



# ***AAPS-NERDG***

*AMERICAN ASSOCIATION OF PHARMACEUTICAL SCIENTISTS  
NORTH EAST REGIONAL DISCUSSION GROUP*

**April 24, 2009**  
Marriott Hotel  
Rocky Hill, CT

**12<sup>th</sup>**  
**Annual Meeting**

## 12th Annual AAPS - Northeast Regional Discussion Group (NERDG)

April 24, 2009

Marriott Hotel, Rocky Hill, Connecticut

### “Biopharmaceutics of Oral Absorption”

|                     |  |  |
|---------------------|--|--|
| 8:00 am – 9:00 am   | General Session Poster and ARA Session Poster Setup<br>Registration<br>Continental Breakfast   | Nutmeg Ballroom<br>Grand Ballroom Foyer<br>Nutmeg Ballroom |
| 9:00 am – 4:00 pm   | General Poster Session<br>Vendor Displays  | Nutmeg Ballroom<br>Grand Ballroom Foyer                    |
| 9:00 am – 9:10 am   | Opening Remarks  | Grand Ballroom   |
| 9:10 am – 10:10 am  | <b>Characterizing transporter-mediated drug-drug interaction potential for sparingly soluble drugs</b><br>Presented by Philip S. Burton, Ph.D<br>Co-Founder, CEO, and CSO<br>ADMETR <sub>x</sub>   | Grand Ballroom   |
| 10:10 am – 10:20 am | Break  | Nutmeg Ballroom  |
| 10:20 am – 11:20 am | <b>Overview of historical and futuristic thoughts as well as current research on molecular and in vivo aspects of oral drug absorption</b><br>Presented by Gordan Amidon, Ph.D.<br>Professor of Pharmacy and Professor of Pharmaceutical Sciences<br>College of Pharmacy, University of Michigan | Grand Ballroom   |
| 11:20 am - 12:30 pm | Lunch  | Hartford Room  |
| 12:10 pm – 1:30 pm  | <b>STP#1: Making Choices in Discovery and Development</b><br>PRESENTERS: see next page   | Grand Ballroom   |
| 1:30 pm – 2:50 pm   | <b>STP #2: Formulation Technology</b>  | Grand Ballroom   |
| 1:30 pm – 2:30 pm   | <b>STP #3: Control and Evaluation of Exposure</b>  | Hartford Room  |
| 1:30 pm – 2:50 pm   | <b>STP #4: The importance of Biopharmaceutics</b>  | Connecticut Suite  |
| 2:50 pm – 3:00 pm   | Break  | Nutmeg Ballroom  |
| 3:00 pm – 4:00 pm   | <b>Food Effect, FDA’s view, regulation and recommendation with case studies</b><br>Presented by Barbara Davit, Ph.D., J.D.<br>Acting Director, Division of Bioequivalence<br>Office of Generic Drugs, CDER, US-FDA   | Grand Ballroom   |
| 4:00 pm - 4:20 pm   | NERDG Management Summary, NERDG-ARA Presentation, and Closing Remarks  | Grand Ballroom   |

## NERDG Short Topic Presentations (STP):

| Session  | Time Slot     | Title   | Presenter         | Affiliation              |
|--|---------------|---|-------------------|--------------------------|
| <b>STP #1:</b><br><i>Making Choices in Discovery and Development</i><br>(12:10-1:30) | 12:10 - 12:30 | High Throughput Technologies for Physical Form Selection and Bioavailability Enhancement                                      | Akash Jain        | Novartis                 |
|  | 12:30 - 12:50 | Development of a Medium Throughput Oxidative Stability Assay for the Evaluation of Potential Drug Candidates                  | Michelle Nophsker | BMS                      |
|  | 12:50 - 1:10  | Preparation and Characterization of Oxcarbazepine/Polymer Dispersions   | Ymin Sun          | Penwest                  |
|  | 1:10 - 1:30   | The Influence of Aqueous Content in Small Scale Salt Screening: Improving Hit Rate for Poorly Soluble Drugs                   | Peter Tarsa       | Novartis                 |
| <b>STP #2:</b><br><i>Formulation Technologies</i><br>(1:30-2:50)                     | 1:30 - 1:50   | Intravenous Administration of Nanoparticles to Assess Cardiovascular Properties   | Dawn Parker       | BMS                      |
|  | 1:50 - 2:10   | Tablet Punch Sticking: The Effects of Excipients and Particle Sizes   | Darryl Simmons    | Pfizer                   |
|  | 2:10 - 2:30   | E-tongue vs. Human-tongue: Evaluation of Taste for Powder-in-Bottle Approach for Clinical Studies                             | Vishal Saxena     | Novartis                 |
|  | 2:30 - 2:50   | The Importance of the Extent of Lubrication on Solid Doage Forms and Its Impact on Intrinsic Tablet Mechanical Properties     | C. (Kim) Tye      | Pfizer                   |
| <b>STP #3:</b><br><i>Control &amp; Evaluation of Exposure</i><br>(1:30-2:30)         | 1:30 - 1:50   | Dissolution Improvement by Co-grinding With Common Excipients   | Lipa Shah         | Novartis                 |
|  | 1:50 - 2:10   | The Mechanistic Conundrum Underlying Multiple Peaking Phenomena in Pharmacokinetic Disposition                                | Jaime Yáñez       | Schering-Plough          |
|  | 2:10 - 2:30   | Simulated Studies of Immediate Release, Extended Release and Delayed Release Solid Dosage Forms for Food and Beverage         | Monica Chuong     | Mass College of Pharmacy |
| <b>STP #4:</b><br><i>The Importance of Biopharmaceutics</i><br>(1:10-2:50)           | 1:30 - 1:50   | Selection of Lead Candidates for Development: Science Driven or Pipeline Driven?  | Sudhakar Garad    | Novartis                 |
|  | 1:50 - 2:10   | Solubility and Permeability: The Importance of Human Clinical Data to Confirm Biopharmaceutical Problems and Validate Solutio | John McDermott    | Pharmaceutical Profiles  |
|  | 2:10 - 2:30   | Predicting Relative Drug Bioavailabilities in Canines Using an Artificial Gastro-Intestinal Modeling System                   | John Morrison     | BMS                      |
|  | 2:30 - 2:50   | In Vitro Prediction of Food Effect for a Poorly Water Soluble Compound  | Weijia Zheng      | Novartis                 |