

RDD 2010 FLORIDA Respiratory Drug Delivery

Omni Orlando Resort at ChampionsGate
ORLANDO, FLORIDA
APRIL 25 - 29, 2010

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SUNDAY • APRIL 25 • 2010

3:00 p.m. – 6:45 p.m.	Registration	<i>International Ballroom I</i>
7:00 p.m. – 9:00 p.m.	Welcome Reception	<i>Poolside</i>
	Sponsor: 'Our Platinum & Gold Sponsors'	

Please ensure that your Poster / Technology Exhibit is set up in its assigned location during the preferred set up period on Sunday April 25 from 3:00 p.m. - 6:00 p.m. in the National Ballroom. You may find it convenient to register at the same time. Monday, April 26 from 7:30 a.m. - 11:00 a.m. is the back-up time for setting up. Poster and Technology Exhibits must be removed either between 7:00 p.m. - 9:00 p.m. on Tuesday, April 27 (preferred) or between 7:30 a.m. and 10:00 a.m. on Wednesday, April 28. RDD does not assume any responsibility for equipment lost or damaged during this event. Please direct any special requests to Richard Dalby or visit the Poster and Technology Exhibit registration table located outside the National Ballroom.

MONDAY • APRIL 26 • 2010

- 7:30 a.m. **Continental Breakfast** *Ballroom Commons & Rotunda*
- 7:30 a.m. - 6:00 p.m. **Registration** *International Ballroom I*
- 8:30 a.m. **Welcome & Introduction** *International Ballroom*
Peter R. Byron, Ph.D.,
Professor, School of Pharmacy
Virginia Commonwealth University
- 8:45 a.m. **Presentation of the Charles G. Thiel Award**
- 9:00 a.m. **PLENARY LECTURE** *International Ballroom*
Sponsors: 'Our Platinum Sponsors'
Moderator: Peter R. Byron, Ph.D.
*Pulmonary Hypertension, Etiology and Pathogenesis:
New Treatments and Targets*
Norbert F. Voelkel, M.D., Director,
Victoria Johnson Center for Obstructive Lung Diseases,
Virginia Commonwealth University, Richmond, VA
- 10:00 a.m. **REFRESHMENTS**
- 10:30 a.m. - 12:00 noon **SESSION 1:** *International Ballroom*
Modulating Systemic Drug Delivery Via the Lung
Sponsor: Vectura
Moderator: Igor Gonda, Ph.D.
- 10:30 a.m. *The Staccato® System: Inhaler Design
Characteristics for Rapid Treatment of CNS Disorders*
Peter D. Noymer, Ph.D.,
Alexza Pharmaceuticals,
Mountain View, CA
- 11:00 a.m. *Contrasting Pharmacokinetics and
Pharmacodynamics of Afrezza® and Exubera®*
Robert A. Baughman, Pharm.D. Ph.D.,
MannKind Corporation, Danbury, CT
- 11:30 a.m. *Beyond Insulin: The Shrinking Pulmonary
Delivery Window For Systemic Biotech Drugs*
Masahiro Sakagami, Ph.D.,
Virginia Commonwealth University, Richmond, VA
- 12:00 noon **SESSION 1 ENDS • LUNCHTIME**
- 11:30 a.m. - 2:30 p.m. **SCIENTIFIC POSTER SESSION
& TECHNOLOGY EXHIBITION** *National Ballroom*
Light Refreshments Served
Sponsor: Copley Scientific
Moderator: Richard N. Dalby, Ph.D.

- 2:00 p.m. - 4:00 p.m. **SESSION 2:** *International Ballroom*
Infections and Cancer: Enhancing Host Defenses
Sponsor: Next Breath
Moderator: John S. Patton, Ph.D.
- 2:00 p.m. *Aerosol Cytokines and Chemotherapy of Cancer:
Practical Considerations and Experience*
Peter M. Anderson, M.D. Ph.D.,
University of Texas MD Anderson Cancer Center,
Houston, TX
- 2:30 p.m. *Pulmonary Vaccination: Dendritic Cells
and Other Antigen Presenters in the Lung*
Christophe von Garnier, M.D.,
Bern University, Bern, Switzerland
- 3:00 p.m. *Inhaled Gentamicin: Making a Dry Powder
Formulation to Satisfy a Clinical Need*
James D. Talton, Ph.D.,
NanoTherapeutics, Alachua, FL
- 3:30 p.m. *Inhaled Liposomal Ciprofloxacin: Once a Day
Management of Respiratory Infections*
Paul R. Bruinenberg, M.D.,
Aradigm Corporation, Hayward, CA
- 4:00 p.m. **SESSION 2 ENDS • REFRESHMENTS**
- 4:30 p.m. - 5:30 p.m. **SESSION 3:** *International Ballroom*
Identifying Active Transporters that Count!
Sponsor: 'Our Gold Sponsors'
Moderator: Per Gerde, Ph.D.
- 4:30 p.m. *Assessing the Role of Transporters in the
Disposition of Inhaled Drugs Using a Respiratory
Epithelial Cell Culture Model*
Cynthia Bosquillon, Ph.D.,
University of Nottingham, Nottingham, United Kingdom
- 5:00 p.m. *Cation Transporters in the Lung: Significance
and Implications for Long Acting Cholinergic Drugs*
John Keogh, C.Biol., MSB.,
GlaxoSmithKline, Ware, United Kingdom
- 5:30 p.m. **SESSION 3 ENDS**
- 5:00 p.m. - 7:00 p.m. **SCIENTIFIC POSTER SESSION** *National Ballroom*
& TECHNOLOGY EXHIBITION
Light Refreshments Served
Sponsor: Copley Scientific
Moderator: Richard N. Dalby, Ph.D.

TUESDAY • APRIL 27 • 2010

7:30 a.m.	Continental Breakfast	<i>Ballroom Commons & Rotunda</i>
7:30 a.m. - 6:00 p.m.	Registration	<i>International Ballroom I</i>
8:30 a.m. - 9:30 a.m.	SESSION 4: Patient Focused Nasal Delivery	<i>International Ballroom</i>
	Sponsor: DPT Laboratories Moderator: Wallace P. Adams, Ph.D.	
8:30 a.m.	<i>New Approaches to Nasal Spray Evaluation: Pediatric Versus Adult Actuation Profiles and Anatomically Based Spray Pattern Tests</i> Richard N. Dalby, Ph.D., University of Maryland, Baltimore, MD	
9:00 a.m.	<i>Sinus Drug Delivery by Pulsating Aerosol: Clinical Proof of Concept Studies</i> Winfried Möller, Ph.D., Helmoltz Zentrum München, Gauting, Germany	
9:30 a.m.	SESSION 4 ENDS • REFRESHMENTS	
10:00 a.m. - 12:00 noon	SESSION 5: Economic and Environmental Initiatives for Inhaled Products*	<i>International Ballroom</i>
	Sponsor: V.A.R.I. Moderator: John N. Pritchard, Ph.D.	
10:00 a.m.	<i>Responsible Inhaler Development in Article 5 Countries: Navigating the Scientific, Regulatory, Political and Commercial Challenges</i> Ashley Woodcock, M.D., University of Manchester, Manchester, United Kingdom	
10:30 a.m.	<i>Inhaler Development in Developing Markets: Overcoming Barriers to Implementation</i> David J. Howlett, B.A., PharmaDelivery Solutions, Grimston, United Kingdom	
10:50 a.m.	<i>Status, Challenges and Regulatory Strategies for Replacement of Chlorofluorocarbon Propellants in Metered Dose Inhalers in China</i> Shuguang Hou, Ph.D., 3M Drug Delivery Systems, St. Paul, MN	
11:10 a.m.	<i>Inhalers for the Indian Subcontinent: Therapeutic and Environmental Imperatives</i> Raj B. Singh, M.D., Apollo Hospital, Chennai, India	

* Presentations and the resulting discussion will be (voice only) recorded. Slides and recording will be available at www.rddonline.com. By participating in this session your agreement to be recorded and broadcast on the internet is assumed.

- 11:30 a.m. **PANEL DISCUSSION***
 Chairperson: Ashley Woodcock, M.D.,
 University of Manchester, Manchester, United Kingdom
Panel:
 Badrul A. Chowdhury, M.D. Ph.D.,
 Food and Drug Administration, Silver Springs, MD
 Shuguang Hou, Ph.D.,
 3M Drug Delivery Systems, St Paul, MN
 David J. Howlett, B.A.,
 PharmaDelivery Solutions, Grimston, United Kingdom
 Fang Jin, Ph.D.,
 Shanghai Institute of Pharmaceutical Industry,
 Shanghai, China.
 Raj. B. Singh, M.D.,
 Apollo Hospital, Chennai, India
- 12:00 noon **SESSION 5 ENDS • LUNCHTIME**
- 11:30 a.m.- 2:30 p.m. **SCIENTIFIC POSTER SESSION
 & TECHNOLOGY EXHIBITION** *National Ballroom*
Light Refreshments Served
 Sponsor: 'Our Gold Sponsors'
 Moderator: Richard N. Dalby, Ph.D.
- 2:00 p.m. - 3:00 p.m. **SESSION 6:** *International Ballroom*
Posters on the Podium
 Sponsor: 'Our Platinum Sponsors'
 Moderators: Richard N. Dalby, Ph.D. and Joanne Peart, Ph.D.
*These five poster authors have been selected to summarize their work
 and answer questions during a fast-paced interactive podium session.*
- 2:05 p.m. *Pilot Study of Surfactant Aerosol Carriers
 to Promote Post-Deposition Dispersion*
 Tim Corcoran,
 University of Pittsburgh, Pittsburgh, PA
- 2:15 p.m. *Novel Cinnamic Acid-Based Dehydropolymers
 for Emphysema: Triple Inhibitors of Elastase,
 Inflammation and Oxidation*
 Bhawana Saluja,
 Virginia Commonwealth University, Richmond, VA
- 2:25 p.m. *Mandibular Advancement Achieved
 Through a Stepped Mouthpiece Design
 Can Change the Size of the Upper Airways*
 Kurt Nikander,
 Philips Respironics, Parsippany, NJ

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- 2:35 p.m. *Performance of a New Single-Use Disposable Dry Powder Inhaler Prototype*
Christian Friebel,
Christian Albrecht University, Kiel, Germany
- 2:45 p.m. *Evaluation of the Rate and Extent of Pulmonary Absorption After Administration of Two Salmeterol HFA pMDI Formulations In Healthy Volunteers*
Juliet Rebello,
Cipla, Mumbai, India
- 3:00 p.m. **SESSION 6 ENDS • REFRESHMENTS**
- 3:30 p.m. - 5:00 p.m. **SESSION 7:** *International Ballroom*
New Solutions to Manufacturing and Testing Problems
Sponsor: Trudell Medical International
Moderator: Helmut Bender, Ph.D.
- 3:30 p.m. *Expanding QbD with Probabilistic Design: Ensuring Mechanically Reliable Inhalers*
Nic Bowman, B.Sc. FIMechE.,
Pfizer, Cambridge, United Kingdom
- 4:00 p.m. *Achieving Homogeneity: Combination Product Case Studies with Raman Spectroscopy*
Brent A. Donovan, Ph.D.,
Merck Research Laboratories, Summit, NJ
- 4:30 p.m. *Cascade Impactor Calibration, Mensuration and In-Use Qualification Methods: A Practical Guide*
Jolyon P. Mitchell, Ph.D.,
Trudell Medical International, London, Canada
- 5:00 p.m. **SESSION 7 ENDS**
- 5:00 - 7:00 p.m. **SCIENTIFIC POSTER SESSION & TECHNOLOGY EXHIBITION** *National Ballroom*
Light Refreshments Served
Sponsor: 'Our Gold Sponsors'
Moderator: Richard N. Dalby, Ph.D.
- 7:00 - 9:00 p.m. **AAPS Inhalation and Nasal Technology Focus Group** *St Andrew's*
Imaging in Pulmonary and Nasal Product Development – Not Just Pretty Pictures
Stephen P. Newman, Ph.D.,
Scientific Consultant, Nottingham, United Kingdom

WEDNESDAY APRIL 28 • 2010

7:30 a.m. **Continental Breakfast** *Ballroom Commons & Rotunda*

MEETING BREAK FOR RECREATION

Participants are free to golf, play tennis and relax poolside or can select from one of the following special excursions

- 8:00 a.m. **Airboat Tour of Old Florida** (\$80)
This excursion takes you into the seldom visited heart of natural Florida! Enjoy the natural, protected wetland hammocks, walk through ancient Flatwoods and travel by airboat into sections of fresh water marshes and upriver into the bald cypress swamp - home of the Florida Alligator, American Bald Eagle and other wildlife. Certified eco-guides, biologists, botanists and other experts will accompany the group. Wear comfortable clothes, sunglasses and sunscreen! Departs Convention Entrance at 8:00 am and returns at 12:00 noon (approx.).
- 8:00 a.m. **Kayak Wilderness Nature Tour** (\$95)
Take an easy paddle in 2 person kayaks along the shore line of the calm inland waterway from Manatee Cove to the estuary's wild uninhabited barrier island. There will be a guided nature walk on the island. Eco-guides will explain the significance of this endangered backwater estuary. Look out for manatee, dolphins, alligators, a variety of water birds and other wildlife. Wear comfortable shoes, sunglasses and sunscreen! Departs Convention Entrance at 8:00 am and returns at 12:00 noon (approx.).
- 9:30 a.m. **Sky Diving without the Plane!** (\$130)
Pretend you're a particle! Enjoy the sensation of free falling during skydiving without the need for the parachute, plane or any previous skydiving experience. Sky Venture of Florida is a state-of-the-art vertical wind tunnel with an air flow linear velocity of 120 mph, replicating the skydiving experience without the fear of the jump! Wear comfortable clothing and athletic shoes. Note participants cannot weigh more than 250 lbs; participants will be asked to sign a liability waiver on-site and no one with shoulder dislocation or back problems can participate. Departs Convention Entrance at 9:30 am and returns at 12:00 noon (approx.).
- 9:40 a.m. **Fantasy of Flight** (\$70)
Fantasy of Flight is an aviation-themed attraction featuring a collection of vintage aircraft, themed sight and sound 'immersion experiences' from aviation history and flight simulators that use real-time motion technology to capture the sensation of participating in a World War II aerial battle. You will experience different eras of aviation. The experiences range from a trip back in time to the trenches of World War I to a re-enactment of an aerial bombing mission over Europe aboard a B-17 Flying Fortress. Flight times last from six to ten minutes. Be sure to wear comfortable clothes and athletic shoes. Departs Convention Entrance at 9:40 am and returns to the hotel by 1:00 pm.

RDD 2010 Accepts No Responsibility for Personal Injury, Loss of Life or Property Damage

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- 1:30 p.m. - 5:30 p.m. **SESSION 8:** *International Ballroom*
Drug Deposition Modeling: Advancing the Art
Sponsor: Philip Morris International
Moderator: Bo Olsson, Ph.D.
- 1:30 p.m. *Choosing 3-D Mouth-Throat Dimensions:
A Rational Merging of Medical Imaging and Aerodynamics*
Warren H. Finlay, Ph.D.,
University of Alberta, Alberta, Canada
- 2:00 p.m. *Can Pediatric Throat Models and Air Flow
Profiles Improve Our Dose Finding Strategy?*
Herbert Wachtel, Ph.D.,
Boehringer Ingelheim, Ingelheim, Germany
- 2:30 p.m. *Dosimetry Implications of Uncertainties in
Lung Architecture: Is Weibel Good Enough?*
Michael J. Oldham, Ph.D.,
Altria Client Services, Richmond, VA
- 3:00 p.m. **REFRESHMENTS**
- 3:30 p.m. *Stepping into the Trachea with Realistic Physical Models:
Uncertainties in Regional Drug Deposition from Powder Inhalers*
Peter R. Byron, Ph.D.,
Virginia Commonwealth University, Richmond, VA
- 4:00 p.m. *Comparing Aerosol Size Distributions that Penetrate
Mouth-Throat Models Under Realistic Inhalation Conditions*
Bo Olsson, Ph.D.,
AstraZeneca, Lund, Sweden
- 4:30 p.m. *Beyond the Throat: Preferred Methods of
Assessing Regional Distribution in the Lung*
Andrew R. Clark, Ph.D.,
Novartis, San Carlos, CA
- 5:00 p.m. **PANEL DISCUSSION**
- 5:30 p.m. **SESSION 8 ENDS**
- 6:30 p.m. **Cocktail Reception** *Ballroom Commons*
Sponsored by 'Our Platinum & Gold Sponsors'
- 7:30 p.m. **Banquet and Dancing** *National Ballroom*
Sponsored by 'Our Platinum & Gold Sponsors'

THURSDAY APRIL 29 • 2010

- 7:30 a.m. **Continental Breakfast** *Ballroom Commons & Rotunda*
- 7:30 a.m. - 5.00 p.m. **Registration** *International Ballroom I*
- 8:30 a.m. - 12:15 p.m. **SESSION 9:** *International Ballroom*
Role of Pharmacokinetics in Establishing Bioequivalence for Orally Inhaled Drug Products*
Coordinated with Product Quality Research Institute (PQRI)
Chairperson: Dennis O'Connor, B.S.
- 8:30 a.m. *Role of Pharmacokinetics in Establishing Bioequivalence for Orally Inhaled Drug Products*
Dennis O'Connor, B.S.
Boehringer Ingelheim, Ridgefield, CT
- 8:45 a.m. *Evolution of Regulatory and Scientific Paradigms for Establishing Equivalence of Systemic Exposure from Orally Inhaled Drugs: Current Status and Possible Challenges*
Gur Jai Pal Singh, Ph.D.,
Scientific Advisor, Corona, CA
- 9:15 a.m. *Demonstrating Bioequivalence Using Pharmacokinetics: Theoretical Considerations across Drug Classes*
Günther Hochhaus, Ph.D.,
University of Florida, Gainesville, FL
- 9:45 a.m. *The Clinical Utility of Pharmacokinetics in Demonstrating Bioequivalence of Locally Acting Orally Inhaled Drugs*
Peter T. Daley-Yates, Ph.D.,
GlaxoSmithKline, Uxbridge, United Kingdom.
- 10:15 a.m. **REFRESHMENTS**
- 10:45 a.m. *Aspects of Pharmacokinetic Study Design to Differentiate Between Different Orally Inhaled Drug Products*
Lars Borgström, Ph.D.,
AstraZeneca, Lund, Sweden
- 11:15 a.m. *Application of the EU Guidelines for Pharmacokinetic Studies of Locally Acting Orally Inhaled Drug Products*
Sanjeeva Dissanayake, M.R.C.P.,
Medicines and Healthcare Products Regulatory Agency (MHRA),
London, United Kingdom

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- 11:45 a.m. **PANEL DISCUSSION***
- Panel:**
- Lars Borgstrom, Ph.D.,
AstraZeneca, Lund, Sweden
- Badrul A. Chowdhury, M.D. Ph.D.,
Food and Drug Administration, Silver Springs, MD
- Dale Conner, Ph.D.,
Food and Drug Administration, Rockville, MD
- Peter T. Daley-Yates, Ph.D.,
GlaxoSmithKline, Uxbridge, United Kingdom
- Sanjeeva Dissanayake, M.R.C.P.,
Medicines and Healthcare Products Regulatory Agency (MHRA),
London, United Kingdom
- Günther Hochhaus, Ph.D.,
University of Florida, Gainesville, FL
- Gur Jai Pal Singh, Ph.D.,
Scientific Advisor, Corona, CA
- 12:15 p.m. **SESSION 9 ENDS • LUNCHEON** *National Ballroom*
- 1:30 p.m. - 2:30 p.m. **SESSION 10:** *International Ballroom*
Regulatory Perspectives on Bioequivalence
- Sponsor: Teva Pharmaceuticals
Moderator: Peter R. Byron, Ph.D.
- 1:30 p.m. *A Lawyer's Perspective on the Approval and Legal Challenges for Topically Active Generic Inhalers*
Kurt R. Karst, J.D.,
Hyman, Phelps & McNamara, Washington, DC
- 2:00 p.m. *Regulatory Uncertainties in Bioequivalence: Exhaled Nitric Oxide as a Possible Efficacy Endpoint for Inhaled Corticosteroids*
Badrul A. Chowdhury, M.D. Ph.D.,
Food and Drug Administration, Silver Springs, MD
- 2:30 p.m. **SESSION 10 ENDS • REFRESHMENTS**

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- 3:00 p.m. - 5:00 p.m. **SESSION 11:** *International Ballroom*
MDIs and DPIs:
Fundamental Pharmaceutics
Sponsor: Chiesi Farmaceutici
Moderator: Carsten Niederlaender, Ph.D.
- 3:00 p.m. *Understanding the Power Requirements for
Efficient Dispersion in Powder Inhalers: Comparing
CFD Predictions and Experimental Measurements*
James A. Tibbatts, M.Eng.,
Concept Flow, Cambridge, United Kingdom
- 3:30 p.m. *Powder Rheology: A New Technique to Predict
the Performance of Inhaled Powder Formulations*
Jagdeep Shur, Ph.D.,
University of Bath, Bath, United Kingdom
- 4:00 p.m. *A Picture Tells a Thousand Words – Discovering
Sites of Deposition, Cavitation and Gasket Deformation
in MDIs Using Improved High Speed Photography*
Darren J. Hodson, C.Eng.,
AstraZeneca, Loughborough, United Kingdom
- 4:30 p.m. *Modeling MDI Delivery: A Priori
Predictions, Empirical Models and Experiments*
Stephen W. Stein, Ph.D.,
3M Drug Delivery Systems, St Paul. MN
- 5:00 p.m. **END OF RESPIRATORY DRUG DELIVERY 2010**



**PQRI WORKSHOP:
ROLE OF PHARMACOKINETICS IN ESTABLISHING
BIOEQUIVALENCE FOR ORALLY INHALED DRUG PRODUCTS***

**Omni Orlando Resort at ChampionsGate
ORLANDO, FLORIDA
FRIDAY, APRIL 30, 2010
NATIONAL BALLROOM D**

Meeting Objectives: To evaluate the current state of knowledge and identify gaps in information relating to the potential use of pharmacokinetics (PK) as the sole indicator of *in vivo* bioequivalence of locally acting OIPs. The strengths of the PK approach to detect differences in product performance compared with *in vitro* and PD/clinical studies will be addressed.

- | | |
|-----------|---|
| 8:15 a.m. | Introduction
Moderator: Myra Herrle, Ph.D., R.Ph.,
Novartis Pharmaceuticals |
| 8:30 a.m. | <i>Salmeterol/Fluticasone propionate Diskus®</i>
<i>versus Salmeterol/Fluticasone propionate RPID®</i>
Peter Daley-Yates, Ph.D.,
GlaxoSmithKline |
| 8:55 a.m. | <i>Formoterol Certihaler™ versus Formoterol Aerolizer®</i>
Beverley Patterson, Ph.D.,
Novartis Pharmaceuticals |
| 9:20 a.m. | <i>Salbutamol (INN) MDI versus Salbutamol Originator MDI</i>
Anders Fuglsang, Ph.D.,
Aeropharm GmbH |

* Please note that this session is not a part of RDD 2010 and a separate registration fee of \$500 is levied by PQRI. If you are not pre-registered for the PQRI Workshop you can register and pay at the RDD registration desk anytime before Friday.

9:45 a.m. **PANEL DISCUSSION**

10:00 a.m. **COFFEE BREAK**

10:30 a.m. **BREAKOUT SESSIONS**

Meeting participants may select and attend one of four breakout sessions indicated below:

SESSION 1:

Wentworth

PK and Lung Deposition

Facilitators:

Günther Hochhaus, Ph.D., University of Florida

Sau Lee, Ph.D., Food and Drug Administration

Stephen Newman, Ph.D., Scientific Consultant

SESSION 2:

Augusta A

PK and *In Vitro* Assessment

Facilitators:

Wallace P. Adams, Ph.D., Food and Drug Administration

Martin Oliver, R.Ph., Vectura Limited

Guirag Poochikian, Ph.D., Scientific Consultant

SESSION 3:

Congressional B

PK and PD Relationships

Facilitators:

Hartmut Derendorf, Ph.D., University of Florida

Murray Ducharme, Pharm.D., Cetero Research

Sandra Suarez-Sharp, Ph.D., Food and Drug Administration

SESSION 4:

Royal Dublin B

Effective PK Study Designs

Facilitators:

John Davis, Ph.D., Pfizer

Partha Roy, Ph.D. and Bing Li, Ph.D., Food and Drug Administration

Tushar Shah, M.D., Teva Pharmaceuticals

12:00 noon	LUNCH	
1:00 p.m.	BREAKOUT SESSIONS CONTINUED Breakout sessions will be repeated and facilitators will be asked to include feedback from earlier sessions.	
	Repeat of Session 1: PK and Lung Deposition	<i>Wentworth</i>
	Repeat of Session 2: PK and <i>In Vitro</i> Assessment	<i>Augusta A</i>
	Repeat of Session 3: PK and PD Relationships	<i>Congressional B</i>
	Repeat of Session 4: Effective PK Study Designs	<i>Royal Dublin B</i>
2:30 p.m.	COFFEE BREAK	
3:30 p.m.	REVIEW OF BREAKOUT SESSIONS	
4:30 p.m.	PANEL DISCUSSION	
5:00 p.m.	CLOSING REMARKS	