

# INHALATION & NASAL DRUGS: THE REGULATORY LANDSCAPE

6-8 November 2006

Bethesda North Marriott Hotel and Conference Center

5701 Marinelli Road

North Bethesda, MD 20852

[www.ipacrs.com/conf2006.html](http://www.ipacrs.com/conf2006.html)

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) is proud to host a premier conference on current regulatory and scientific issues for the orally inhaled and nasal drug products (OINDP) industry. The conference will bring together scientists and regulators from FDA, international regulatory agencies, industry, academia, USP and other stakeholders. Many challenges and questions face industry and FDA as they transition from old approaches to the new Quality by Design paradigm. Solutions are still evolving. The IPAC-RS conference seeks to contribute to these solutions through public discussion on how development and manufacture of OINDP could change under this new paradigm.

Among the topics to be discussed are:

- Application of PAT, Quality by Design, and Risk Management to OINDP
- Relevance of Design Space to OINDP
- Role of Control Strategies Under the New Paradigm
- Quality Attributes in OINDP
  - Leachables and Extractables
  - Foreign Particulates
  - Aerosol Particles
- GMP for Suppliers of OINDP Components
- International Regulatory Perspectives
- OINDP for Systemic Delivery

## IPAC-RS Conference Planning Committee

Liuda Shtohryn, PharmD, Chair, IPAC-RS Conference Planning Committee, Director, CMC Regulatory Affairs, AstraZeneca  
David Cipolla, Senior Director of Pharmaceutical Sciences, Aradigm Corp.

Jon Clark, Associate Director for Policy Development, Food & Drug Administration  
David Cummings, Chemist, Food & Drug Administration

Claire D'Abreu-Hayling, Head of Analytical Technology, sanofi-aventis

Ray A. Ormiston, Ph.D., Director, CMC Regulatory Affairs, GlaxoSmithKline

Steven Pilewski, Director, Inhalation Technologies, PPD

Jackie Schumacher, Associate Research Fellow, Regulatory CMC, Pfizer

Julie D. Suman, President, Next Breath LLC

Terrence Tougas, Ph.D., Highly Distinguished Scientist, Boehringer Ingelheim Pharmaceuticals, Inc.

## Conference Goals

- Stimulate constructive dialogue between the OINDP industry, regulators and others
- Explore the new FDA paradigm of Quality by Design as applicable to OINDP
- Promote best scientific and regulatory practices for OINDP

## Conference Deliverables

Recommendations and perspectives on applying Quality by Design to OINDP will be conveyed to FDA and industry for further consideration and discussion.



## PROGRAM OVERVIEW

### Monday, 6 November 2006

(8:00 AM – 5:15 PM)

#### Plenary Sessions:

- Evolving US Regulatory Environment: Transition from Old to New FDA Paradigm for OINDP
- New Regulatory Initiatives and their Relationship to OINDP Development and Regulation

#### Breakout Sessions:

- Practical Expectations: OINDP Industry's Use of PAT in Submissions
- Applying Risk-Management, Risk-Assessment, and Design Space to OINDP Development and Regulation
- Q&A and Discussion on Control Strategies and Linking Quality, Safety and Efficacy in a Quality by Design Development Program

Network Reception: 5:15-7:00 PM

### Tuesday, 7 November 2006

(8:00 AM – 5:30 PM)

#### Plenary Sessions:

- Quality by Design Approach to OINDP Supplier Quality Control
- Aerosol Particles in a Quality by Design Environment
- Development of ISO Standards for Inhalation Products
- Considerations for OINDP Quality Attributes in a Quality by Design Environment

#### Breakout Sessions:

- Progress Report and Q&A on ISO Standards for MDI/DPI and Nebulizers
- Application of Parametric Tolerance Interval (PTI) Tests
- Q&A and Discussion on Supplier Quality Control for OINDP, its Role in Quality by Design, and the Use of the IPAC-RS GMP Guideline

### Wednesday, 8 November 2006

(8:00 AM – 2:40 PM)

#### Plenary Sessions:

- International Regulatory Perspectives
- Development of Inhalation Products for Systemic Delivery Application

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



## Program Faculty

Robert G. Baum, Head, Office of Global Regulatory CMC Policy, Pfizer Global Research & Development

Jim Blanchard, Ph.D., Principal Scientist, Aradigm Corp.

Peter R. Byron, Ph.D. Professor & Chairman, Virginia Commonwealth University

J. David Christopher, Associate Director, Statistics, Schering-Plough Research Institute

David Cipolla, Senior Director of Pharmaceutical Sciences, Aradigm Corp.

Jon Clark, Associate Director for Policy Development, CDER, Food & Drug Administration

David Cummings, Chemist, CDER, Food & Drug Administration  
Elizabeth Erdos, Director, Quality Control, Novo Nordisk Delivery Technologies

Barbara Falco, Executive Director, QA, Kos Pharmaceuticals, Inc.  
Thomas Gaspar, Vice President, Quality Assurance Manufacturing & Development Support, West Pharmaceutical Services

Michael Golden, Director, CMC Regulatory Affairs, GlaxoSmithKline

Igor Gonda, President & CEO, Aradigm Corp.

Ann A. Graham, Branch Chief, Anesthesiology & Respiratory Devices Branch, Food & Drug Administration

Gordon Hansen, Vice President, Analytical Sciences, Boehringer Ingelheim Pharmaceuticals, Inc.

Nancy J. Harper, Ph.D., Research Fellow, Pfizer Inc.

John L. Hart, Senior Director, Pfizer Ltd.

Walter Hauck, Senior Scientific Fellow, United States Pharmacopeia

Stephen Horhota, Highly Distinguished Scientist, Boehringer Ingelheim Pharmaceuticals, Inc.

Laurence Huxham, Programme Leader, Pharmaceutical and Analytical R&D, AstraZeneca

Michael J. James, Ph.D., Head of CMC Regulatory Advocacy and Intelligence, GlaxoSmithKline

Stefan Leiner, CMC Expert, Boehringer Ingelheim Pharma GmbH & Co. KG

Richard (Rik) Lostritto, Ph.D., Director, ONDQA, Division-III, Food & Drug Administration

Charles E. Mader, Ph.D., Director, Process Understanding & Innovation, GlaxoSmithKline

Tim McGovern, Supervisory Pharmacologist, Food & Drug Administration

Jolyon P. Mitchell, Director, Scientific Affairs, Trudell Medical International

Steve Newman, Ph.D., Scientific Consultant

S. C. Nichols, New Technology Coordination Manager, sanofi-aventis

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

Ray A. Ormiston, Ph.D., Director, CMC Regulatory Affairs, GlaxoSmithKline

Tunde Otulana, M.D., Senior Vice President, Development, Aradigm Corp.

Jackie Schumacher, Associate Research Fellow, Regulatory CMC, Pfizer

Sally Seymour, M.D., Medical Officer, Food & Drug Administration

Liuda Shtohryn, PharmD, Director, CMC Regulatory Affairs, AstraZeneca

Julie D. Suman, President, Next Breath, LLC

Mikael Sundahl, Ph.D., Principal Scientist, Novo Nordisk A/S

Terrence Tougas, Ph.D., Highly Distinguished Scientist, Boehringer Ingelheim Pharmaceuticals, Inc.

Caroline Vanneste, Project Manager, Good Review Practices, Health Canada

Diana van Riet, Principal Assessor, Chemical Pharmaceutical Assessment (CFB), Centre for the Quality of Chemical-Pharmaceutical products (KCF) of RIVM

Roger L. Williams, Executive Vice President & CEO, United States Pharmacopeia

Helen N. Winkle, Director, Office of Pharmaceutical Sciences, CDER, Food & Drug Administration

Hal Yeager, Senior Regulatory Advisor, Global Product Safety, Eli Lilly & Company

**Day One — Monday, November 6, 2006****Registration and Continental Breakfast  
(7:00-8:00 AM)****Opening of Conference****Welcome Address, Background on IPAC-RS, Future of OINDP Regulatory Environment, and Introduction to Day 1**

8:00-8:30 AM

*Liuda Shtohryn, PharmD, Director, CMC Regulatory Affairs, AstraZeneca***Opening Plenary Lecture — Challenges and Opportunities for FDA and OINDP Industry**

8:30-9:00 AM

*Helen N. Winkle, Director, Office of Pharmaceutical Sciences, CDER, FDA***Q&A**

9:00-9:15 AM

*Helen N. Winkle, Director, Office of Pharmaceutical Sciences, CDER, FDA***Morning Plenary Session: Evolving US Regulatory Environment — The Transition from Old to New FDA Paradigm for OINDP***Session Moderator: John L. Hart, Senior Director, Pfizer***Evolution of Regulatory Paradigm for OINDP: Industry Perspective**

9:15-9:45 AM

*Gordon Hansen, Vice President, Analytical Sciences, Boehringer Ingelheim***Refreshment and Networking Break**

(9:45-10:00 AM)

**QbD for OINDP: FDA Perspective**

10:00-10:30 AM

*Richard (Rik) Lostritto, Ph.D., Director, ONDQA, Division-III, FDA***Q&A on Transition to New Paradigm**

10:30-10:45 AM

**Panel:***John L. Hart, Senior Director, Pfizer**Richard (Rik) Lostritto, Ph.D., Director, ONDQA, Division-III, FDA**Gordon Hansen, Vice President, Analytical Sciences, Boehringer Ingelheim***Morning Plenary Session: New Regulatory Initiatives and their Relationship to OINDP Development and Regulation***Session Moderator: Jackie Schumacher, Associate Research Fellow, Regulatory CMC, Pfizer***Quality by Design (QbD) for OINDP**

10:45-11:15 AM

*Michael Golden, Director, CMC Regulatory Affairs, GlaxoSmithKline***Quality Risk Management and Design Space in Device Development**

11:15-11:45 AM

*Laurence Huxham, Programme Leader, Pharmaceutical and Analytical R&D, AstraZeneca***Change Protocols**

11:45 AM-12:15 PM

*Jon Clark, Associate Director for Policy Development, CDER, FDA***Luncheon (12:15-1:15 PM)**

## Afternoon Plenary Session: New Regulatory Initiatives and their Relationship to OINDP Development and Regulation, Continued

*Session Moderator: Stefan Leiner, CMC Expert, Boehringer Ingelheim*

### Quality by Design

1:15–1:45 PM

*Jon Clark, Associate Director for Policy Development, CDER, FDA*

### IPAC-RS Model OINDP Initiative

1:45–2:15 PM

*Terrence Tougas, Ph.D., Highly Distinguished Scientist, Boehringer Ingelheim*

### Q&A on QbD and Risk Management

2:15–2:45 PM

#### Panel:

*Jackie Schumacher, Associate Research Fellow, Regulatory CMC, Pfizer*

*Stefan Leiner, CMC Expert, Boehringer Ingelheim*

*Michael Golden, Director, CMC Regulatory Affairs, GlaxoSmithKline*

*Laurence Huxham, Programme Leader, Pharmaceutical and Analytical R&D, AstraZeneca*

*Terrence Tougas, Ph.D., Highly Distinguished Scientist, Boehringer Ingelheim*

*Jon Clark, Associate Director for Policy Development, CDER, FDA*

*Refreshment and Networking Break (2:45-3:00 PM)*

## Breakout Sessions: Modern Regulatory Approaches to OINDP

### Parallel-Tracks A/B/C (3:00-5:15 PM)

(Each session will be conducted three times: 3:00-3:45 PM, 3:45-4:30 PM, and 4:30-5:15 PM. Participants can therefore attend all sessions.)

- Track A:** Practical Expectations: OINDP Industry's Use of PAT in Submissions

**Moderators:**  
*Stephen Horhota, Highly Distinguished Scientist, Boehringer Ingelheim*  
*Charles E. Mader, Ph.D., Director, Process Understanding & Innovation, GlaxoSmithKline*
- Track B:** Applying Risk-Management, Risk-Assessment, and Design Space to OINDP Development and Regulation

**Moderators:**  
*Terrence Tougas, Ph.D., Highly Distinguished Scientist, Boehringer Ingelheim*  
*Laurence Huxham, Programme Leader, Pharmaceutical and Analytical R&D, AstraZeneca*
- Track C:** Q&A and Discussion on Control Strategies and Linking Quality, Safety and Efficacy in a Quality by Design Development Program

**Moderators:**  
*Daniel L. Norwood, Director, Physical and Chemical Analysis, Boehringer Ingelheim*  
*Michael Golden, Director, CMC Regulatory Affairs, GlaxoSmithKline*

**End of Day One: 5:15 PM**

**Cocktail Reception (5:15-7:00 PM)**

**Day Two — Tuesday, November 7, 2006****Networking and Continental Breakfast  
(7:00-8:00 AM)****Welcome, Recap of Day 1 and Introduction  
to Day 2**

8:00-8:05 AM

*David Cipolla, Senior Director of Pharmaceutical  
Sciences, Aradigm***Keynote Address: Role of Pharmacopoeial  
Monographs and Other Finished Product  
Testing under the Quality by Design  
Paradigm**

8:05-8:35 AM

*Roger L. Williams, Executive Vice President & CEO,  
USP***Recap of Day 1**

- 8:35-8:45 AM Track A Breakout Session  
Feedback  
*Stephen Horhota, Highly Distinguished  
Scientist, Boehringer Ingelheim*  
*Charles E. Mader, Ph.D., Director, Process  
Understanding & Innovation, GlaxoSmithKline*
- 8:45-8:55 AM Track B Breakout Session  
Feedback  
*Terrence Tougas, Ph.D., Highly Distinguished  
Scientist, Boehringer Ingelheim*  
*Laurence Huxham, Programme Leader,  
Pharmaceutical and Analytical R&D,  
AstraZeneca*
- 8:55-9:05 AM Track C Breakout Session  
Feedback  
*Michael Golden, Director, CMC Regulatory  
Affairs, GlaxoSmithKline*  
*Daniel L. Norwood, Director, Physical and  
Chemical Analysis, Boehringer Ingelheim*

**Morning Plenary Session: Quality by Design  
Approach to Supplier Quality Control***Session Moderator: Elizabeth Erdos, Director,  
Quality Control, Novo Nordisk Delivery Technologies***Control of Suppliers, Component Quality  
and QbD**

9:05-9:35 AM

*David Cummings, Chemist, FDA***Role of the IPAC-RS GMP Guideline in  
Promoting OINDP Component Quality**

9:35-10:05 AM

*Barbara A. Falco, Executive Director, QA, Kos  
Pharmaceuticals, Inc.***Refreshment and Networking Break**

(10:05-10:20 AM)

**Promoting Quality OINDP Components:  
Supplier Perspective**

10:20-10:50 AM

*Thomas Gaspar, Vice President Quality Assurance  
Manufacturing & Development Support, West  
Pharmaceutical Services***Q&A on Supplier Quality Control and GMP  
Guideline**

10:50-11:10 AM

**Panel:***Elizabeth Erdos, Director, Quality Control, Novo  
Nordisk Delivery Technologies**David Cummings, Chemist, FDA**Barbara A. Falco, Executive Director, QA, Kos  
Pharmaceuticals, Inc.**Thomas Gaspar, Vice President Quality Assurance  
Manufacturing & Development Support, West  
Pharmaceutical Services***Morning Plenary Session: Aerosol Particles  
in a Quality by Design Environment***Session Moderator: Julie D. Suman, President, Next  
Breath, LLC***What Do Cascade Impaction Measurements  
Tell Us?**

11:10-11:40 AM

*Jolyon P. Mitchell, Director, Scientific Affairs,  
Trudell Medical International***Clinical Relevance of In-vitro Particle Sizing  
Data**

11:40 AM-12:10 PM

*Steve Newman, Ph.D., Scientific Consultant***FDA Perspectives on Quality by Design**

12:10-12:20 PM

*Jon Clark, Associate Director for Policy  
Development, CDER, FDA*

### Q&A on Assessment of Aerosol Particles Within a Design Space Paradigm

12:20–12:40 PM

#### Panel:

*Julie D. Suman, President, Next Breath, LLC*  
*Jolyon P. Mitchell, Director, Scientific Affairs, Trudell Medical International*  
*Steve Newman, Ph.D., Scientific Consultant*  
*Jon Clark, Associate Director for Policy Development, CDER, FDA*  
*J. David Christopher, Associate Director, Statistics, Schering-Plough*

### ISO Process and Standards Under Development

12:40 – 1:00 PM

*S.C. Nichols, New Technology Coordination Manager, sanofi-aventis*

*Luncheon (1:00-2:00 PM)*

### Afternoon Plenary Session: Considerations for OINDP Quality Attributes in a Quality by Design Environment

*Session Moderator: Jim Blanchard, Ph.D., Principal Scientist, Aradigm*

### Linking Safety and Quality: Examples from L&E and Foreign Particles in OINDP

2:00-2:30 PM

*Tim McGovern, Supervisory Pharmacologist, FDA*

### Considerations for Foreign Particulates in a Quality by Design Environment

2:30–3:00 PM

*Mikael Sundahl, Ph.D., Principal Scientist, Novo Nordisk A/S*

### Considerations for Leachables and Extractables in a Quality by Design Environment

3:00–3:30 PM

*Daniel L. Norwood, Director, Physical and Chemical Analysis, Boehringer Ingelheim*

### Q&A on Control of OINDP Quality Attributes

3:30–3:45 PM

#### Panel:

*Jim Blanchard, Ph.D., Principal Scientist, Aradigm*  
*Tim McGovern, Supervisory Pharmacologist, FDA*  
*Mikael Sundahl, Ph.D., Principal Scientist, Novo Nordisk A/S*  
*Daniel L. Norwood, Director, Physical and Chemical Analysis, Boehringer Ingelheim*

*Refreshment and Networking Break (3:45-4:00 PM)*

### Breakout SessionS: ISO Standards for MDI/DPI and Nebulizers, PTIT, and OINDP Control Strategies and Supplier GMP Parallel-Tracks D/E/F (4:00-4:45 PM and 4:45-5:30 PM)

(Session will be conducted twice. Choose to attend two of the three sessions.)

- **Track D:** Progress Report and Q&A on ISO Standards for MDI/DPI and Nebulizers  
**Moderators:**  
*Ann A. Graham, Branch Chief, Anesthesiology & Respiratory Devices Branch, FDA*  
*Hal Yeager, Sr. Regulatory Advisor, Global Product Safety, Eli Lilly & Company*  
*S.C. Nichols, New Technology Coordination Manager, sanofi-aventis*
- **Track E:** Application of Parametric Tolerance Interval (PTI) Tests  
**Moderators:**  
*J. David Christopher, Associate Director, Statistics, Schering-Plough*  
*Walter Hauck, Senior Scientific Fellow, USP*
- **Track F:** Q&A and Discussion on Supplier Quality Control for OINDP, its Role in Quality by Design, and the Use of IPAC-RS GMP Guideline  
**Moderators:**  
*Elizabeth Erdos, Director, Quality Control, Novo Nordisk Delivery Technologies*  
*David Cummings, Chemist, FDA*  
*Barbara A. Falco, Executive Director, QA, Kos Pharmaceuticals, Inc.*  
*Thomas Gaspar, Vice President Quality Assurance Manufacturing & Development Support, West Pharmaceutical Services*

**End of Day Two : 5:30 PM**

## Day Three — Wednesday, November 8, 2006

### *Networking and Continental Breakfast (7:00-8:00 AM)*

#### **Opening of Day 3**

Welcome, Recap of Day 2 and Introduction to Day 3

8:00-8:05 AM

*Terrence Tougas, Ph.D., Highly Distinguished Scientist, Boehringer Ingelheim*

#### **Keynote for Day 3**

8:05-8:35 AM

*Igor Gonda, President & CEO, Aradigm Corp.*

#### **Recap of Day 2**

- **8:35-8:50 AM** Track D Breakout Session  
Feedback  
*S.C. Nichols, New Technology Coordination Manager, sanofi-aventis*
- **8:50-9:05 AM** Track E Breakout Session  
Feedback  
*J. David Christopher, Associate Director, Statistics, Schering-Plough*
- **9:05-9:20 AM** Track F Breakout Session  
Feedback  
*Barbara A. Falco, Executive Director, QA, Kos Pharmaceuticals, Inc.*

### *Refreshment and Networking Break (9:20-9:30 AM)*

#### **Morning Plenary Session: International Perspectives**

*Session Moderator: Ray A. Ormiston, Ph.D., Director, CMC Regulatory Affairs, GlaxoSmithKline*

#### **Canadian Approach to Regulation of OINDP**

9:30-9:50 AM

*Caroline Vanneste, Project Manager, Good Review Practices, Health Canada*

#### **European Approach to Regulation of OINDP**

9:50-10:10 AM

*Diana van Riet, Principal Assessor, CFB, RIVM*

#### **Industry Perspectives on OINDP Regulatory Challenges in a Global Environment**

10:10-10:30 AM

*Ray A. Ormiston, Ph.D., Director, CMC Regulatory Affairs, GlaxoSmithKline*

#### **International Roundtable: Industry, FDA, EMEA, Health Canada**

10:30-11:30 AM

Panel:

*Ray A. Ormiston, Ph.D. Director, CMC Regulatory Affairs, GlaxoSmithKline*

*Caroline Vanneste, Project Manager, Good Review Practices, Health Canada*

*Diana van Riet, Principal Assessor, CFB, RIVM*

*Jon Clark, Associate Director for Policy Development, CDER, Food & Drug Administration*

*Michael J. James, Head of CMC Regulatory Advocacy & Intelligence, GlaxoSmithKline*

*Robert G. Baum, Ph.D., Head, Office of Global Regulatory CMC Policy, Pfizer*

### *Luncheon (11:30 - 12:30 PM)*

#### **Afternoon Plenary Session: Development of Inhalation Products for Systemic Application**

*Session Moderator: David Cipolla, Senior Director of Pharmaceutical Sciences, Aradigm*

#### **Regulatory Challenges**

12:30-1:00PM

*Sally Seymour, MD, Medical Officer, FDA*

#### **Case Study 1: Development of Inhaled Insulin for Diabetes**

1:00-1:30 PM

*Nancy J. Harper, Ph.D., Research Fellow, Pfizer*

**Case Study 2: Systemic Delivery of Small Molecules via the Lungs**

1:30-2:00 PM

*Tunde Otulana, M.D., Senior Vice President,  
Development, Aradigm***Q&A on Systemic Delivery**

2:00-2:30 PM

**Panel:***David Cipolla, Senior Director of Pharmaceutical  
Sciences, Aradigm**Sally Seymour, MD, Medical Officer, FDA**Nancy Harper, Research Fellow, Pfizer**Tunde Otulana, M.D., Senior Vice President,  
Development, Aradigm**Peter R. Byron, Ph.D., Professor and Chairman,  
Pharmaceutics, Virginia Commonwealth University**Igor Gonda, President & CEO, Aradigm***Concluding Remarks**

2:30 - 2:40 PM

*Liuda Shtohryn, PharmD, Director, CMC  
Regulatory Affairs, AstraZeneca***End of Conference : 2:40 PM**