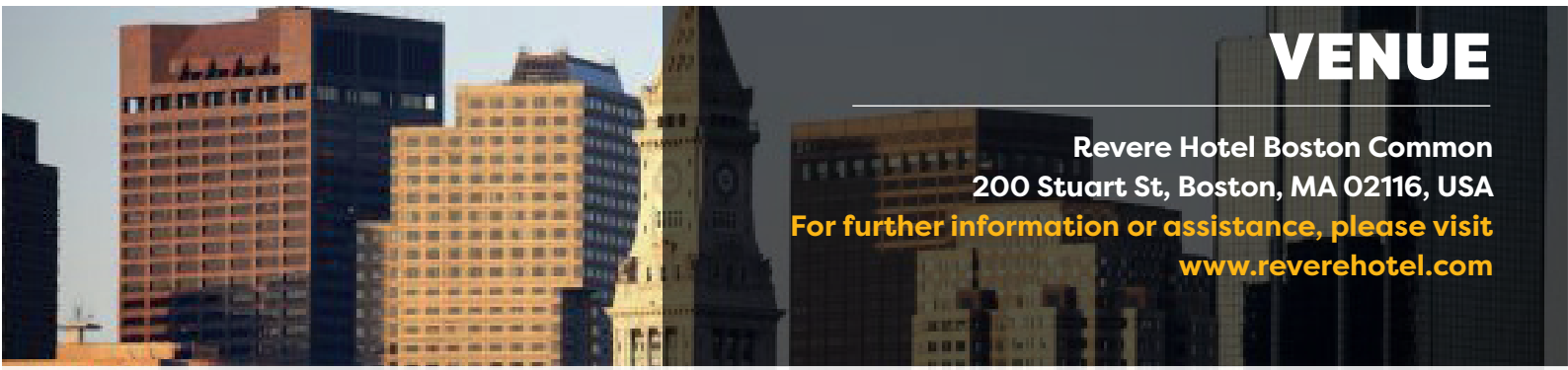
Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Contact: register@hansonwade.com

SECURE YOUR PLACE

PHARMA/BIOTECHS PRICING	Register & Pay before Friday November 3, 2017	Register & Pay before Friday December 15, 2017	Standard Prices
CONFERENCE + 3 WORKSHOPS	$3896 **(save $700)**	$4096 **(save $500)**	$4296 **(save $300)**
CONFERENCE + 2 WORKSHOPS	$3397 **(save $600)**	$3597 **(save $400)**	$3797 **(save $200)**
CONFERENCE + 1 WORKSHOP	$2898 **(save $500)**	$3098 **(save $300)**	$3298 **(save $100)**
CONFERENCE ONLY	$2399 **(save $400)**	$2599 **(save $200)**	$2799
WORKSHOPS (EACH)	**$599**		

SOLUTION PROVIDER PRICING	Register & Pay before Friday November 3, 2017	Register & Pay before Friday December 15, 2017	Standard Prices
CONFERENCE + 3 WORKSHOPS	$4696 **(save $500)**	$4796 **(save $400)**	$4896 **(save $300)**
CONFERENCE + 2 WORKSHOPS	$4197 **(save $400)**	$4297 **(save $300)**	$4397 **(save $200)**
CONFERENCE + 1 WORKSHOP	$3698 **(save $300)**	$3798 **(save $200)**	$3898 **(save $100)**
CONFERENCE ONLY	$3199 **(save $200)**	$3299 **(save $100)**	$3399
WORKSHOPS (EACH)	**$599**		



VENUE

Revere Hotel Boston Common
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Full payment is due on registration. Cancellation and Substitution Policy:
Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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