

**IPAC-RS SUPPLIER
QC GUIDELINE
TRAINING SESSION
28 MAY 2008
8:30 AM - 3:00 PM**

Hosted by Abbott Laboratories
Abbott House
Vanwall Business Park - Vanwall Road
Maidenhead UK SL6 4XE

8:00 am - 8:30 am	Check-In and Continental Breakfast	
8:30 am - 8:45 am	<p>I. Introduction and Background Introduction and background to IPAC-RS, The Supplier QC Working Group and the GMP Guideline. Barbara Falco, Abbott</p>	
8:45 am - 9:45 am	<p>II. Developing Quality Systems to Supply to OINDP: Practical Applications of the Guideline Practical application and demonstration of the GMP Guideline through use of supplier-pharma agreements.</p>	
	<p>8:45 am - 9:15 am A. Quality Aspects of an Agreement Thomas Haselwander, Novartis</p>	<p>9:15 am - 9:45 am B. Technical Aspects of an Agreement Andrew Wood, Valois</p>
9:45 am - 10:00 am	BREAK	
10:00 am - 11:00 am	<p>III. Change Control The supply chain and change control. Jim Riddell, Pfizer Rob de Jong, SABIC Innovative Plastics</p>	
11:00 am - 11:45 am	Morning Sessions Open Discussion (Panelists)	
11:45 am - 12:30 pm	LUNCH	
12:30 pm - 1:00 pm	<p>IV. Extractables Expectations for understanding extractables. Understanding the material matrix, sharing knowledge and information. Cheryl Stults, Nektar Therapeutics</p>	
1:00 pm - 1:30 pm	<p>V. Process Controls Understanding and controlling component manufacturing processes. Practical examples. Andrew Wood, Valois</p>	
1:30 pm - 2:30 pm	<p>VI. Developing a "Roll Out Plan" Supplier and Pharma perspectives on "rolling-out" the GMP Guideline: who, what and how. Andy Saunders, sanofi-aventis Jo Ward, Bepak</p>	
2:30 pm - 3:00 pm	Afternoon Sessions Open Discussion (Panelists)	
3:00 pm	Closing	