Membership Program

Presenter: Doug Hausner

IAB Meeting
March 02-03, 2017
Overview

• Review C-SOPS Program and Updates
• Key Events and Interactions
• New features for members
C-SOPS

Partnerships and Services

Research Program
Education Program
Industrial & Associated Projects/Groups
Regulatory Harmonization Program

Convergence Group

Mini Consortia
C-SOPS Core Program

1. Research Program – based on C-SOPS 2.0 projects

2. Educational Program – Basic and Hands-On Training, Webinars, Curriculum Development

3. Regulatory Harmonization Program – Regulatory School, Malta Meeting, Regulatory Working Group, etc.

4. Industrial Groups – PAT, Regulatory, Large N, Dissolution/RTR, S88, etc.
Mini Consortia

• This model is necessary, but has struggled largely due to contracting

• New mechanism allows initiating of mini consortia through amendment of existing membership agreement

• Potential way for companies to initiate programs they want to be absorbed by the core program

• Currently, the H2Optx user group (Pfizer, GSK) invoking this model
CSOPS 2.0 Project Portfolio

- CSOPS 2.0 Core Project Goals: Address technology gaps & provide innovations to advance Continuous Manufacturing of pharmaceuticals while continuing the train the next generation of engineers for advanced pharmaceutical manufacturing

- Projects features:
  - Funding Source: Industrial Membership Fees Only
  - Scope: 1-2 yrs with specific deliverables
  - Project team: Maximum of 1 post-doc + 1 grad student plus faculty
  - Selection based on priorities determined by industrial members
1. Predicting & managing API blend properties for batch and continuous manufacturing

2. 2. Hot Melt Extrusion: Model Development

3. Staged Powder Addition in Twin-Screw Granulation

4. NIR evaluation of Low Drug Concentration Blends

5. Science-based statistical comparison of dissolution profiles

6. Value of Information in Sensor Networks

7. A Comparative Assessment of Nanocomposites versus Amorphous Solid Dispersions for Dissolution Enhancement

8. Microwave-Based Fluid Bed Drying
Global Alignment

Increasing Familiarity with Advanced Pharmaceutical Manufacturing

- May 2017 - Summit in Malta the day ahead of an existing HMA meeting; invited by Maltese Medical Authority
- May 2017 - Workshop in Mumbai in conjunction with USP
- TBD – Planning similar programmatic activity for Japan
66 DAYS TO THE EVENT

i2APM presents
Emerging Pharmaceutical Manufacturing Summit
OSD Continuous Manufacturing in the Current Regulatory Landscape

May 8 - 9, 2017
Grand Hotel Excelsior Malta,
Great Siege Road, Floriana
FRN1810, Malta

Draft Agenda
updated: 01/23/2017

Conference registration details:

Registration fees:
Early bird (till March 31st, 2017): $500
Regular: $750

i2APM invites you to an intensive one-day program that brings together first and second wave CM technology adopters, regulators, and academics. We hope to stimulate further dialogue and adoption of CM by bringing in examples of early commercially approved implementations of the technology.
New Website

ABOUT US

C-SOPS Overview

Founded in 2016, the Center for Structured Organic Particulate Systems (C-SOPS) brings together a cross-disciplinary team of researchers from major universities to work closely with industry leaders and regulatory authorities to improve the way pharmaceuticals, foods and agriculture products are manufactured. C-SOPS focuses on advancing the scientific foundation for the optimal design of SOPS with advanced functionality while developing the methodologies for their active control and manufacturing.

Headquartered at Rutgers University, C-SOPS partners include the New Jersey Institute of Technology, Purdue University, the University of Puerto Rico at Mayaguez, and more than 40 industrial consortium member companies.

OUR MISSION

C-SOPS is committed to modernizing pharmaceutical manufacturing by developing the science and engineering methods for designing, testing, and manufacturing these particles in a way that meets and exceeds current standards.

WHY C-SOPS?

In the changing global pharmaceutical market, competition, regulation, and economic conditions are dictating that we introduce new processes in a more advanced and efficient manner.

WHAT WE DO?

At C-SOPS, we focus on understanding the biophysical characteristics of pharmaceutical and manufacturing science whereas our research offers a fundamentally better method. NSF Engineering Research Center for Structured Organic Particulate Systems (C-SOPS)
Welcome to the Industry Member page

Here you will find helpful links and registration pages for all your C-SOPS activities.

Latest IAB Spring 2017

Quick Links

C-SOPS: Main Discussion Portal

C-SOPS: Reports

C-SOPS Main Discussion

Explore our forum below to share ideas, connect with other researchers and post questions or feedback.

General Discussions

Use this forum for any general discussion regarding all things C-SOPS.

Project Specifics

Do you have any specific question or comments regarding a C-SOPS project? Post them here to help fellow researchers!

NSF 10 yr report (2015)

C-SOPS 2.0 Brochure
C-SOPS 10 yr Report

Technology Platform

Current facilities at C-SOPS

The C-SOPS mission to be the national focal point for the science-based development of structured organic composite products and their manufacturing processes requires state-of-the-art laboratory facilities to conduct basic research and improve the pharmaceutical engineering knowledge-base.
C-SOPS New Member Registration

Member Profile Submission
Fill in our Member Profile Form below to keep C-SOPS record up-to-date with your information. It will also help to process your site membership to CSOPS Online faster!

Name *

Email *

Membership Type *
C-SOPS Researcher

Institution *

Position *

Phone *

Address
Street Address

City

State

Postal / Zip Code

United States

Profile Pic
Max upload size: 5MB

Upload

Submit