CSOPS Agency Interactions (primarily FDA)

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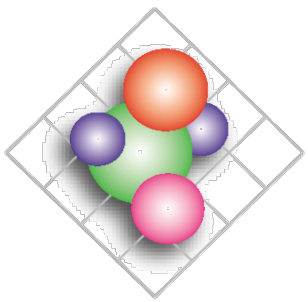

ENGINEERING RESEARCH CENTER FOR
STRUCTURED **O**RGANIC **P**ARTICULATE **S**YSTEMS

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

FDA meeting – 9/20/06

FDA: Janet Woodcock, Helen Winkle, Moheb Nassr, Mansoor Khan, Nakissa Sadrieh

NSF: Lynn Preston and Judy Raper

ERC: Fernando Muzzio

Goals:

(1) To identify new ERC research initiatives that facilitate the FDA approval process

(2) To begin to develop a structure for research collaboration

(3) To identify FDA's education needs and develop a strategy for ERC support

Outcomes:

FDA to be IAB and SAB member

FDA will integrate project teams

FDA will propose test beds

FDA is a level II member of CSOPS

Benefits

- To CSOPS
  - *Commercialization of CSOPS technology*
- To pharma companies
  - *Speeds approval process*
- To technology suppliers
  - *Enhances acceptance of technology by FDA*

Interactions

- ERC member
  - *Reports*
  - *IAB meetings*
- Training sessions
- White paper for guidance

Partnership with FDA

- Center provides scientific support for FDA regulatory efforts in product and process development and manufacturing
- Other organizations
  - *Rutgers and Purdue are founding members of the National Institute of Pharmaceutical Technology and Education, and FDA partner in research and education*
- 9 faculty (all 4 partner schools) interact individually with FDA

ERC Faculty FDA Interactions

ERC faculty	Activity
Michniak-Kohn	Serves on SAB of International Pharmaceutical Excipients Council which advises the FDA
Morris, Muzzio	Serve on FDA-CDER-OPS Advisory Committee for Pharmaceutical Sciences and Clinical Pharmacology
Pedersen	ERC lead on NIPTE Subcontract to design and develop for the FDA a scientific training program in the state-of-art pharmaceutical manufacturing and development technologies
Romanach	Organized PAT/QbD Symposium in Puerto Rico for FDA and local pharmaceutical industry
Reklaitis, Muzzio, Litster, Cuitino	Through NIPTE, developing quality by design (QbD) guidance elements for design space and scale-up of unit operations.
Muzzio	Provided training on acceptance sampling and on continuous manufacturing
Romanach	With IBS Caribe, prepared PAT Certification Program for FDA inspectors
Muzzio	Working with J&J regulatory people to prepare filing for product approval by continuous manufacturing line
Muzzio	Presented a training session of powder sampling and blend homogeneity testing to the compliance division of CDER
Muzzio	Provided two lectures on stratified sampling and continuous manufacturing on a PQRI/FDA sponsored course on large-n based methods for regulatory decision making
Muzzio	Presented an invited lecture on effect of electrostatics on flow properties of powder blends for the CMC review team at CDER
Morris, Muzzio	Special government employees for Helen Winkle in FDA-CDER-OPS
Dave	Informal discussion with Christine Moore (Acting Deputy Director of the Office of Pharmaceutical Sciences) regarding Testbed 2, who suggested a presentation should be given at FDA to help develop standard protocols for strip films