

IPAC-RS Conference
6-8 November 2006

Breakout Session Track F Feedback Supplier Quality Control

Session Moderators:

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Feedback - Communication

- ÿ Communication and trust are key
 - Ø Pharma needs to define requirements and needs for supplier
 - Ø Supplier needs to define capabilities for customers
 - Determine if/how to address any gap between requirements and capabilities
 - Ø Need change in attitude – suppliers and pharma need to meet each other on same level
 - Sharing Risks and Critical Information
 - Ø Pharma companies can learn from suppliers as well – take initiative to ask your suppliers about their processes and product knowledge
 - Ø One useful tool suggested: yearly quality meeting with suppliers

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Further Feedback & Clarifications

- Ÿ Device world has been successful in dealing with supplier quality for some time – maybe pharma can learn from device colleagues (may not be able to adopt all aspects)
 - Ø More open to changes that result in quality improvements
- Ÿ Suppliers – It is not necessary to implement QbD in order to have a strong QMS
- Ÿ OINDP Manufacturers – need to embrace use of Guideline. Company-specific requirements should go into technical or quality agreements
- Ÿ QMS is the infrastructure; QbD is a component of QMS

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