



Closing Remarks

Barbara Falco, Abbott

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Take-Home Points

- OINDP components are critical to the quality and performance of OINDP
- The IPAC-RS GMP Guideline is intended to harmonize and clarify quality expectations for OINDP component suppliers
- Suppliers should use the Guideline as an internal guide to help improve quality systems, *i.e.*, for internal audit, audit preparation, and to demonstrate commitment to meeting required quality standards
- IPAC-RS expects that OINDP manufacturers will begin using the Guideline as an auditing standard
- Suppliers and OINDP manufacturers must communicate

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Benefits of Using 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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Benefits of Using the Guideline

- Patients:
 - Better products



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Next Steps

- Continued education/dissemination of information about IPAC-RS Guideline
- Considering incorporation of IPAC-RS Guideline into next version of ISO 15378
- Workshop at RDD Europe (April 17-20 2007, Paris France)

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Feedback? Comments? Questions?



Please direct them to Melinda Munos
(melinda.munos@dbr.com) or Dede
Godstrey (dede.godstrey@dbr.com)
at the IPAC-RS Secretariat



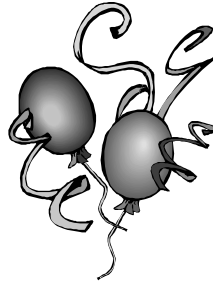
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THANK YOU!

For attending and being engaged
in the process



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THANK YOU

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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 Members of Supplier QC Working Group



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IPAC-RS Supplier QC Working Group

Boehringer-Ingelheim	Ray Oksala	Presspart*	Bert Calvert Susan Hall Annette Thompson
Eli Lilly*	Ben Dai Marcia Arentz	Rexam	Philippe Pitard Christian Meusinger
Abbott	Barbara Falco, Chair	Schering-Plough	Michael Lusty*
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Novartis	Rainer Frueh	West	Fran DeGrazio Tom Gaspar
Novo Nordisk	Lisa Erdös	*Former WG members	
Sanofi-Aventis	Linda Nield		
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Reviewers

- FDA
- PQG
- OINDP Suppliers
 - 3M
 - Bepak
 - Honeywell
 - Kinetics
 - Pfeiffer
 - Presspart
 - West
 - Valois

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