

# WORKSHOP ON EXTRACTABLES AND GMP FOR COMPONENTS OF INHALATION & NASAL DRUG PRODUCTS MONDAY - TUESDAY, SEPTEMBER 24-25, 2007

aprentas Ausbildungszentrum Muttenz  
Room AZM 22.03  
Lachmattstrasse 81  
Basel, Switzerland  
[www.ipacrs.com/supplier.html](http://www.ipacrs.com/supplier.html)

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) is excited to host a workshop on September 24-25, 2007 for suppliers of materials and components used in orally inhaled and nasal drug products (OINDP) and for OINDP pharmaceutical manufacturers. The materials and components used in OINDP are critical to the quality and performance of the drug product. Historically, however, communication between OINDP manufacturers, suppliers of components and raw materials, and intermediates has been limited. This workshop will address the expectations for quality (including GMPs) and extractables evaluation of components and materials intended for use in OINDP, and will provide opportunities for interaction and dialogue between all links in the OINDP supply chain, from base material suppliers to pharma companies, and with regulators.

Topics to be covered include:

- analytical and toxicological evaluation of extractables in development and routine control;
- regulatory expectations;
- managing change;
- the IPAC-RS GMP Guideline for Suppliers; and
- communication between OINDP manufacturers and suppliers.

## Workshop Faculty:

**Barbara Falco**, Executive Director, QA, Abbott Laboratories;  
Co-Chair IPAC-RS OINDP Materials & Chair Supplier QC  
Working Groups

**Cheryl L.M. Stults, Ph.D.**, Staff Scientist, Nektar Therapeutics;  
Co-Chair IPAC-RS OINDP Materials Working Group

**Tina Arounsack**, QA Compliance Manager, Novo Nordisk  
Delivery Technologies

**Douglas J. Ball**, Research Fellow, Pfizer, Inc.

**Matthew Coates**, Team Leader, Inhalation and Device Centre of  
Emphasis, Pfizer Global Research & Development

**William P. Beierschmitt, Ph.D.**, Associate Research Fellow,  
Pfizer, Inc.

**Jason M. Creasey**, Manager, GlaxoSmithKline

**David Cummings**, OPS Quality Systems Manager, FDA

**Rob de Jong**, Industry Manager Healthcare, SABIC Innovative  
Plastics

**Elizabeth Erdos**, Director, Quality Control, Novo Nordisk  
Delivery Technologies

**Sylvie Georgeon**, Validation Manager - Equipment & Facilities,  
Rexam Pharma

**Sultan Ghani**, Director, Therapeutic Products Directorate,  
Health Canada

**Manfred Hoffmann**, Team Leader Packaging Chemistry and  
Analyses, Alcan Technology & Management Ltd.

**Romain Lelièvre**, Senior Manager Technical Support Europe,  
West Pharmaceutical Services

**James O. Mullis**, Senior Scientist, Analytical Sciences,  
Boehringer Ingelheim Pharmaceuticals, Inc.

**Daniel L. Norwood, Ph.D.**, Director, Physical and Chemical  
Analysis, Boehringer Ingelheim Pharmaceuticals, Inc.

**Diane Paskiet**, Associate Director, West Monarch Analytical  
Laboratories

**Gaby Reckzügél**, Principal Scientist, Boehringer Ingelheim

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

**Michael Ruberto, Ph.D.**, Head of Regulatory Services,  
NAFTA, Ciba Specialty Chemicals Corporation

**Andrew Saunders**, QA Manager - Supplier Quality, sanofi-  
aventis



## Day One — Monday, September 24, 2007

Complimentary continental breakfast and lunch will be served on each day.

### ***Check-In and Continental Breakfast (9.30-10.00)***

Welcome and Overview of Workshop  
10.00 - 10.05  
*Cheryl Stults, Nektar Therapeutics*

### **Morning Session**

Moderator: *Barbara Falco, Abbott*

### **I. Overview of OINDP: Extractables and Related Issues and Challenges**

10.05–10.30

*Cheryl Stults, Nektar Therapeutics*

### **II. Guidance on GMP for OINDP Components: IPAC-RS GMP Guideline**

10.30–11.15

*Elizabeth Erdos, Novo Nordisk*

### **III. Panel Discussion: Practical Examples of IPAC-RS Guideline Implementation**

11.15–12.15

*Tina Arounsack, Novo Nordisk*

*Andrew Saunders, sanofi-aventis*

*Romain Lelièvre, West Pharmaceutical Services*

***Lunch (12.15-13.00)***

### **Afternoon Session**

Moderator: *Jason Creasey, GlaxoSmithKline*

### **IV. Guidance on Extractables for Materials/Components used in OINDP: Tools for Suppliers**

13.00–13.30

*Diane Paskiet, West Monarch Analytical Laboratories*

### **V. Panel Discussion: Regulatory Perspectives on Extractables and GMP for OINDP Components**

13.30–14.30

*David Cummings, FDA/CDER/OPS*

*Sultan Ghani, Health Canada*

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

#### **Selection & Qualification of Materials**

14.30 - 15.00

*Douglas Ball, Pfizer*

#### **Leachables & Extractables - A Toxicologist's Perspective**

15.00 - 15.30

*William Beierschmitt, Pfizer*

***Refreshment and Networking Break  
(15.30-15.45)***

#### **Extractables - During Development and Routine Control**

15.45–16.45

*Daniel Norwood, Boehringer Ingelheim*

*Jamie Mullis, Boehringer Ingelheim*

***Recap of Day 1 and Overview of Day 2  
(16.45 - 17.00)***

*Cheryl Stults, Nektar Therapeutics*



## Day Two — Tuesday, September 25, 2007

### *Networking and Continental Breakfast (8.30-9.00)*

#### **Morning Session**

Moderator: *Cheryl Stults, Nektar Therapeutics*

#### **VII. Supplier - Pharma Relationship**

##### **Audits and Supply/Quality Agreements**

9.00-9.45

*Andrew Saunders, sanofi-aventis*

##### **Partnership and Communication between Pharma and Suppliers**

9.45-10.15

*Matthew Coates, Pfizer*

##### **Control of Suppliers, Component Quality, and Quality by Design**

10.15 -10.45

*David Cummings, FDA*

### *Refreshment and Networking Break (10.45-11.00)*

#### **Managing Change Together - Panel Discussion with Suppliers and Pharma**

11.00-12.00

*Gaby Reckzuegel, Boehringer Ingelheim*

*Michael Ruberto, Ciba*

*Sylvie Georgeon, Rexam Pharma*

*Manfred Hoffmann, Alcan*

*Rob de Jong, SABIC Innovative Plastics*

### *Lunch (12.00-12.45)*

#### **VIII. QbD Initiative**

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

12.45-13.15

*Andy Rignall, AstraZeneca*

##### **OINDP Pharmaceutical Manufacturer and Supplier Breakout Sessions**

13.15-14.00

**Moderators:**

*Doug Ball, Pfizer*

*Jason Creasey, GlaxoSmithKline*

*Elizabeth Erdos, Novo Nordisk*

*Barbara Falco, Abbott*

*Andy Rignall, AstraZeneca*

*Cheryl Stults, Nektar Therapeutics*

*Collectively implementing the QbD  
paradigm and identifying challenges and  
opportunities*

#### **Report Back**

14.00-14.30

#### **IX. Why Supply to the OINDP Industry?**

14.30-14.50

*Barbara Falco, Abbott*

#### **14.50 - 15.00 Closing**

*Barbara Falco, Abbott*