



IPAC-RS Materials Forum

Tuesday, 12 May 2009

Hosted at: Laboratorios Almirall

Laurea Miro 408-410

08980 Sant Feliu de Llobregat

Barcelona, SPAIN

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) is hosting a 1-day workshop to be held in Barcelona, Spain on Tuesday, 12 May 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 consist of three sessions: (i) Material Variability; (ii) Focused Testing; and (iii) Current Initiatives.

Forum Moderator: Jason Creasey, GlaxoSmithKline

I. Material Variability: How Much? (8:30 am – 12:00 pm)

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?

8:30 – 10:00 AM Speakers (1 hour 30 minutes)

1. Regulatory Perspectives (30 minutes) **Kumudini Nicholas, Health Canada**
2. OINDP Manufacturer (20 minutes) **Cheryl Stults, Novartis**
3. Converter (20 minutes) **Steve Lovatt, Bepak**
4. Raw Materials Supplier (20 minutes) **Guido Draijer, DuPont**

10:00 – 10:15 AM Break

10:15 AM – 12:00 PM Panel (1 hour 45 minutes)

Proposed: All speakers, plus other pharma, suppliers, regulators. Panel discussion to be started with a question.

Cheryl Stults, Novartis
Steve Lovatt, Bepak
Peter Claessens, Alcan
Dima Al-hadithi, MHRA

Guido Draijer/Daniel Ayglon, DuPont
John Wong, ExxonMobil
Kumudini Nicholas, Health Canada

LUNCH (12:00 – 1:00 pm)

II. Focused Testing: Is it Possible? (1:00 pm – 3:30 pm)

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?

Speakers (50 minutes)

1. Regulatory Perspectives (30 minutes) **Prasad Peri, FDA (via teleconference)**
2. Focused Testing Overview (20 minutes) **Mike Hodgson, Pfizer**

Panel (1 hour 40 minutes, including 15 minute break)

Representatives from a variety of aspects of the supply chain, pharma, and regulators.

Mike Hodgson, Pfizer
Gaby Reckzügel, BI
Timo Latvakangas, Borealis
Rob de Jong, SABIC

Michael Lütke, Basell
Carl Hathaway, Bepak
Dima Al-hadithi, MHRA
Kumudini Nicholas, Health Canada
Prasad Peri, FDA (via teleconference)

III. Current Initiatives to Promote Product Quality and Safety (Materials Focus) (3:30 – 5:30 pm)

Discussion Topics

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

Speakers (1 hour)

1. IPAC-RS representative (20 minutes) **Barbara Falco, Abbott**
2. Polymer Forum representative (20 minutes) **Taina Tjäder, Bayer Schering Pharma Oy**
3. ELSIE representative (20 minutes) **Andrew Feilden, AstraZeneca**

Panel (1 hour)

Representatives from each of the current initiatives. Discuss any new initiatives from first two sessions.

Barbara Falco, Abbott
Andrew Feilden, AstraZeneca

Taina Tjäder, Bayer Schering Pharma Oy

IV. Wrap-up (5:30 pm)