

PRELIMINARY PROGRAM FOR 2011 IPAC-RS CONFERENCE
BRINGING VALUE TO THE PATIENT IN A CHANGING WORLD

Hilton Washington DC/Rockville Hotel & Executive Meeting Center Maryland, USA, March 29-31, 2011 (Tuesday-Thursday)

Registration: www.signmeup.com/71508 ♦ Hotel Reservations: www.washingtondcrockville.hilton.com Use Group/Convention Code: IPA

Day One (Tuesday, March 29, 2011)

8:00–8:30 AM REGISTRATION, CONTINENTAL BREAKFAST & POSTER SET-UP		12:30 – 1:30 PM LUNCH & POSTER SESSION	
Morning Focus: Voice of the Customers <i>Session Chairs: Martin Shott (Vectura) and Mary Ann Smith (Novartis)</i>		Afternoon Focus: Patient Interface <i>Session Chairs: Sue Holmes (GSK) and Paul Lucas (Pfizer)</i>	
8:30-8:45 AM	Welcome <i>Sue Holmes, GSK, Co- Chair, IPAC-RS Conference Committee</i>	1:30 – 2:00 PM	Understanding and Addressing Patient Adherence and Overview of Workshop “Ensuring Patient Success: Improving Adherence Through Concordance” <i>Frank Cerasoli, Pfizer, Chair IPAC-RS Patient Adherence WG</i>
8:45-9:30 AM	KEYNOTE ADDRESS: Asthma and its Many Unmet Needs: Directions for Novel Therapeutic Approaches <i>William W. Busse, M.D. Professor of Medicine; Allergy, Pulmonary and Critical Care Medicine, University of Wisconsin</i>	2:00 – 2:30 PM	The MDI – In Vitro Measures to Confirm Patient Perceptions: HFA vs. CFC <i>William Doub, FDA</i>
		2:30 – 3:00 PM	Lifting Medication Adherence: Lessons from Internet Connected Packaging <i>Joshua Wachman, Vitality</i>
9:30–10:00 AM	COPD Patient’s Needs <i>Stephen I. Rennard, Professor, University of Nebraska Medical Center</i>	3:00 – 3:30 PM	Talking Packs: Making Packaging Part of the Treatment <i>Tim Chesworth, AstraZeneca</i>
10:00-10:30 AM	BREAK & POSTER SESSION	3:30 – 4:00 PM	BREAK & POSTER SESSION
10:30–11:00 AM	A Global Perspective on Patient Educational Requirements and Needs Related to Inhaled Therapies <i>Monica Fletcher, Chief Exec of Education for Health, Warwick, UK & East Virginia, US</i>	4:00 – 4:30 PM	Regulatory Expectations for User Testing <i>Paul Lucas, Pfizer</i>
		4:30 – 5:00 PM	Human Factors and the Design of Inhalation Devices <i>Stephen Eason, Vectura and Julian Dixon, Team Consulting</i>
11:00–11:30 AM	Matching Patient to the Device <i>Professor Søren Pedersen, on behalf of ADMIT. Pediatric Research Unit Kolding Hospital. University of Southern Denmark</i>	5:00 – 5:30 PM	Human Factors “Usability” in the Review of New Medical Devices at FDA’s Center for Devices and Radiological Health (CDRH) <i>Ron Kaye, FDA, CDRH</i>
11:30 AM – 12:00 PM	FDA Efforts on Liaising with Patients <i>Deborah J. Miller, Ph.D., R.N., Health Programs Coordinator FDA/OC/Office of Special Health Issues</i>	5:30 – 6:00 PM	Panel Discussion <i>Moderated by Session Chairs</i>
12:00 PM – 12:30 PM	Summary of the 2010 ISAM/IPAC-RS Equivalence Workshop, with a Focus on Patient-Related Aspects <i>Dennis O’Connor, BI, ISAM/IPAC-RS Workshop Org. Committee</i>	6:00 – 8:00 PM	POSTER SESSION & COCKTAIL PARTY

Day Two (Wednesday, March 30, 2011)

8:00–8:30 AM		CONTINENTAL BREAKFAST	12:30 – 1:30 PM		LUNCH & POSTER SESSION
Morning Focus: Product Quality <i>Session Chairs: Stefan Leiner (BI) and Julie Berry (Merck)</i>			Afternoon Focus: Product Quality (continued) <i>Session Chair: Cheryl Stults (Novartis) and Lennart Brunnberg (SHL Group)</i>		
8:30 - 8:45 AM	Recap of Day 1 and Overview of Day 2 <i>Stefan Leiner, BI</i>		1:30 – 2:00 PM	Outreach to the Global Pharma and Supplier Industry to Enhance Product Quality <i>Barbara Falco, IPAC-RS Supplier QC WG</i>	
8:45 – 9:30 AM	KEYNOTE ADDRESS: FDA View On Assessing Quality Of Inhaled Products And Links To Efficacy And Safety <i>Prasad Peri (FDA)</i>		2:00 – 2:30 PM	Collaborating with the Global Supply Chain on Materials Requirements and a Rationalized Testing Paradigm <i>Jamie Mullis, BI, IPAC-RS OINDP Materials WG</i>	
			2:30 – 3:00 PM	BREAK	
9:30 - 10:00 AM	Analytical Methods Quality by Design <i>Andy Rignall, AstraZeneca, IPAC-RS QBD Analytical Methods WG</i>		3:00 – 3:30 PM	Supply Chain Approaches to Ensuring Component Quality <i>Manny Nyakako, Flextronics</i>	
10:00-10:30 AM	BREAK & POSTER SESSION		3:30 – 4:00 PM	Regulatory Perspectives on Supply Chain Quality and Security <i>Vibhakar Shah, FDA</i>	
10:30 – 11:00 AM	So You Want to Use Parametric Tolerance Testing for Control of Delivered Dose Uniformity? <i>Greg Larner, Pfizer, IPAC-RS DDU/PTIT WG</i>		4:00 – 4:45 PM	Regulatory/Industry Panel Discussion <i>Moderator: Cheryl Stults (Novartis) and Lennart Brunnberg (SHL Group)</i> <i>Panelists: Barbara Falco, Jamie Mullis (BI), Cheryl Stults (Novartis), Manny Nyakako (Flextronics), Vibhakar Shah (FDA)</i>	
11:00 – 11:30 AM	Overview of Effective Data Analysis <i>Terrence Tougas, Ph.D., Boehringer Ingelheim, IPAC-RS Cascade Impactor WG</i>				
11:30 AM– 12:00 PM	Dissolution Testing For Inhaled Products <i>Trevor Riley, GSK and J. David Christopher, Merck, IPAC-RS Dissolution WG</i>		4:45 – 5:00 PM	Plenary Conference Summary, Poster Awards and Overview of Day 3 Awards: Jackie Schumacher (Pfizer), IPAC-RS Chair, Closing: Cheryl Stults (Novartis) and Sue Holmes (GSK), Co-Chairs of the Organizing Committee	
12:00 – 12:30 PM	Regulatory/Industry Panel Discussion <i>Moderator: Stefan Leiner (BI)</i> <i>Panelists: Prasad Peri (FDA), Marjolein Weda (rivm) and industry speakers from this morning session</i>				

Day Three (Thursday, March 31, 2011)

Concurrent, Specialty Workshops

Workshop #1: Leachables & Extractables Experience to Date with PQRI Recommendations (Qualification and Analytical Evaluation Thresholds)

8:00–8:30 AM	CONTINENTAL BREAKFAST
<i>Moderator: Cheryl Stults (Novartis)</i>	
8:30 – 9:00 AM	Brief Overview of PQRI Recommendations Challenges and Successes <i>Daniel L. Norwood, Ph.D., Boehringer Ingelheim Pharmaceuticals, Inc.</i>
9:00 – 9:30 AM	Leachables and Extractables: Genesis of Regulatory Aspects and Perspectives on PQRI Recommendations <i>Guirag Poochikian, Ph.D., Poochikian Pharma Consulting</i>
9:30 - 10:00 AM	Work of the PQRI PODP <i>Michael Ruberto, Material Needs Consulting</i>
10:00-10:30 AM	BREAK
10:30 AM – 12:00 PM	Case Studies (Innovator and Generics)
10:30 – 11:00 AM	Case Study: A Problematic Extractable for a Pulmonary Delivery Device System <i>Bill Beierschmitt, Pfizer</i>
11:00 – 11:30 AM	<i>Andrea Mieth, Sandoz</i>
11:30 – 12:00 PM	Experiences with the Adoption of the PQRI Best Practice Guidelines When Applied to Development of an E&L Development Package for a DPI <i>Jason Creasey, GSK</i>
12:00 – 1:00 PM	LUNCH
1:00 – 3:00 PM	Open Discussion and Q&A with participants <i>Panelists: Prasad Peri, FDA; Kumudini Nicholas, Health Canada; Tim McGovern, SciLucent, LLC</i>
3:00 – 3:30 PM	Closing Summary

Day Three (Thursday, March 31, 2011)

Concurrent, Specialty Workshops

Workshop #2: AIM/EDA¹ – Implementing a New Best Practice for OIP Aerosol Particle Size Analysis

8:00–8:30 AM		CONTINENTAL BREAKFAST		12:00 – 1:00 PM		LUNCH & POSTER SESSION	
<i>Morning Session Chair: Lana Lyapustina, DBR</i>				<i>Afternoon Session Chair: Helen Strickland, GSK</i>			
8:30 - 9:00 AM	Lifecycle Strategies for Using EDA, AIM and Full Resolution Impactor <i>Terrence Tougas, Ph.D., Boehringer Ingelheim</i>			1:00 – 1:30 PM	Considerations for Applying EDA to an Existing Product <i>Helen Strickland, GSK</i>		
9:00 – 9:30 AM	Control Strategies for APSD <i>Rajni Patel, Ph.D., Boehringer Ingelheim</i>			1:30 – 2:00 PM	Road to Adopting AIM/EDA as a Standard <i>Adrian Goodey, Merck</i>		
9:30 - 10:00 AM	Panel Discussion: Lifecycle and Control Strategies for APSD <i>Moderator: Svetlana Lyapustina, DBR</i> <i>Participants: Terrence Tougas, Ph.D. and Rajni Patel, Ph.D., Boehringer Ingelheim</i>			2:00 – 2:30 PM	Panel Discussion: Case Studies and the Road to Adopting AIM/EDA as a Standard <i>Moderator: Helen Strickland, GSK</i> <i>Panelists: Jolyon Mitchell, J. David Christopher, Rajni Patel, Lana Lyapustina, Adrian Goodey</i>		
10:00-10:30 AM	BREAK			2:30 – 3:00 PM	General Panel on AIM/EDA <i>Moderator: Helen Strickland (GSK)</i> <i>Panelists: Terrence Tougas Ph.D., (BI), Jolyon Mitchell (Trudell), J. David Christopher (Merck), Rajni Patel (BI), Lana Lyapustina (DBR), Adrian Goodey (Merck)</i>		
10:30 – 11:15 AM	Equipment Options for AIM and Beyond <i>Jolyon Mitchell, Trudell Medical International</i>			3:00 – 3:30 PM	Future Directions and Wrap-Up <i>Terrence Tougas, Ph.D., Boehringer Ingelheim</i>		
11:15 AM – 12:00 PM	Precision and Accuracy of AIM <i>J. David Christopher, Merck and Rajni Patel, Boehringer Ingelheim</i>						

¹ AIM/EDA stands for Abbreviated Impactor Measurements and Effective Data Analysis

Day Three (Thursday, March 31, 2011)

Concurrent, Specialty Workshops

Workshop #3: Ensuring Patient Success: Improving Adherence Through Concordance

Workshop Focus: This workshop will focus on the most critical issues in adherence from the perspectives of patients, health care providers, and purchaser, disease management/health outcomes/cost and cost effectiveness, and how these issues can be resolved through concordance.

8:00–8:30 AM CONTINENTAL BREAKFAST		10:30 AM – 12:00 PM	Breakout Session 1 <i>These concurrent, rotating breakout sessions will give participants the opportunity to review and discuss the Steering Committee's learnings, their own perspectives and endorse recommendations on how to resolve these issues. Participants are encouraged to attend one session related to their own personal perspective or area of expertise, as well as one other.</i> <ul style="list-style-type: none"> ▪ Track A: Patient Perspective Moderators: Nancy Sander, John Walsh, and Sandra Fusco-Walker ▪ Track B: Care Provider Perspective Moderator: Barbara Yawn and Suzanne Lareau ○ Track C: Disease Management, Cost, and Cost Effectiveness Moderators: Len Fromer, Peter Hayes, Jake Flaitz, Director, Benefits & Human Capital
8:30-8:40 AM	Introductory Talk <i>Frank Cerasoli, Chair, Patient Adherence Steering Committee, Senior Director, Allergy and Respiratory Team Leader, Medical Affairs, Primary Care Business Unit, Pfizer</i>		
8:40 – 9:00 AM	The Voice of the Patient <i>Nancy Sander, Allergy & Asthma Network Mothers of Asthmatics</i>		
9:00 – 10:15 AM	Learnings on Patient Adherence from the Steering Committee <i>Members of the Steering Committee and invited experts will present key learnings from their respective perspectives.</i>		
9:00 – 9:25 AM	Patient Perspective <i>Sandra Fusco-Walker, Director of Patient Advocacy, Allergy & Asthma Network Mothers of Asthmatics</i> <i>John Walsh, President and CEO, Alpha – 1 Foundation</i>		
9:25 – 9:50 AM	Health Care Provider Perspective <i>Barbara Yawn, MD, MSc, FAAFP</i> <i>Director of Research, Olmsted Medical Center</i> <i>Suzanne Lareau, RN, MS, FAAN, Senior Instructor, College of Nursing, University of Colorado</i>	12:00 – 1:00 PM	LUNCH
		1:00 – 2:30 PM	Breakout Session 2 (Same as Session 1)
		2:30 – 3:00 PM	BREAK
9:50 – 10:15 AM	Disease Management and Health Outcomes Perspective/Purchaser Perspective <i>Len Fromer, MD, FAAFP, Executive Medical Director, Group Practice Forum</i>	3:00 – 4:15 PM	Panel Discussion and Audience Q&A <i>Frank Cerasoli, Len Fromer, Nancy Sander and Barbara Yawn</i> <i>During this interactive session, panel members will summarize the outcomes of their breakout sessions and discuss these with the audience.</i>
10:15-10:30 AM	BREAK	4:15 – 4:30 PM	Closing/Summary