As IPEC-Americas committee members have come to expect and appreciate in recent years, those who attend the “general update” session during the regular quarterly meetings often receive information not reported earlier or elsewhere. The February 24th session led by IPEC-Americas Chair Janeen Skutnik was no exception.

For example, in her report Ms. Skutnik provided details concerning the planned training initiative for members and non-members, presented a preview of the first meeting of the NSF-ANSI excipient GMP standard development team, outlined new IPEC initiatives, reported on a February 23rd meeting at FDA, described the new IPEC Federation structure, and encouraged member participation in the ongoing legislative initiative. All this occurred in a meeting that lasted less than an hour and a half!

To access and review The General Update slides, go to:  
http://www.ipecamericas.org/public/Whatsnew.html
Planning for IPEC-Americas Member Activities at ExcipientFest

As previously announced in recent IPEC-Americas committee meetings, four committees are planning to meet at the Ritz Carlton Hotel in San Juan, Puerto Rico, in advance of ExcipientFest provided anticipated participation is sufficient to justify their expense. Members of the committees listed in the schedule below, therefore, are requested to notify their committee’s chair and IPEC-Americas staff (ipecamer@aol.com) whether they plan to participate in person.

**Monday, May 3**

<table>
<thead>
<tr>
<th>Event</th>
<th>Time</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good Manufacturing Practices</td>
<td>8:15 AM - 12:00 PM</td>
<td>La Luna Room</td>
</tr>
<tr>
<td>Joint Luncheon</td>
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<tr>
<td>Excipient Qualification</td>
<td>1:00 PM – 5:00 PM</td>
<td>La Luna Room</td>
</tr>
<tr>
<td>IPEC Dinner &amp; Update</td>
<td>6:00 PM – 8:00 PM</td>
<td>TBD</td>
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**Tuesday, May 4**

<table>
<thead>
<tr>
<th>Event</th>
<th>Time</th>
<th>Location</th>
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<tbody>
<tr>
<td>Compendial Review/Harmonization</td>
<td>8:15 AM – 12:00 PM</td>
<td>La Luna Room</td>
</tr>
<tr>
<td>Joint Luncheon</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality by Design/Excipient Composition</td>
<td>1:00 PM – 5:00 PM</td>
<td>La Luna Room</td>
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In addition to the above, if IPEC-Americas member attendance warrants it, our ExcipientFest Planning Committee is thinking of holding a special cocktail reception on Tuesday evening, May 4. It’s purpose would be two-fold: first, to welcome IPEC members to ExcipientFest and secondly, to encourage then to promote IPEC-Americas membership to non-member representatives throughout the conference.

More information will be reported as it becomes available.

2010 ExcipientFest Americas Program

A Two-Day Educational Experience and Pharma Expo with in-depth Workshops & Education Sessions from Industry’s Top-Excipient Experts
DAY 1 – Wednesday, May 5th

- Workshops I & II (9AM – 5PM)
- Educational Sessions – 14 Presentations (9:15AM – 5PM)
- Pharma Expo (10AM – 6PM)
- Poster Sessions (10AM – 6PM)
- Lunch (12PM – 1:30PM)
- ExcipientFest Cocktail & Music (5PM – 7PM)

DAY 2 – Thursday, May 6

- Workshops III & IV (9AM – 5PM)
- Educational Sessions – 10 Presentations (9:15AM – 5PM)
- Speakers Round Table (3:45PM – 4:45PM)
- Pharma Expo (10AM – 5PM)
- Poster Session (10AM – 5PM, Awards presented at Round Table)
- Lunch (12PM – 1:30PM)
- ExcipientFest Cocktail & Music (5:15PM – 8PM)

Educational Sessions

DAY 1  Wednesday, May 5th

From 7:00 AM  Registration, Coffee & Local Pastries

9:15 – 10:00 AM  Conference Hall A
Preparation of MUPS (Multiple Unit Particles System)
Tablets using Celphere and Preliminary Blend of Microcrystalline Cellulose and Pregelatinized Starch
Ms. Priscilla Zawislak - Ashland (IPEC)

9:15 – 10:00 AM  Conference Hall B
IPEC’s Excipient Composition Guideline
Ms. Priscilla Zawislak - Ashland (IPEC)

10:00 – 10:45 AM  Conference Hall A
Magnesium Stearate; Let’s play cards
Mr. Pieter Gommans - Peter Greven

10:00 – 10:45 AM  Conference Hall B
IPEC’s New Excipient Evaluation Procedure
Mr. Christopher DeMerlis - Colorcon (IPEC)

10:45 – 11:15 AM  Breakfast

11:15 – 12:00 PM  Conference Hall A
Assuring Supply Chain Security
Mr. Edwin Rivera Martinez – FDA CDER (IPEC)

11:15 – 12:00 PM  Conference Hall B
IPEC’s Excipient Stability Guideline
Mr. Phil Merrell - Jost Chemical (IPEC)

12:00 – 1:30 PM  Conference Hall A
Lunch (Ball Room I)

12:00 – 1:30 PM  Conference Hall B
Conforming to the IPEC CoA Guide
Mr. David Klug - Sanofi Aventis (IPEC)

1:30 – 2:15 PM  Conference Hall A
Excipients for Future – Identification of the Need, Discovery, and the Regulatory Journey to Market
Mr. Ranga Velagaleti - BASF, Dr. Sherry Ku - Wyeth

1:30 – 2:15 PM  Conference Hall B
Mr. David Klug - Sanofi Aventis (IPEC)

2:15 – 3:00 PM  Conference Hall A
3rd Party and Shared Supplier Audits
Mr. Eric Berg - Amgen & Mr. Irwin Silverstein - IPEA

2:15 – 3:00 PM  Conference Hall B
Co-processing: A Versatile Pathway to Modify Excipients: Lactose Excipients
Mr. Franz Penz – Meggle

3:00 - 3:30 PM  Coffee Break & Networking Break
3:30 P - 4:15 PM  Orally Disintegrating Tablets  
Mr. Joseph Zeleznik - JRS Pharma  
Best Practices for Assuring Supply Chain Security  
Including Quality Agreements  
Mr. Dale Carter - JM Huber & Alex Smith – Colorcon (IPEC)  

4:15 – 5:00 PM  Formulation Facilitation of Powder Blends, Sugar-Free  
Film Coatings and HME with a unique Polyol  
Mr. Bodo Fritzsching - Beneo Palatinit  
QBD - Impact of Excipient Variability on Formulation Flexibility and Excipient Functionality  
Mr. Bill Busch - Dow Chemical (IPEC)  

5:00 – 7:00 PM  ExcipientFest Cocktail with Live Local Music  

DAY 2  Thursday May 6th  

From 7:00 AM  Registration, Coffee & Local Pastries  

Conference Hall A  
9:15 – 10:00 AM  Commercially available options for BCS Class II, III & IV compounds in all Dosage Forms  
Dr. Guido Baumoeller – Cognis  

Conference Hall B  
9:15 – 10:00 AM  The Future of Co-Processed Excipients  
Mr. Brian Carlin, PhD - FMC BioPolymers USA (IPEC)  

10:00 – 10:45 AM  New Tests for Ingredients: The Role of USP NF in Setting Revised Standards Identifying Harmful and Potentially Deadly Adulterants in Pharmaceutical  
Ms. Catherine Sheehan - USP  

10:45 – 11:15 AM  Coffee Break & Networking Break  

11:15 – 12:00 PM  Bringing Added Value to the Excipient Supply Chain  
Mr. Dwight Mutchler - Mutchler Inc. PR & Ms. Elizabeth Plaza – PharmaBioServ  

11:15 – 12:00 PM  Regulation of Excipients in the Nutraceutical/Dietary Supplement Industry or Assuring the Quality of Dietary Supplements: Importance of Ingredient Supplier Qualification  
Ms. Catherine Sheehan - USP  

12:00 – 1:30 PM  Lunch (Ball Room I)  

1:30 – 2:15 PM  Excipient DMF’s in China  
Mr. Sun Huimin - Chinese National Institute of Control of Pharmaceutical & Biological Products (IPEC)  

1:30 – 2:15 PM  Solubility Enhancement with Methacrylates  
Dr. Abhishek Kathuria - Evonik Polymers (IPEC)  

2:15 P - 3:00 PM  FDA - PR Investigator’s Perspective on Review of Supplier Qualification Programs During Audits  
Ms. Maridalia Torres - FDA Director PR  

2:15 P - 3:00 PM  Excipient GMPs and The Global Certification Project  
Mr. Dale Carter - JM Huber (IPEC)  

3:00 - 3:45 PM  Coffee Break & Networking Break  

3:45 – 4:45 PM  SPEAKER’S ROUND TABLE: Leveling the Playing Field for Excipients (Moderated by Pharmaceutical Technology)  
Speakers from FDA, BASF, Pfizer, USP, Warner Chilcott, IPEC, RX360  

3:45 – 4:45 PM  Academic Poster Awards & Closing Remarks  

5:00 – 7:00 PM  ExcipientFest Cocktail with Live Local Music  

Scroll down to see more
May 5th – Wednesday 9:00 AM – 5:00 PM

I Design of Experiments (DoE) as a Tool for Pharmaceutical Manufacturing, Tech Transfer & Troubleshooting (Conference Room: La Luna)

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.

Work Shop Leaders: Mr. Stephen Levin and Mr. Robert Tuohy - Emerson Resources

II Film Coating Technology for Pharmaceutical Applications (Conference Room: El Morro)

Presented By Colorcon: A global manufacturer and leader in Film Coating products and Excipients for the Pharma Industry.

Work Shop Leaders: Mr. Jeff Moore and Mr. Gus LaBella – Colorcon (USA)

May 6th – Thursday 9:00 AM – 5:00 PM

III Pharmaceutical Formulation on Tablet Dosage Forms (Conference Room: La Luna)

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.

Work Shop Leaders: Mr. Stephen Levin and Mr. Robert Tuohy - Emerson Resources

IV The Role of Supplier Audit in Supplier Qualification, Supply Chain Security, and Incoming Ingredient Approval (Conference Room: El Morro)

Presented By IPEA (International Pharmaceutical Excipient Auditing):

Work Shop Leaders: Mr. Irwin Silverstein – IPEA

Continuing Education

ExcipientFest Workshops are accredited for Continuing Education by the College of Chemists and the College of Pharmacists of Puerto Rico. Accreditation is available separately for each of the workshops above mentioned. Call ExcipientFest (787-714-3000), for accreditation details on each conference segment. Cost of Continuing Education: $50 additional to Conference Fees.

Check-in for Continuing Education must be before 8:40 AM each day (5th & 6th) Plan Accordingly!

Hotel Accommodations

- The Ritz Carlton Hotel & Casino & The Caribe Hilton
  Rate $199 per night from Sat. May 2nd to Sat, May 8th. Reserve ASAP to guarantee rooms and dates at this rate.
  Call direct (787) 253-1700 or (800) 542-8680 & request reservations for ExcipientFest.

Attendance Fees

Total Conference Expo: $180
Educational Sessions, Lunches, Cocktails & Presentation Book.

Total Conference Workshop: $350
Includes all above, participation in one of several workshops on May 5th & 6th and Lunches

Workshop Group Payment Discount: 5 people or more: take $40 off each Total Conference fee. Must register together and have one method of payment.

Continuing Education: $50 additional (for workshops only)

REGISTER ONLINE AT
www.excipientfest.com
Current FDA Viewpoints on Improving Supply Chain Security of It’s Regulated Products

Following below are links to two important events IPEC members globally need to be aware of and the messages they define. The first is a recent speech of FDA Commissioner Margaret Hamburg, M.D. that was presented at the Center for Strategic and International Studies on February 4.

In her remarks Dr. Hamburg highlighted the scope of FDA’s current responsibilities and the challenges they entail. For example,

- FDA regulated products are imported from more than 150 countries by over 130,000 importers;
- 20 million food, drug and cosmetic shipments will arrive this year at U.S. ports and be handled by less than 500 FDA inspectors.
- About 40% of drugs Americas take are imported and as much as 80% of APIs are from foreign sources – including many from countries “....with less sophisticated regulatory systems” than FDA’s.

In addition, the supply chain from manufacturer to consumer has gotten much longer and complex, involving re-packagers and distributors.

As a result, less than 1% of products coming into the U.S. are inspected and only about 8% of foreign drug manufacturing facilities are inspected each year. At this rate it would take over 13 years for FDA to register all the registered drug manufacturing sites.

So what’s ahead – a new approach which reaches the entire supply chain and acts to prevent problems at every point globally “...from the raw ingredients...through production...and distribution...all the way to U.S. consumers.

Thus, FDA has begun to expand its reach by working with regulators, manufacturers and suppliers wherever they are located. For example, FDA has established 3 permanent offices in China, 2 in India, 1 in Costa Rica, Mexico, and Chile, and another will open soon in Jordan.

In addition, the agency has more than 30 agreements with foreign regulatory agencies to share inspection reports and non-public information and has begun planning and conducting joint inspections with European Union and Australian counterparts of facilities that manufacture starting materials for U.S. drugs.

A second element in FDA’s strategy involves holding companies responsible for their supply chain and to demonstrate that every component of every product throughout its production process complies with applicable U.S. and international safety and quality standards. In addition, Dr. Hamburg continued, “FDA will work with industry to set standards for technologies and other approaches that can help them strengthen the safety of their supply chains.”
She then announced and explained a new FDA program designed to help FDA to more effectively and efficiently conduct import inspections. This is called **PREDICT**, which stands for the “Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting.” It is an information technology system designed for use in border inspections and to target shipments which could present (the greatest) risk.

To review a copy of Dr. Hamburg’s full presentation, this can be found online at: http://www.fda.gov/NewsEvents/Speeches/ucm199926.htm

The second link IPEC-Americas members involved in supply chain security issues will particularly want to examine is the planned program of the April 26-28, 2010 PDA/FDA Pharmaceutical Supply Chain Workshop, which carries the tag line – *Enough Talk: Let’s Find and Implement Solutions.*

In addition to including a keynote address by CDER Director Dr. Janet Woodcock, the program also features presentations by other frequent FDA spokespersons at IPEC-Americas conferences, e.g. Edwin Rivera Martinez, Rick Friedman and Dr. Steven Wolfgang of DMPQ, as well as by Ilisa Bernstein, PharmD, JD from the Commissioner’s Office, Michael Levy, Director of an Office of Compliance division within CDER, and Dr. Frank Perrella, also of DMPQ.

IPEC-Americas member participants include workshop co-chair Dr. Barbara Mary Allan, Senior Director, Global Quality Systems, Eli Lilly & Co.; Martin VanTrieste, Vice President, Operations and Quality, Amgen, Inc.; Chuck Forsaith, Corporate Director, Supply Chain Security, Purdue Pharma Technologies, Inc.; Eric Berg, Director of Supplier Quality, Amgen, Inc.; Gwyn Murdoch, Director, Quality Systems for Materials/Packaging. Eli Lilly & Co.; Phyllis Sedar, Director, QA Program Management, Abbott Laboratories; Zena Kaufman, Division Vice President, Abbott Laboratories; and David Colombo, Supply Chain Consultant, Eli Lilly & Co.

To access the full program and its breakout topics, these are available online at http://www.pda.org ....in conferences.

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**Connect with IPEC-Americas Through Social Networking**

One of IPEC-Americas strategic planning goals is “to implement the use of appropriate technology as needed to advance our objectives”. To support this goal, IPEC will be launching a new website, which is in the final phases of completion! The new site is expected to be fully functional and live by the end of March.

The new website will offer IPEC members and the general public a streamlined way to access critical information related to the excipient industry; to download IPEC guidance documents; view committee
goals and projects; register for webinars, conferences and training workshops; and to collaborate on white papers, coalition documents and IPEC guidance. In the members only section, the social media application will offer IPEC members the ability to connect with other IPEC members via blogs, wiki’s and private forums for special interest committees, groups and discussions. Each member will have a unique and personalized on-line experience.

Get connected with IPEC!
Linked in: If you already have a Linked in account please join the: International Pharmaceutical Excipients Council Group
Twitter: Follow IPEC on twitter - IPEC-Americas
Facebook – Become a fan of - IPEC-Americas

For assistance, comments or suggestions, please contact Kim Beals, IPEC-Americas Executive Director at ipecamer@aol.com

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IPEA Workshop Well Attended Despite DC Blizzard of 2010

During the week of February 8th, the Washington, D.C. area was buried in record setting snowfalls. Despite this, a three day Excipient Auditor workshop scheduled at the IPEA and IPEC-Americas central office location in Arlington, VA went on as planned. Attendees arrived just hours before the massive blizzard began making its way through the area. Fifteen people from various member and non member companies flew, rode Amtrack, or drove themselves to the DC area to attend the training, which was led by Dr. Art Falk and Dr. Irwin Silverstein. Clad with snow gear and treading to the workshop on foot from nearby hotels, participants arrived on schedule for the full three days. Meanwhile, staff made sure to keep the meeting space functioning during a period where most area businesses were essentially shut down. Fortunately the heat and electricity were functioning. As the workshop came to an end the storm finally ceased. Consequently, attendees from as far as Nebraska, Wisconsin, and Kentucky were able to return home on schedule.
IPEA Workshops Now Open for Registration

(3 Day) Excipient Auditing Workshop in Newark, NJ area June 8-10, 2010
This workshop offers participants training in the assessment of excipient manufacturer conformance to appropriate GMP requirements. The workshop leaders are Drs Art Falk and Irwin Silverstein.
This workshop will take place at the Courtyard Newark Elizabeth in Elizabeth, New Jersey. Registration is currently open and available online. Register now by going to this link: http://www.ipecinc.com/auditingworkshop10.htm

(1 Day) Excipient Significant Change Workshop
Presenter: Dr. R. Christian Moreton
An effective Change Control system should be part of the quality system used by the excipient manufacturer. Some key concepts covered in this workshop is understanding the impact of a change on an excipient and its use, evaluation of the change, and understanding the reporting requirements and customer expectations. This course includes a review of the IPEC Significant Change Guide 2009.

Course Outline:
- Introduction to Excipients (Incl. Types, Sources, Variability)
- Changes in Excipients (Manufacturing, Additives, Specs, Documenting)
- Change from the Manufacturer’s perspective
- How to evaluate the impact of the change on the customer.
- Change from the User’s perspective (Risks analysis)
- Making it work (Confidentiality, Change control, Communication)

(1 Day) Validation Workshop
Where: IPEA’s central office location in Arlington, VA
Presenter: Dr. Sidney A. Goode
Validation is the key element in assuring that quality assurance goals are met and a consistent excipient quality is regularly achieved. The scope of this workshop includes removing some of the misunderstanding and preconceptions concerning validation.

Course Outline:
- Basic Explanation of Validation
- Purpose and Gains of Validation
- Compliance Requirements
- Validation Planning and Resources
- Issues to be addressed
- Validation Master Plan
- Validation Protocol preparation
- Implementing protocol and
collections of data
- Interpretation and analysis of the data
- Management of changes
- Addressing re-validation
- Writing the final report

For questions about any workshops, or to reserve a space:
Please contact Valeria Stewart at IPEA, Inc. at 703-351-5266 or email: ipeainc@aol.com

Register now for either (or both) of the 1 day workshops by going to this link:
http://www.ipeainc.com/OneDayIPEAWorkshops.htm

IPEC Federation Formed to be Voice for Regional Councils

February 23, 2010

The IPEC Federation has been formed to provide a single voice for the regional councils, Americas, Europe, Japan and China, and promote quality in pharmaceutical excipients. Forming a unified body to represent the International Pharmaceutical Excipient Councils (IPEC) is viewed as an important step in promoting the harmonization of standards, supply chain security and further developing third-party certification.

Patricia Rafidison, chair of the IPEC Federation, added: "The excipient industry has always been complex, with huge diversity among suppliers, and globalization has added to that complexity. "For that reason it is more important than ever before that the industry can speak with one unified voice."

Important Industry Meetings

March 11 – 13

CHPA – Consumer Healthcare Products Association
Annual Executive Conference
The Fairmont Turnberry Isle Resort & Club
Aventura, Florida
Register: http://www.chpa-info.org/meetings/AEC.aspx
March 15 – 18

34th Annual Georgia GMP Conference
- Spotting Risk Management –
University of Georgia Center, Athens, Georgia
Register: http://www.InternationalGMP.com

March 15 – 19

PDA Annual General Meeting
Gaylord Palms Resort and Convention Center
Kissimmee, Florida
Register: http://www.pda.org/

March 21 – 25

American Chemical Society
National Meeting & Exposition
San Francisco, California
Register: http://portal.acs.org/portal/acs/corg/content

April 12-15

Biopharmaceutical Change Control, including separate half-day
Short courses on Quality by Design and Biosimilars
Hilton San Diego Resort, San Diego, CA
Register: Healthtech.com/BCC

April 26-28

2010 PDA/FDA Pharmaceutical Supply Chain Workshop
“Enough Talk: Let’s Find and Implement Solutions”
Hyatt Regency, Bethesda, MD
Register: http://www.pda.org in training/education

April 29-30

PQRI Coordinated Workshop with RDD 2010 Florida on Role of
Pharmaceutics in Establishing Bioequivalence for Orally Inhaled Drug Products
OMNI Orlando Resort at Champions Gate
Orlando, FL
Register: http://www.rddonline.com/rdd2010

May 13-14

2010 CHPA Regulatory and Scientific Conference
Hyatt Regency, Bethesda, MD
Register: http://www.chpa.org