

Membership Program

Presenter: *Doug Hausner*

***IAB Meeting
March 02-03, 2017***



NSF Engineering Research
Center for **S**tructured **O**rganic **P**articulate **S**ystems (**C-SOPS**)



RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

PURDUE
UNIVERSITY

NJIT
New Jersey's Science &
Technology University

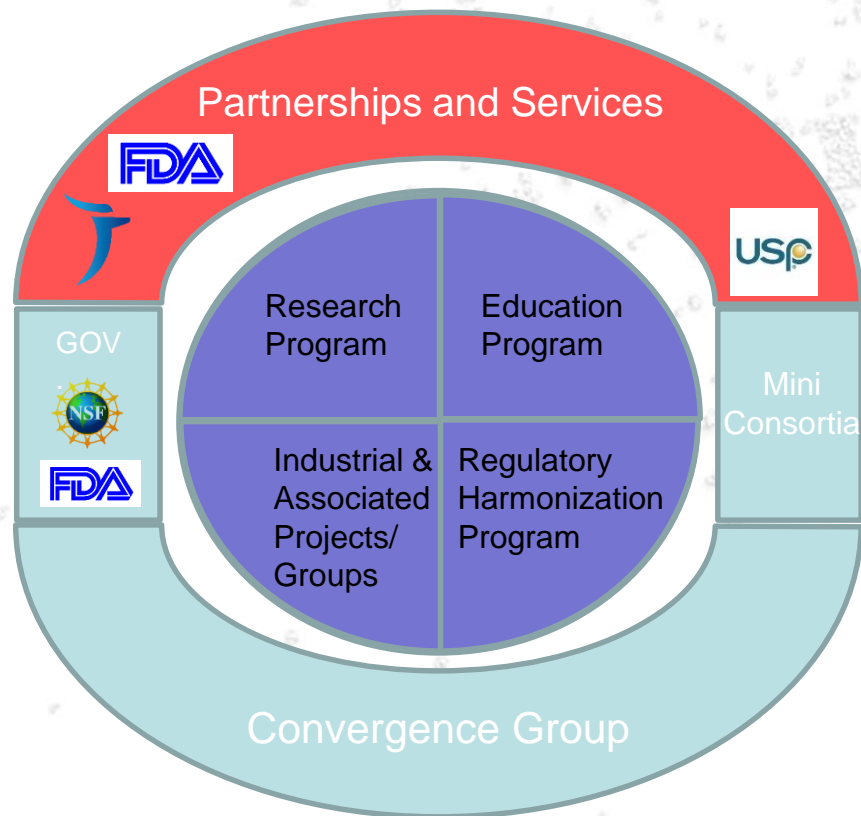


Overview

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



C-SOPS



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

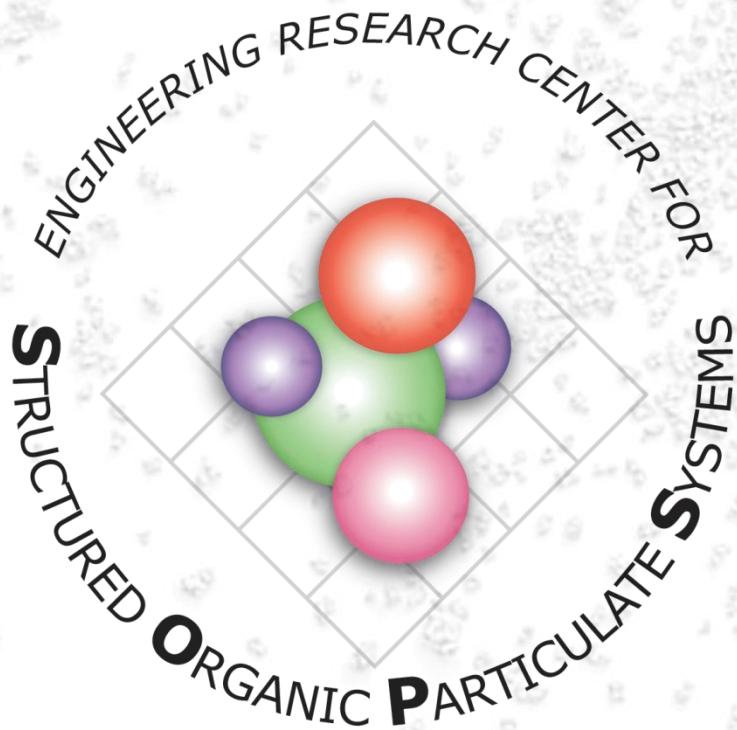
CSOPS 2.0 Project Portfolio

- 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



CSOPS 2017 Project Portfolio

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

Malta Meeting

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.



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Center for Structured Organic Particulate Systems (C-SOPS)

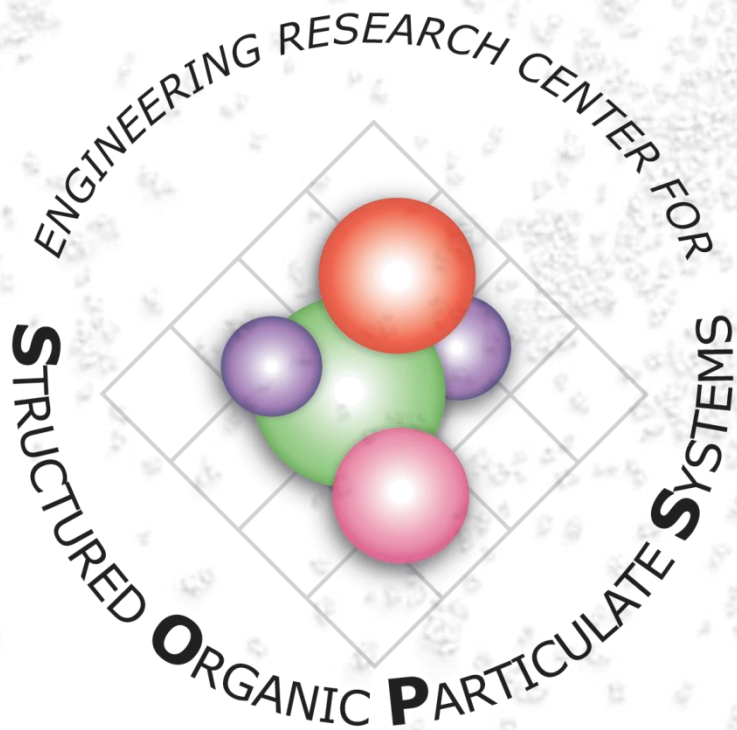


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New Website



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ABOUT US



C-SOPS Overview

Founded in 2006, 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,



WHY C-SOPS?

In the changing global pharmaceutical market, competition, regulation, and economic conditions are driving the need to introduce new processes and



WHAT WE DO?

At C-SOPS, we focus on understanding basic aspects of pharmaceutical and manufacturing science where lack of knowledge has been a fundamental barrier to



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IAB MEETING Spring 2017

Latest: C-SOPS IAB Meeting Spring 2017 Update

IAB Agenda

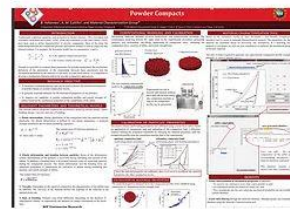
Poster Presentations

1. Dosing of Powder Slurries by a Dropwise Process

Andrew J Radcliffe, Gintaras V. Reklaitis, Zoltan K. Nagy

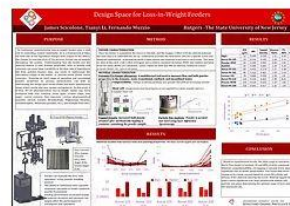
2. Mechanistic Materials Database for Predicting Properties of Powder Compacts

Beruket Youhannes, Alberto Cuitino



3. Finding Critical Parameters and Failure Modes in a Direct Compaction Continuous Line

Gerardo Callegari



4. Effect of Material Properties on Loss-in-Weight Feeding Equipment

J.V. Scicolone, T. Li, F.J. Muzzio

5. Enabling direct compaction at high drug loading via dry coating of APIs: Towards a predictive framework

Kuriakose Kunnath, Zhonghui Huang, Rajesh N. Dave

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INDUSTRY MEMBERS

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

[IAB Agenda](#)[Poster Presentations](#)

Quick Links

[New Member Registration](#)[C-SOPS Member Search](#)[C-SOPS Sakai Portal](#)

C-SOPS: Main Discussion Portal

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!

C-SOPS: Reports

[NSF 10 yr report \(2015\)](#)[C-SOPS 2.0 Brochure](#)

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C-SOPS 10 yr Report

Center Overview
Current Facilities

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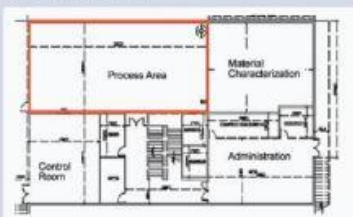
Technology Platform Current facilities at C-SOPS

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 headquarters is located at the Rutgers Pharmaceutical Engineering facility, in the C-Wing of the main engineering building at Rutgers University. This facility, which was renovated in 1998, is composed of 11,400 sq. ft. of laboratory space specifically designed for pharmaceutical manufacturing research. This facility comprises a suite of 5 offices that house the Director, the AD, the Director of Industrial Relations, and the ERC Staff (Business Manager and Administrative Assistant). The facility was specifically designed for pharmaceutical manufacturing research, including GMP-quality seamless epoxy flooring and an environmentally-controlled laboratory capable of reproducing moisture and temperature conditions used in pharmaceutical manufacturing. The research facility currently contains extensive solids-processing equipment that are used by virtually major pharmaceutical company for the formulation of new products. This combination of equipment is virtually never found in engineering programs

at educational institutions. This space has been augmented by an additional 5,000 sq. ft. of office and research space immediately adjacent to the existing facility, consisting of three additional laboratories and five offices that house 18 graduate students and postdocs. Main space renovations at Rutgers consist of two efforts: (1 - in advanced planning) an electronic classroom/videoconferencing facility will be implemented during

January-July 2008, and (2 - completed) a dedicated laboratory has been created for Test Bed 1, requiring renovation of utilities, a new seamless floor, and air handling equipment. This facility will house a number of major equipment units (three blenders, 10 feeders, a roller compactor, and a tablet press) that have already been received (mostly as in-kind contributions of ERC Industrial members).



Floor Plan for Center for Pharmaceutical Engineering Development and Learning of C-PEDaL



The main facilities-related project of the ERC is to enlarge the existing facilities at Puerto Rico, which in their present form focus primarily on process analytics and control, with the addition the new Center for Pharmaceutical Engineering Development and Learning of C-PEDaL to be built at Puerto Rico. The concept for C-PEDaL started at UPRM and has been refined with input from representatives of the industry (Merck, Pfizer, Wyeth) and the concept submitted to the design company for further elaboration. The input received has concentrated in two types: 1) structural design or organization and 2) strategic purposes. These purposes aim at supporting the learning of undergraduate student, basic and applied research, technology transfer and training of professionals. For this, C-PEDaL will include an area for pharmaceutical operations (1,800 ft²), process control (PAT) (200 ft²), material characterization (800 ft²), lectures, and administration (1,200 K ft²). It will be constructed using funds \$2MM that have already been committed by the industrial membership



of the ERC and from UPR funds, and plans to raise additional funds from the local industry and from and PR government agencies are under way. The floor plan on the adjoining page depicts a preliminary layout. In parallel with design (nearly completed) and construction (to be started in Feb 08) activities, UPRM is purchasing lab-scale pharmaceutical processing equipment, using other funding sources, which will be used for undergraduate and graduate education and research and for industrial practitioner training



under UPR outreach efforts.

Center facilities at Purdue have also experienced rapid growth. The ERC Purdue headquarters facility is located in the Potter Engineering Building (PEB), a multidisciplinary building which also houses the Engineering Library. The current space allocation consists of 4000 sq ft of laboratory space and 800 sq ft of office space. About 1/4 of the lab space is dedicated to Test Bed 1 realization, is located at the basement level, and contains a roller compactor,

[Researcher Login/](#)

MEMBER REGISTRATION

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 *

First

Last

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