CSOPS Agency Interactions
(primarily FDA)

Eric H. Erenrich, ILO
June 20, 2012
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

<table>
<thead>
<tr>
<th>ERC faculty</th>
<th>Activity</th>
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<tbody>
<tr>
<td>Michniak-Kohn</td>
<td>Serves on SAB of International Pharmaceutical Excipients Council which advises the FDA</td>
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<td>Morris, Muzzio</td>
<td>Serve on FDA-CDER-OPS Advisory Committee for Pharmaceutical Sciences and Clinical Pharmacology</td>
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<tr>
<td>Pedersen</td>
<td>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</td>
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<td>Romanach</td>
<td>Organized PAT/QbD Symposium in Puerto Rico for FDA and local pharmaceutical industry</td>
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<tr>
<td>Reklaitis, Muzzio, Litster, Cuitino</td>
<td>Through NIPTE, developing quality by design (QbD) guidance elements for design space and scale-up of unit operations.</td>
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<tr>
<td>Muzzio</td>
<td>Provided training on acceptance sampling and on continuous manufacturing</td>
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<td>Romanach</td>
<td>With IBS Caribe, prepared PAT Certification Program for FDA inspectors</td>
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<tr>
<td>Muzzio</td>
<td>Working with J&amp;J regulatory people to prepare filing for product approval by continuous manufacturing line</td>
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<td>Muzzio</td>
<td>Presented a training session of powder sampling and blend homogeneity testing to the compliance division of CDER</td>
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<tr>
<td>Muzzio</td>
<td>Provided two lectures on stratified sampling and continuous manufacturing on a PQRI/FDA sponsored course on large-n based methods for regulatory decision making</td>
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<tr>
<td>Muzzio</td>
<td>Presented an invited lecture on effect of electrostatics on flow properties of powder blends for the CMC review team at CDER</td>
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<tr>
<td>Morris, Muzzio</td>
<td>Special government employees for Helen Winkle in FDA-CDER-OPS</td>
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<td>Dave</td>
<td>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</td>
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