

## UPCOMING EVENT

# 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



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.

### Agenda Highlights:

- Welcome to Malta: Hon. Helena Dalli, Minister for Social Dialogue, Consumer Affairs and Civil Liberties
- Kickoff : *Advanced Pharmaceutical Manufacturing as an Enabler of QbD and Science Based Regulation: Solid Dose Case Study*  
Fernando J. Muzzio, IIAPM, C-SOPS, Rutgers University
- In-Market Talk: *A Spotlight on a Major Corporate Implementation Strategy for Continuous Manufacturing*  
Lawrence De Belder, Janssen Pharmaceuticals, Senior Principal Engineer
- Industrial Adoption Perspective: *Anticipated Regulatory Challenges for Worldwide Approval of Continuous Manufacturing*  
Christine Moore, MSD, Executive Director and Global Head for CMC Policy
- Regulatory Perspective: *Challenges and Opportunities for Continuous Manufacturing: An EMA perspective*  
Robert Bream, EMA, Scientific Administrator for Quality of Medicines
- Academic Panel: *Overview of IIAPM and Support Capabilities in CM*  
Alastair Florence(CMAC), Wen Kai (RCPE), Gavin Walker (SSPC), Marianthi Ierapetritou (C-SOPS)
- Impact - Development and Clinicals: *CM in Clinical Development and Initial Commercialization*  
Ahmad Almaya, Eli Lilly, Research Advisor
- Impact – Sampling and Control: *Appropriate Control Strategies for Continuous Direct Compression*  
Robert Meyer, MSD, Head of Innovation & New Technology Development
- Regulatory Perspective: *Perspectives on Early Adopter Continuous Process Implementation*  
Ewan Norton, Medicines and Healthcare Products Regulatory Agency, GMDP Inspector
- International Coordination: *Public Private Partnerships Activities Supporting International Adoption*  
Alberto Cuitino, IIAPM, C-SOPS, Rutgers University
- International Coordination: *Supporting Continuous Manufacturing Innovation Globally*  
Ding Ming, USP, VP of Innovation

Learn more & register at  
[csops.org/event-registration](https://csops.org/event-registration)