

Why This Conference?

NIPTE has received several research awards from the U.S. Food and Drug Administration (FDA) to conduct research in pharmaceutical technology and education.

One of these research awards was to study the effect of excipient properties and its variability on pharmaceutical manufacturing robustness.

NIPTE will share the findings of its research with the entire pharmaceutical community to receive feedback.

NIPTE's goal is to make available all its research findings in the public domain such that scientists and engineers from academia, industry and the regulatory agencies from all around the world can have easy access to the science, technologies and tools.

Who Should Attend?

All pharmaceutical personnel involved in process development and engineering, process improvement, process optimization, implementation of new technology, implementation of PAT and QbD; those who are interested in learning how to use state-of-the-art pharmaceutical science and technology to speed up process development and to develop robust manufacturing process.

Register online at:

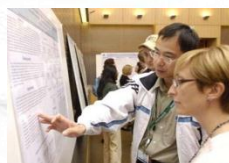
www.nipte.org

About NIPTE

The *National Institute for Pharmaceutical Research & Education (NIPTE)* is a not-for-profit organization dedicated to fundamental research and education in pharmaceutical research and education in pharmaceutical product development and manufacturing.

NIPTE's goal is to increase the scientific and engineering-based understanding of pharmaceuticals such that novel state-of-the-art technologies can be developed and science-based regulations can be implemented. These technologies will also enable new drug discoveries.

The *mission* of *NIPTE* is to improve human health through multi-university collaborative research to advance the quality, safety, affordability and speed to market of medicines through interdisciplinary research and education in pharmaceutical technology.



Graduate and Post-Doctoral Students at the NIPTE universities who were involved in research in pharmaceutical sciences and engineering will present posters on their research at this conference. The posters will present detailed results of various aspects of their research.

NIPTE RESEARCH CONFERENCE

Understanding Excipient Performance – Key to Successful QbD Formulation Design

June 13-14, 2012

FDA Conference Facilities
White Oak, Silver Spring, MD

Register at www.nipte.org

**No Registration Fee for this
Conference**

NIPTE The National Institute for
Pharmaceutical Technology and Education
Improving quality and lowering costs of pharmaceuticals

❖ A goal of FDA's Center for Drug Evaluation and Research is to implement the International Conference on Harmonization (ICH) guidances Q8, Q9, and Q10 covering drug product development (through Quality by Design), risk management, and quality management systems. The ICH guidances are aligned with CDER's Critical Path Initiative, moving manufacturing into the 21st Century. Realization of the QbD paradigm requires a systematic framework for determining the design space for specific operations and their processes as a whole. An often underappreciated factor in the creation of the design space is an understanding of how material inputs affect pharmaceutical formulations and manufacturing. Without knowledge of excipient properties, the influence of material attributes on product quality cannot be assessed, and a pharmaceutical manufacturers' ability to assess and manage risk and improve product quality will be severely limited.

❖ Excipients have a profound influence on the therapeutic efficacy, stability, and manufacturability of a dosage form. Typically, excipients are derived from natural products or synthetically modified natural products, and are available from multiple vendors. As a result, their physical properties may vary from lot-to-lot and vendor-to-vendor. It is these variations in physical properties that are responsible for many of the manufacturing problems that emerge unpredictably throughout the life cycle of a drug product. These problems result in costly rework, lot rejections, and quality investigations for the manufacturer and make it difficult for regulators to have meaningful regulations based upon science. Assessing the risk of this excipient natural variation is very difficult because the principles that govern how excipient material properties influence the critical quality attributes of a finished dosage form are not well understood. Consequently, this knowledge gap often leads to over specification and arbitrary regulation in an effort to control all the sources of variation, but still leaves the manufacturer vulnerable because the sources of risk are not defined or known.

❖ Processing behavior and product performance are also associated with multiple correlated properties; for example, flow behavior can be measured as a "property," but is in essence a complex function of particle size, particle shape, bulk density, surface area, surface energy, cohesiveness, internal and wall frictions, static charge, hygroscopicity and possibly other attributes. In part due to this complexity, today's formulation scientist faces a knowledge gap when attempting to design pharmaceutical products and manufacturing processes. A good first step is to establish a publicly accessible information system that is used to maintain values of fundamental pharmaceutical excipient material properties, and which contains models, best practices, and methods for using this data in the systematic design of pharmaceutical products and

processes.

At this conference, NIPTE faculty & their collaborators will:

- Discuss the issues associated with excipient product performance; 2:30-3:00 Rapid screening for excipient quality surveillance; Lucinda Buhse, FDA/CDER
- Present physical property databases for various material classes; 3:00-3:30 Break
- Demonstrate the database; 3:30-4:00 Solid form aspects of excipients and their influence on formulation and process; Paul Luner, Boeringer-Ingelhiem
- Seek input from scientists & engineers from industry, regulatory agencies & academia on the research conducted so far; 4:00-4:30 Interplay between API, excipient and manufacturing stress in formulation design; Ira Buckner, Duquesne University
- Identify what works, what does not work & the gaps still to be address by the database; 4:30-5:00 Measurement techniques of excipient properties for functionality evaluation; Carl Wassgren, Purdue University
- Develop a strategy for incorporating the input received & planning a path forward to advance the database. 5:00-6:00 Panel Discussion

AGENDA

Wednesday, June 13, 2012

Morning Session: Moderator-Prof Stephen Hoag

- 8:00 – 8:15 Welcome & update; Prabir Basu, NIPTE
- 8:15-8:45 Importance of Academic Research in Science Based Implementation of QbD; Janet Woodcock, FDA/CDER
- 8:45-9:15 FDA-NIPTE collaboration; Helen Winkle, Joan Clark, FDA/CDER
- 9:15-9:45 Science of Excipients-importance & issues; Brian Carlin, FMC/IPEC
- 9:45-10:00 Break
- 10:00-10:40 NIPTE-FDA Project on Excipients; Stephen Hoag, University of Maryland
- 10:40-11:20 Manufacturing Experience with Excipients Variability; Jim Michaels, Merck
- 11:20-12:00 Excipient risk assessments: developing design space using excipient properties as process parameters; Bruno Hancock, Pfizer
- 12:00-1:00 Lunch
- Future Direction of the Handbook of Pharmaceutical Excipients; Paul Sheskey, Dow

Afternoon Session: Moderator-Dr. Bruno Hancock

- 1:00-1:30 Excipient Issues-From a reviewer's viewpoint; Jeff Medwid, FDA/CDER/ONDQA
- 1:30-2:00 Excipient issues in generic drug development; Bob Iser, FDA/OGD
- 2:00-2:30 Safety and efficacy challenges in excipient substitutions in drug formulations; Monsoor Khan, FDA/CDER

5:00-6:00

6:00

Thursday, June 14, 2012

Morning Session: Moderator-Prof Carl Wassgren

- 8:00-8:30 Development of mixing rules with excipient properties; Greg Amidon, University of Michigan
- 8:30-9:00 Flow properties of excipients-characterization and enhancement strategies; Calvin Sun, University of Minnesota
- 9:00-9:30 Lubrication properties of excipients; Jennifer Wang, BMS
- 9:30-10:00 Panel Discussion
- 10:00-10:30 Break
- 10:30-12:00 Demonstration of NIPTE excipient database; Ann Christine Catlin, Purdue University
- 12:-1:00 Lunch - Incorporating multivariate analysis of excipient properties into drug product design; Joseph Kushner, Pfizer

Afternoon Session: Moderator – Prof Stephen Hoag

- 1:00-2:30 Break Out Sessions for All Attendees
- 1. Excipient lot-to-lot variability & design space
- 2. Value and use of NIPTE excipient database
- Facilitators: Stephen Hoag; Bruno Hancock; Carl Wassgren; Ann Christine Catlin; Brian Carlin
- Break
- Break-out presentations
- 4:00 Wrap up; Stephen Hoag

