

Welcome to the PDA Interest Group Quality Systems!

As usual for any PDA Interest Group, we come together once annually in a face-to-face meeting to discuss new and current items in our specialties.

<b>INTRODUCTION</b>		
<b>10:00</b>	<b>Welcome Coffee</b>	All
<b>10:30</b>	<b>Opening of the Meeting &amp; Introduction of the IG QS EU</b>	Lothar Hartmann, <i>Phact</i>
<b>KEY NOTE PRESENTATION</b>		
<b>11:00</b>	<b>“Big Data” What does the future look like?</b>	Toni Manzano, <i>Bigfinite</i>
<b>SUB-GROUP’S FLOOR</b>		
<b>11:45</b>	<b>Comparability of ICH Q10 with ISO 9000</b>	Heribert Dahmen, <i>Merck</i>
<b>12:15</b>	<b>CPV</b>	Agnès Hardy-Boyer, <i>Sanofi-Pasteur</i>
<b>12:45</b>	<b>Lunch Break</b>	
<b>SUB-GROUP’S FLOOR</b> ( <i>contin'd</i> )		
<b>13:30</b>	<b>Process Owner</b>	Sofia van Berlekom, <i>AstraZeneca</i>
<b>14:00</b>	<b>Management Review</b>	Pia Sandau, <i>Novo Nordisk</i>
<b>WORKSHOPS SESSION</b>		
<b>14:30</b>	<b>Group 1: Does the PQS/QMS fit into the true lifecycle (ICH Q8 – 14)?</b>	Lothar Hartmann, <i>Phact</i>
	<b>Group 2: What does a QMS look like in a digitalised world?</b>	Jeremie Arrault, <i>Novartis</i> Michele Simone, <i>Bracco</i>
<b>15:30</b>	<b>Coffee Break</b>	
<b>PLENARY DISCUSSION</b>		
<b>16:00</b>	<b>Presentation and Conclusions of the Discussions from the Workshops</b>	Moderator: Lothar Hartmann, <i>Phact</i>
<b>17:00</b>	<b>End of IG Meeting</b>	

### IG Leader



**Lothar Hartmann, Ph.D.** *Managing Director, Phact GmbH*

Lothar Hartmann worked for Hoffmann-La Roche and Johnson & Johnson for more than 25 years before he became independent with ‘Phact’. Lothar served in numerous organizations such as APIC/CEFIC (Vice-Chairman), EBEs (European Biopharmaceutical Enterprises) BioManufacturing Working Group (Chair) and PDA (“Board of Directors”, Quality Systems Interest Group Chair). Lothar is co- and lead-author of various documents published by CEFIC/APIC and EBE, co-founder of PDAs “Paradigm Change in Manufacture” (PCMO; practical, hands-on application of ICH Q8 – Q11) and was part of the Expert Working Group of ICH Q7a. In this effort, he was FDA awarded in May 2004.