

# IPAC-RS 2006 Conference

## Inhalation & Nasal Drugs: The Regulatory Landscape



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# Welcome Address

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# Overview

- Welcome
- Acknowledgements
- IPAC-RS Background
- OINDP Regulatory Environment
- Housekeeping
- Introduction to Day 1

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# WELCOME



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# ACKNOWLEDGEMENTS



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## Acknowledgements

- IPAC-RS Board of Directors
- Conference Faculty
- FDA
- Conference Participants
- IPAC-RS Conference Planning Committee
- IPAC-RS Secretariat
- Dede Godstrey

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# IPAC-RS BACKGROUND



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## IPAC-RS Background

- **Mission:** to advance consensus-based and scientifically driven standards and regulations for OINDP
- **Purpose:** to improve public health by facilitating the availability of safe, effective, and quality OINDP
- IPAC-RS seeks to:
  - provide the OINDP Industry with a forum for discussion and development of science-based best practices for OINDP

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## IPAC-RS Current Members

- Aradigm
- AstraZeneca
- Boehringer-Ingelheim
- GlaxoSmithKline
- Kos
- Nektar
- Novartis
- Novo Nordisk
- Pfizer
- sanofi-aventis
- Schering-Plough
- Teva

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## Evolution of IPAC-RS Focus

- Original IPAC-RS topics were chosen in response to US guidances and standards published in the late 1990s
- Current IPAC-RS activities focus on
  - proactively affecting the regulatory environment for OINDP
  - constructively contributing to new and emerging international regulatory initiatives impacting OINDP

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## IPAC-RS Conference Plan

### 1<sup>st</sup> Day:

- Quality by Design (QbD) for OINDP

### 2<sup>nd</sup> Day:

- QbD Approach to OINDP Projects / Attributes

### 3<sup>rd</sup> Day:

- International Perspectives on QbD
- Inhaled Products for Systemic Application

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## IPAC-RS Conference Goals

- Stimulate constructive dialogue between the OINDP industry, regulators, and others
- Explore the new FDA paradigm of QbD as applicable to OINDP
- Learn together how to promote best scientific and regulatory practices for OINDP

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# OINDP REGULATORY ENVIRONMENT



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## Growing Importance of Inhaled Drugs

- Nasal and pulmonary delivery of drugs has well-recognized advantages over conventional drug delivery routes:
  - Fast onset of action
  - Avoidance of hepatic clearance
  - Avoidance of GI digestion of proteins
  - Improved convenience and compliance
- Scope of indications is increasing, and includes:
  - Asthma
  - COPD
  - Migraine
  - Osteoporosis
  - Pain
  - Diabetes
  - Allergies
- Sophisticated technology platforms are available and are being developed

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## Challenges and Opportunities

- OINDP are complex combination product dosage forms, and continue to increase in complexity and sophistication, providing patients with a range of potential new therapies
- Regulatory environment for OINDP continues to evolve, providing new opportunities

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## Quality by Design

- Is critical to the continuing evolution of pharmaceutical product quality understanding and regulation
- Underlies the drive toward better and more science-based approaches to pharmaceutical development, manufacturing, control and regulatory decision-making
- Provides the OINDP industry, IPAC-RS, and regulatory authorities with important opportunities and challenges
  - Complexity of OINDP means that applying QbD is also more complex than for traditional dosage forms
  - QbD can also be a powerful tool to rationalize development and regulation of OINDP

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# HOUSEKEEPING



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## Housekeeping

- Presentations and breakout summaries will be posted on the IPAC-RS website shortly after the Conference
- IPAC-RS Board members can be easily identified by their blue ribbons attached to their Conference name tags
- IPAC-RS Secretariat team is available to help

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# INTRODUCTION TO DAY 1



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## Overview of Day 1

- Opening Plenary Lecture: Challenges and Opportunities for FDA and OINDP Industry
- Plenary Sessions:
  - Evolving US Regulatory Environment – The Transition from Old to New FDA Paradigm for OINDP
  - New Regulatory Initiatives and their Relationship to OINDP Development and Regulation
- Breakout Sessions: Modern Regulatory Approaches to OINDP

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Carpe diem!

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## Challenges and Opportunities for FDA and OINDP Industry

Helen N. Winkle  
Director, Office of Pharmaceutical Sciences  
CDER, FDA



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