

**Understanding Excipient Performance – Key to Successful QbD Formulation Design**

**Venue: FDA Conference Facilities, White Oak, Silver Spring, MD**

**Dates: June 13 and 14, 2012**

**June 13, 2012 AM**

1	Prabir Basu	NIPTE	Welcome & NIPTE Update	8:00 am
2	Dr. Janet Woodcock	FDA/CDER	Importance of Academic Research in Science-Based Implementation of QbD Dr. Janet Woodcock	8:15 am
3	Helen Winkle/Jon Clark	FDA/CDER	FDA-NIPTE Collaboration	8:45 am
4	Brian Carlin	FMC/IPEC	Science of Excipients – importance and issues	9:15 am
			Break	9:45 am
5	Steve Hoag	Maryland	NIPTE-FDA Project on Excipients	10:00 am
6	Jim Michaels, Merck	Merck	Manufacturing Experience with Excipients Variability	10:40 am
7	Bruno Hancock	Pfizer	Excipient risk assessments: developing design space using excipient properties as process parameters	11:20 am
9			Lunch <b>Lunch Speaker: Paul Sheskey, Dow</b> Future Direction of The Handbook of Pharmaceutical Excipients	12:00 am

**June 13, 2012 PM**

1	Jeff Medwid	CDER/ONDQA	Excipient Issues – From a Reviewer's Viewpoint	1:00 pm
2	Bob Iser	FDA/OGD	Excipient Issues in Generic Drug Development	1:30 pm
3	Mansoor Khan	FDA/CDER	Safety and efficacy challenges in Excipient Substitutions in Drug Formulations	2:00 pm
4	Lucinda Buhse	CDER	Rapid Screening for Excipient Quality Surveillance	2:30 pm
			Break	
5	Paul Luner	Boeinger-Ingelhiem	Solid Form Aspects of Excipients and their Influence on Formulation and Process	3:30 am
6	Ira Buckner	Duquesne	Interplay between API, Excipient and Manufacturing Stress in Formulation Design	4:00 pm
6	Carl Wassgren	Purdue	Measurement techniques of Excipient Properties for functionality evaluation	4:30 pm
8			Panel Discussion	5:00 pm
			Adjourn	6:00 pm

**June 14, 2012 AM**

1	Greg Amidon	Michigan	Development of Mixing Rules with Excipient Properties	8:00 am
2	Calvin Sun	Minnesota	Flow Properties of Excipients – Characterization and Enhancement Strategies	8:30 am
3	Jennifer Wang	BMS	Lubrication Properties of Excipients	9:00 am
			Panel Discussion	9:30 am
			Break	10:00 am
3	Ann Christine Catlin	Purdue	Demonstration of NIPTE Excipient Database	10:30 am
7			Lunch <b>Lunch Speaker: Joseph Kushner, Pfizer</b> Incorporating Multivariate Analysis of Excipient Properties into Drug Product Design	12:00 pm

**June 14, 2012 PM**

1	All Attendees Facilitators: Stephen Hoag Bruno Hancock Carl Wassgren Ann Christine Katlin Brian Carlin		Break-Out Sessions 1. Excipient Lot-to-Lot Variability and Design Space 2. Value and Use of NIPTE Excipient Database	1:00 – 2:30 pm
2			Break	2:30 pm
3			Break-Out Presentations	3:00 – 4:00 pm
4	Stephen Hoag		Wrap Up	4:00 pm