

NIPTE Research Conference

The Future of Pharmaceutical Manufacturing

June 18-19, 2013

The Universities at Shady Grove, Rockville, MD
GV Reklaitis (Purdue) and J Clark (FDA) co-chairs

What is NIPTE?

- NIPTE is a multi-university, non-profit organization addressing long-term, fundamental research and education in the science of pharmaceutical development and manufacturing.
- NIPTE projects are intend to be interdisciplinary and multi-institutional to leverage the broad range of expertise, experience and resources available at the NIPTE member institutions.
- NIPTE member universities came together in 2005, formed a non-profit organization in June, 2007 and the collaboration has been going strong.
- NIPTE's goal is to develop a reliable public knowledge base that can become the foundation for innovation in pharma. This would include advanced knowledge of process development, engineering and manufacturing of pharmaceutical products.

The National Institute for Pharmaceutical Technology and Education (NIPTE)

Duquesne University	University of Iowa
Illinois Institute of Technology	University of Kansas
Purdue University	University of Kentucky
Rutgers University	University of Maryland
University of Puerto Rico	University of Minnesota
University of Connecticut	University of Michigan
University of Wisconsin	

Current Membership

NIPTE Leadership

- Chair of NIPTE Board of Directors:
 - Dean Natalie Eddington, U MD Baltimore
- Acting Executive Director
 - Prof Jordan Cohen, retired Dean & VP for Research, U Iowa
- Retired Executive Director
 - Dr Prabir Basu
- Chair of Faculty Committee,
 - Outgoing 2012-13: Prof Mike Pikal, UConn
 - Incoming 2013-14: Prof Steve Hoag, UMD

NIPTE-FDA Research Conferences

- NIPTE research conferences held in 2011 and 2012
 - NIPTE-FDA Collaborative Study On Model-based Design Space Development Across Scales & with Stability Considerations, GV Reklaitis, chair
 - Excipient Properties Knowledge Base, S Hoag, chair
- NIPTE conferences: public forums where results of research from NIPTE-FDA collaboration are disseminated and public input is sought.
- 2013 conference is focused on exploring trends in pharmaceutical manufacturing and identifying needs for research in manufacturing innovation

Agenda: June 18

Time	Speaker	Topic
8:30	Keith Weber, Director (Acting) OPS CDER	Importance of Manufacturing in Pharma
9:00	Jon Clark Associate Director, OPS CDER	Status of Quality and where we go from here?
9:30	Henry Wixon Chief Counsel, NIST	NIST's role in Advanced Manufacturing Initiatives
10:15	Break	
10:30	Paul McKenzie VP, Manufacturing & Technical Opns, Janssen Supply Chain	Driving Pharma Development & Manufacturing to Think Differently and Do Better
11:15	Elaine Morefield Depty Director ONDQA CDER	Pharmaceutical Manufacturing: New Drugs
12:00	W. Nicholson Price Harvard Law School	Innovation Policy and Manufacturing

Time	Speaker	Topic
1:00	Mike Thien Sr VP, Global Science, Tech & Commercialization, Merck	Vision of Manufacturing of the Future
1:40	Lawrence Yu, Depty Director (Acting) OPS CDER	Understanding Process Capability: Value and Opportunity
2:20	Shou-Bai Chau Sr VP, Manufacturing Medimune (Div Astra Zeneca)	Biomanufacturing: Vision for the Future
3:00	Break	
3:20	Steve Kozlowski Director, OBP, CDER	Pharmaceutical Manufacturing – Biotechnology Products
4:00	Ranjit Deshmukh Sr Director, Corporate Manufacturing, Medimune	Driving Continuous Improvement in Commercial Biomanufacturing
4:40	Panel Discussion	
5:30	Adjourn	

Agenda: June 19

Time	Speaker	Topic
8:00	Fernando Muzzio C-SOPS, Rutgers University	Continuous Manufacturing-Current Status & Research Needs
8:40	GV Rex Reklaitis C-SOPS, Purdue University	Developments in Drop on Demand Technology for Dosage Formation
9:20	Randall B Bass Director, Product & Process Development, Amgen	Biopharmaceutical Attributes & Considerations for Manufacturing
10:20	Break	
10:35	Michael Miller Microbiology Consultants LLC	Rapid Microbiology Methods
11:20	Zoltan Nagy C-SOPS, Purdue University	Advance Process Control in Pharmaceutical Manufacturing
12:00	Lunch	

Agenda

Time	Speaker	Topic
1:00	Jim Drennen Duquesne University	Status of PAT and the Future of PAT& Real time testing
1:40	Abhay Gupta Sr Staff Fellow, OPS CDER	Use of PAT – Case Studies and FDA Experience
2:20	Break	
2:30	Linus Mockus ChE, Purdue University	PharmaHUB: A knowledge sharing tool for advanced pharmaceutical manufacturing
3:10	Panel discussion	
4:00	Adjourn	