



International Pharmaceutical Aerosol Consortium on Regulation and Science

Workshop on Extractables and GMP for Components of Inhalation & Nasal Drug Products

Hosted by the IPAC-RS OINDP Materials and Supplier QC Working Groups

24-25 September 2007
Basel, Switzerland
Venue To Be Determined

Preliminary Program

Day 1

****There will be time allotted for Q&A after each presentation****

Morning Moderator: Barbara Falco, Abbott

- I. Overview of OINDP: Extractables and Related Issues and Challenges
Cheryl Stults, Nektar Therapeutics

- II. Guidance on GMP for OINDP Components: IPAC-RS GMP Guideline
Elizabeth Erdos, Novo Nordisk

- III. Panel Discussion: Practical Examples of IPAC-RS Guideline Implementation
Tina Arounsack, Novo Nordisk; Andrew Saunders, sanofi-aventis

Coffee Break

- IV. Guidance on Extractables for Materials/Components used in OINDP: Tools for Suppliers
Diane Paskiet, West Monarch Analytical Laboratories

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- V. Panel Discussion: Regulatory Perspective on Extractables and GMP for OINDP Components**
Regulators representing: EU; Health Canada; FDA (David Cummings, CDER/OPS)

Lunch

- VI. Extractables in the Component/Material Lifecycle**

Selection & Qualification of Materials

Douglas Ball, Pfizer

William Beierschmitt, Pfizer

Selection - Information Needed by Customers & Suppliers

Safety Evaluation and the Role of the Supplier

Extractables – During Development and Routine Control

Daniel Norwood, Boehringer Ingelheim

Coffee Break

- VII. Options/Logistics for Filing Information with a Regulatory Body**

Day 2

Moderator: Cheryl Stults, Nektar Therapeutics

- VII. Supplier - Pharma Relationship**

Audits and Supply/Quality Agreements

Andrew Saunders, sanofi-aventis

Partnership and Communication between Pharma and Suppliers

Matthew Coates, Pfizer

FDA Perspective on OINDP Manufacturer-Supplier Relationship

David Cummings, FDA/CDER/OPS

Coffee Break

**Managing Change Together—Panel Discussion with Suppliers and
Pharma**

***Gaby Reckzuegel, Boehringer Ingelheim; Michael Ruberto, Ciba; Christian
Meusinger, Rexam***

VIII. QbD Initiative

**Introduction to QbD and Review of Current Regulatory and Industry
Activities**

Andy Rignall, AstraZeneca

Breakout Discussion Groups

**Leveraging the supplier-pharma relationship to achieve QbD
Improving Communication**

Report Back

IX. Why Supply to the OINDP Industry

Barbara Falco, Abbott