

SYMPOSIUM: EXTRACTABLES IN MATERIALS FOR OINDP
TUESDAY, FEBRUARY 13, 2007
AND
WORKSHOP: OINDP SUPPLIER GMPS
WEDNESDAY, FEBRUARY 14, 2007

Drinker Biddle Gardner Carton
191 N. Wacker Drive
Chicago, Illinois 60606
www.ipacrs.com/supplier.html

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) is hosting two complementary one-day events for suppliers of materials and components used in orally inhaled and nasal drug products (OINDP) and for OINDP pharmaceutical manufacturers. These events will provide opportunities for interaction and dialogue between all links in the OINDP supply chain, including pharma companies.

The *Symposium on Extractables in Materials for OINDP* will be held on Tuesday, February 13, 2007. The objectives of the symposium are to improve understanding of the particular requirements for materials used in OINDP and to promote dialogue on these critical issues.

The IPAC-RS second *Workshop on OINDP Supplier GMPs* will be held on Wednesday, February 14, 2007. The Workshop will introduce suppliers and OINDP pharmaceutical manufacturers to the IPAC-RS GMP Guideline for OINDP Suppliers, and will discuss the use of the Guideline and its requirements. The first Workshop, which was held in Washington, DC in June 2006, provided an excellent opportunity for dialogue between OINDP suppliers and their customers and was very useful to attendees.

Symposium and Workshop Faculty:

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

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

Tina Arounsack, QA Compliance Manager, Novo Nordisk
Delivery Technologies

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

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

Steve Blazey, Ph.D., President, Diamond Polymers Inc.

Jon Clark, Associate Director for Policy Development, FDA

John Colwell, Development Chemist, Bepak Plc

Jason M. Creasey, Manager, GlaxoSmithKline

David Cummings, OPS Quality Systems Manager, FDA

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

Thomas Gaspar, Vice President, Quality Assurance,
Manufacturing & Development Support, West Pharmaceutical
Services

Hedden V. Miller, Healthcare Marketing Specialist, Ticona

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

Linda Nield, Quality Assurance Manager, sanofi-aventis

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

Diane Paskiet, Associate Director, West Monarch Analytical
Laboratories

Guirag Poochikian, Ph.D., Consultant

Gaby Reckzuegel, Head of Laboratory, Boehringer Ingelheim

Jennifer Riter, Manager Technical Customer Support and
Laboratory Business Development, West Pharmaceutical
Services

Suzette M. Roan, JD, RAC, Senior Scientist, Regulatory
CMC, Pfizer, Inc.

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

Mary Ann Smith, Associate Director, Regulatory Affairs,
Nektar Therapeutics



Day One — Tuesday, February 13, 2007
Extractables Symposium

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

Check-In and Continental Breakfast
(7:30-8:00 AM)

Morning Session

Moderator: *Jason M. Creasey, GlaxoSmithKline*

Overview of OINDP, Importance of Extractables in OINDP, and Challenges

8:00–8:30 AM

Cheryl L.M. Stults, Ph.D., Nektar Therapeutics

Review Guidance on Extractables for Materials/Components used in OINDP: Tools for Suppliers

8:30–9:00 AM

Diane Paskiet, West Monarch Analytical Laboratories

Selection and Qualification of Materials

9:00–10:00 AM

Douglas J. Ball, Pfizer, Inc.

William P. Beierschmitt, Ph.D., Pfizer, Inc.

Refreshment and Networking Break
(10:00-10:15 AM)

Extractables in the Product Development Process

10:15–11:00 AM

Mary Ann Smith, Nektar Therapeutics

Routine Control of Extractables

11:00–12:00 PM

Daniel L. Norwood, Ph.D., Boehringer Ingelheim

James O. Mullis, Boehringer Ingelheim

Lunch (12:00-1:00 PM)

Afternoon Session

Moderator: *Jennifer Riter, West Pharmaceutical Services*

Change Control Within a Supplier: Understanding and Knowing your Supplier and Their World

1:00–2:00 PM

Thomas Gaspar, West Pharmaceutical Services

Clarifying Expectations: Panel Discussion with Suppliers

2:00–3:00 PM

Steve Blazey, Diamond Polymers Inc.

John Colwell, Bepak Plc

Hedden V. Miller, Ticona

Guirag Poochikian, Ph.D., Consultant

Gaby Reckzuegel, Boehringer Ingelheim GmbH

Michael Ruberto, Ciba Specialty Chemicals Corporation

Refreshment and Networking Break
(3:00-3:15 PM)

Why Supply to the OINDP Industry

3:15–4:00 PM

Barbara Falco, Abbott Laboratories

4:00 PM *Closing*

**Day Two — Wednesday, February 14, 2007
Supplier QC Workshop**

**Networking and Continental Breakfast
(8:30-9:00 AM)**

Opening

9:00-9:10 AM

Barbara Falco, Abbott Laboratories

Session I: Overview of IPAC-RS GMP

Guideline: Use and Application

Moderator: *Suzette M. Roan, JD, RAC, Pfizer, Inc.*

Use and Application of IPAC-RS Guideline

9:10-9:55 AM

Elizabeth Erdos, Novo Nordisk Delivery Technologies

Control of Suppliers, Component Quality, and QbD

9:55 -10:25 AM

*John Clark, FDA
David Cummings, FDA*

**Refreshment and Networking Break
(10:25-10:40 AM)**

Auditing Against the IPAC-RS Guideline

10:40-11:25 AM

Linda Nield, sanofi-aventis

Session II: Using the IPAC-RS Guideline to Strengthen Quality Systems

Moderator: *Barbara Falco, Abbott Laboratories*

Extractables - Characterization and Control

11:25 AM-12:40 PM

*Daniel L. Norwood, Ph.D., Boehringer Ingelheim
Suzette M. Roan, JD, RAC, Pfizer, Inc.*

Lunch (12:40-1:40 PM)

Component and Equipment Cleaning

1:40-2:15 PM

Elizabeth Erdos, Novo Nordisk Delivery Technologies

Change Control

2:15-2:55 PM

Thomas Gaspar, West Pharmaceutical Services

Quality Agreements/Control of Suppliers and Sub-Contractors

2:55-3:15 PM

Tina Arounsack, Novo Nordisk Delivery Technologies

**Refreshment and Networking Break
(3:15-3:25 PM)**

Panel Discussion

3:25-3:50 PM

Panel:

*Daniel L. Norwood, Ph.D., Boehringer Ingelheim
Suzette M. Roan, JD, RAC, Pfizer, Inc.*

Elizabeth Erdos, Novo Nordisk Delivery Technologies

Tina Arounsack, Novo Nordisk Delivery Technologies

Thomas Gaspar, West Pharmaceutical Services

Closing Remarks

3:50-4:00 PM

Barbara Falco, Abbott Laboratories

