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January 29 – 31, 2019 | Boston, MA

www.continuous-processing-pharma.com

CCP SUMMIT 2019

COMMERCIALIZING CONTINUOUS PROCESSING IN PHARMA

From Momentum to Reality: Progressing towards Robust GMP Continuous Manufacturing

Your 30 Expert Speakers Include:

Giustino Di Pretoro
Associate Director, Continuous Manufacturing
Janssen

David Cho
Senior Advisor
FDA

Ahmad Almaya
Director, Small Molecule Design & Development
Eli Lilly & Company

Douglas Hausner
Associate Director
C-SOPS

Lawrence De Belder
Senior Principal Engineer, Continuous Manufacturing
Janssen

Marcus Fiadeiro
Associate Director, DSP, Continuous Manufacturing Skill Center
Sanofi

Partners

Alkemy Innovation · ChromaTan · Emerson · sartorius stedim biotech · LEWA · YMC

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Why Join Our CCP Community?

Since we embarked on this journey with you in 2017, we have witnessed how pharma and biotechs' perceptions to continuous manufacturing have shifted from being a buzzword to reality, fast-tracking pilot projects to commercialization.

Following 2 years of success, the CCP community will unite 130+ industry pioneers once again in Boston to discuss lessons learned, benchmark against best practice and share technology innovations to get ready for the next set of challenges!

As the only peer-led industry summit exclusive to commercialization, our community is growing rapidly.

Join our **3rd CCP Summit 2019** in Boston, and we promise you these 3 days will make an impact on your CM projects, helping you to stay ahead of the curve, and benefit patients with quality, more affordable and accessible medicines.

What previous CCP attendees have said about our meetings

"It was a very well organized meeting that I especially like the blend of small molecule and biologics, and how they were represented in the program agenda"

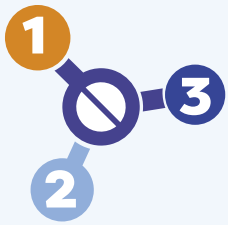
Senior Manager, Technical Development, Biogen

"The conference was very valuable and well executed. I appreciated that it was focused toward real life applications and experiences with CP that I can easily transfer those actionable insights"

Senior Scientist, Engineering, Merck

5 Key Highlights of CCP 2019:

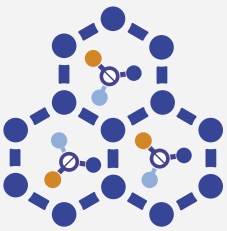
1.
Streamed tracks for biologics and small molecules for in-depth upstream and downstream scientific discussions – offering you a comprehensive CM journey



2.
Janssen to guide you on cost-risk analysis for continuous manufacturing

3.
FDA's CBER shares their view on continuous manufacturing

4.
Eli Lilly showcases implementation and project updates



5.
Pre-Conference Workshop Day focuses on PAT, control strategy, implementation roadblocks, and an exclusive site visit to **CONTINUUS Pharmaceuticals**, equipping you for a successful and quality set-up of CM

"It was a great and success CM meeting, bringing both small molecules and biologics for knowledge sharing. I really enjoyed the panel and breakout discussions, and gained insights from fellow colleagues from other organizations!"

Head of Continuous Manufacturing Skills Center, Sanofi

Your Expert Speakers

Giustino Di Pretoro
Associate Director, Continuous Manufacturing
Janssen

Neil Soice
Director, Drug Substance Technologies
Amgen

David Cho
Senior Advisor
FDA

Ahmad Almaya
Director, Small Molecule Design & Development
Eli Lilly & Company

Narasimha Rao Nedunuri
Managing Director & CEO
CLONZ Biotech Pvt Ltd.

Douglas Hausner
Associate Director
C-SOPS

Lawrence De Belder
Senior Principal Engineer, Continuous Manufacturing
Janssen

Robert Worsham
Director of Manufacturing Science & Technology
Insmed Inc.

Sujit Jain
Group Leader, Downstream Process Development & Technology
Shire

Marcus Fiadeiro
Associate Director, DSP, Continuous Manufacturing Skill Center
Sanofi

Jorg Thommes
Head of CMC
Bill & Melinda Gates Medical Research Institute

Gregory Connelly
Associate Director, Formulation Development
Vertex Pharmaceuticals

Frederic Buono
Senior Principal Scientist
Boehringer Ingelheim

Flavien Susanne
Fellow, PDS Continuous Process Lead
GSK

Satish Sharma
Scientist II
Bristol-Myers Squibb

Lisa Graham
CEO
Alkemy Innovation, Inc.

Luke Webster
Associate Consultant Engineer
Eli Lilly & Company

Jeff Doyle
Senior Manager, Manufacturing Process Analytics & Control
Pfizer

Thomas Muller-Spath
Senior Scientist
ETH Zurich

Oleg Shinkazh
President & CEO
Chromatan

Salvatore Mascia
Founder & CEO
CONTINUUS Pharmaceuticals

Thomas Erdenberger
Process Development Consultant
Sartorius Group North America

Bob Lenich
Life Science Business Director
Emerson Automation Solutions

Keith Selvitelli
Scientist, Drug Product, Engineering & Technology
Biogen

Morten Munk
Global Technology Partner
NNE

Niels Guldager
Senior Technology Partner
NNE

Tommy Alfast
Senior Process Engineer
NNE

Ian Leavesley
President
Modern Pharma Consulting LLC

Nikhil Padhye
Postdoctoral Scholar
University of California Berkeley

Blair Brettmann
Assistant Professor
Georgia Institute of Technology

SITE VISIT

TUESDAY, JANUARY 29, 2019

CONTINUUS™
pharmaceuticals

End-to-End Integrated Continuous Manufacturing Facility

CONTINUUS Pharmaceuticals is a spin-out company from a multi-year collaboration between MIT And Novartis on continuous manufacturing, who specialize in end-to-end integrated continuous manufacturing (ICM), with the application of novel process technologies that enable rapid production of pharmaceuticals at significantly reduced costs and better quality.

Hosted by CONTINUUS Pharmaceuticals, attendees will be able to visit their facility in Woburn to see first-hand the state-of-the-art and fully integrated continuous manufacturing facility. The 2-hour site visit will include a presentation of the end-to-end system and Q&As enabling you to:

- Understand the potential and opportunities in ICM
- Improve affordability and accessibility of pharmaceuticals on a global scale
- Evaluate investment, implementation and build-out of commercial ICM plants

Session 1: 08.30 – 11.30
Session 2: 11.30 – 14.30
Session 3: 14.30 – 17.30

We'll provide transportation to and from the conference venue to CONTINUUS Pharmaceuticals, and **places are strictly limited to 10 participants per session** to ensure interaction and best learning experience.

Salvatore Mascia
Founder & CEO
Continuus Pharmaceuticals

PRE-CONFERENCE WORKSHOP DAY

Tuesday, January 29, 2019

Workshop A

8:00am – 11:00am

Establish a Robust Quality Control Strategy for Industrializing Continuous Bioprocessing

The advantages of continuous bio-processing include increased productivity, flexibility of operations and decreased facility footprint. That being said, a detailed thought process needs to be incorporated during process control, PAT to support validation and quality assurance.

The workshop will be based on a 2018 **case project for continuous bioprocessing of mAbs** (monoclonal antibodies). We will use the case approach to explore key aspects of continuous bioprocessing and in this way enable interaction and networking between participants and facilitators.

The workshop will show **how the control strategy can be used as baseline foundation for industrializing a continuous biotech process**. Participants will get the opportunity to prototype design ideas and share their perspectives on continuous bioprocessing. The emphasis is on industrialization of continuous bioprocessing and 360 degree facility design and operations.

- Bioprocessing: state of the industry
- Upcoming bioprocessing paradigm shift
- Regulatory considerations
- Control strategy as baseline for industrialization
- Biotech facility design considerations for continuous bioprocessing
- Control strategy in action: ASTM-E2500 and industry 4.0 perspectives

Morten Munk
Global Technology Partner
NNE

Niels Guldager
Senior Technology Partner
NNE

Tommy Alfast
Senior Process Engineer
NNE

Workshop B

15:30pm – 18:30pm

How to Adopt Continuous Manufacturing? From Proof of Concept to Submission to Implementation

Continuous manufacturing is still a new concept in pharma and biotech. The implementation will require multiple teams' collaboration and stakeholder management - from investment to regulatory affairs to CMC.

This workshop will help participants build a strategy and roadmap appropriate for their company to guide them from their current situation through to submission.

The workshop will include **a short case study of one example of the journey taken from concept through to submission.** The bulk of the workshop will be break-out sessions where participants will work with other attendees and the workshop leader to create a variety of different roadmaps to submission with key milestones along the way.

The different roadmaps will depend on different starting points, key stakeholder and supporter / skeptic identification and fit with corporate and organizational strategies. This will enable participants to leave with a fit-for-purpose strategy appropriate for their situation.

Ian Leavesley
President
Modern Pharma Consulting LLC

CONFERENCE DAY ONE

Wednesday, January 30, 2019

7.30 **Morning Coffee & Registration**

8.30 **Chair's Opening Remarks**

Commercial Environment for Continuous Manufacturing

David Cho
Senior Advisor
FDA

8.40 **Opening Address: FDA's Engagement in Continuous Manufacturing**

Giustino Di Pretoro
Associate Director, Continuous Manufacturing
Janssen

9.10 **Janssen's Success Story in Implementing Continuous Manufacturing**

- The journey from switching to project implementation and tech transfer
- Lessons learned and looking beyond: what's next for API continuous manufacturing?

9.40 **Panel Discussion: Tailoring your Technology and Business Strategy for Success**

- How to establish an investment roadmap?
- Implementing an effective strategy to drive technology investment
- Creating a culture of innovation in manufacturing

Led by:
Lisa Graham
CEO
Alkemy Innovation, Inc.

Jorg Thommes
Head of CMC
Bill & Melinda Gates Medical Research Institute

Salvatore Mascia
Founder & CEO
CONTINUUS Pharmaceuticals

10.30 **Speed Networking & Morning Coffee**

Small Molecules Track

12.00 **Development, Tech Transfer, and Implementation of a Flow Process for Production of an API**

- A synthetic route was selected and developed specifically for use in flow
- A new facility dedicated to flow chemistry was built and the process was transferred
- Four synthetic steps were run simultaneously to produce API

Luke Webster, Associate Consultant Engineer, **Eli Lilly & Company**

Biologics Track

12.00 **Integrated Continuous Biomanufacturing (ICB) Adaptation to Complex Modalities**

- Recent success in commercialization of enzyme with an ICB v1 process
- Benefits to footprint decrease, rapid integrated purification and continuous perfusion operations
- Expansion of Sanofi's ICB platform – business case consideration, including complex modalities where in-process kinetics can impact on product quality outcome
- Suitability of adaptation for complex modalities

Marcus Fiadeiro, Associate Director, DSP, Continuous Manufacturing Skill Center, **Sanofi**

12.30 Latest Research on Applications of Continuous Processing in Drug Products

- What's electrospinning and future of this application in continuous manufacturing?
- Removal of multi-steps from APIs to finished dosage forms
- Potential to scale up to commercial use
- 3D printing model to demonstrate feasibility

Blair Brettmann, Assistant Professor, **Georgia Institute of Technology**

12.30 Integrated Continuous Bioprocessing Platform Development – New Data, Partnership strategies, Integration, and PAT

- Steady-state CCTC data from multiple modalities
- PAT and manufacturing – overcoming challenges with effective partnerships
- Integration of multiple unit operations – challenges and successes and the path forward

Oleg Shinkazh, President & CEO, **Chromatan**

13.00 Networking Lunch

14.00 The Breaking Point - PAT & Real-Time Product Release

- Latest advancements of PATs
- When should you do product release? Is real time a reality?
- Product control to ensure quality medicines

Douglas Hausner, Associate Director, **C-SOPS**

14.00 Impurity in Continuous Processing

- The complexity of impurity and crystallization during continuous processing
- Progress in using PAT to drive purification during CM

Satish Sharma, Scientist II, **Bristol-Myers Squibb**

14.30 Equipment Validation for CM

- The need for industry standards harmonization for equipment providers
- How should you assess and certify your CM equipment that will be fit-for-purpose and cGMP compliant?
- 'Cleanability' of your equipment

Session reserved for Program Partner

14.30 Different Continuous Chromatography Systems for Continuous Capture

- Different continuous chromatography technologies are currently available in the market, which differ in configuration, control elements
- Each technology comes with different benefits and limitations, selection of one can be based on requirements and feasibility
- Comparison of different systems will be presented with feasibility data and operational aspects

Sujit Jain, Group Leader, Downstream Process Development, **Shire**

15.00 Roundtable Discussion:

This session will split the audience into mini-groups for more in-depth discussion based on this morning's sessions, focusing on:

- Does CM offer more flexibility on equipment requirements?
- Assessing CM for legacy products and new candidates – how to choose?
- What data and validation should we consider during filing?

We will re-group at the end of the session for learning sharing.

15.00 Roundtable Discussion:

This session will split the audience into mini-groups for more in-depth discussion based on this morning's sessions, focusing on:

- The bottlenecks in bio-continuous manufacturing
- From science to CMC: how can we maintain product quality?
- Risk management and guidelines

We will re-group at the end of the session for learning sharing.

15.30 Afternoon Tea & Networking

Thomas Muller-Spath
Senior Scientist
ETH Zurich

16.00 Scale-Up and Validation Aspects of Continuous Twin-Column Chromatography for mAb Capture

- Demonstrating data and confidence of scale-up of twin-column chromatography for mAb capture
- The importance of validation and control design

Spotlight Talk by

Led by Speakers of the Day

16.30 Panel Discussion: The Need to Harmonize CM Standards

- From USP to ICH: How can we define and standardize CM framework and guidance globally?
- What is a batch and what is continuous?
- Clarifying quality management and cGMP environment for CM

17.15 Chair's Closing Comments of Day 1

17.20 Poster Session - **Nikhil Padhye**, Postdoctoral Scholar, **University of California Berkeley**

18.30 End of Day 1

CONFERENCE DAY TWO

Thursday, January 31, 2019

8.00 **Morning Coffee & Registration**

9.00 **Chair's Opening Remarks**

Continuous Manufacturing Progress Updates

Lawrence De Belder
Senior Principal Engineer, Continuous Manufacturing
Janssen

9.10 **Cost-Risk Benefits – Convincing Your Stakeholders of CM Benefits** (Keynote Address)
- Comparison between launching CM to your new candidates vs. legacy products
- From yield to efficiency to facility requirements – understand the total cost and process economics
- Gaining support from organization's sponsor
- It's a long-term commitment: cost/ risk analysis for 5+ years timeline

Neil Soice
Director, Pre-Pivotal BiDrug Substance Technologies
Amgen

9.40 **Leveraging Continuous Manufacturing to Reduce Facility Footprint**
- - Development of integrated continuous operations
- - Explore the benefits of and constraints of continuous processing
- - Evaluate the impacts of the application of disposables to enable the design and construction of facilities
- - What does it mean to capital investment and build time?

Thomas Erdenberger
Process Development Consultant
Sartorius Group North America

10.10 **Perspectives on Intensified & Continuous Processing**
- Can continuous and intensified bioprocessing promise smaller facilities, reduced scale-up risks, and more consistent product quality and higher throughputs?
- Technical challenges for practical implementation
- The need for PAT controls and inter-connect unit operations, balancing flow and feedback loop
- Innovations and real life examples

Bob Lenich
Life Science Business Director
Emerson Automation Solutions

10.40 **Agile and Continuous, How to Automate Next Generation Manufacturing**
- How are users approaching flexible continuous manufacturing
- What is Ballroom / Plug & Play
- What kind of automation architecture is needed

11.10 **Morning Coffee Break**

Small Molecules Track

11.40 **Not to Ignore – Formulation Considerations in Drug Product Continuous Manufacturing**
- The importance to engage formulation scientists before the talk of manufacturing method
- Relating formulation to CMC
- Can we translate this to drug substance?

Gregory Connelly, Associate Director, Formulation Development, **Vertex Pharmaceuticals**

12.10 **Development & Commercialization with Continuous Manufacturing for Drug Products**
- Control strategy elements for drug product continuous manufacturing
- Elements for assuring State of Control with continuous manufacturing
- Process control and product testing opportunities

Ahmad Almaya, Director, Small Molecule Design & Development, **Eli Lilly & Company**

Biologics Track

11.40 **Potential of Continuous Processing in Liposomal Drug Products**
- Novel process designs for continuous liposome drug product manufacturing – liposome formation and formulation
- Challenges of continuous processing – sterility assurance, materials of construction, real time release
- Productivity and CAPEX comparison, batch vs. CP
- Translating pilot study into commercial environment – lesson learnt and future opportunities

Robert Worsham, Director of Manufacturing Science & Technology, **Insmed Inc.**

12.10 **The Start-Up Story: Application of Continuous Processing in Biosimilar MAb Production**
- CM's benefits to biosimilars MAb manufacturing – costs of goods and overall economic implications
- Case study of Clonz Biotech's mAb manufacturing in hybrid upstream bioprocessing
- Challenges and lessons learned: the future vision of having a fully integrated E2E continuous manufacturing

Narasimha Rao Nedunuri, Managing Director & CEO, **CLONZ Biotech Pvt Ltd.**

12.40 GSK Journey in End-to-End Continuous Manufacturing

- Strategic development of continuous manufacturing
- Implementation and lessons learned
- The start of an end-to-end CM rig
- What does future look like?

Flavien Susanne, Fellow, PDS Continuous Process Lead, **GSK**

12.40 Building Efficiency in Process Development with Continuous Unit Operation Trains

- Demonstrating the use and adaptation of a direct membrane only continuous process
- Assess and compare product quality to traditional bead based batch processing method with proof of concept data
- Benefits from such innovative approach particularly during scale-up to enable speed to clinic

Keith Selvitelli, Scientist, Drug Product, Engineering & Technology, **Biogen**

13.10 Networking Lunch

Delivering a Quality Product to Patients

Joined by Speakers of the Day

14.10 Roundtable Discussion: Chicken or the Egg? Preparing for CM Capacity

- How to ensure capacity is available once your CM takes off?
- Overview of CMO market in CM capabilities
- How to incentivize CMO's investment and commitment?

Jeff Doyle
Senior Manager, Manufacturing Process Analytics & Control
Pfizer

14.40 Multivariate Process Characterization

- Designing a drug substance data architecture and info system
- Management of multidimensional data
- Techniques for modeling across time and run

Frederic Buono
Senior Principal Scientist
Boehringer Ingelheim

15.10 Breaking Barriers to Manufacturing: Innovation with Continuous Flow Technology

- Recent experience in scale-up on multi-kilogram continuous processing project
- Flow technology evaluation and understand the mechanism behind the scene
- Understand your design set up and molecule before setting criteria for technology selection

15.40 Chair's Closing Comments & Close of Conference

"This was a great event with a good networking and focused presentations"

Ache Laboratory

Tel: +1 617 455 4188 **Mail:** info@hansonwade.com
www.continuous-processing-pharma.com

hansonwade

WHY PARTNER WITH US?

We've seen our continuous manufacturing community mature since 2017: pilot projects being initiated, scaled up and progressed towards commercialization.

Our audience continues to seek help from solution providers, for technology disruptions and project alignments, particularly and not limited to:

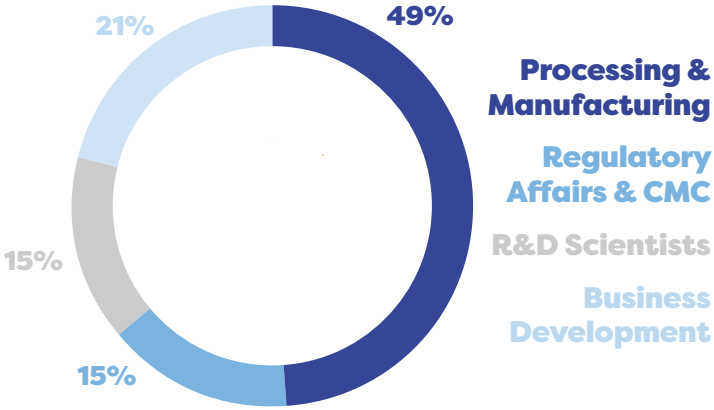
- **CMO/ CDMO**
- **Real-Time PAT & Control Software**
- **Equipment Provider**
- **Facility Upgrade & Redesign Specialist**
- **Consultancy**

If you are a leading KOL in this space, and can assist our audience to accelerate CM, we'd love to hear from you and helping you to position as a thought leader in front of 130+ senior fellow colleagues at this unique summit.

GET INVOLVED

Peter Trebelev
Partnerships Director
Tel: 1 617 455 4188
Email: sponsor@hansonwade.com

ATTENDEES' JOB FUNCTIONS:



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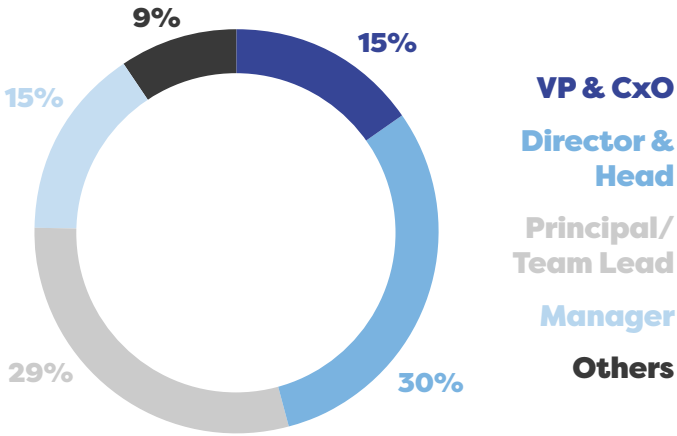

*Based on market research and previous events' statistics

WHO ATTENDS THE CCP SUMMIT

agenus · BAYER · Biogen · Bristol-Myers Squibb · Boehringer Ingelheim · Lilly · FDA · Genentech · gsk · insmed · janssen · BARDA · LEO · MERCK · MIT · SANOFI · Shire · Takeda · VERTEX

2019 PARTNERS

Program Partner

Sartorius Stedim Biotech delivers and implements rapid and cost-effective Biomanufacturing solutions from early phase development through scale-up to commercial manufacturing. Benefit from the most comprehensive bioprocess technology portfolio coupled with our expertise in single-use bioprocess engineering. Our global bioprocess teams are available to discuss your process development and manufacturing requirements.

www.sartorius.com

Program Partner

Life Sciences manufacturers strive to create innovative and reliable products that help people lead healthier lives. Emerson has the automation expertise and technology to solve your greatest cGMP manufacturing challenges and create effective solutions for improving your data management, real-time product quality, reliability, and operating costs. From design to implementation and startup to on-going optimization, rely on Emerson to stay competitive in a global economy.

www.emerson.com

Program Partner

The innovation and growth of the EcoPrime product line has attracted the attention of leading technology suppliers and users. YMC Co., Ltd. assumes all rights and production for the EcoPrime suite of systems in late 2018 from LEWA-Nikkiso America, Inc. This acquisition brings a broad spectrum of chromatographic resins, and columns ideal for large and small molecule purification. More about this new chapter for EcoPrime at

www.ymcpt.com

Expertise Partner

Chromatan is solving a major process bottleneck in therapeutic protein production while significantly lowering the cost of goods for biotech and contract manufacturing companies. In 2017 the company has won contracts and awards from the US NIH and the FDA to develop end-to-end continuous bio-production based on CCTC technology. Chromatan will be launching the process development system in 2019 and is currently engaged in R&D partnerships with multiple biotechnology companies that are testing our with various feed streams and chromatographic modalities.

www.chromatan.com

Hosting Partner

Alkemy Innovation is an engineering company, founded on the premise that there is opportunity to rethink the approach to process development in the pharmaceutical market. Utilizing a well-developed acumen in crafting process analytical technology (PAT) and data analytics solutions, Alkemy Innovation works with clients to identify opportunities to implement these solutions that will ultimately drive innovation and growth while reducing costs. Alkemy Innovation also values working with their established partnerships to support the effective development and implementation for client-specific solutions.

www.alkemyinnovation.com

READY TO REGISTER?

3 EASY WAYS TO BOOK

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Team Discounts*

- **10% discount – 3 delegates**
- **15% discount – 4 delegates**
- **20% discount – 5 or more delegates**

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

Academic discounts available upon request.

SECURE YOUR PLACE

Pharma & Biotech	Register & Pay before Friday October 26, 2018	Standard Prices
Conference + 2 Workshops + Site Visit	$3996 **(save $700)**	$4396 **(save $300)**
Conference + 2 Workshops	$3497 **(save $600)**	$3897 **(save $200)**
Conference + 1 Workshop + Site Visit		
Conference + 1 Workshop	$2998 **(save $500)**	$3398 **(save $100)**
Conference + 1 Site Visit		
Conference Only	$2499 **(save $400)**	$2899
Workshops/Site Visit (each)	$599	

Solution Provider Pricing	Register & Pay before Friday October 26, 2018	Standard Prices
Conference + 2 Workshops + Site Visit	$5096 **(save $700)**	$5496 **(save $300)**
Conference + 2 Workshops	$4397 **(save $600)**	$4797 **(save $200)**
Conference + 1 Workshop + Site Visit		
Conference + 1 Workshop	$3698 **(save $500)**	$4098 **(save $100)**
Conference + 1 Site Visit		
Conference Only	$2999 **(save $400)**	$3399
Workshops/Site Visit (each)	$799	

VENUE

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For further information or assistance, please visit www.hyatt.com