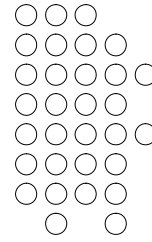
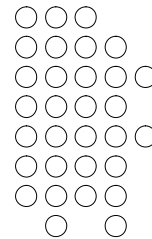


ISO Standards

Session Moderators:
Steve Nichols (sanofi-aventis)
Hal Yeager (Lilly)
Ann Graham (FDA)



Highlights from Discussions

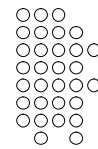




Knowledge about ISO

- | About half of the attendees knew about the development of these ISO standards
- | Many attendees familiar with other ISO approaches

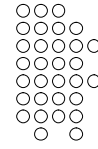
3



Issues Raised

- | Do we really need these ISO standards?
 - | Aren't these products already well-regulated?
 - | Isn't there a risk for redundancy with respect to existing regulations?
 - | How does it relate to the EU device directive?
- | How do you ensure that these two standards are as consistent as possible since nebulizers and OINDPs are not fundamentally different?

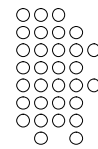
4



Issues Raised (II)

- | Shouldn't methods be included in the pharmacopeias rather than in these standards?
 - | Most attendees believe that the methods should be in the pharmacopeias
- | What are the expected timelines on activities to come?
 - | Three years to accomplish the task
 - § Inhaler Standard (January 2008)
 - § Nebulizers (January 2009)

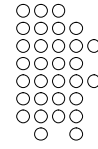
5



Issues Raised (III)

- | How was the statistical assessment decided?
 - | Based on TC84 family of standards, but also is based on the risk assessment outcomes
- | Standard lays out the minimum requirements but the risk assessment may indicate more is needed

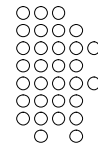
6



Issues Raised (IV)

- | Concept of performance profile in the inhaler standard did not cause any concern
- | Do the ISO standards have retroactive applicability?

7



Interested in Getting Involved?

- | Email Ann Graham:

isotc121sc2@gmail.com

8