



presents
**EXCIPIENT
FEST[®] Americas**

April 23 - 25, 2012

The Ritz Carlton Hotel
San Juan, Puerto Rico

A Two-Day Educational Experience and Pharma Expo with in-depth Workshops & Education Sessions from Industry's Top-Excipient Experts

DAY 1

Monday, April 23th

- Workshops I, II, III & IV (9AM – 5PM)

DAY 2

Tuesday, April 24th

- Keynote Speaker (8:30 – 9:15 AM)
- Educational Sessions – 10 Presentations (9:15AM – 5PM)
- Pharma Expo (9AM – 6PM)
- Poster Sessions (9AM – 6PM)
- Lunch (12AM – 1:30PM)
- Speakers' Round Table
- ExcipientFest Cocktail (5 – 7PM)

DAY 3

Wednesday, April 25th

- Keynote Speaker (9:00 – 9:45 AM)
- Educational Sessions – 10 Presentations (9:45 AM – 5:15PM)
- Workshop V (9AM – 12M)
- Pharma Expo (9AM – 5PM)
- Poster Sessions (9AM – 5:15PM Awards)
- Lunch (12AM – 1:30PM)

Educational Sessions (*Invited Speaker)

DAY 2 Tuesday, April 24th Theme: Corporate Responsibility: Supplier Selection and Supply Chain Security

From 7:00 AM	Registration, Coffee & Pastries	Conference Hall A (Expo Area)	Conference Hall B (Expo Area)
8:30 – 9:15 AM	KEYNOTE SPEAKER: "Corporate Responsibility" Mr. Michael Beatrice* – Abbott VP Quality and Regulatory		
9:15 – 10:00 AM	"Risk Management for Excipients" Ms. Londa Ritchey* - Director, Supplier Qualification Pfizer		"Excipient News for Novel Formulations" Mr. Stephen Levine – Emerson Resources
10:00 – 10:45 PM	"The method of fine dissolution control of tablets by direct compression in different test media using a novel pregelatinized starch" Ms. Yurika Tanaka – Asahi Kasei		"What does it mean to have an IPEA Certification? (International Pharmaceutical Excipient Audit)" Speaker from Grace Davison* – (IPEC)
10:45 – 11:15 AM	Coffee & Networking Break		
11:15 – 12:00 PM	"cGMP Enforcement for the Pharmaceutical Industry" Mr. Edwin Ramos - FDA SJDO Compliance Director		"Meeting Formulation Challenges for Poorly Soluble Drugs" Mr. Nigel Langley – BASF
12:00 – 1:30 PM	Lunch and Networking at Vista Mar Terrace		
1:30 – 2:15 PM	"Up-Stream Supply, Chain Security for Excipients through Distribution" Ms. Griselle Vargas - Mutchler Inc.		"Excipact Update on Excipients" Mr. Koen Bontinck – NSF International
2:15 PM – 3:00 PM	"Supplier Management, Assuring a Secure Supply Chain" Mr. Louis Yu - Perrigo		"Application Studies of L-HPC and HPMCAS for Pharmaceutical Solid Dosage forms - An Update" Mr. Sakae Obara – Shin-Etsu
3:00 PM – 3:45 PM	Coffee Break & Networking Break		
3:45 – 5:00 PM	SPEAKERS' ROUND TABLE: "Visible Particles in Excipients" (Moderated by Pharmaceutical Technology) Speakers from FDA - Ms. Cindy Buhse, Pfizer - Ms. Janeen Skutnik, DowWolff Cellulosics - Ms. Ann Van Meter, USP - Ms. Catherine Sheehan		
5:00 – 7:00 PM	ExcipientFest Cocktail with Live Local Music		

DAY 2 Wednesday, April 25th Theme: Developments in Excipient Legislation and Regulation

From 7:00 AM	Registration, Coffee & Local Pastries	Conference Hall A	Conference Hall B
9:00 – 9:45 AM		KEY-NOTE SPEAKER: "Future of Excipient Regulation - Revised GMPs and Excipient Expectations" Ms. Maridalia Torres - FDA Director SJDO	
9:45 – 10:30 AM		"Legislative Update; An Industry Perspective" Mr. James Willtraut - Buchannon Ingersoll (IPEC)	"Innovative Techniques for Effective Cleaning of Time Release Polymers and Color Coatings" Mr. Kristina Wesley – Dober
10:30 – 11:15 AM	Coffee Break & Networking Break		
11:15 – 12:00 PM		"USP Monograph Modernization Initiative: Excipient update" Ms. Catherine Sheehan - USP	"Inactive Ingredient Database" Ms. Priscilla Zawislak - Ashland
12:00 – 1:30 PM	Lunch and Networking at Vista Mar Terrace		
1:30 – 2:15 PM		"Enhancing Excipient and Raw Material Surveillance through the FDA Spectral Library Initiative" Ms. Cindy Buhse - Director, Div. Pharmaceutical Analysis, CDER, FDA	"Beware of the Non-Critical Excipient in QbD" Mr. Brian Carlin – FMC
2:15 - 3:00 PM		"Controlled Release the Co-Processed "Whey" Mr. Joseph Zeleznik – Meggle	"NSF Reference Standards for Excipients" Mr. Steven Lane – NSF International
3:00 – 3:30 PM	Coffee Break & Networking Break		
3:30 – 4:15 PM		"Quality by Design Approach for Determining Excipient Specifications" Mr. Madhu Kallam – Avantor Performance Materials	"Elemental Impurities - Excipient Realities" Mr. Dave Schoneker – Colorcon (IPEC)
4:15 – 5:15 PM		KEY-NOTE SPEAKER: "ANDA Deficiencies Related to Excipients" Mr. Lawrence Yu - Director for Science, Office of Generic Drugs CDER FDA (IPEC)	
5:15 – 7:00 PM	Poster Award & Closing Remarks ExcipientFest Cocktail with Live Music		



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Full-Day Workshops

Speaker Biographies and detailed workshop outlines available at www.excipientfest.com

DAY 1 – April 23 rd - Monday	
9:00 AM – 5:00 PM	<p>I Pharmaceutical Formulation Workshop on Tablet Dosage Forms (Conference Room: El Coqui) Presented By Emerson Resources: An organization servicing the Pharma and Nutritional Supplement Industries. The company has three areas of focus: Formulation development and technical support, technical training and value added ingredient supply. Workshop Leaders: Stephen Levine and Aaron Barkley - Emerson Resources</p>
	<p>II Overview and Implementation of Selected IPEC Guides (Conference Room: La Luna) Presented By IPEC: The industry association that develops, implements, and promotes global use of appropriate quality, safety, and functionality standards for pharmaceutical excipients and excipient delivery systems. Workshop Leaders: Dale Carter - JM Huber, Engineered Materials, David Schoneker - Colorcon, Linda Herzog - Asahi Kasei America, David Klug - sanofi-aventis, Alexa Smith - Colorcon, Ann Van Meter - DowWolff Cellulosics.</p>
	<p>III IPEC's initiatives in the area of QbD, Excipient Variability and USP General Chapter <1059> (Conference Room: El Caribe) Presented By U.S. Pharmacopeia: A scientific nonprofit organization that sets standards for the quality, purity, identity, and strength of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. Workshop Leaders: Dave Schoneker – Colorcon, Catherine Sheehan - U.S. Pharmacopeia</p>
	<p>IV Excipient Supplier Auditing & Qualification (Conference Room: El Morro) Presented By IPEA, Inc.: International Pharmaceutical Excipients Auditing, Inc. is the industry leader in excipient Good Manufacturing Practice auditing and accreditation services. Workshop Leaders: Irwin Silverstein – IPEA Inc.</p>

DAY 3 – April 25 th - Wednesday	
9AM - 12 M	<p>V Troubleshooting the Film Coating Process: R&D through Production Scale (Conference Room: El Rio) Presented By Colorcon: A global manufacturer and leader in Film Coating products and Excipients for the Pharma Industry. Work Shop Leaders: Laura Scattergood & Pankaj Rege - Colorcon (USA)</p>

Attendance Fees

- **Total Conference Expo: \$220**
Two-Day admission pass to Expo, Educational Sessions, Lunches, Cocktails & Presentation Book.
- **Total Conference Workshop: \$390**
Includes all above and participation in one of four workshops on April 23rd.
- **Workshop Group Payment Discount:** 5 people or more: take \$40 off each Total Conference fee (workshops not included). Must register together and have one method of payment.

Hotel Accommodations

The Ritz Carlton Hotel – San Juan, PR

Call 787-253-1700 ext. 4161, 787-253-8051 and use Group Code MIEMIEA or send an email to Veronica Sostre, Reservation Coordinator at veronica.sostre@ritzcarlton.com

ExcipientFest Rates:

\$209 per night from April 21st through April 28th.

Deadline: March 11th, 2012 or until rooms last.