

# International Pharmaceutical Excipients Council OF THE AMERICAS

## 2008 Regulatory Affairs Conference

SEPTEMBER 15-16, 2008 | EMBASSY SUITES OLD TOWN ALEXANDRIA, VIRGINIA

Pharmaceutical Supply Chain Integrity

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Excipient Qualification Next Steps

|

Excipient Information Package (EIP) Implementation

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Excipient Quality by Design — Functionality and Performance

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Novel Excipients and Their Approval Process

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New and Co-Processed Excipients

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A Case for a Global Excipient Forum



# Program

MONDAY, SEPTEMBER 15

8:00AM – 12:00PM **MORNING SESSION**

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**Welcoming Remarks** Janeen Skutnik, Director/Team Leader, Quality and Regulatory Policy-Global Regulatory CMC, Pfizer, IPEC-Americas Chair Elect

**Chairman's Report** David Schoneker, Director, Global Regulatory Affairs, Colorcon

**Panel Session** Moderator: Phyllis Walsh, Senior Compendial Manager, Schering-Plough

**Supply Chain Integrity** Planned Topics/Speakers:  
U.S. Customs representative (invited and approved)  
FDA spokesperson  
Excipient Manufacturer – Dale Carter, Manager, Product Quality Management Systems, Archer Daniels Midland  
Excipient Distributor – Linda Herzog, U.S. General Manager & Director of Sales, Mutchler, Inc.  
Pharmaceutical Manufacturer – Robert Wiens, GMH Coordinator/Sr. Quality Representative, Eli Lilly & Co.  
Panel discussion and audience questions to follow

1:45PM – 5:00PM **AFTERNOON SESSION**

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**Panel Session** Moderator: Dr. Maria Jacobs, Director of Quality and Regulatory Policy, Pfizer

**Excipient Qualification Next Steps** Planned Topics/Speakers:  
New Excipient Qualification Guidance – Dr. R. Christian Moreton, FinnBrit Consulting  
Quality Agreements – Londa Ritchey, Director, Supplier Quality Systems, Global Compliance and Quality Systems, Wyeth Consumer Healthcare  
Excipient Pedigree – Dr. Arthur Falk, Chief Executive Officer, IPEA

**Panel Session** Moderator: Alexa Smith, Regulatory Services Manager, Colorcon

**Excipient Information Package (EIP) Implementation** Planned Topics:  
Progress, Issues, and Solutions

6:30PM – 8:30PM **DINNER**

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**Speaker** Janet Woodcock, MD  
Director, Center for Drug Evaluation and Research, Food and Drug Administration

TUESDAY, SEPTEMBER 16

8:00AM – 12:30PM **MORNING SESSION**

Panel Session Moderator: Janeen Skutnik, Director/Team Leader, Quality and Regulatory Policy-Global Regulatory CMC, Pfizer

**Excipient Quality by Design – Functionality and Performance**

Planned Topics/Speakers:  
EDQM Perspective – Dr. Henk de Jong, Chairman, European Pharmacopoeial Commission (invited)  
Excipient Manufacturer – Dr. R. Christian Moreton, FinnBrit Consulting  
USP/NF Perspective – Dr. Kevin Moore, Scientist, U.S. Pharmacopeia  
Pharmaceutical Manufacturer – Dr. David Hobbs, Principal Research Scientist, Eli Lilly & Co.

Panel Session Moderator: Christopher DeMerlis, Regulatory Affairs Manager, Colorcon

**Novel Excipients and their Approval Process**

Planned Topics/Speakers:  
Current Methods for Excipient Safety Assessment – Dr. Jay Goldring, Director of Toxicology, Wyeth Consumer Healthcare  
Role of Excipients in Drug Delivery – Dr. Alen Guy, Vice President, R&D and Commercial Development, JRS Pharma LP  
Excipient Safety Assessment New Paradigms – Dr. William Brock, Brock Scientific Consulting  
Procedure for Ingredient Safety Evaluation – Dr. Robert Osterberg, Aclairo PDG, Inc.

2:00 PM – 5:00PM **AFTERNOON SESSION**

Panel Session Moderator: Janeen Skutnik, Director/Team Leader, Quality and Regulatory Policy-Global Regulatory CMC, Pfizer

**New and Co-Processed Excipients**

Planned Topics/Speakers:  
How Co-Processed Excipients are Defined – Dr. R. Christian Moreton, FinnBrit Consulting  
How Co-Processing Takes Place in Excipient Manufacturing – Dr. Brian Carlin, Global Manager, Pharmaceutical R & D, FMC BioPolymer  
What the Regulatory Implications Are – Jon Clark, Program Activities Review Staff, CDER, FDA

Discussion Topic The Need for a Global Excipient Forum and Whom Should Participate

## Accomodations

**Hotel** A block of rooms has been reserved for conference participants at the Embassy Suites Old Town Alexandria at the rate of \$239 per night single/double. Reservations must be secured on or before August 15, 2008. After this date, reservations can be made on a space and rate-available basis only.

**Reservations** Reservations should be made by contacting the Embassy Suites hotel directly at 1-800-EMBASSY or 703-684-5900 and reference IPEC-Americas.

**Cancellation** Cancellation of hotel reservations is the responsibility of the meeting registrant.

**for information** For Assistance, contact Tammy Kramer in the IPEC-Americas office at 703-351-5265 or [ipecamer@aol.com](mailto:ipecamer@aol.com)

# Registration



Registration Fees	Member Company Employee	\$795.00
	Nonmember	\$895.00
	Government/Academic	\$150.00
	Student	\$ 50.00

Registration fee includes all refreshment breaks, luncheon, reception and dinner.

**3 Ways to Register** Use form below; online at [ipecamerica.org](http://ipecamerica.org); or call 703-875-2127

**Cancellations** Cancellations for this conference must be made in writing to:  
IPEC-Americas  
1655 N. Ft. Myer Drive, Suite 700  
Arlington, VA 22209  
or by email to [ipecamer@aol.com](mailto:ipecamer@aol.com) or fax at 703-525-5157

**Refunds** The registration fee is fully refundable (less credit card service fees if payment is made by credit card) if cancellation is received before 8/24/08.  
Cancellations received after 8/27/08 will be subject to a \$100 administrative fee.  
Cancellations received after 9/3/08 will not be refunded.

**Substitutions** Registrations are transferable to another company representative at any time.

## REGISTRATION FORM

**One registration per form; copy this form as needed.**

**Full payment must accompany the registration form before it will be processed.**

Last Name	First Name	Middle Initial	Degree
Title			
Name for Badge		Spouse/Guest	
Organization			
Address			
City		State	Zip
Daytime Phone		Fax	
email			

### Fee Schedule

Credit card holders may fax this form to 703-525-5157

Or mail to  
IPEC-Americas  
Regulatory Affairs  
Conference  
1655 N. Ft. Myer Dr  
#700  
Arlington, VA 22209

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|--|-----------|
| <input type="checkbox"/> Member              | \$ 795.00 |
| <input type="checkbox"/> Nonmember           | \$ 895.00 |
| <input type="checkbox"/> Government/Academic | \$ 150.00 |
| <input type="checkbox"/> Student             | \$ 50.00  |
- Check:** Enclosed is my check for \$ \_\_\_\_\_ (U.S. dollars) payable to IPEC-Americas
- Charge:**  Mastercard  Visa  American Express

Account Number	Expiration Date
Account Holder (please print)	Signature