



# IPAC-RS Materials Forum

13-14 September 2009

**Hosted at: Drinker Biddle & Reath LLP**  
**One Logan Square (18<sup>th</sup> and Cherry Streets)**  
**20<sup>th</sup> Floor**  
**Philadelphia, PA 19103**

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) is hosting a 1.5-day workshop to be held in Philadelphia, PA on 13-14 September 2009. The purpose of the workshop is to bring together OINDP manufacturers, supply chain representatives, and regulators to discuss and formulate solutions to current challenges in materials supply and testing. The workshop will address three key areas: (i) Material Variability; (ii) Focused Testing; and (iii) Current Initiatives.

**Sunday, 13 September**

**Forum Moderator: Jamie Mullis, BI**

**I. Background on IPAC-RS (3:00 – 3:20 pm) Barbara Falco, IPAC-RS**

1. IPAC-RS and Initiatives (20 minutes)

**II. Material Variability: How Much? (3:20 – 4:40 pm)**

1. OINDP Sponsor (20 minutes) **Bobbijo Redler, Schering Plough**
2. Procurement/technical purchasing Perspectives (20 minutes) **Ken Ferrari and Mark Warner, Boehringer-Ingelheim Roxane Inc.**
3. Converter (20 minutes) **Keith Wilbourn, Rio Tinto Alcan**
4. Raw Materials Supplier (20 minutes) **Michael Luetke, LyondellBasell**

*Break (4:40-4:50)*

**III. Focused Testing: Is it Possible? (4:50 – 5:10 pm)**

1. Focused Testing Overview (20 minutes) **Jamie Mullis, BI**

**IV. Standards Bodies Perspective (5:10 – 5:30 pm)**

1. USP, **Desmond Hunt** (20 minutes)

**V. Review of Day 1 & Overview of Day 2 (5:30 – 5:40 pm)**

- Pass out cards on Day 1 for people to submit questions that can be addressed on Day 2

**REFRESHMENTS AND DISCUSSION (5:40 – 6:45 PM)**

**Monday, 14 September**

**Forum Moderator: Cheryl Stults, Novartis**

*Light Breakfast (7:45 am)*

**VI. Material Variability: How Much? (8:30 – 11:30)**

**Speaker (8:30 – 9:00)**

1. **Kumudini Nicholas, Health Canada** (30 minutes)

**Panel (9:00 – 11:30)**

*Bobbijo Redler (Schering Plough), Dima Al-Hadithi (MHRA), Kumudini Nicholas (Health Canada), Prasad Peri (FDA) [Invited], Steve Blazey (Diamond Polymers), Ken Ferrari (BI), Michael Luetke (LyondellBasell)*

**Discussion Points**

- What are the drivers of compositional variability (e.g., addition of ingredients, changes in ingredient amounts) in materials?
- What are the advantages and disadvantages with respect to this variability?
- What is considered “normal” or “acceptable” variability?
- What issues/requirements do suppliers and pharma need to consider to ensure quality as well as economics? How can each entity of the chain work to mutually meet and understand needs?
- IP and/or trade secret issues: strategies for discussing these topics outside of agreements, that would be appropriate/helpful for suppliers?
- Communication with suppliers after product launch
  - What are material requirements and how does that get represented in commercial environment? Are procurement objectives in alignment with what has been decided in development?
  - What specific issues are different between development and operations regarding communications with suppliers?

**LUNCH (11:30 – 12:30 pm)**

**VII. Focused Testing: Is it Possible? (12:30 pm)**

**Speaker (12:30 – 1:00)**

1. **Dima Al-Hadithi, MHRA** (30 minutes)

**Panel (1:00 – 3:00)**

*Jamie Mullis (BI), Dima Al-Hadithi (MHRA), Kumudini Nicholas (Health Canada), Prasad Peri (FDA)[Invited], Owen Hodges (TOTAL Petrochemicals), Diane Paskiet (West Pharmaceutical), Loy Britto (GSK), Mark Warner (BI)*

### ***Discussion Points***

- How much and what kind of extractables and leachables testing is necessary (and adds value) at different points in the supply chain?
- What types of testing is normally done by a raw materials supplier and converter and why?
- What information about materials do suppliers provide to customers and vice versa?
- What information is needed during specific development phases of a drug product, and how do companies get this information?
- What kind of testing does pharma request from suppliers and why?
- Can a common approach to focused testing be developed?

*Break (3:00-3:15)*

### **VIII. Current Initiatives (3:00 – 5:00 pm)**

#### ***Speakers (3:15 – 4:15 PM)***

1. ELSIE representative (20 minutes) **Art Shaw, Pfizer**
2. Rubber Industry (20 minutes) **Marisa Kreider, ChemRisk**
3. Polymer Forum representative (20 minutes) **Cheryl Stults, Novartis**

#### ***Panel (4:15 – 5:20)***

*Representatives from each of the above groups*

#### ***Discussion Topics***

- What are drivers behind these initiatives?
- What are current activities of these efforts?
- Identify gaps, overlaps, potential “synergies.”

### **IX. Wrap-up (5:20 pm)**