INNOVATION + INTELLIGENCE + PASSION

INTERPHEX™ 2013

Tuesday, April 23, 2013

8:45am-9:00am	**Welcome and Introduction**				
9:00am-10:00am	Keynote: TBD 1E15-1E16				
	Regulatory QA/QC Room 1E07	**Product Development Room 1E08**	**Facility & Process Design Room 1E09**	**Manufacturing & Packaging Room 1E10**	**Supply Chain Room 1E11**
10:15am-11:15am	Current Development Best Practices for IR & MR Dosage Forms - Glenn Van Buskirk, Nonclinical Drug Development Consulting Services. LLC	Process Robustness: From Development to Life Cycle Management Richard Creekmore, AstraZeneca Pharmaceuticals	Effective Cleaning Procedure for Medical Devices Using Laboratory Studies, Elizabeth Rivera, STERIS	Risk Management of Contamination and Cross Contamination in Pharmaceutical Manufacturing - Alan Fisher, Dycem USA	How Commercial Payers Restrict the Specialty Supply Chain - Lee Goldberg, The Zitter Group
11:30am-12:30pm	Become a Better CAPA Sleuth - Walt Murray, MasterControl Inc.	The Role Of Process Analytical Technologies In The Current Quality By Design Framework - Benoit Inge, Duquesne University	Establishing a Design Space Cleaning Process Development and Validation - Keith Bader, Hyde Engineering & Consulting	Highly Potent, Poorly Soluble Product Manufacturing Contract, with 100% OTIF - Fidelma Callanan, Alkermes	Business Continuity for Biopharmaceutical Companies: Real Implementation of Operational Excellence - Dave Goswami, IPS - Integrated Project Services
12:30am - 1:30pm	**Lunch**				
1:30pm-2:30pm	Keynote: Reorganizing For the Future : Succeeding In The New Pharmaceutical Industry, Dr. Rajesh Nair, President, Indegene 1E15-1E16				
2:45pm - 3:45pm	Panel: Understanding GDUFAI - Edward Price, PCI Synthesis; Dr. Padam Bansal, Amneal Pharmaceuticals; David Gaugh, GPhA (2:45pm-4:15pm)	Regulatory Strategy For Implementation Of Qbd And Pat In A Pharmaceutical Manufacturing Environment - Carl Anderson and James K. Drennen III, Duquesne University (2:45pm-4:45pm)	Implementing Single-Use Biomanufacturing Systems into Traditional Stainless Steel-based Facilities - Jeff Odum, IPS - Integrated Project Services	Mechanical Characterization, Testing and Defect Monitoring of Tablets: A Review - Cetin Cetinkaya, Clarkson University	Commercialization Outside of the US – What Are the Challenges - Stephen Fadden, Johnson & Johnson Process Engineering
4:00pm-4:45pm			**Technical Workshop**		

Wednesday, April 24, 2013

	Regulatory QA/QC Room 1E07	**Product Development Room 1E08**	**Facility & Process Design Room 1E09**	**Manufacturing & Packaging Room 1E10**	**Supply Chain Room 1E11**	**Mini Course - Serialization 1E14**
9:00am - 10:00am	Keynote: Recalibrating The Pharmaceutical Services Opportunity , Jim Miller, President, PharmSource Information Services, Inc. 1E15-1E16					
10:15am - 11:15am	Panel: Lessons Learned: Successes and Challenges in Implementing Quality by Design - Jennifer Markarian, Pharmaceutical Technology	Combination Product Development: Drug Products for Device Companies - David Armbruster, DePuy Synthes	Design Aspects for a Bio Fill and Finish Facility - Josef Trapl, M+W Group	Biopharma's Flexible Imperative - Robert Dream, HDR COMPANY LLC	Establishing Quality Agreements with a Unified Approach for all Suppliers - Morgan Palmer, EtQ. Inc.	Manufacturing Intelligence: Serialization to improve processes - Jean-Pierre Allard, Optel Vision
11:30am - 12:30pm	Application of Quality by Design in API Process Development - Nirav Shah and Erik Johnson, Umetrics - An MKS Company;	Pharmaceutical Technology Transfer Practices into Design Control for Convergent Products - Roy Fennimore, Product & Process Scientific Solutions (P2S2) - Johnson & Johnson	Purpose-driven Design: Savings for Pharmaceutical Facilities - John Cunningham, ACi and Hank Jibaja, Nephron Pharmaceuticals	OEE Master Class: How to Increase Production Time by 20% - Adrian Pask, Vorne Industries	Supply Agreements in Pharmaceutical Outsourcing: Strengthening the Linchpin of your Outsourcing Partnership - Curtis L. Gingles, Jubilant HollisterStier Contract Manufacturing & Services	Implementing Unit - Level Serialization on a New Packaging Line - Mike Salinas, M+W US Inc.
12:30pm-1:30pm	**Lunch**					
1:30pm - 2:30pm	New Product Assessment in a Multiproduct Environment – A Risk-based Approach - Veda Walcott, Cook Pharmica LLC	Current Continuous Process Validation Program (CCVP) Following FDA Current Guidelines - Victor Hernandez, EMD Millipore	Panel: Getting Excitied about the Modular Experience! - Par Almhen, Modular Partners, Detlef Kehm, Grifols, Craig Sandstrrom, Fluor, Inc. (1:30pm-3:00pm)	Panel: Road Map to Implementing EBR - Chuck Krumwide, Malcome and Associates; David Gleeson, BMS	Managing Your Suppliers with Scorecard Metrics - Shane Yount, Competitive Solutions	Economic Impact Of Implementing A National Serialization And Traceability System - Joel Grosser, Booz Allen Hamilton; Gabrielle Cosel, Pew Charitable Trusts
2:45pm - 3:45pm				Warehouse Management Systems (WMS) - How to Achieve a Warehouse of the Future - Joe Scioscia, VAI	Securing Information as Part of the Global Supply Chain - Bikash Chatterjee, Pharmtech Associates, Inc.	Wrap Up Panel: Understanding the Complexities of Serialization - Jean-Pierre Allard, Optel Vision; Mike Salinas, M+W US Inc; Joel Grosser, Booz Allen Hamilton
4:00pm-4:45pm	**Technical Workshop**					

Thursday, April 25, 2013

9:30am - 10:30am	Case Study and Framework for Implementing the New Process Validation Guidance - Bikash Chatterjee, Pharmtech Associates Inc.
10:45am- 11:45am	Pushing the Limits: Questioning the Methodology - Jaspreet S Sidhu Ph.D., Molecular Epidemiology
12:00pm - 1:00pm	
	Conference Ends

1/30/2013