

# NSF Engineering Research Center for Structured Organic Particulate Systems (C-SOPS)

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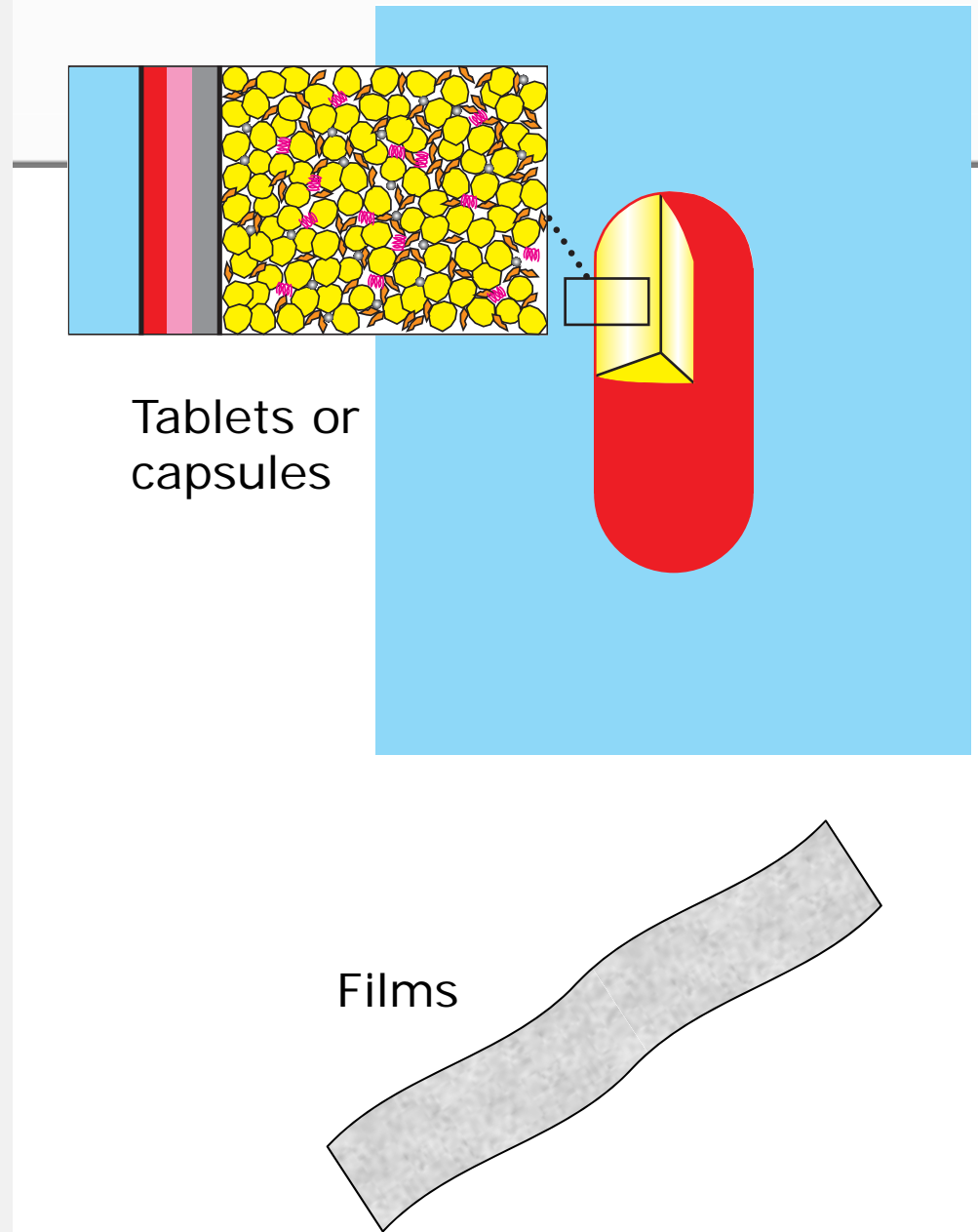
**ENGINEERING RESEARCH CENTER FOR**  
**STRUCTURED ORGANIC PARTICULATE SYSTEMS**

RUTGERS UNIVERSITY  
PURDUE UNIVERSITY  
NEW JERSEY INSTITUTE OF TECHNOLOGY  
UNIVERSITY OF PUERTO RICO AT MAYAGÜEZ



# C-SOPS Vision:

To be the national focal point for science-based development of structured organic particle-based products and their manufacturing processes.



# Test Bed 1: Continuous Tablet Manufacturing

## *Improved product quality*

- *Uniformity* Reduction of effects of segregation and agglomeration
- *Better stability*

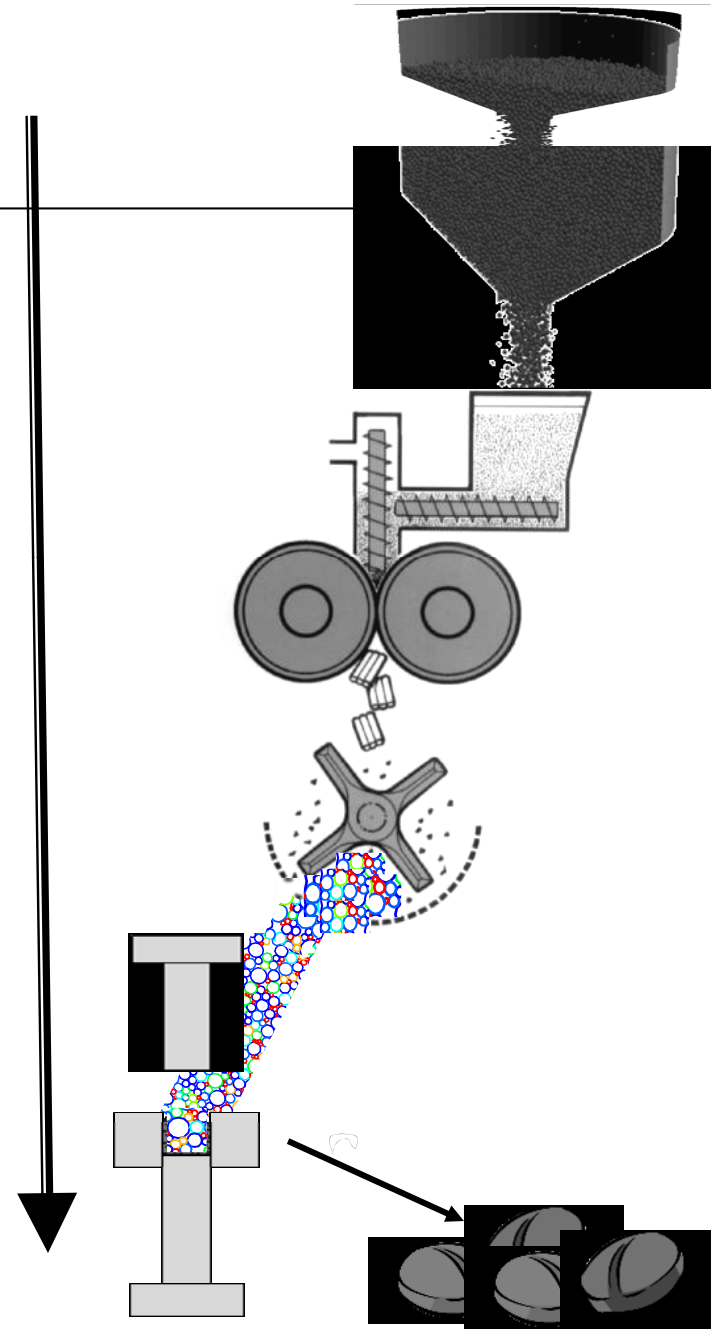
## *Cost reduction*

- *Improved supply chain management*
- *Lower investment, raw material & labor cost*

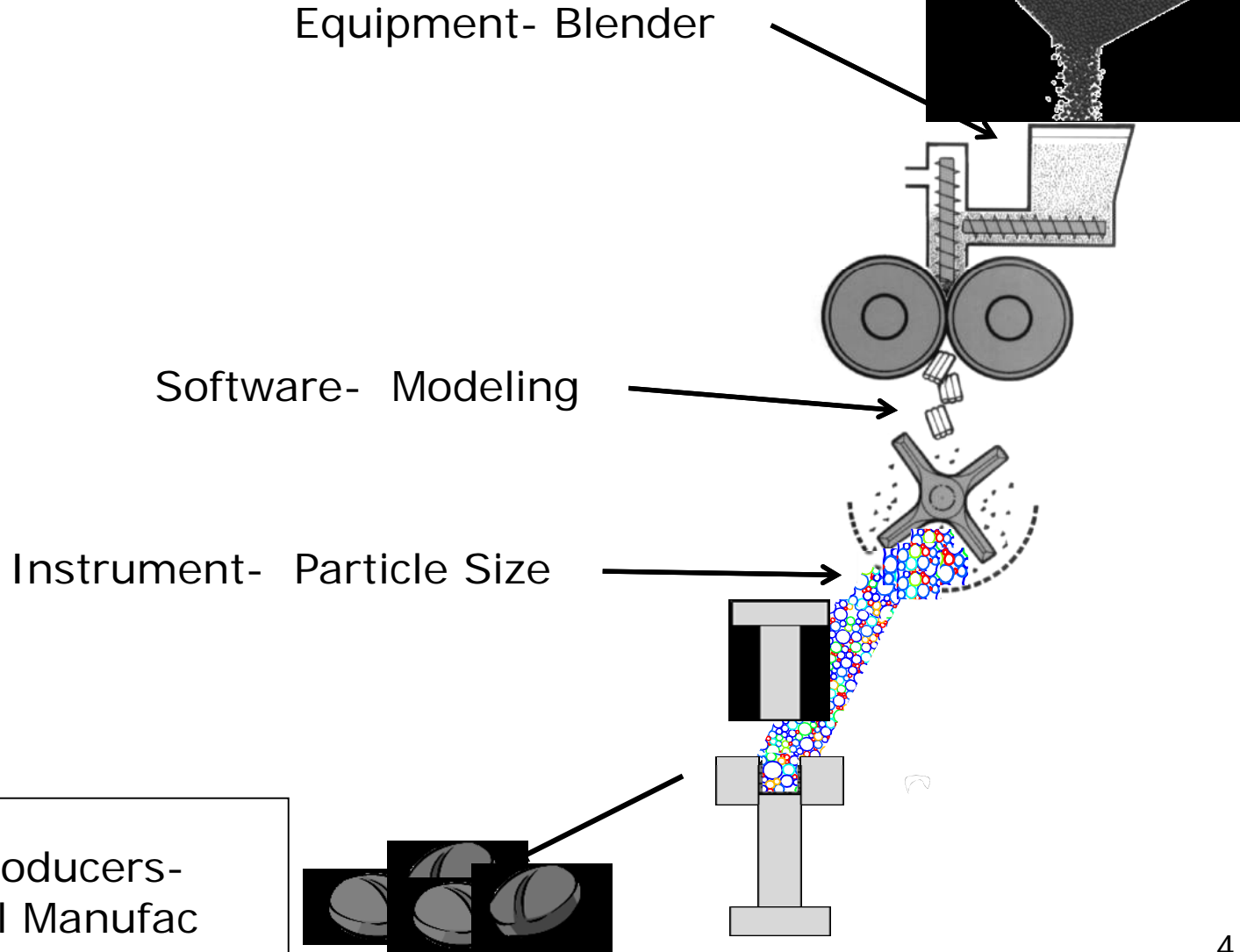
## *Simplified scale up*

- *Same equipment for development and production*

*from blending to tableting*



# Test Bed 1: Continuous Tablet Manufacturing



# Current Membership

– *Level 1 – 9*

- *Pfizer, Eli Lilly, Abbott, Glaxo SmithKline, Pepsico, Schering Plough, Bristol-Meyers Squibb, Wyeth, Boehringer Ingelheim*

– *Level 2 – 15*

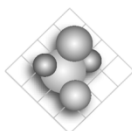
- *Sepracor, Proctor & Gamble , KTron, Gericke, Tunnell, Johnson & Johnson, Schenck-Accurate, Astra Zeneca, CAMP, FDA, Catalent, DEM Solutions, Itasca, Malvern, Automation Tooling Systems*

– *Level 3 & 4 – 5*

- *Allergan, Pharmalaser, Metropolitan Computing Corporation, Advanced Ingredient Systems, Freeman Technology*

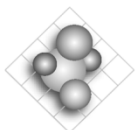
# Member types

- Formulating companies- 15
  - *13 Pharmaceutical*
  - *1 Food, 1 Consumer products*
- Equipment- 6
- Instrument- 3
- Software- 2
- Regulatory, consulting, trade- 3



# Systemic Challenges- Pharma

- Cost / time for new product introduction
  - *~\$800 MM, 10-15 years*
- Generic competition
- Outsourcing
- Investment in biopharma
- FDA manufacturing initiatives
- Mergers



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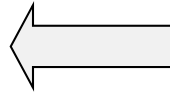


# Industry Involvement

## Executive Committee

(Level 1 members)

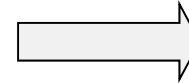
- Strategic advice on policies, research goals, education, industry, regulatory policy, and other long-term matters
- Provides input on priorities
- Contributes to gap inventory



## Industrial Advisory Board

(Level 1-4 members including FDA)

- Project evaluation
- Tactical advice on project implementation
- Contributes to gap inventory



## Project Mentors

(Level 1 & 2 members)

- Participate on project teams
- Facilitates incorporation of center findings into practice

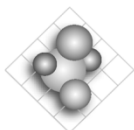
- Project summaries
- Management presentations

- Semi annual in-person meetings
- Technical reports
- Workshops
- Poster sessions
- Student resume books

- Monthly project meetings
- Web based work spaces

# Project Mentors- “Job description”

- Provides industrial perspective and expertise to center researchers
  - *Helps students (and faculty) gain understanding of issues in using center research findings in practical applications*
- Facilitates incorporation of center findings into practice
- Serves as a project "champion", helping convey to his company and center steering committee a sense of the value delivered by the project.
- Helps center researchers gain additional resources (materials, equipment) from vendors and industrial contributors.



# Project Mentors- Status

- Currently have ~120 mentors from 15 companies
- Each project has 3-10 mentors
- Mentor involvement varies
- Significant impact on projects
- Significant impact on company involvement



# Flexibility in membership

- Dilemma- Balancing flexibility with fairness to all members
- Payments
  - *Cash- payment terms*
  - *In-kind-*
    - *Type and pieces of equipment*
    - *Location*
    - *Software- number of licenses*
    - *Services- e.g., installation, project manager*

