Embark on the Continuous Processing Journey Now to Drive Quality & Efficiency

Rethink, Re-Plan, Revitalize Your Manufacturing Processes

Expert Speaker Panel Including:

Stephanie Krogmeier  
Snr Director, Global Regulatory CMC Strategy, Vertex Pharmaceuticals

Shawn Barrett  
Associate Scientific Director, Continuous Manufacturing Skill Center, Biopharmaceutical Development, Sanofi Genzyme

Michelle Bailey  
Associate Director, Head of Validation for Continuous Manufacturing & Automation, Vertex Pharmaceuticals

David Pollard  
Executive Director, Bio Process Technology & Expression, Merck

The difference between this event and others is that this allows us to exchange ideas with those with whom we share many common challenges.

AbbVie, Past Attendee

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Tel: +44 (0) 203 141 8700  |  Email: info@hansonwade.com
Welcome to Commercializing Continuous Processing Forum

Revitalize The Way You Make Drugs

The Commercializing Continuous Processing Forum is the only commercial pharmaceutical conference dedicated to continuous processing.

Following FDA’s Draft Guidance in April 2016 and 2 CM-products approvals, pilot projects are now being fast-tracked to scale-up. It’s time for you to act!

Through a series of technical and commercial case studies, the agenda will:

- Provide you with a 360° view of continuous manufacturing market landscape
- Take you through the journey from start to finish – how to define the framework, evaluate, implement and execute
- Share technical updates on tools and processes to enable a smooth drug development plan

Walk away with practical tips from our expert speaker panel to avoid pitfalls.

Why Should You Join Us?

1. Engage with regulatory agencies and what they expect – case study by Vertex
2. Learn how to mitigate commercial risks in continuous manufacturing – tips from Eli Lilly
3. Can you create a seamless process and tackle downstream CM challenges? Amgen Inc. and Merck to share their project updates with you
4. Grasp the latest technical developments, including real time product release from Pfizer Inc., perfusion studies from Sanofi Genzyme and diafiltration from Biogen
5. Discuss and benchmark best practices with your industry peers to accelerate commercialization and CP deployment

What Previous Attendees Have To Say:

Great conference which was well situated! PCI Services, Past Attendee

This conference was of outstanding value. First class presentations, great opportunity for networking and perfect logistics! AstraZeneca, Past Attendee

The meeting was well organized. The agenda well balanced and there was enough flexibility to engage in discussion. The networking sessions were great. Gilead, Past Attendee
## Speakers

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Company</th>
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<tbody>
<tr>
<td>Ken Green</td>
<td>Head of MS&amp;T, Shire</td>
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<tr>
<td>Daniel C. Vellom</td>
<td>Srn Director, End-to-End Innovation, Sanofi Pasteur Biologics</td>
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<tr>
<td>Shawn Barrett</td>
<td>Associate Scientific Director, Continuous Manufacturing Skill Center, Biopharmaceutical Development, Sanofi Genzyme</td>
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<tr>
<td>Rahul Singhvi</td>
<td>Chief Operating Officer, Takeda Vaccines, Inc.</td>
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<tr>
<td>Lada Ivana Horvat</td>
<td>Senior Director, Alliston MSAT Head, Genzyme</td>
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<tr>
<td>Stephanie Krogmeier</td>
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<tr>
<td>Matthew Westoby</td>
<td>Associate Director, Bio-Manufacturing Innovation Lead, Biogen</td>
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<tr>
<td>Joel Hawkins</td>
<td>Senior Research Fellow, Pfizer Inc.</td>
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<tr>
<td>Ian Leavesley</td>
<td>Senior Consultant Engineer, Eli Lilly</td>
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<tr>
<td>Keith Jensen</td>
<td>Associate Director &amp; Principal Investigator, Novartis-MIT Center for Continuous Manufacturing</td>
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<tr>
<td>Steffen Kreye</td>
<td>Scientist USP Development, Glycotope GmbH</td>
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<tr>
<td>Jerry Salan</td>
<td>CEO, Nalas Engineering</td>
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<td>David am Ende</td>
<td>President, Nalas Engineering</td>
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<td>Margit Holzer</td>
<td>Scientific Advisor, Ypso-Facto</td>
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<tr>
<td>Samantha Wang</td>
<td>Senior Bioprocess Engineer, Boehringer Ingelheim, Inc.</td>
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<tr>
<td>Amy Walia</td>
<td>Director, Global Regulatory Affairs (CMC), Vertex Pharmaceuticals</td>
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<td>GSK, Past Attendee</td>
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Outstanding... Excellent presentations, variety, very good organization and great networking sessions. Thanks for preparing and please repeat again next year!

GSK, Past Attendee
Conference Day One | Monday January 30, 2017

8.00 Breakfast & Registration

9.00 Chair’s Opening Remarks

Regulatory & Commercial Landscape

9.10 Lesson Learnt – How to Engage with Regulatory Agencies on Continuous Manufacturing

• Vertex journey – strategies and approaches
• Engagement examples from FDA and EMA
• Opportunities and challenges for submission with new technology

9.40 Mitigating Commercial Risks in Continuous Manufacturing

• Comparing risks in continuous with batch manufacturing
• Reducing API consumption in mid and late stage development
• Quality by control – leveraging a variety of different types of controls to assure quality
• ’Low value, high volume’ vs. ‘High value, low volume’ strategy

10.10 Morning Refreshments & Speed Networking

Feasibility of Upstream Processing Development

11.40 Exploring Options for the Continuous Diafiltration of Biologics

• Little work has been reported on converting diafiltration operations into continuous formats
• We explore several diafiltration options using theoretical design equations to determine top system configurations, which were then tested in the laboratory
• Integration of the optimal diafiltration process into a continuous purification train will be discussed

12.10 Upstream Continuous Processing for Biologics

• Feasibility of continuous processing of biologics vs. APIs
• Understanding your molecule – mapping of design space and media for process monitoring
• Translating upstream continuous processing experiences in cell culture to downstream manufacturing

12.40 Lunch & Networking

13.40 Intensification of a Multi-Product Perfusion through Medium Process Development

• Push to high productivity and low perfusion rate
• Application of a standardized approach to different classes of molecules
• Engineering and economic considerations for commercial scale
# Conference Day One | Monday January 30, 2017

## Bridging the Gap of Downstream Processing Development

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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| 14.10 | **Advances towards Automated Continuous Biologics Production with Real Time Release**  
*From development to implementation challenges for end-to-end single use system, enabling automated mAb continuous processing*  
*Feasibility of automated continuous processing at lab scale (lights out approach >50 days)*  
*Implementation of PAT tools to enable real time release*  

*Keynote Address*

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<tr>
<th>14.40</th>
<th><strong>Afternoon Refreshments &amp; Networking</strong></th>
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<tr>
<th>Time</th>
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| 15.10 | **Downstream Continuous Manufacturing Challenges**  
*Unit operation design and integration*  
*Impact on equipment and facility utilization*  
*Integrating single-use technologies* |

*Project Update*

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<thead>
<tr>
<th>Time</th>
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| 15.40 | **Continuous and Integrated Processing for Pre-Clinical & Clinical Manufacturing**  
*Key challenges and how to develop the right platform*  
*Developing a cell line for integrated processing*  
*How to scale up and considerations* |

*Project Update*

<table>
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| 16.10 | **Work with Your Partners & Teams**  
*How to incorporate your manufacturing plan into product development consideration earlier on*  
*How to select your partners – from technical to quality compliance viewpoints*  
*Synchronizing all platforms into one – problems with multiple suppliers for continuous processing*  
*Evaluate the pros and cons of selecting a single supplier source vs. best of breed for each component* |

*Roundtable Discussion*

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<tr>
<td>16.40</td>
<td><strong>Chairman’s Closing Remarks</strong></td>
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<th>Time</th>
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<tr>
<td>16.45</td>
<td><strong>Close of Day One</strong></td>
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**Adopting Continuous Manufacturing Will:**

- Reduce operating costs by up to 50%
- Increase yield by reducing waste by 33%
- Cut manufacturing and testing cycle times by 80%

### Conference Day Two | Tuesday January 31, 2017

<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>8.00</td>
<td><strong>Breakfast &amp; Registration</strong></td>
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<tr>
<td>9.00</td>
<td><strong>Chair’s Opening Remarks</strong></td>
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<tr>
<td>9.10</td>
<td><strong>Encouraging Continuous Manufacturing through the Development of Medical Countermeasures</strong></td>
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<td>- Updates on BARDA’s initiatives</td>
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<td>- Challenges and opportunities of continuous manufacturing in pharmaceuticals</td>
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<td>- Next steps</td>
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<td>9.40</td>
<td><strong>Innovations &amp; Breakthroughs in Continuous Crystallization Processing</strong></td>
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<td>- The 5 critical aspects of crystallization: Yield, purity, polymorph, particle size, and number of crystallization stages</td>
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<td>- Successfully continuous crystallizing</td>
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<td>- From isolation to drying – how to execute this in a continuous manner?</td>
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<td>- What’s next?</td>
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<td>9.40</td>
<td><strong>Application of Continuous Manufacturing for Viral Vaccines</strong></td>
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<td>- Process design approach and considerations for continuous manufacturing</td>
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<td>- Case study – Polio</td>
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<td>- Cost of goods and capital efficiencies – cost benefit analysis</td>
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<td>- Capacity deployment of efficiency</td>
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<td>10.40</td>
<td><strong>Morning Refreshments &amp; Speed Networking</strong></td>
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<td><strong>Quality by Design (QbD) &amp; Process Control</strong></td>
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<td>- Embedding QbD into your continuous manufacturing planning</td>
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<td>- The big question – what is the process control and how to mitigate risks?</td>
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<td>- PAT to support continuous monitoring and quality assessment</td>
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<td>- What is the benchmark for best practice?</td>
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<td>12.10</td>
<td><strong>Holistic Approach to Tackle Upstream &amp; Downstream Continuous Manufacturing</strong></td>
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<td>- How to integrate and optimize?</td>
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<td>- Current issues and approach – case study</td>
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<td>- The next stage of scaling up</td>
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# Conference Day Two | Tuesday January 31, 2017

## From Proof of Concept to Roll Out – How to Validate Your Methodology?

- Define technical scope and critical quality attributes (CQAs)
- From theory to lab to commercial scale: moving from discontinuous to continuous to validate your methodology for quality results
- Validating to support your control strategy

### Case Study

### Being Proactive – Modelling & Real Time Analytics

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<td>13.10</td>
<td>Lunch &amp; Networking</td>
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<tr>
<td>14.00</td>
<td>Real Time Analytics for Feedback &amp; Feedforward Control</td>
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<tr>
<td>14.30</td>
<td>Development &amp; Application of Continuous Hydrogenations for API Synthesis</td>
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<tr>
<td>15.00</td>
<td>How to Develop the Control Strategy for Continuous Processing?</td>
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<tr>
<td>15.30</td>
<td>Chairman’s Closing Remarks</td>
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**Michelle Bailey**, Associate Director, Head of Validation for Continuous Manufacturing & Automation, **Vertex Pharmaceuticals**

**Jeffrey Doyle**, Manager, PAT Projects, **Pfizer Inc.**

**Joel Hawkins**, Senior Research Fellow, **Pfizer Inc.**

**Margit Holzer**, Scientific Advisor, **Ypso-Facto**

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**www.continuous-processing-pharma.com**
# Commercializing Continuous Processing in Pharma

**January 30 – February 1, 2017**

**Wednesday February 1, 2017**

## Workshop A  
**Global Regulatory Landscape for Innovative Manufacturing Approaches**

**Time:** 08:00–10:30

Regulatory authorities are encouraging pharmaceutical companies to use innovative technologies including continuous manufacturing. Scientific evidence can be used in place of traditionally accepted practices within the existing regulatory framework. Commitment from all corporate stakeholders is needed to achieve success.

**Attend this workshop to:**
- Learn from case examples of CM and other emerging manufacturing technology
- Through group discussion and exercise, you will get a clear picture of how to navigate the regulatory landscape to achieve successful submission and lifecycle management

**Workshop leaders**
- **Amy Walia**, Director, Global Regulatory Affairs (CMC), Vertex Pharmaceuticals
- **Michelle Bailey**, Associate Director, Head of Validation for Continuous Manufacturing & Automation, Vertex Pharmaceuticals
- **Tom Hansen**, Associate Director, Global Regulatory Affairs (CMC), Vertex Pharmaceuticals

## Workshop B  
**How to Develop a Continuous Process?**

**Time:** 10:30–13:00

In this session, the workshop leader will go through the following considerations when building a continuous processing model. This technical session will give you the opportunity to plan ahead and prepare for scale-up.

**Attend this workshop to:**
- Learn about latest techniques in analytics and reaction monitoring
- Assess what mass balance is in CP
- Develop the right CP model
- Transition to commercialization seamlessly

**Workshop leaders**
- **Jerry Salan**, CEO, Nalas Engineering
- **David am Ende**, President, Nalas Engineering

## Workshop C  
**End-to-End Continuous Manufacturing: Is This Possible?**

**Time:** 13:00–15:30

This workshop is the guidebook for E2E CM approach and implementation. Attend this workshop to:
- Learn the definitions, processes and technologies in the context of continuous bio-manufacturing
- Set the objectives and goals for continuously run unit operations and whole process lines
- Evaluate examples of how to develop and what to consider during implementation

**Workshop leader**
- **Margit Holzer**, Scientific Advisor, Ypso-Facto

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**Email:** info@hansonwade.com  
**www.continuous-processing-pharma.com**
About Sponsorship

Why sponsor

Our audience is actively seeking solution providers to partner with them through the journey of CP implementation. Do you have a service or product matching their needs?

Why should you join us as a sponsor or exhibitor?

**Tech Demo:**
Showcase your latest continuous processing technologies and equipment at our exhibition hall with a live demo to our audience.

**Tech Talk:**
Present your work on continuous processing at our breakfast briefings and tech talks sessions, convince the industry that it can be ‘easier done than said’.

**Engage:**
Forge relationships with drug makers earlier on and align your services to meet their needs through our structured networking breaks.

Who Will You Meet?

![Typical Attendee Sector](chart)
- Pharma: 50%
- Biotech: 20%
- CMO/CDMO: 10%
- Academics and Others: 20%

![Typical Attendee Seniority](chart)
- C-Level: 15%
- VP: 30%
- Director and Head: 15%
- Manager: 15%
- Scientist: 30%

*Based on industry research

Companies Who Have Attended Hanson Wade Conferences

- Abbott
- abbvie
- AMGEN
- Bayer
- Genentech
- GILEAD
- Janssen
- Novartis
- UCB
- Daiichi Sankyo
- Teva
- FDA

"Speed networking session was fantastic!"

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"Excellent organization and venue, I was very impressed!"

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Get Involved

Contact

Chris Rainger
Partnerships Manager

Tel: +44 (0) 203 141 8777  
Email: chris.rainger@hansonwade.com
Pricing

**Register**

[www.continuous-processing-pharma.com/register](http://www.continuous-processing-pharma.com/register)

**Tel:** +44 (0)203 141 8700  
**Email:** register@hansonwade.com

*Team Discounts*  
- 10% discount – 3 delegates  
- 15% discount – 4 delegates  
- 20% discount – 5 + delegates

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

**Top 3 Benefits of Attending**

1. Learn how to successfully implement continuous manufacturing
2. Accelerate speed to market and protect long-term financial benefits
3. Assess latest technologies to enable continuous processing

### Industry Pricing

<table>
<thead>
<tr>
<th>Conference + Workshops</th>
<th>Register &amp; Pay before Friday October 7 2016</th>
<th>Register &amp; Pay before Friday November 4 2016</th>
<th>Register &amp; Pay before Friday December 16 2016</th>
<th>Standard Prices</th>
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<tr>
<td>3 Workshops</td>
<td>$3896 (save $900)</td>
<td>$4096 (save $700)</td>
<td>$4296 (save $500)</td>
<td>$4396 (save $400)</td>
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<td>$3098 (save $300)</td>
<td>$3198 (save $200)</td>
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### Solution Provider Pricing

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### Venue

**Sheraton Boston, USA**  
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**One of the best conferences I’ve ever attended. Thoughtfully constructed, seamlessly executed, and brilliantly innovative in both design and delivery.**

Novartis, Past Attendee