USP Workshop: Identifying and Addressing the Barriers to Continuous Manufacturing Adoption July 18 & 19, 2023

DAY ONE: Tuesday, July 18, 8:30am to 5:30pm

SPALDING AUDITORIUM, USP

Opening

8:30 – 9:00 AM **Registration and coffee**

9:00 – 9:15 AM **Welcome and introduction**
Dennis Hall, Vice President, Advanced Manufacturing Technologies, USP

Session I: Keynote Address

Objective: This session will provide information on FDA perspectives regarding the use of continuous manufacturing (CM).

9:15 – 10:00 AM **FDA updates and the regulatory landscape regarding CM**
Adam Fisher, Ph.D., Director, Science Staff - Office of Pharmaceutical Quality, CDER, FDA

Session II: Making the Case for CM: An Industry Perspective

Objective: This session will provide industry case studies that demonstrate the value and return on investment of CM.

10:00 – 10:30 AM **Case study: Implementing process analytical technology for advanced process understanding and control: case studies in synthetic drug substance processes**
Todd Maloney, Ph.D., Executive Director, Eli Lilly

10:30 – 10:45 AM Morning Break

Session II (cont'd)

10:45 – 11:15 AM **Case study: Flow chemistry–issues, adaptation, and path forward**
Srividya Ramakrishnan, Ph.D., Vice President and Head - API Process Engineering, Dr. Reddy's

11:15 – 11:45 AM **Case study: Development of a modular platform for a rapid implementation of continuous manufacturing for clinical material production under c-GMP**
Olivier Dapremont, Ph.D., Executive Director for Process Technologies, AMPAC Fine Chemicals

11:45 – 12:15 PM **Barriers to CM: Why batch is often preferred over CM**
Eric Jayjock, Ph.D., Director, Process Engineering, Vertex Pharmaceuticals

12:15 – 1:00 PM Lunch

Session II (cont'd)

1:00 – 1:30 PM **Case study: Commercializing a continuous direct compression product with a novel control strategy**
Frank Witulski, Director of Engineering, Merck & Co.

1:30 – 2:00 PM **Panel Q&A discussion**
Industry Guest Speakers

2:00 – 2:15 PM Afternoon Break

Session III: Leading Disruptive Technology Changes

Objective: This session will highlight key approaches to successfully navigating the disruptions that significant new technologies can cause.

2:15 – 3:00 PM **How to survive & thrive in the face of disruptive change**
Judy Frels, Ph.D., Senior Fellow, Executive Development Programs, University of Maryland – Robert H. Smith School of Business

Session IV: Facilitated Discussion: What are the Barriers?

Objective: Generate shared understanding of challenges and concerns around adopting CM platforms, and identify key "themes" for further discussion in Day 2.

3:00 – 4:15 PM **Facilitated discussion: key challenges and barriers to adoption**
Facilitators: Mason Hines & Maggie Gallagher, Resolve, Inc.

4:15 – 5:30 PM Networking Reception

Join speakers and attendees for a social gathering with light refreshments immediately following the first day's events.

DAY TWO: Wednesday, July 19, 8:30am to 2:00pm

SPALDING AUDITORIUM, USP

Opening

8:30 – 9:15 AM **Continental breakfast and networking**

9:15 – 9:30 AM **Welcome back**
Dennis Hall, Vice President, Advanced Manufacturing Technologies, USP

Session V: Facilitated Discussions: Overcoming the Barriers

Objective: These sessions will provide attendees with the opportunity to engage with industry, USP, and others on the challenges related to adopting CM, discuss ways to overcome them based on collective experiences and how to collaborate moving forward.

Facilitator: Ernie Hillier, EJH Consulting

9:30 – 10:25 AM **Facilitated discussion: Financial challenges**
Matthew Beaver, Director, Process Development, Amgen

9:30 – 9:35	Review challenges voted “most important”
9:35 – 9:40	Opening reflections from expert speaker
9:40 – 10:20	Facilitated discussion on top two challenges: How has this challenge manifested in your organization? What would help you overcome this challenge? What kind of support and from whom?
10:20 - 10:25	Closing

10:25 – 10:40 AM Morning Break

10:40 – 11:35 AM **Facilitated discussion: Quality in CM**
Lawrence de Belder, Continuous Manufacturing Practice Lead, Pharmatech Associates, Inc.

10:40 – 10:45	Review challenges voted “most important”
10:45 – 10:55	Opening reflections from expert speaker

	10:55 – 11:30	Facilitated discussion on top two challenges: How has this challenge manifested in your organization? What would help you overcome this challenge? What kind of support and from whom?
	11:30 - 11:35	Closing

11:35 – 12:30 PM **Facilitated discussion: Regulatory considerations**
Riley Myers, Ph.D., Chief, Advanced Pharmaceutical Manufacturing Laboratory, Office of Testing and Research, FDA

11:35 – 11:40	Review challenges voted “most important”
11:40 – 11:45	Opening reflections from expert speaker
11:45 – 12:25	Facilitated discussion on top two challenges: How has this challenge manifested in your organization? What would help you overcome this challenge? What kind of support and from whom?
12:25 - 12:30	Closing

Session VI: Closing Session

12:30 –1:00 PM **Closing and next steps**
Dennis Hall, Vice President, Advanced Manufacturing Technologies, USP

1:00 – 2:00 PM Networking Lunch