CONFERENCE-AT-A-GLANCE

Current as of 2/11/13. Schedule is subject to change. See the most current conference schedule at www.INTERPHEX.com

INNOVATION + INTELLIGENCE + PASSION
INTERPHEX™ 2013

TUESDAY, APRIL 23, 2013

8:45am-9:00am	**Welcome and Introduction**				
9:00am-10:00am	**Keynote**: Policy Recommendations for Improving Patient Access to Drugs in Shortage - Congressman Bill Cassidy M.D. (R-LA) - **1E15**				
	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
12:30pm-1:30pm	**Lunch**				
1:30pm-2:30pm	**Keynote**: Reorganizing for the Future: Succeeding In The New Pharmaceutical Industry - Dr. Rajesh Nair, President, Indegene - **1E15**				
2:45pm-3:45pm	Panel: Understanding GDUFA - Chris Verbicky, Coldstream Labs; Padam Bansal, Amneal Pharmaceuticals; Jason R. Money, GPhA, Edward Price, PCI Synthesis (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	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 - Cetin Cetinkaya, Clarkson University	Commercialization Outside the US: What are the Challenges - Stephen Fadden, Johnson & Johnson
4:00pm-4:45pm			**Technical Workshops**: Belimed, Bosch, Fette		

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**
9:00am-10:00am	**Keynote**: Recalibrating the Pharmaceutical Services Opportunity - Jim Miller, President, PharmSource Information Services, Inc. - **1E15**					
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: 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 Corporation	Panel: Getting Excited about the Modular Experience! - Sandra Lueken, Baxter Pharmaceuticals; Par Almhen, Modular Partners, Detlef Kehm, Grifols, Craig Sandstrrom, Fluor, Inc. (1:30pm-3:00pm)	Panel: Road Map to Implementing EBR - Michelle J. Alleman Adkins, Emerson; David Gleeson, BMS; Chuck Krumwiede, Malcolm and Associates	Managing Your Suppliers with Scorecard Metrics - Shane Yount, Competitive Solutions, Inc.	Economic Impact of Implementing a National Serialization and Traceability System - Joel Grosser, Booz Allen Hamilton; Gabrielle Cosel, Pew Charitable Trusts
2:45pm-3:45pm		Process Validation (PV): Designing an Effective PV Program - Mike Porter, Commissioning Agents Inc.		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 - Steven Kennedy, M+W US Inc.; Jean-Pierre Allard, Optel Vision; Mike Salinas, M+W US Inc; Joel Grosser, Booz Allen Hamilton
4:00pm-4:45pm	**Technical Workshops**: EMD Millipore Corp, GEA Process Engineering, Glatt Air Techniques, Inc, Thermo Fisher Scientific					

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**