

I2APM

International Institute for
Advanced Pharmaceutical Manufacturing

Emerging Pharmaceutical Manufacturing Summit 2017: OSD Continuous Manufacturing in the Current Regulatory Landscape

May 8-9, 2017

Grand Hotel Excelsior Malta,
Great Siege Road,
Floriana FRN1810,
Malta

UPCOMING EVENT

As continuous manufacturing of pharmaceutical solid dose products begins to take hold as a transformative manufacturing technology, much attention is being paid to the regulatory landscape. As commercial implementation for pharmaceutical applications is still new, perceptions of uncertainty remain for early adopters and the markets the plan to file in for regulatory approval. Much of the uncertainty out there is less about technical capability and more about how this technology should be implemented or what the conditions should be for approval. Up until recently most of the discussion was theoretical, though that is changing significantly as more and more companies look to come to market with this technology in the US, Europe, and other established markets.

The International Institute for Advanced Pharmaceutical Manufacturing (I2APM), of which C-SOPS is a founding member, is a collection of academic centers from around the globe seeking to bring educational programming aimed at highlighting the current state of an emerging technology to aid in generating familiarity with actual commercial implementation activities of continuous manufacturing of pharmaceutical solid dose products. As this technology takes hold within the industry the I2APM group is eager to help foster and support this technology across the globe. In Malta in May of 2017 we hope to stimulate further dialogue and adoption by bringing in examples of early commercially approved implementations of the technology. An intensive one-day program has been outlined that brings together first and second wave technology adopters, regulators, and academics.

Emerging Pharmaceutical Manufacturing Summit, May 2017 - Agenda

May 8, Monday

Registration and Poster Session
(Yacht Marina @ 5:00 pm)

Welcome Reception on evening Harbor Cruise
(boat leaves Yacht Marina @ 6:00 pm)

Welcome Dinner
(Yacht Marina @ 7:30 pm)

May 9, Tuesday (Main Program - Full day)

Welcome to Malta: Hon. Helena Dalli,
(Minister for Social Dialogue, Consumer Affairs and Civil
Liberties)

Program Introduction and Meeting goals:
Douglas B. Hausner
(I2APM, C-SOPS, Rutgers University)

Kickoff Talk: Fernando J. Muzzio
(I2APM, C-SOPS, Rutgers University)
*"Advanced Pharmaceutical Manufacturing as an Enabler of
QbD and Science Based Regulation: Solid Dose Case Study"*

In-Market Talk: Lawrence De Belder,
(Janssen Pharmaceuticals, Senior Principal Engineer)
*"A Spotlight on a Major Corporate Implementation Strategy
for Continuous Manufacturing"*

Industrial Adoption Perspective: Christine Moore, (MSD,
Executive Director and Global Head for CMC Policy)
*"Anticipated Regulatory Challenges for Worldwide Approval
of Continuous Manufacturing"*

Regulatory Perspective: Robert Bream, (EMA, Scientific
Administrator, Quality of Medicines)
*"Challenges and Opportunities for Continuous
Manufacturing: An EMA perspective"*

Academic Panel: Alastair Florence(CMAC), Wen Kai
Hsiao (RCPE), Jon O'Halloran (SSPC),
Marianthi Ierapetritou (C-SOPS), *" Overview of IAPM and
Support Capabilities in CM "*
*[Posters on academic center capabilities available for viewing
onsite throughout the conference]*

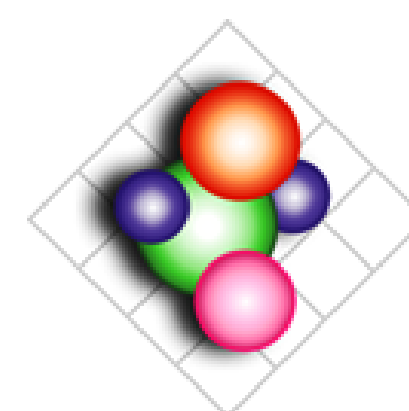
Impact - Development and Clinicals: Ahmad Almaya, (Eli Lilly,
Research Advisor)
"CM in Clinical Development and Initial Commercialization"

Impact – Sampling and Control: Robert Meyer, (MSD, Head of
Innovation & New Technology Development)
*"Appropriate Control Strategies for Continuous Direct
Compression"*

International Coordination 1: Alberto Cuitino, (I2APM, C-
SOPS, Rutgers University)
*"Public Private Partnerships Activities Supporting International
Adoption"*

International Coordination 2: Ding Ming, (USP, VP of
Innovation)
"Supporting Continuous Manufacturing Innovation Globally"

Learn more & register at
csops.org/event-registration



C-SOPS
Center for Structured Organic Particulate Systems