

# 2011

## IPAC-RS

# Conference

Rockville, MD USA

*Bringing Value  
to the Patient  
in a  
Changing  
World*



**Tuesday-Thursday, March 29-31, 2011**

Hilton Washington DC/Rockville Hotel & Executive Meeting Center

### IPAC-RS 2011

#### Conference Organizing Committee:

Sue Holmes, Co-Chair, GlaxoSmithKline  
Cheryl Stults, Co-Chair, Novartis  
Julianne Berry, Merck  
Gaetano Brambilla, Chiesi  
Frank Cerasoli, Pfizer  
Tim Chesworth, AstraZeneca  
Frank Koppenhagen, Teva  
Paul Lucas, Pfizer  
Ray Ormiston, GlaxoSmithKline  
Martin Shott, Vectura  
Mary Ann Smith, Novartis  
Patricia Watson, Boehringer Ingelheim  
Eileen Wyka, MannKind Corporation



# 2011 Conference Faculty

**William P. Beierschmitt, Ph.D., DABT**, Regulatory Strategy Lead, Pfizer

**Julianne Berry, Ph.D.**, Fellow, Respiratory Product Development, Merck

**Lennart Brunnberg**, Technical Director, SHL Group

**William W. Busse, M.D.**, Professor of Medicine, University of Wisconsin School of Medicine and Public Health

**Franklin Cerasoli, Jr., Ph.D.**, Senior Director, Allergy & Respiratory Team Leader, Pfizer, Inc.; Chair IPAC-RS Patient Adherence WG

**Ken Chesney**, Global RA/QA/Qlty Engineering, Flextronics

**Tim Chesworth**, Device and Packaging Technology Team Manager, AstraZeneca

**J. David Christopher**, Associate Director, Statistics, Merck Research Laboratories

**Jason Creasey**, Manager E&L Team, GlaxoSmithKline

**Julian Dixon**, Head of User Research, Team Consulting

**William H. Doub, Ph.D.**, Research Chemist/Division of Drug Analysis, OTR/OPS/CDER/FDA

**Stephen Eason**, Director of Device Development, Vectura

**Barbara A. Falco**, Consultant/Owner, Barbara Falco Pharma Consult, LLC

**Tom Feinberg**, Director of Structural Chemistry, Catalent Pharma Solutions

**Jake Flaitz**, Director, Benefits & Human Capital, Paychex, Inc.

**Monica Fletcher**, Chief Executive, Education for Health

**Leonard Fromer, M.D., FAAFP**, Executive Medical Director, Group Practice Forum

**Sandra Fusco-Walker**, Director of Patient Advocacy, Allergy & Asthma Network Mothers of Asthmatics

**Adrian Goodey, Ph.D.**, Senior Scientist, Merck

**Peter F. Hayes**, Principal, Healthcare Solutions

**Susan Holmes**, Director, GSK; Co- Chair, IPAC-RS Conference Organizing Committee

**Ronald D. Kaye**, Human Factors Specialist, Center for Devices and Radiological Health, Food & Drug Administration

**Suzanne Lareau, RD, MS, FAAN**, Senior Instructor, College of Nursing, University of Colorado

**Greg Larner**, Manager, Statistics, Pfizer

**Stefan Leiner, Ph.D.**, CMC Expert, Boehringer Ingelheim

**Paul Lucas, Ph.D.**, Research Fellow, Pfizer Global Chemistry Manufacturing and Controls

**Lana Lyapustina, Ph.D.**, Senior Science Advisor, Drinker Biddle & Reath; IPAC-RS Secretariat

**Timothy J. McGovern, Ph.D.**, Consultant, SciLucent, LLC

**Andrea Mieth, Ph.D.**, Analytical Expert, Sandoz

**Deborah J. Miller, Ph.D., RN**, Health Programs Coordinator, Office of Special Health Issues, Food & Drug Administration

**Jolyon P. Mitchell, Ph.D.**, Scientific Director, Trudell Medical International

**James Mullis**, Principal Scientist, Boehringer Ingelheim, IPAC-RS OINDP Materials WG

**Kumudini Nicholas, B.Sc., M.Sc.**, Advisor/Team Leader, Generic Drugs Quality Division II, Health Canada

**Daniel L. Norwood, Ph.D.**, Distinguished Research Fellow, Boehringer Ingelheim Pharmaceuticals, Inc.

**Dennis O'Connor**, Clinical Supplies Release Officer, Boehringer Ingelheim Pharmaceuticals; ISAM/IPAC-RS Workshop Organizing Committee

**Rajni Patel, Ph.D.**, Director, Pharmaceutical -Analytical Development, Boehringer Ingelheim Pharmaceuticals Inc.

**Søren Pedersen, M.D., Ph.D., Dr. Med. Sci.**, on behalf of ADMIT. Department of Pediatrics, Kolding Hospital; Professor of Pediatric Respiratory Medicine, University of Southern Denmark

**Prasad Peri, Ph.D.**, Acting Branch Chief, Division of Pre-Market Assessment, Office of New Drug Quality Assessment, Food and Drug Administration

**Guirag Poochikian, Ph.D.**, Consultant, Poochikian Pharma Consulting

**Stephen I. Rennard, M.D.**, Professor, University of Nebraska Medical Center

**Andy Rignall, Ph.D.**, Associate Director, Analytical Sciences, AstraZeneca

**Trevor Riley, Ph.D.**, Manager, Inhaled Product & Device Technology, GlaxoSmithKline

**Nancy Sander**, President & Founder, Allergy & Asthma Network Mothers of Asthmatics

**Jackie Schumacher**, Research Fellow, Pfizer; IPAC-RS Chair

**Vibhakar Shah, Ph.D.**, Senior Policy Advisor Division of Manufacturing and Product Quality, Office of Compliance, Food and Drug Administration

**Martin J. Shott, Ph.D.**, Director of Pharmaceutical Operations, Vectura Ltd.

**Mary Ann Smith, RPh, M.S.**, Senior Regulatory Affairs Expert, Novartis

**Helen N. Strickland**, Statistical Consultant, Global Manufacturing and Supply, GlaxoSmithKline

**Cheryl L.M. Stults, Ph.D.**, Senior Fellow, Novartis

**Terrence P. Tougas, Ph.D.**, Highly Distinguished Research Fellow, Boehringer Ingelheim

**Joshua Wachman**, President, Vitality, Inc.

**John W. Walsh**, President and CEO, Alpha-1 Foundation

**Marjolein Weda, Ph.D., Pharmacist**, Senior Pharmaceutical Assessor, RIVM

**Barbara Yawn, M.D., FAAFP**, Director of Research, Olmsted Medical Center

# DAY ONE

Tuesday, March 29, 2011

8:00 - 8:30 AM

**Registration, Continental Breakfast  
& Poster Set-up**

## Morning Focus: Voice of the Customers

Session Chair: **Martin J. Shott**, Vectura Ltd. and  
**Mary Ann Smith**, Novartis

8:30 - 8:45 AM

**Welcome**

**Sue Holmes**, GlaxoSmithKline, Co- Chair, IPAC-RS  
Conference Organizing Committee

8:45 - 9:30 AM

**Keynote Address: Asthma and its Many Unmet  
Needs: Directions for Novel Therapeutic  
Approaches**

**William W. Busse**, University of Wisconsin School of  
Medicine and Public Health

9:30 - 10:00 AM

**COPD Patient's Needs**

**Stephen I. Rennard**, University of Nebraska Medical  
Center

10:00 - 10:30 AM

**Break & Poster Session**

10:30 - 11:00 AM

**It's Easy, Just Take Two Puffs: A Global Perspective  
on Patient Educational Requirements and Needs  
Related to Inhaled Therapies**

**Monica Fletcher**, Education for Health

11:00 - 11:30 AM

**Matching Patient to the Device**

**Søren Pedersen**, on behalf of ADMIT,  
University of Southern Denmark

11:30 AM - 12:00 PM

**FDA Efforts on Liaising with Patients**

**Deborah J. Miller**, FDA, Office of Special Health  
Issues

12:00 - 12:30 PM

**Summary of the 2010 ISAM/IPAC-RS Equivalence  
Workshop, with a Focus on Patient-Related Aspects**  
**Dennis O'Connor**, Boehringer Ingelheim, ISAM/  
IPAC-RS Workshop Organizing Committee

12:30 - 1:30 PM

**Lunch & Poster Session**

## Afternoon Focus: Patient Interface

Session Chairs: **Sue Holmes**, GlaxoSmithKline and  
**Paul Lucas**, Pfizer

1:30 - 2:00 PM

**Understanding and Addressing Patient Adherence  
and Overview of Workshop "Ensuring Patient  
Success: Improving Adherence Through  
Concordance"**

**Frank Cerasoli**, Pfizer, Chair, IPAC-RS Patient  
Adherence Working Group

2:00 - 2:30 PM

**The MDI – In Vitro Measures to Confirm Patient  
Perceptions: HFA vs. CFC**

**William H. Doub**, Food & Drug Administration

2:30 - 3:00 PM

**Lifting Medication Adherence: Lessons from Internet  
Connected Packaging**

**Joshua Wachman**, Vitality

3:00 - 3:30 PM

**Talking Packs: Making Packaging Part of the  
Treatment**

**Tim Chesworth**, AstraZeneca

3:30 - 4:00 PM

**Break & Poster Session**

4:00 - 4:30 PM

**Regulatory Expectations for User Testing**

**Paul Lucas**, Pfizer

4:30 - 5:00 PM

**Human Factors and the Design of Inhalation  
Devices**

**Stephen Eason**, Vectura and **Julian Dixon**, Team  
Consulting

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)**

**Ronald D. Kaye**, Food & Drug Administration, CDRH

5:30 - 6:00 PM

**Panel Discussion**

Moderator: **Sue Holmes**

Panelists: **Frank Cerasoli**, **William Doub**, **Joshua  
Wachman**, **Tim Chesworth**, **Paul Lucas**, **Stephen  
Eason**, **Julian Dixon**, and **Ronald Kaye**

6:00 - 8:00 PM

**Poster Session & Cocktail Party**

# DAY TWO

Wednesday, March 30, 2011

8:00 - 8:30 AM

**Continental Breakfast**

## **Morning Focus: Product Quality**

Session Chairs: **Stefan Leiner**, Boehringer Ingelheim and **Julianne Berry**, Merck

8:30 - 8:45 AM

## **Recap of Day 1 and Overview of Day 2**

**Stefan Leiner**, Boehringer Ingelheim

8:45 - 9:30 AM

## **Keynote Address: FDA View on Assessing Quality of Inhaled Products and Links to Efficacy and Safety**

**Prasad Peri**, Office of New Drug Quality Assessment, Food & Drug Administration

9:30 - 10:00 AM

## **Applying Quality by Design Principles to Analytical Methods Associated with OINDPs**

**Andy Rignall**, AstraZeneca, IPAC-RS Analytical Methods Working Group

10:00 - 10:30 AM

**Break & Poster Session**

10:30 - 11:00 AM

## **So You Want to Use Parametric Tolerance Testing for Control of Delivered Dose Uniformity?**

**Greg Larnar**, Pfizer, IPAC-RS DDU/PTIT Working Group

11:00 - 11:30 AM

## **Overview of Effective Data Analysis**

**Terrence Tougas**, Boehringer Ingelheim, IPAC-RS Cascade Impactor Working Group

11:30 AM - 12:00 PM

## **Dissolution Testing For Inhaled Products**

**Trevor Riley**, GlaxoSmithKline and **J. David Christopher**, Merck, IPAC-RS Dissolution Working Group

12:00 - 12:30 PM

## **Regulatory/Industry Panel Discussion**

Moderators: **Stefan Leiner** and **Julianne Berry**  
Panelists: **Prasad Peri**, **Andy Rignall**, **Greg Larnar**, **Terrence Tougas**, **Trevor Riley**, **J. David Christopher** and **Marjolein Weda**, RIVM

12:30 - 1:30 PM

**Lunch & Poster Session**

## **Afternoon Focus: Product Quality (continued)**

Session Chairs: **Cheryl Stults**, Novartis and **Lennart Brunberg**, SHL Group

1:30 - 2:00 PM

## **Strong Foundations: Building Quality Through the Supply Chain**

**Barbara Falco**, Barbara Falco Pharma Consult LLC, IPAC-RS Supplier Quality Working Group

2:00 - 2:30 PM

## **Collaborating with the Global Supply Chain on Materials Requirements and a Rationalized Testing Paradigm**

**James Mullis**, Boehringer Ingelheim, IPAC-RS OINDP Materials Working Group

2:30 - 3:00 PM

**Break**

3:00 - 3:30 PM

## **Supply Chain Approaches to Ensuring Component Quality**

**Ken Chesney**, Flextronics

3:30 - 4:00 PM

## **Regulatory Perspectives on Supply Chain Quality and Security**

**Vibhakar Shah**, Food & Drug Administration

4:00 - 4:45 PM

## **Regulatory/Industry Panel Discussion**

Moderators: **Cheryl Stults**, Novartis and **Lennart Brunberg**, SHL Group

Panelists: **Barbara Falco**, **James Mullis**, **Ken Chesney** and **Vibhakar Shah**

4:45 - 5:00 PM

## **Poster Awards**

Awards: **Jackie Schumacher**, Pfizer, IPAC-RS Chair

## **Closing and Overview of Day 3**

**Cheryl Stults**, Novartis and **Sue Holmes**, GlaxoSmithKline; Co-Chairs of the Organizing Committee

## Workshop #1: Leachables & Extractables

Experience to Date with PQRI Recommendations (Qualification and Analytical Evaluation Thresholds)

8:00 - 8:30 AM

### Continental Breakfast

Workshop Moderator: **Cheryl Stults**, Novartis

8:30 - 9:00 AM

### Brief Overview of PQRI Recommendations Challenges and Successes

**Daniel Norwood**, Boehringer Ingelheim

9:00 - 9:30 AM

### Leachables and Extractables: Evolution of Regulatory Aspects and Perspectives on PQRI Recommendations

**Guirag Poochikian**, Poochikian Pharma Consulting

9:30 - 10:00 AM

### Work of the PQRI PODP

**Tom Feinberg**, Catalent Pharma Solutions

10:00 - 10:30 AM

### Break

10:30 - 12:00 PM **Case Studies**

10:30 - 11:00 AM

### Case Study: A Problematic Extractable for a Pulmonary Delivery Device System

**William P. Beierschmitt**, Pfizer

11:00 - 11:30 AM

### A Step-wise Approach for Leachables & Extractables Evaluation in pMDI Product Development

**Andrea Mieth**, Analytical Expert, Sandoz

11:30 AM - 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

**Jason Creasey**, GlaxoSmithKline

12:00 - 1:00 PM

### Lunch

1:00 - 3:00 PM

### Open Discussion and Q&A with Participants

Panelists: **Prasad Peri**, FDA, **Kumudini Nicholas**, Health Canada, **Tim McGovern**, SciLucent, LLC, **Daniel Norwood**, **Guirag Poochikian**, **William Beierschmitt**, **Tom Feinberg**, **Jason Creasey**

3:00 - 3:30 PM

### Closing Summary

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

8:00 - 8:30 AM

### Continental Breakfast

Morning Session Chair: **Lana Lyapustina**, DBR

8:30 - 9:00 AM

### Lifecycle Strategies for Using EDA, AIM and Full Resolution Impactor

**Terrence Tougas**, Boehringer Ingelheim

9:00 - 9:30 AM

### Control Strategies for APSD

**Rajni Patel**, Boehringer Ingelheim

9:30 - 10:00 AM

### Panel Discussion: Lifecycle and Control Strategies for APSD

Moderator: **Lana Lyapustina**, DBR

Participants: **Terrence Tougas** and **Rajni Patel**

10:00 - 10:30 AM

### Break

10:30 - 11:15 AM

### Equipment Options for AIM and Beyond

**Jolyon P. Mitchell**, Trudell Medical International

11:15 AM - 12:00 PM

### Precision and Accuracy of AIM

**J. David Christopher**, Merck and **Rajni Patel**, Boehringer Ingelheim

12:00 - 1:00 PM

### Lunch

Afternoon Session Chair: **Helen Strickland**, GlaxoSmithKline

1:00 - 1:30 PM

### Considerations for Applying EDA to an Existing Product

**Helen Strickland**, GlaxoSmithKline

1:30 - 2:00 PM

### Road to Adopting AIM/EDA as a Standard

**Adrian Goodey**, Merck

2:00 - 3:00 PM

### Panel Discussion: Case Studies and the Road to Adopting AIM/EDA as a Standard (30 min.)

### General Panel on AIM/EDA (30 min.)

Moderator: **Helen Strickland**

Panelists: **Terrence Tougas**, **Jolyon P. Mitchell**, **J. David Christopher**, **Rajni Patel**, **Adrian Goodey**

3:00 - 3:30 PM

### Future Directions and Wrap-Up

**Terrence Tougas**

**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**

8:30 - 8:40 AM

**Introductory Talk**

**Frank Cerasoli**, Pfizer; Chair of the Patient Adherence Steering Committee

8:40 - 9:00 AM

**The Voice of the Patient**

**Nancy Sander**, Allergy & Asthma Network Mothers of Asthmatics

9:00 - 10:15 AM

**Learnings on Patient Adherence from the Steering Committee**

*Members of the Steering Committee and invited experts will present key learnings from their respective perspectives.*

9:00 - 9:25 AM **Patient Perspective**

**Sandra Fusco-Walker**, Allergy & Asthma Network Mothers of Asthmatics

**John W. Walsh**, Alpha-1 Foundation

9:25 - 9:50 AM

**Health Care Provider Perspective**

**Barbara Yawn**, Olmsted Medical Center

**Suzanne Lareau**, University of Colorado

9:50 - 10:15 AM

**Disease Management and Health Outcomes Perspective/  
Purchaser Perspective**

**Len Fromer**, Group Practice Forum

10:15 - 10:30 AM

**Break**

10:30 AM - 12:00 PM

**Breakout Session 1**

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.

**Track A: Patient Perspective**

*Moderators:* **Nancy Sander**, **John W. Walsh**,  
**Sandra Fusco-Walker**

**Track B: Care Provider Perspective**

*Moderators:* **Barbara Yawn**, **Suzanne Lareau**

**Track C: Disease Management, Cost, and Cost Effectiveness**

*Moderators:* **Len Fromer**, **Peter Hayes**,  
Healthcare Solutions, **Jake Flaitz**, Paychex, Inc.

12:00 - 1:00 PM

**Lunch**

1:00 - 2:30 PM

**Breakout Session 2**

(Same as Session 1)

2:30 - 3:00 PM

**Break**

3:00 - 4:15 PM

**Panel Discussion and Audience Q&A**

**Frank Cerasoli**, **Len Fromer**, **Nancy Sander** and **Barbara Yawn**

During this interactive session, panel members will summarize the outcomes of their breakout sessions and discuss these with the audience.

4:15 - 4:30 PM

**Closing/Summary**