

# 2008 IPAC-RS CONFERENCE

Monday – Wednesday, September 22-24, 2008  
(<http://ipacrs.com/ipac2008.html>)

North Bethesda, Maryland, USA,  
Bethesda North Marriott Hotel & Conference Center  
(<http://cwp.marriott.com/wasbn/ipacrs/>)

“Doing the Right Thing”  
in the **Changing Culture**  
of Design and Development of  
Inhalation and Nasal Drug Products:  
**Science, Quality,  
and Patient-Focus**



## IPAC-RS 2008 Conference Organizing Committee:

Jackie Schumacher, Chair, Pfizer  
Mary Devlin Capizzi, Drinker Biddle & Reath  
Don Chambers, Schering-Plough  
Dave Christopher, Schering-Plough  
David Cipolla, Aradigm

Claire D'Abreu-Hayling, Teva  
Barbara Falco, Abbott  
John Hart, Pfizer  
Steve Horhota, Boehringer Ingelheim  
Frank Koppenhagen, Teva

Kathy Ledoux, 3M  
Ray Ormiston, GlaxoSmithKline  
Andy Rignall, AstraZeneca  
Brett Thompson, sanofi-aventis  
Cheryl Rogerson, Novartis

MONDAY, SEPTEMBER 22, 2008

Focus: Product Development Paradigm Shift: How Far Have We Come?

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8:30 – 9:30 AM

Registration and Continental Breakfast

9:30 – 9:45 AM

Welcome, Introduction to IPAC-RS and Overview of Conference

**Jackie Schumacher**, Chair,  
IPAC-RS Conference Organizing Committee  
Research Fellow, Global CMC, Pfizer

9:45 – 10:15 AM

Keynote Address  
Embracing Challenges & Opportunities to Enhance Quality of Orally Inhaled and Nasal Drug Products (OINDP)

**James Spavins**, Vice President,  
Pharmaceutical Sciences/PGM, Global CMC, Pfizer

## Morning Plenary Session

[The Evolving Regulatory Landscape](#)

Focus: The essence and implications of recent regulatory developments. A review and analysis of new and updated guidances, changes in EU variation legislation and ICH guidelines with the focus on the broader industry context.

10:15 – 11:00 AM

[Quality by Design and OINDP: Setting the Stage](#)

**John C. Berridge**, Ph. D.  
European Regulatory Affairs Advisor, ISPE

11:00 – 11:30 AM

[Break & Poster Session](#)

11:30 – 12:30 PM

[Lessons Learned from Implementation of ICH Q8, Q9 and Q10 – Regulatory Agency Perspectives](#)

Session Moderators:

**Bill Paulson**, Editor-in-Chief, International Pharmaceutical Quality (IPQ)  
**Carol DeSain**, President, The Tamarack Group

Panelists:

**John C. Berridge**, Ph. D., European Regulatory Affairs Advisor, ISPE  
**Michael Golden**, Vice President,  
Regulatory Affairs and Quality, Pearl Therapeutics  
**Chris Marriott**, Emeritus Professor of Pharmaceutics, King's College London  
**Moheb Nasr**, Ph.D., Director, Office of New Drug Quality Assessment, CDER, FDA  
**Krishnan Tirunellai**, Ph.D, Senior Scientific Advisor, Therapeutic Products Directorate, Health Canada

12:30 – 1:30 PM

[Lunch & Poster Session](#)

1:30 – 2:00 PM

[Patient Perspectives](#)

Alpha-1 Foundation  
**John W. Walsh**, President and CEO

## Afternoon Plenary Session

[The Evolving Regulatory Landscape: Application to OINDP](#)

Focus: Changes in OINDP regulatory landscape based on recent regulatory guidances (ICH, EU, US, and Canada), legislation, updates to medical device directive, GHTF, ISO standards, risk management. Considerations for communicating process knowledge to regulatory authorities.

2:00 – 3:00 PM

[Evolving Regulatory Developments](#)

**Stefan Leiner**, Ph.D., CMC Expert, Boehringer Ingelheim

3:00 – 3:30 PM

[Break & Poster Session](#)

3:30 – 4:00 PM

[Role of Standards in Drug and Device Development](#)

Focus: This session will include an overview of the legal framework for applying voluntary consensus standards to drug products and devices. The presentation will highlight recent developments in standards development as well as current challenges and opportunities.

**Pat A. Picariello**, J.D., CStd, Director, Developmental Operations, ASTM

4:00 – 5:00 PM

[Application of Evolving Regulatory Landscape to OINDP](#)  
– Panel Discussion

Focus: This panel will discuss regulations impacting OINDP. Industry and regulator panelists will provide timely and practical perspectives in a lively and interactive exchange.

Session Moderator:

**Michael Golden**, VP, Regulatory Affairs and Quality, Pearl Therapeutics

Panelists:

**John C. Berridge**, Ph. D., European Regulatory Affairs Advisor, ISPE  
**Blair Fraser**, Ph.D., Director, Division of Pre-Marketing Assessment 1, FDA  
**Sabina Hoekstra-van den Bosch**, Pharm.D., Senior Advisor, Ministry of Health, Welfare and Sport, Directorate of Pharma Affairs and Medical Technology, The Netherlands  
**Stefan Leiner**, Ph.D., CMC Expert, Boehringer Ingelheim  
**Joseph Lim**, Ph.D., Pharmaceutical Assessor, MHRA

5:00 PM

[Closing](#)

**Jackie Schumacher**, Chair, IPAC-RS Conference Organizing Committee

5:15 – 7:00 PM

[Reception](#)

TUESDAY, SEPTEMBER 23, 2008

## Focus: OINDP Lifecycle – Current Approaches and Challenges

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8:00 – 9:00 AM

Continental Breakfast

9:00 – 9:15 AM

Day 2 Overview

**Barbara Falco**, Executive Director of Quality, Global Pharmaceutical Operations, Abbott Laboratories

9:15 – 9:45 AM

Keynote Presentation

Changing the Culture: Why Walking the Green Walk Globally Matters

**Paul F. Narog**

Manager, Environmental Operations, 3M

### Morning Plenary Session

The Emerging Importance of Environmental Stewardship

Focus: Intensification of corporate practices that meet environmental objectives in pharmaceutical as well as other industry sectors. A review of existing collaborative efforts among FDA, EPA and pharmaceutical manufacturers to encourage green chemistry and engineering. An industry dialogue on environmental issues and green practices.

9:45 – 10:30 AM

Potential for Green Chemistry and Green Engineering in OINDP: Design for Environment

Presenters:

**Sharon Austin**, Green Engineering Program, EPA, Office of Pollution Prevention and Toxics, Economics, Exposure and Technology Division

**David J. C. Constable**, Ph.D., Director, EHS Product Stewardship, GSK

**Berkeley Cue, Jr.**, Ph.D., Independent Consultant on Green Chemistry & Green Engineering

**Chris Watts**, Ph.D., Standards and Technology Team, FDA

10:30 – 11:00 AM

Break & Poster Session

11:00 AM – 12:00 PM

Industry Roundtable Discussion: Green Product Development is Good Business - Highlighting Industry's Best Green Practices

Moderator:

**Barbara Falco**, Executive Director of Quality, Global Pharmaceutical Operations, Abbott Laboratories

Panelists:

**Paul J. Atkins**, Ph.D., Chief Operating Officer and President, Oriel Therapeutics, Inc.

**David J. C. Constable**, Ph.D., Director, EHS Product Stewardship, GSK

**Joanne Jaeger**, PE, CIH, Director, WW EHS Programs, Ortho Clinical Diagnostics, A Johnson & Johnson Company

**Paul F. Narog**, Manager, Environmental Operations, 3M

**Elizabeth C. Girardi Schoen**, Sustainability Executive

12:00 – 1:00 PM

Lunch & Poster Session

1:00 – 1:30 PM

Patient Perspectives

Allergy & Asthma Network - Mothers of Asthmatics

**Nancy Sander**, President and Founder

### Afternoon Plenary Session

1:30 – 4:30 PM (includes break and poster session 3:15-3:45 PM)

Design Control for Orally Inhaled and Nasal Drug Products (OINDP)

Focus: An interactive session providing key insights into design control and development of OINDP devices. This session will include a professional's eye-view on current requirements in design control and a fascinating OINDP Case Study. A highlight of the session will be real-time interactive polling on device design followed by a panel discussion on the polling results, as well as questions from the attendees.

Moderator

**John Hart**, Ph.D., Pfizer

Panelists:

**Guillaume Brouet**, Director, Business Development Pulmonary, Valois SAS

**Tim Chesworth**, Team Manager - Packaging & Devices, AstraZeneca

**David Christopher**, Associate Director, Statistics, Schering-Plough

**Paul Lafferty**, Principal Consultant, Quintiles Consulting

4:30 – 5:00 PM

Practical Perspectives in the Application of QbD to OINDP

**Dave A. Parkins**, Ph. D., Director DPI Product Development, GlaxoSmithKline

5:00 PM

Closing

**Barbara Falco**, Executive Director of Quality, Global Pharmaceutical Operations, Abbott Laboratories

WEDNESDAY, SEPTEMBER 24, 2008

Focus: Development throughout the OINDP Lifecycle –Future Opportunities

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7:30 AM – 8:15 AM

Continental Breakfast

8:15 – 8:30 AM

Day 3 Overview

**Don Chambers**, Ph.D., Senior Director,  
Respiratory Product Development, Schering-Plough

8:30 – 9:00 AM

Keynote Address

Future Opportunities in OINDP Development

**Paul Hucke**, Ph.D., Senior Vice President,  
Global Regulatory Affairs, GlaxoSmithKline

## Morning Plenary Session

Opportunities for Enhancing and Progressing OINDP Product Quality

Focus: Discussion of “incremental” factors influencing and advancing the quality of OINDPs: importance of positive supplier relationships, holistic approach to specification development, and analytical method optimization.

9:00 – 9:40 AM

Lessons Learned from Other Industries

Overcoming Supplier-Manufacturer Challenges: Perspectives from Toyota North America and ArvinMeritor, LVS

**Dennis Cuneo**, Formerly, Senior Vice President, Toyota NA,  
**Sherry Welsh**, Vice President, Global Sales & Marketing,  
ArvinMeritor, LLC

9:40 – 10:10 AM

QbD & Manufacturer-Supplier Partnerships

**Barbara Falco**, Executive Director of Quality, Global  
Pharmaceutical Operations, Abbott Laboratories

**Jo Ward**, Quality Systems Manager, Bepak

10:10 – 10:30 AM

Break

10:30 – 11:00 AM

Case Study: Optimization of Cascade Impactor Methods—The AIM (Abbreviated Impactor Measurement) Concept

**Jolyon Mitchell**, Ph.D., Scientific Director, Trudell Medical

11:00 AM – 11:30 AM

Lifecycle Approach to Specification Setting

**David Christopher**, Associate Director,  
Statistics, Schering-Plough

11:30 AM – 12:00 PM

Patient Perspectives

Cystic Fibrosis Foundation

**Suzanne R. Pattee**, J.D., Vice President of Regulatory and  
Patient Affairs

12:00 – 1:00 PM

Lunch

## Afternoon Plenary Session

OINDP Development and Regulation - Future Directions

Focus: Future Quality-by-Design opportunities, including considerations for clinical trial designs linking to critical quality attributes; and presenting and communicating pharmaceutical development information to regulatory authorities. Panelists will discuss key industry QbD initiatives and how best to develop and manufacture OINDP in a risk-based environment.

1:00 – 2:15 PM

Application of QbD to Clinical Trial Design for OINDP: Regulatory CMC & Clinical Perspectives

Moderator: **Don Chambers**, Ph.D., Senior Director,  
Respiratory Product Development, Schering-Plough

Panelists:

**Wallace P. Adams**, Ph. D., Pharmacologist, Science Team, Office of  
Generic Drugs, FDA

**Badrul Chowdhury**, M.D., Ph.D., Director, Division of Pulmonary and  
Allergy Drug Products, FDA

**Kenneth J. Furnkranz**, Chemist, Office of Generic Drugs, FDA

**Joseph Lim**, Ph.D., Pharmaceutical Assessor, MHRA

**Prasad Peri**, Ph.D., Pharmaceutical Assessment Lead, Division of  
Pre-Marketing Assessment 1, FDA

**Jun Zhang**, M.D., MPH, A/manager, Allergy and Respiratory Drugs  
Division (ARDD), Health Canada

2:15 – 2:45 PM

Clinical Relevance of Aerosol Quality Attributes:

Exubera Case Study

**Nancy Harper**, Ph.D., Research Fellow, Parenteral Center of Emphasis,  
Pfizer

2:45 – 4:00 PM

Moving Towards the Desired State

Roundtable: Regulatory and Industry Perspectives, including Status  
of Industry Trade Group QbD Efforts

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

Panelists:

**Sabina Hoekstra-van den Bosch**, Pharm.D., Senior Adviser, MoHWS,  
Directorate of Pharmaceutical Affairs and Medical Technology, The Netherlands

**Chuck Hoiberg**, Ph.D., Executive Director, Pfizer, Vice Chair, ISPE International  
Board of Directors

**Richard Levy**, Ph.D., Senior Vice President Scientific and Regulatory Affairs,  
Parenteral Drug Association (PDA)

**Joseph Lim**, Ph.D., Pharmaceutical Assessor, MHRA

**Rik Lostritto**, Ph.D., Director, Division of Pre-Marketing Assessment III &  
Manufacturing Science, ONDQA, CDER, FDA

**Reggie Saraceno**, Chair, Development Technical Committee, Product  
Quality Research Institute (PQRI), Senior Associate Director, Analytical Sciences,  
Boehringer Ingelheim Pharmaceuticals Inc.

**Terrence Tougas**, Ph.D., Chair, IPAC-RS Board of Directors, Highly  
Distinguished Scientist, Boehringer Ingelheim

4:00 PM

Recap and Closing

**Jackie Schumacher**, Chair, IPAC-RS Conference Organizing Committee