



OINDP Supplier GMP Workshop: Using the IPAC-RS GMP Guideline

14 February, 2007

Chicago, IL



Welcome!



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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 QC Working Group

- One of first IPAC-RS Working Groups
 - Initially addressed all topics related to component quality. Now focuses on GMP at component suppliers
 - Leachables and Extractables then spun off as a separate topic and later addressed by Product Quality Research Institute (PQRI)
 - PQRI L&E Working Group has issued specific recommendations regarding extractables and leachables control, testing, and thresholds
- OINDP suppliers were invited to join the Supplier QC Working Group. Current supplier members:

Valois 

WEST *Pharmaceutical*
SERVICES 

REXAM

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Working Group Mission

- To encourage quality through design rather than through testing and enable the provision of consistently high quality OINDP components by promoting the implementation of robust quality systems at OINDP component manufacturers
- To simplify the quality control process by promoting harmonized quality standards for OINDP components

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Working Group Objectives

- p** Survey OINDP Suppliers and Manufacturers to determine:
 - Whether a quality guideline for OINDP suppliers is needed
 - If so, what topics this guideline should address
- p** Develop guideline for OINDP component suppliers
- à** Conduct education/training for OINDP manufacturers and their suppliers on use of the GMP Guideline
- q** Consider development of an auditing service or certification of suppliers against the GMP Guideline



Overarching Objectives

Product Quality
Patient Safety



Workshop Objectives

- Understand the organization, application, and use of the IPAC-RS GMP Guideline
- Understand how to apply the Guideline to your processes and products and use it to foster process improvements (Suppliers)
- Understand how to use the Guideline as a tool for communicating with and auditing your suppliers (OINDP Manufacturers)



Overview of Day

- Regulatory Framework, Use, and Application of the IPAC-RS Guideline
- Auditing Against the Guideline
- Using the Guideline to Improve your Quality Systems
 - Extractables
 - Component/Equipment Cleaning
 - Change Control
 - Quality Agreements
 - Control of Suppliers and Sub-contractors



Active Participation

- Ask Questions
- Provide Feedback
- Share Experiences



Thank You!