
2011 IPAC-RS Conference
Bringing Value to the Patient in a Changing
World

29-31 March 2011

Washington DC



Welcome to the Conference

Sue Holmes (GSK)



Conference Objectives

In line with the mission of IPAC-RS, the 2011 IPAC-RS Conference will focus on ways industry increases the value to the patients using orally inhaled and nasal drug products (OINDPs)

The goal of the IPAC-RS 2011 Conference is to make the voice of the customer more central in the constructive dialogue about best scientific and regulatory approaches to OINDPs

Organizing Committee Members

- Julianne Berry, Merck
- Gaetano Brambilla, Chiesi
- Frank Cerasoli, Pfizer
- Tim Chesworth, AZ
- **Sue Holmes, GSK (Co-Chair)**
- Frank Koppenhagen, Teva
- Paul Lucas, Pfizer
- Ray Ormiston, GSK
- Martin Shott, Vectura
- Mary Ann Smith, Novartis
- **Cheryl Stults, Novartis (Co-Chair)**
- Pat Watson, BI
- Eileen Wyka, MannKind
- DBR Staff

Program Overview – Day 1

- **Morning : Voice of the Customers**
 - Clinical focus on asthma and COPD and the unmet needs
 - Patient needs including education, device matching and FDA liaising efforts
 - Feedback from the EU bioequivalence conference
- **Afternoon: Patient Interface**
 - Patient adherence – an outline of the issues, specific examples and solutions from both industry and FDA perspectives (prelude to Day 3)
 - Expectations for user testing and human factors from both industry and FDA perspectives
 - Panel discussion
- **Evening: Poster Session and Cocktail Party**
 - A chance to mingle and review the posters (don't forget to vote for your top 3 favorites)

Program Overview – Day 2

- **Morning : Product Quality**
 - Keynote address from FDA linking quality to efficacy and safety
 - Presentations from the IPAC-RS working groups covering analytical methods, dose delivery/PTIT, cascade impaction EDA (prelude to Day 3) and dissolution testing
 - Panel discussion
- **Afternoon: Product Quality (continued)**
 - Supply chain approaches from both industry and FDA perspectives
 - Panel discussion
 - Poster awards

Program Overview – Day 3

- **3 Concurrent Workshops:**
 - **Leachable and Extractables**
 - Experience to date with PQRI recommendations (qualification and analytical evaluation thresholds)
 - Overview and perspectives on the use of the recommendations
 - Case studies
 - **AIM/EDA**
 - Lifecycle and control strategies for AIM, EDA and full APSD
 - Equipment options, precision and accuracy
 - Case Studies
 - **Patient Adherence**
 - Improving adherence through concordance
 - Perspectives of patients, health care providers, purchaser
 - Rotating break-out sessions (opportunity to attend 2 of 3 sessions)
 - Track A : Patient perspective
 - Track B : Care provider perspective
 - Track C : Disease management, cost and cost effectiveness

Housekeeping Items

- Turn off cell phones
- Vote on your top 3 favorite posters
- Complete the evaluation forms
- Breakfast on Day 2 and Day 3 will be served in the Atrium

Housekeeping Items

- Nametag Designations

 - **Amphibias & Extractions Workshop**

 - Day 3 - Roosevelt Room

 - **AIM/EDA Workshop**

 - Day 3 - Plaza 1 Ballroom

 - **Ensuring Patient Success Workshop**

 - Day 3 - Regency Room

 - Day 1 and Day 2 Attendees

- Questions about IPAC-RS

 - See Conference Committee members (Red Ribbon)
 - IPAC-RS Board members (Blue Ribbon)

- Issues/Comments/Concerns

 - See Dede Godstrey at Registration Desk

Thanks for attending!