



Workshop on Extractables and GMP for Components of OINDP

24-25 September 2007

Basel, Switzerland



Welcome!



Cheryl Stults, Nektar
Co-Chair, IPAC-RS OINDP Materials Working
Group

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IPAC-RS: International Pharmaceutical Aerosol Consortium on Regulation and Science

- **1989:** International Pharmaceutical Aerosol Consortium (IPAC) formed to address regulatory consequences for MDIs of Montreal and Kyoto Protocols
- **1999:** IPAC formed a Working Group to prepare comments on the FDA draft CMC Guidances for MDIs, DPIs, Nasal Sprays, and Inhalation Solutions/Suspensions
- **2001:** International Pharmaceutical Aerosol Consortium for Regulation and Science (IPAC-RS) formed as a separate Consortium
 - **IPAC-RS Mission:** To advance consensus-based and scientifically driven standards and regulations for inhaled and nasal drug products (OINDP)
 - **IPAC-RS Goal:** Development of scientifically justified regulatory approaches for orally inhaled and nasal drug products

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IPAC-RS Member Companies



3M	Novartis
Abbott	Novo Nordisk
Aradigm	Pfizer
AstraZeneca	sanofi-aventis
Boehringer Ingelheim	Schering-Plough
GlaxoSmithKline	Teva
Nektar Therapeutics	

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Supplier Quality Control and Materials Working Groups

- IPAC-RS Supplier Quality Control Working Group
 - Supplier GMP and quality systems
- IPAC-RS OINDP Materials Working Group
 - Technical expectations for materials
- Overarching mission:
 - Product Quality
 - Patient Safety

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Workshop Objectives

- Foster dialogue and advance understanding among pharma and suppliers on GMP and technical expectations for OINDP materials supply
 - Discuss the organization, application, and use of the IPAC-RS GMP Guideline
 - Discuss technical challenges and expectations regarding evaluation of materials for OINDP

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Overview of Workshop

- Extractables in Materials for OINDP: Challenges and Perspectives
- The IPAC-RS GMP Guideline for Suppliers: Use and Application
- Regulatory Perspectives
- Extractables Throughout the Product Lifecycle
- Supplier-Pharma Relationship
- Quality by Design
- Why Supply to the OINDP Industry?

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Active Participation

- Ask Questions
- Provide Feedback
- Share Experiences



Thank You!

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