

# IPEC-Americas News

May, 2008

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## **IPEC-Americas Gains Four New Members in May**

During the past month four companies, e.g. two finished pharmaceutical product manufacturers, an excipient producing company, and a chemical distributor all became IPEC-Americas members. With these additions, membership now stands at 61 and includes:

- 39 full member companies that either manufacture excipients or finished drugs;
- 1 affiliate member, which is a division of a full member;
- 19 associate member companies that provide services to full members; and
- 2 academic faculty members of graduate institutions that offer degrees in pharmacy or pharmaceuticals.

A brief outline of the four new members' areas of interest follows below.

Amgen Inc. is a leading U.S. biotechnology company headquartered in Thousand Oaks, California, that is recognized globally as a pioneer in the development of novel Rx products developed through advances in recombinant DNA and molecular biology. Its focus continues on finding medicines to treat the serious diseases of mankind.

Eurand Inc. is a specialty pharmaceutical company that develops, manufactures and commercializes enhanced pharmaceutical and biopharmaceutical products using its proprietary drug formulation technologies. Originally part of American Home Products Corporation, Eurand became independent in 1999. It presently has manufacturing facilities in Vandalia, Ohio in the U.S., Milan and Trieste in Italy, and Paris, France.

Antares Health Products, Inc. is an excipient producing start-up company located in Batavia, Illinois that was created to produce and market a Vitamin E TPGS material offered both for pharmaceutical use and as a food grade product. Antares is a largely-owned but separately organized and managed subsidiary of InCon Processing LLC. InCon is a toll processing company that provides high vacuum distillation to separate mixtures of organic or silicon compounds for the food, industrial chemical, and specialty chemical industries.

Brenntag Specialties Inc. services the pharmaceutical, food and beverage, cosmetic and personal care, and other industries by offering a broad product portfolio produced by the world's leading specialty manufacturers. Its sales and marketing personnel are supported by six regional customer service centers, seventeen warehouses throughout the U.S. and Canada, as well as technical, regulatory and analytical laboratory support.

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### **FDA Official Recognizes IPEC Contributions in Supply Chain Security Area**

During his presentation at the May 6 Temple University/FDA Conference in Philadelphia, PA, Richard Friedman, Director of the Division of Manufacturing and Product Quality in CDER's Office of Compliance, referred several times to existing IPEC and IPEC-Americas guidance. In connection with the IPEC/PQG GMP Guide, for example, Mr. Friedman referred to it as a "major initiative taken by an independent organization to create clear standards. Not regulatory guidance, but often used by FDA and Industry."

Later, when reviewing responsibility and activities of FDA's Pharmaceutical Ingredient Safety Task Force, a group convened last year to deal with the DEC/glycerin incident, to develop measures to prevent similar contamination situations, and to address ingredient supply chain integrity, Mr. Friedman referred to several published guidelines which he characterized as including "effective practices." Included in his list were the

- IPEC Good Distribution Practices (GDP) Guide;

- IPEC Certificates of Analysis (COA) guidance; and
- IPEC Supplier Qualification (part 1) guidance.

He also acknowledged meeting with members of IPEC-Americas to discuss supply chain integrity and noted that these contacts were continuing as the problem was one that affected all segments of industry, government regulators, and the pharmacopeias on a global basis.

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### **IPEC Americas General Update Meeting**

As has become the practice in recent years, a general update event is held during the quarterly committee meeting schedule to provide an opportunity for members who attend some - - but not all - - of the meetings to learn more about other things that affect member companies in one way or another. During the May 20-22 series of meetings, the general update took place during the May 21 evening hours and IPEC-Americas Chair David Schoneker presided.

A copy of Mr. Schoneker's presentation is posted on the IPEC-Americas WebBoard for member company personnel to access and print for review. Copies also are available through Tammy Kramer, IPEC-Americas office manager at (703) 351-5265

In his presentation Mr. Schoneker reported on:

- current supply chain security issues, including fallout from the heparin incident, the Congressional response, and details of pending legislation including both the Kerry/Kennedy and Dingell bills;
- IPEC-Americas and IPEA's response – how we are working with FDA to share industry's best practices and guidelines to prevent future problems;
- creation of an IPEC China and an update on proposed excipient regulations and planned SFDA visits to Europe this summer and to the U.S. in the fall to review excipient and API manufacturing practices in the different regions;

- the need for IPEC – related industry groups in India and Brazil and planned meetings in both areas with government regulatory authorities and existing industry organizations;
  - impact of the 2007 European Union pediatric medicine regulation and how elements might spread into U.S. regulations, particularly as they might affect excipient suitability for use in pediatric products.
  - agenda topics for the June 4-6 TriPEC and TriPEC/PDG meetings in Portland, Oregon; and
  - both a program and speaker update for the September 15-16 Regulatory Affairs Conference.
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### **FDA Announces Launch Of The Sentinel Initiative**

On May 22<sup>nd</sup> FDA and its parent body, the U.S. Department of Health and Human Services, announced launch of a new national strategy for monitoring medical product safety which is called “The Sentinel Initiative.” This will involve implementation of a national electronic safety system said to be “... capable of tracking the performance of a drug or medical product, beginning with the earliest stages of clinical research through its effects on millions of Americans who use it to treat or to recover from an illness or condition.”[1]

As announced in the cover notice, the program will utilize electronic health care data (such as claims data, other transactional data, and information from electronic health records) to evaluate results of use of medicines”... in the real world.”

It is expected that this will be a long-term effort and one which will have to proceed in stages, beginning with the FY 2008 appropriations and the FY 2009 President’s budget request. Public Meetings with potential partners in the public and private sectors, including industry groups also are likely in order to develop short and long-term project timetables.

[1] Message from the Commissioner

<http://www.fda.gov/oc/initiatives/advance/reports/report0508.html>

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## **FDA Acknowledges IPEC's Novel Excipient Evaluation Procedure**

In recent correspondence with IPEC-Americas, FDA agreed that the issues considered by the IPEC Novel Excipient Evaluation Panel in its first report are the same as would be considered by a reviewing division in a New Drug Application which would include the excipient. By way of background, IPEC created an Expert Panel to evaluate safety data for novel excipients before they are included in New Drug Applications in the U.S. The Panel determines consistency with FDA's 2005 "Guidance for Industry: Non-clinical Studies for the Safety Evaluation of Novel Excipients" and concludes the likelihood of approval in a drug formulation under the proposed conditions of use. Although FDA evaluates excipients in specific formulations and therefore there is no guarantee that FDA's determination would follow that of the Panel, FDA's acknowledgment indicates that the Panel's review processes are consistent with those of their own reviewing divisions.

Currently, FDA only evaluates novel excipients in the context of New Drug Applications and drug developers can only determine whether a novel excipient is approvable at that stage. Therefore, pharmaceutical manufacturers have been reluctant to include novel excipients in their formulations under development due to the added risk of rejection. This procedure provides a proxy for FDA review at an early stage and a positive conclusion should give excipient manufacturers and their pharmaceutical customers confidence that the excipient would be approved at the NDA stage. With the FDA acknowledgement, excipient manufacturers should consider this procedure for their novel excipients.

Excipient manufacturers interested in the procedure should contact Dr. Robert Osterberg at Aclairo Pharmaceutical Development Group, Inc. in Vienna, Virginia, [rosterberg@aclairo.com](mailto:rosterberg@aclairo.com), the current administrator of the process. Under IPEC's agreement with Aclairo, we are not involved directly with the evaluation process, but Aclairo will let us know that a submission was made for tracking purposes only. No information about the submitter or the excipient under consideration will be given to IPEC.

If you have additional questions about the procedure or IPEC's limited role, please contact Alan Mercill in the IPEC-Americas office.

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### **Tablets and Capsules Focuses Its "Eye on Excipients"**

The May issue of Tablets and Capsules magazine, an IPEC-Americas associate member, includes a major article on how excipient suppliers and users have to work together in order to qualify an excipient for use in a pharmaceutical manufacturer's product. Authored by Excipient Qualification Committee Chair Dr. Maria Jacobs of Pfizer, past IPEC-Americas Chair Dr. Chris Moreton of FinnBrit Consulting, and Dr. Irwin Silverstein of IPEA and IBS Consulting in Quality, the article previews elements of comprehensive global industry guidance from the three-part IPEC excipient qualification process that will issue later this year.

The article is well worth reading, as the authors are among those whom have been involved with the project since its beginning more than four years ago.

For more information go to [www.tabletscapsules.com](http://www.tabletscapsules.com)

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### **Next IPEA GMP Auditing Workshop To Be Held In Houston, Texas**

A comprehensive three day excipient GMP Auditor Training Workshop offered by International Pharmaceutical Excipients Auditing (IPEA) will be held September 23-25, 2008 in Houston, Texas at the Marriott Houston Hobby Airport hotel. IPEA is IPEC-Americas GMP auditing subsidiary company that also conducts on-site training for company auditors and offers its workshops on a global basis using the IPEC-PQG GMP Guide and related materials.

The Houston workshop on excipient auditing is designed to benefit both makers and users of pharmaceutical excipients. Training will analyze the essential elements of excipient good manufacturing practice for materials intended for use in pharmaceuticals, dietary supplements, food, or as industrial chemicals and explains how applicable product standards differ.

The workshop also will focus on excipient GMP compliance and attendees will learn auditing techniques, report writing, observation, and classification techniques that relate to the manufacture of excipient ingredients. It contains exercises to hone observation skills through participation in a hands-on mock excipient GMP audit. Participants also gain a thorough understanding of risk-based excipient auditing and learn how to assess whether an excipient GMP quality system can achieve a satisfactory level of compliance. Finally, attendees learn how to differentiate the requirements for excipient manufacture from those of APIs.

The three-day auditing workshop will be facilitated by Dr. Arthur Falk, IPEA President and Chief Executive Officer and Dr. Irwin Silverstein, IPEA Vice President and Chief Operating Officer.

For more information and for registration details – please contact Valeria Stewart at [ipeainc@aol.com](mailto:ipeainc@aol.com) telephone: 703-351-5266. The workshop fills quickly, so early registration is recommended. The next US workshop is scheduled for December 2 – 4, 2008 in St. Louis, Missouri.

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### **Online Regulatory Conference Registration Now Available!**

Online registration for IPEC-Americas 2008 Regulatory Affairs Conference, September 15-16, at the Embassy Suites Old Town in Alexandria, Virginia is now available! Cost for IPEC-Americas member company employees will be \$795; non-members \$895; \$150 for government/USP/academic faculty registrants; and \$50 for graduate students in pharmacy and related sciences. Hotel fees are extra, but an excellent rate has been obtained for conference attendees. Hotel reservations should be made early, as those who tried to register late last year discovered. The Embassy Suites Old Town is a popular stay-over site for Alexandria visitors; it contains a fine restaurant, is adjacent to the city's historical district, and is directly across the street from a Washington Metro station that services Reagan National Airport and the District of Columbia. To make reservations call: 1-800-362-2779 or 703-684-5900. To receive the \$239 rate you need to mention IPEC-Americas.

A current conference program is printed below in this bulletin. Looking forward to seeing you – September 15 & 16!

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**2008**  
**IPEC-Americas Regulatory Affairs Conference**

**Current Program**

**Monday, September 15**

7:30 AM – 5:00 PM      Registration

7:30 AM – 8:00 AM      Continental Breakfast

8:00 AM – 12:00 PM      Morning Session

- **Welcoming Remarks**      **Janeen Skutnik, Pfizer**
- **Chairman's Report**      **David Schoneker, Colorcon**
- **Panel Session: Supply Chain Integrity**  
**Moderator: Phyllis Walsh, Schering-Plough**

**Speakers:**

**Excipient Manufacturer – Dale Carter, Archer Daniels Midland**

**Excipient Distributor – Linda Herzog, Mutchler, Inc.**

**Pharmaceutical Manufacturer – Robert Wiens, Eli Lilly & Co.**

**FDA spokesperson – TBA**

**U.S. Customs representative – approved – to be announced soon**

**Panel discussion and audience questions to follow**

12:15 PM – 1:30 PM      Luncheon

1:30 PM – 5:00 PM      Afternoon Session

- **Panel Session: Excipient Qualification Next Steps**  
**Moderator: Dr. Maria Jacobs, Pfizer**  
**Planned Topics/Speakers:**  
**Excipient Pedigree – Dr. Arthur Falk, IPEA**

**Quality Agreements – TBA**  
**New Excipient Qualification Guidance – TBA**

- **Panel Session: Excipient Information Protocol (EIP) Implementation**  
**Moderator: TBA**  
**Planned Topics/Speakers:**  
**Excipient Manufacturer’s Perspective – TBA**  
**Distributor’s Perspective – TBA**  
**User’s Perspective – TBA**

5:30 PM – 6:30 PM      Reception

6:30 PM – 8:30 PM      Dinner

**Speaker – Janet Woodcock, MD (confirmed)**  
**Director, Center for Drug Evaluation and Development**  
**Food and Drug Administration**

## **Tuesday, September 16**

7:30 AM – 5:00 PM      Registration

7:30 AM – 8:00 AM      Continental Breakfast

8:00 AM – 12:00 PM      Morning Session

- **Panel Session: Excipient Quality by Design – Functionality and Performance**  
**Moderator: Janeen Skutnik, Pfizer**  
**Planned Topics/Speakers: from the perspective of the EDQM, USP, an excipient manufacturer and a pharmaceutical manufacturer**
- **Panel Session: Novel Excipients and their Approval Process**  
**Moderator: Christopher DeMerlis, Colorcon**

### **Program under Development**

12:30 PM – 1:45 PM      Luncheon

2:00 PM – 5:00 PM

Afternoon Session

- **Panel Session: New and Co-Processed Excipients**  
Moderator: Janeen Skutnik, Pfizer  
Planned Topics:  
How co-processed excipients are defined  
How co-processing takes place in excipient manufacturing  
What the regulatory implications are
- **Discussion Topic: The Need for a Global Excipient Forum and Whom Should Participate**

**Adjourn**

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**Important Industry Meetings  
June & July 2008**

June 2-3

Statistical Design of Experiments for Pharmaceutical Process R&D and Manufacturing:

A Practical Approach

Hilton Garden Inn, Las Vegas, Nevada

Register: <http://epd.engr.wisc.edu/webJ997>

June 2-4

Pharmaceutical Water Systems Design and Validation

Marriott Raleigh Crabtree Valley Hotel, Raleigh, North Carolina

Register: [www.pdatraining.org/raleigh](http://www.pdatraining.org/raleigh)

June 17-18

ExcipientFest Conference & Pharma Expo

Radison SAS Hotel, Little Island, Cork, Ireland

Register: [www.excipientfest.com](http://www.excipientfest.com)

June 22-25

2008 AAPS National Biotechnology Conference  
Metro Toronto Convention Centre, Toronto, Ontario, Canada  
Register: [www.aapspharmaceutica.com/nationalbiotech](http://www.aapspharmaceutica.com/nationalbiotech)

June22-26

44<sup>th</sup> DIA Annual Meeting  
Boston Convention and Exhibition Center, Boston, Massachusetts  
Register: [www.diahome.org](http://www.diahome.org)

July 12-16

35<sup>th</sup> Annual Meeting and Exposition of the Controlled Release Society –  
Responding to Global Needs Through Delivery Science  
Hilton New York, New York City, New York  
Register: [www.controlledrelease.org/meeting](http://www.controlledrelease.org/meeting)

July 14-17

Cleaning Validation and Critical Cleaning Processes  
Renaissance Chicago Hotel, Chicago, Illinois  
Register: [www.ivthome.com/cleaningvalidation](http://www.ivthome.com/cleaningvalidation)

July 21-23

Pharmaceutical Technology's Quality and Process Excellence Conference  
Westin Arlington Gateway Hotel, Arlington, Virginia  
Register: [www.pharmtechevent.com](http://www.pharmtechevent.com)

July 28-30

3<sup>rd</sup> Annual Drug Delivery 2008 – Where Science and Business Converge  
(sponsored by Pharmaceutical Education Associates LLC)  
Hilton San Diego/Del Mar Hotel, San Diego, California  
Register: [www.pharmedassociates.com](http://www.pharmedassociates.com)

