



OINDP Supplier GMP Guideline Training Course

28 May 2008

Maidenhead, UK



Welcome!



Barbara Falco, Abbott
Chair, IPAC-RS Supplier QC Working Group



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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3



IPAC-RS Member Companies



3M	MannKind Corp
Abbott	Nektar Therapeutics
Aradigm	Novartis
AstraZeneca	Pfizer
Boehringer Ingelheim	sanofi-aventis
Chiesi	Schering-Plough
GlaxoSmithKline	Teva

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4



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:



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5



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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6



Working Group Objectives

- Survey OINDP Suppliers and Manufacturers to determine:
 - Whether a quality guideline for OINDP suppliers is needed
 - If so, what topics this guideline should address
- Develop guideline for OINDP component suppliers
- Conduct education/training for OINDP manufacturers and their suppliers on use of the GMP Guideline

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7



Overarching Objectives

Product Quality
Patient Safety

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8



The IPAC-RS GMP Guideline

- 3-in-1 Guideline with global applicability:
 - ISO 9001:2000
 - PS 9000:2001
 - IPAC-RS GMP Guideline
- Provides tools to achieve and maintain compliance with GMP
 - In alignment with 21 CFR 210-211 and 820
 - Based on ANSI/ISO/ASQ
 - Serves as a framework to address component quality, control of suppliers, consistency within the industry

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9



The IPAC-RS GMP Guideline

- Applies to n-1 suppliers of components for OINDP not regulated by FDA or other device regulations, e.g., canister, reservoir, actuator, pump, etc.
- n-2 and n-3 suppliers who supply to n-1 suppliers are encouraged to read and follow guideline

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10



Benefits of the Guideline

- Regulators:
 - More confidence in OINDP container closure system and device components
- Pharma:
 - Consistent, high quality components
 - Better relationship with suppliers
 - Fewer supply chain events
- Suppliers:
 - Clear understanding of customers' expectations
 - More consistent expectations and audits
 - Better relationship with customers
 - Improved quality systems

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11



Key Sections of Guideline

- OINDP Components/Sub-components
- Quality Unit
- Change Control
- Supply/Quality Agreements & Specifications
- Control of Suppliers and Sub-contractors
- Design and Development Planning
- Monitoring & Measurement of Product
- Contamination Control & Cleaning

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12

● ● ● | Use of Guideline: General Principles

- Review
- Assess
- Train
- Communicate
- Ask Questions
- Goals are
 - Consistently high quality OINDP components
 - Clear, uniform quality standards for OINDP suppliers

● ● ● | Training Course Objectives

- Provide practical and in-depth information on how to:
 - Apply the IPAC-RS GMP Guideline to processes and products
 - Use the Guideline as a tool for communicating with and auditing your suppliers



Overview of Day

- Practical Application: Quality and Technical Aspects of Agreements
- Change Control
- Extractables
- Process Controls
- Developing a Roll-out Plan



Some Terminology

n

Pharmaceutical company (i.e.,
manufacturer of final drug product)

n-1

Supplier of component to
pharmaceutical company

n-2

Supplier to n-1

Etc...



Active Participation

- Ask Questions
- Provide Feedback
- Share Experiences



Thank You!

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17