



Connecting a World of  
Pharmaceutical Knowledge

## WORLD CLASS SUPPLY - END TO END

13 – 14 June 2013 • Prague, Czech Republic



### ISPE Supply Chain Conference Programme Leaders:

- Esther Sadler-Williams & Chedia Abdelkafi, *Investigational Products*
- Jim McKiernan, *Supply Chain Integrity through Process Improvement*

Thursday, 13 June 2013									
08.00 – 09.00	<b>Speaker / Leader Breakfast</b>								
09.00 – 09.20	<b>Introductions and Announcements</b> <b>Overview &amp; Meeting Objectives</b> Jim McKiernan, <i>CEO</i> , McKiernan Associates Esther Sadler-Williams, <i>Senior Director</i> , Catalent Pharma Solutions Chedia Abdelkafi, <i>Head of Global CTS Planning</i> , UCB Pharma								
09.20 – 10.00	<b>Keynote Presentation followed by Q&amp;A Session</b> <i>Responding to the Challenges for Highly Responsive, Integrated Supply Chains</i> Roddy Martin, <i>Senior Vice President Supply Chain</i> , Accenture USA								
10.00 – 10.40	<b>Keynote Presentation followed by Q&amp;A Session</b> <i>An Expert Inspector's View on Current Challenges for GMP</i> Richard Andrews, <i>Exper GMP/GDP Inspector</i> , MHRA								
10.40 – 11.10	Networking Break								
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: center;"><b>CLINICAL SUPPLY CHAIN</b></th> <th style="width: 50%; text-align: center;"><b>COMMERCIAL SUPPLY CHAIN</b></th> </tr> </thead> <tbody> <tr> <td> <b>Welcome and Introduction to Investigational Products</b>            Esther Sadler-Williams, Catalent Pharma Solutions            Chedia Abdelkafi, UCB Pharma         </td> <td> <b>Welcome and Introduction to Supply Chain</b>            Jim McKiernan, McKiernan Associates         </td> </tr> <tr> <td> <b>Keynote Address: 'So What Exactly Happened To Your Shipment...?'</b>            Jason Wakelin-Smith, <i>GCP Inspector</i>, MHRA         </td> <td> <b>Keynote Address: WHAT DOES GMP REALLY MEAN? <i>The Focused Pursuit of Meeting Regulatory Compliance Standards is really not Good Enough</i></b>            Richard Andrews, <i>Operations Manager</i>, MHRA            Brendan Cuddy, <i>Scientific Administrator</i>, EMA         </td> </tr> <tr> <td> <b>Patient Survey – Interim Update</b>            Christine Milligan, ISPE Patient Survey Team         </td> <td></td> </tr> </tbody> </table>	<b>CLINICAL SUPPLY CHAIN</b>	<b>COMMERCIAL SUPPLY CHAIN</b>	<b>Welcome and Introduction to Investigational Products</b> Esther Sadler-Williams, Catalent Pharma Solutions Chedia Abdelkafi, UCB Pharma	<b>Welcome and Introduction to Supply Chain</b> Jim McKiernan, McKiernan Associates	<b>Keynote Address: 'So What Exactly Happened To Your Shipment...?'</b> Jason Wakelin-Smith, <i>GCP Inspector</i> , MHRA	<b>Keynote Address: WHAT DOES GMP REALLY MEAN? <i>The Focused Pursuit of Meeting Regulatory Compliance Standards is really not Good Enough</i></b> Richard Andrews, <i>Operations Manager</i> , MHRA Brendan Cuddy, <i>Scientific Administrator</i> , EMA	<b>Patient Survey – Interim Update</b> Christine Milligan, ISPE Patient Survey Team	
<b>CLINICAL SUPPLY CHAIN</b>	<b>COMMERCIAL SUPPLY CHAIN</b>								
<b>Welcome and Introduction to Investigational Products</b> Esther Sadler-Williams, Catalent Pharma Solutions Chedia Abdelkafi, UCB Pharma	<b>Welcome and Introduction to Supply Chain</b> Jim McKiernan, McKiernan Associates								
<b>Keynote Address: 'So What Exactly Happened To Your Shipment...?'</b> Jason Wakelin-Smith, <i>GCP Inspector</i> , MHRA	<b>Keynote Address: WHAT DOES GMP REALLY MEAN? <i>The Focused Pursuit of Meeting Regulatory Compliance Standards is really not Good Enough</i></b> Richard Andrews, <i>Operations Manager</i> , MHRA Brendan Cuddy, <i>Scientific Administrator</i> , EMA								
<b>Patient Survey – Interim Update</b> Christine Milligan, ISPE Patient Survey Team									
11.10 – 11.25									
11.25 – 12.05									
12.05 – 12.30									
12.30 – 13.30	Networking Lunch								

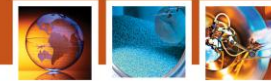
13.30 – 14.45	<b>Introduction to and Regulatory Forum</b>	<b>Pharma Café</b>	<b>Anti-counterfeiting and Supply Chain Integrity Seminars</b>	
13.30 – 15.20	<b>Experience With Managing Clinical Supplies from a Clinical Site Perspective</b> Samantha Carmichael, <i>Lead Pharmacist Clinical Trials, NHS Scotland</i>		13.30 – 14.10	<i>Temperature Controlled - Case Study on Effective Management</i> Marie Boned, <i>Expert in health products cold chain, Cemafruid</i>
			14.10 – 14.50	<i>Anti-counterfeiting</i> TBC
			14.50 – 15.30	<i>Track-and-Trace</i> Ulrike Kreysa, <i>Vice-president Healthcare, GS1</i>
15.20 – 15.50	Networking Break	15.30 – 16.00	Networking Break	
15.50 – 16.00	<b>Introduction to Workshops</b>	<b>Pharma Café</b>	<b>Information Technology Seminars</b>	
			16.00 – 16.30	<b><i>Drug Shortages - Root Causes and Solutions</i></b> Bryan Wright, <i>ISPE European Regulatory Affairs Advisor</i>
<b>Technology Transfer Seminars</b>				
16.00 – 17.00	<b>Workshop A</b>  <b>IRT standardisation from sponsor's perspective of logistics &amp; terminology, front end and site perspective</b> Nimer Yusef, <i>Consultant, Trial-Brain</i> Michael Richter, <i>GTC, Roche</i>  <b>Drug pooling and QP release - case Study and discussion</b> Henryk Junker, <i>Quality Assurance Manager, Allergan,</i> Massimo Eli, <i>Merck &amp;Co</i>  <b>Innovative Approaches to improve clinical supply chain for our users; the patient</b> Samantha Carmichael, <i>NHS Scotland,</i> Christine Milligan, <i>ISPE Patient Survey Team</i>		16.30 – 17.00	<b><i>Technology Transfer to CMOs</i></b> Morten Munk, <i>Vice President, Business Development, CMC Biologics</i>
			17.00 – 17.30	<b><i>Technology Transfer from R&amp;D to Manufacturing</i></b> Paul Bird, <i>Head of Development Engineering, Fujifilm</i>
17.00	Seminar Adjourns, Reception		17.30	Seminar Adjourns, Reception



Connecting a World of  
Pharmaceutical Knowledge

## WORLD CLASS SUPPLY - END TO END

13 – 14 June 2013 • Prague, Czech Republic



### ISPE Supply Chain Conference Programme Leaders:

- Esther Sadler-Williams & Chedia Abdelkafi, *Investigational Products*
- Jim McKiernan, *Supply Chain Integrity through Process Improvement*

Friday, 14 June 2013			
08.30 – 08.40	<b>Introductions</b> Esther Sadler-Williams, <i>Senior Director</i> , Catalent Pharma Solutions Jim McKiernan, <i>CEO</i> , McKiernan Associates		
08.40 – 09.25	<b>Keynote Presentation</b> <i>Industry Trends, and What can Pharma Learn from Other Industries?</i> Colin Terry, <i>Senior Manager</i> , Deloitte		
	<b>CLINICAL SUPPLY CHAIN</b>		<b>COMMERCIAL SUPPLY CHAIN</b>
09.30 – 09.40	<b>Introductions and Summary of day 1</b> Chedia Abdelkafi, <i>Head of Global CTS Planning</i> , UCB Bernd Steffens, <i>Head of Clinical Global Supplies Unit</i> , Boehringer Ingelheim		09.30 – 09.45 <b>Introductions and Summary of day 1</b> Jim McKiernan, <i>CEO</i> , McKiernan Associates
09.40 – 10.00	<b>Introduction to ISPE and IP COP</b> Henryk Junker, <i>Quality Assurance Manager</i> , Allergan		09.45 – 10.30 <b>Effective Supply Chain Integrity through Process Improvement</b> Heike Falkenhagen, Boehringer Ingelheim
10.00 – 10.40	<b>Ensuring Security of Clinical Supply Chain</b> Tom Cochrane, <i>Business Process Development Manager</i> , Napp		
10.40 – 11.10	Networking Break		
11.10 – 12.20	<b>Workshop B</b>  <b>Use of English -only labels on inner packs</b> Hans Heesakkers, <i>Senior Manager</i> , Accenture Karen Gram, <i>Technical Lead</i> , Novo Nordisk  <b>Perils and Pitfalls of Comparator Supply</b> Julian Schultz, <i>Associate Director Clinical Supplies</i> , Takeda		11.00 – 11.45 <b>How Well Connected is the Pharmaceutical Supply Network?</b> Nick Davies, <i>CEO &amp; Principal Consultant</i> , NDA Consultants

	Robert Donnell, <i>Head of Business Development, Durbin</i>  <b>Key Attributes of Simulation Tools</b> Damian McEntegart, <i>Senior Director, Statistics &amp; Product Support Services</i> , Perceptive Informatics Chedia Abdelkafi, <i>Head of Global CTS Planning</i> , UCB Pharma	11.45 – 12.25	<b>Temperature Controlled</b> TBC
12.20 – 13.20	Networking Lunch		
13.20 – 14.00	<b>JIT Packaging and the Role of Pooling – true flexible solutions or potential complexity drivers?</b> Helen Underwood, <i>Client Services Director</i> , Fisher	13.15 – 13.55	<b>Cargo Risk Assessment - Rx360 - Supply Chain Security</b> TBC
14.00 – 15.00	<b>Workshop C</b>	13.55 – 14.35	<b>Risk Evaluation</b> Nia Evans, <i>Head of Regulatory Affairs</i> , Celesio –invited
15.00 – 15.15	<i>Voting for themes for 2014, IP Closing remarks</i>	14.35 – 15.15	<b>Track-and Trace – Serialisation</b> Fatma Taman, <i>General Manager</i> , Pharmavision
15.15 – 15.45	Networking Break		
15.45 – 17.15	<b>PLENARY SESSION:</b>		
	<b>Regulatory Speakers - Guidelines</b> Bryan Wright, <i>ISPE Regulatory Advisor</i> (Session Chair) Tony Orme, <i>Senior GDP Inspector</i> , MHRA Brendan Cuddy, <i>Scientific Administrator</i> , EMA UK Richard Andrews, <i>Expert GMP/GDP</i> , MHRA		
17.15 – 17.30	<b>Discussion and Closing Remarks:</b> Jim McKiernan, <i>CEO</i> , McKiernan Associates Bernd Steffens, <i>Head of Clinical Global Supplies Unit</i> , Boehringer Ingelheim Chedia Abdelkafi, <i>Head of Global CTS Planning</i> , UCB Pharma		