

C-SOPS Industrial Engagement



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Center for Structured Organic Particulate Systems

EMERGING PHARMACEUTICAL SUMMIT 2017

OSD Continuous Manufacturing in the Current Regulatory Landscape
May 8-9, 2017 | Grand Hotel Excelsior Malta, Floriana, Malta

Description:

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 Talk:** *Advanced Pharmaceutical Manufacturing as an Enabler of QbD and Science Based Regulation: Solid Dose Case Study* - **Fernando J. Muzzio**, I2APM, 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
- **A Regulatory Perspective:** *Anticipated Regulatory Challenges for Worldwide Approval of Continuous Manufacturing* - **Christine Moore**, MSD, Executive Director and Global Head for CMC Policy
- **Not Just for Traditional Branded Pharma:** *Development and Deployment of CM Technology* - **Frank Streil**, Teva, Director Technical and Scientific Affairs
- **Academic Panel:** *Overview of I2APM and Support Capabilities in CM* - **Alastair Florence** (CMAC), **Johannes Khinast** (RCPE), **Jon O'Halloran** (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
- International Coordination: *Public Private Partnerships Activities Supporting International Adoption* - **Alberto Cuitino**, I2APM, C-SOPS, Rutgers University
- International Coordination: *Supporting Continuous Manufacturing Innovation Globally* - **Jaap Venema**, USP, CTO

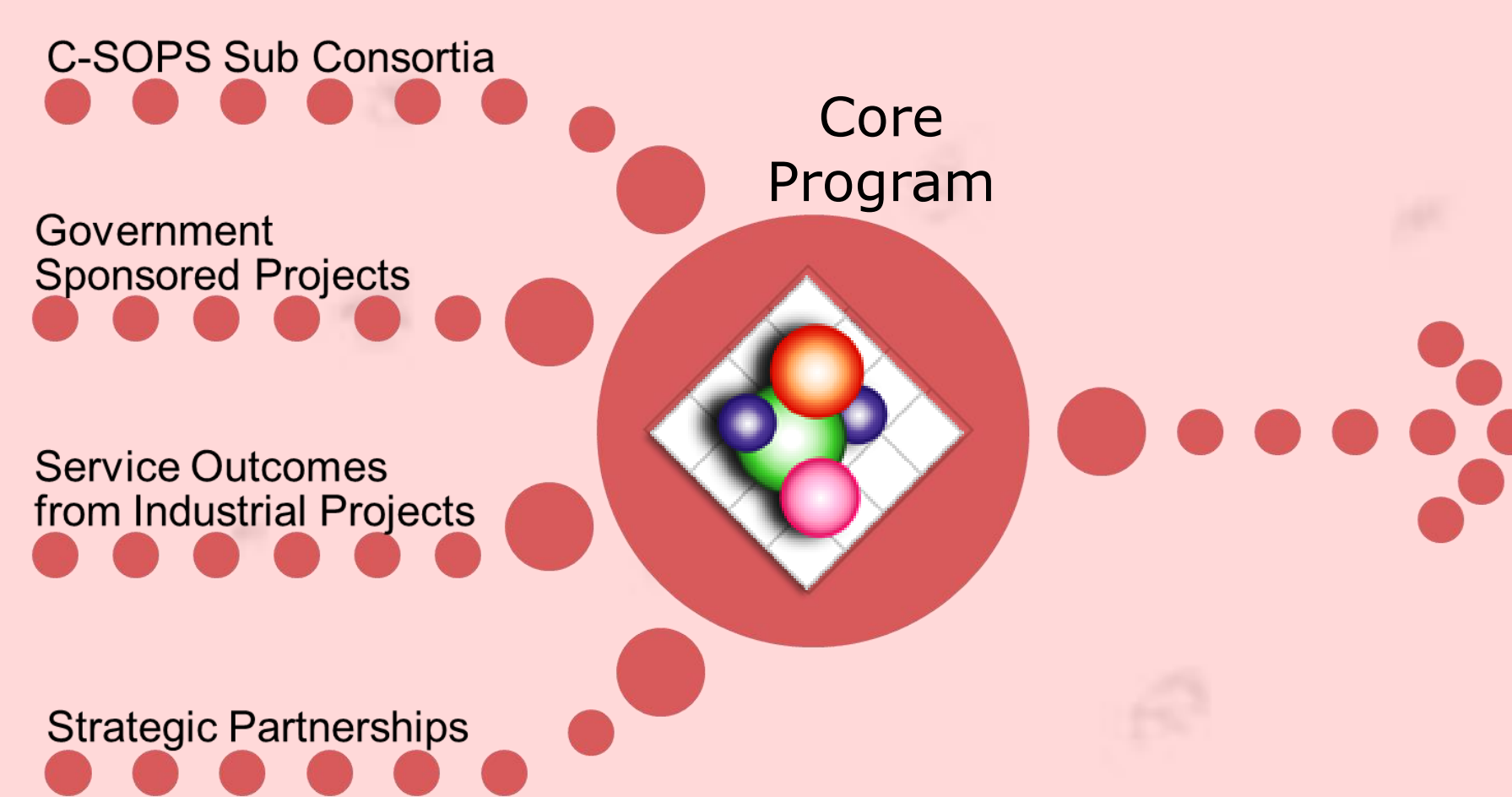
MEMBERSHIP MODEL

C-SOPS is a highly visible open forum and project vehicle for the advancement of pharmaceutical manufacturing that brings together large portions of the industry including vendors, end users, and regulatory agencies.

C-SOPS focuses on:

- Short term project goals
- Government Engagement
- Regulatory Engagement
- International Engagement
- Interactions with Vendors
- Interactions with Standardization Organizations
- Interacting with the broader academic community and overall CM community of practice

C-SOPS Programmatic Activities



The Core Program is composed of:

1. **Research Program** – based on C-SOPS 2.0 projects from last year.
2. **Educational Program** – Basic and Hands-On Training (USP connection), Webinars, Curriculum Development
3. **Regulatory Harmonization Program** – Regulatory School, Conferences like Malta, link/extension of Industrial Regulatory Working Group, etc.
4. **Industrial Discussion Groups** – PAT, Regulatory, Large N, Dissolution/RTR, S88, etc.

The Core Program is also able to pull in output from other affiliated activities which can then be magnified or disseminated through C-SOPS. These are self supported activities with varying sources and objectives. These primarily include:

- **C-SOPS Sub Consortia** – groups of companies coming together to fund specific work that is beyond the scope of the Core Program
- **Government Sponsored Projects** – C-SOPS researchers with government funding projects which have not confidentiality requirements can bring results and learnings from these efforts into the Core Program
- **Service Project Outcomes** – New methodologies and key findings from proprietary projects that are defined as pre-competitive by the sponsor
- **Strategic Partnerships** – By working with other organizations C-SOPS can expand both impact and reach for the benefit of the membership. This includes partnerships with academic groups like CMAC, RCPE, SSPC and others as well as with organizations such as USP

C-SOPS Core Program Membership allows for high levels of involvement and visibility of emerging advanced pharmaceutical manufacturing. Talk with us more about how your organization can get involved.

FUNDING OPPORTUNITIES WITH INDUSTRY PARTNERS

C-SOPS is actively pursuing a number of funding opportunities in the near future where we are seeking industry partnerships. A brief description of the grants being applied and the associated research (and researchers) is provided below:

I. Small Business Innovation Research Program (SBIR) and Small Business Technology Transfer Program Phase I (STTR)

The congressionally mandated SBIR and STTR programs are intended to support scientific excellence and technological innovation with strong emphasis on private-sector commercialization. Because these programs have no topical focus, the NSF offers a very broad solicitation topics that are intended to permit as many eligible science and technology based small businesses as possible to compete for these funds.

Project(s): *Real-Time Release (RTR) tool box* (Dr. Ravendra Singh) & *Integrated Controls* (Dr. Savitha Panikar)

II. Partnership for Innovation: Accelerating Innovation Research Technology Transfer (PFI:AIR-TT)

The PFI:AIR-TT program supports research to overcome technology barriers or knowledge gaps in the transformation of fundamental science and engineering discoveries into market-valued solutions. Researchers are expected to develop a proof of concept, prototype, or scale-up of the prototype that addresses real-world constraints and provides a competitive value in a potential application space. Project(s): *Fette Development and Commercialization* (Dr. Marianthi Ierapetritou)

III. Other Funding Efforts

A. USP – submitting white paper and two proposal
– Douglas Hausner (lead)

B. Convergence Consortium – Bringing together end users to align on pre-competitive aspects of DCCM
– Dr. Fernando Muzzio (lead)

C. NSF: 12-515 Advancing Health Services through system modeling research: NSF, in collaboration with the Health Information Technology (IT) Portfolio at the Agency for Healthcare Research and Quality (AHRQ), will accept and review investigator-initiated proposals that address systems modeling in health services research.
– Dr. Marianthi Ierapetritou and Dr. Rohit Ramachandran

D. International Research Network connections (IRNC) – The IRNC program supports high-performance network connectivity required by international science and engineering research and education collaborations involving the NSF research.
– Dr. Alberto Cuitino

E. BIGDATA – NSF: 17-534 The BIGDATA program seeks novel approaches in computer science, statistics, computational science, and mathematics, along with innovative applications in domain science, including social and behavioral sciences, education, biology, the physical sciences, and engineering that lead towards the further development of the interdisciplinary field of data science.
– Dr. Marianthi Ierapetritou and Dr. Rohit Ramachandran