


Why Supply to the OINDP Industry?

Barbara Falco
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Symposium for Suppliers and Pharma
Manufacturers
13 February 2007



Overview

- n Context
- n Challenges
- n Benefits
- n Case Study
- n Questions

2



Context

- n Pharma industry and regulatory bodies have high expectations for quality of orally inhaled drug products and component parts
 - .. In many cases, delivery of drug directly to compromised lung
 - .. The effectiveness of the delivery device is critical
 - .. Control of extractables from components considered high priority for inhalation products*

* Guidance for Industry, Container Closure Systems for Packaging Human Drugs and Biologics, Chemistry, Manufacturing and Controls Documentation, FDA, 1999

3



Context

- n Quality by Design FDA initiatives
 - .. Seek to strengthen links between quality, and safety and efficacy
 - .. **Build quality into product, rather than testing quality into product**
- n This means suppliers play a critical role in achieving quality by design for OINDP

4



Examples of Challenges for Suppliers to OINDP Industry

- n Provide information on all known changes to formulations (change control and notification)
- n Submission of DMF
- n Extensive quality agreements
- n Extractables knowledge and control
- n Foreign particles control (primarily for n-1 suppliers)

5



Challenges = Opportunities!

- n Improved GMP compliance and technical expertise
- n Develop reputation for quality products
- n Develop strong communication and close relationship with pharma customers
- n Advance GMP and technical knowledge internally
- n Increase range of potential customers (potential for more business!)

6



Synergy with Other Industry Sectors

- n Number of dosage forms deal with issues similar to those faced by the OINDP industry
 - Stand Alone Devices
 - Parenterals
 - Ophthalmics
 - Dermatological products
- n If your product and processes meet the requirements for OINDP components, you will likely meet the requirements for other pharma and device components

7




OINDP Supplier Case Study Discussion

8



THANK YOU

9



QUESTIONS
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10