February 2011

IPEC-AMERICAS NEWS

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Chair's Note: Excellent Participation in February Committee Meetings

A special thanks to all the volunteers from our member companies who made the trek to Washington or dialed in for our first set of 2011 committee meetings. Every day last week we filled the large conference room at Buchanan Ingersoll with lively conversation and bright light from the projection of guidance documents and position papers under discussion. Starting with the 20 year anniversary planning committee followed by the 6 hour Executive Committee meeting; we proceeded with great attendance for the Quality by Design, Excipient Composition, GMP, Excipient Qualification, Compendial Review and Regulatory Affairs committee meetings occurring over four days with exciting groundbreaking contributions to patient safety. We also filled a few smaller conference rooms with subcommittees from the GMP and Excipient Qualification committees.

INSIDE THIS ISSUE

IPEC and ExcipientFest committee members met Tuesday night to recap the final agenda and tie up actions for what is sure to be another successful educational event in Baltimore on May 10th and 11th. The marriage of IPEC's annual Regulatory Affairs Conference with ExcipientFest has proven to be a fruitful union spawning a wealth and mix of educational excipient presentations unmatched by any other single conference. Dave Schoneker presented an exciting preview of PDA's Atypical Actives Conference (March 9 & 10) and an outline of IPEC's premier Total Excipient Control concept at the General Update meeting on Thursday night. IPEC's 20 years of informed guidance from both maker and user's perspectives brings all the ingredients, flavors and fire to pull from our oven the perfect culmination of Total Excipient Control (TEC) to satisfy the world's appetite for excipient quality and safety. This strong foundation sets the floor for the "House That IPEC Built" as our lasting contribution to patient safety. Please register now and don't miss out on our 20th Anniversary Conference and IPEC Foundation gala dinner.

The activity of this week truly makes IPEC a different type of trade organization because of the great participation and centuries of combined experience from our member companies. Catching up with reading during my flight to Washington, I noticed an article in ASQ's January 2011 issue of Quality Progress entitled, "Happiness Helps - Career development breeds employee engagement, boosts organizational performance" by Tom Becker. The article highlights the results of a "Global Benchmarking Study" that found career opportunities drive employee retention, organizational performance, productivity, and that career development prospects tops the list of what's most important when considering a new employer. Reflecting on my own past I thought about the positive influence that development opportunities had in raising my level of job satisfaction and how my involvement in committees and special projects had always brought something back to my day to day responsibilities. Later during the week as I sat in amazement at the depth of experience found in our meetings I felt the soothing warm embrace of confidence in IPEC's capability. Later that evening following great conversation with some IPECians over a small meal and a big drink I thought about our next 20 years, an exercise which inevitably leads to the question of "how much longer will I be doing this?" In that deep dark inter-sanctum of universal reality entered the chilling truth that experience is perishable and eventually expires with age unless renewed.

IPEC needs the ongoing involvement of junior and senior representatives from our member companies working together in committees to continually exchange and refresh our broad range of experience.

Interestingly it appears from the research quoted in Becker's article that our member companies need career development opportunities for their employees. What a perfect symbiotic relationship in the making! IPEC has an ever growing number of subcommittees, project teams, and working groups covering a variety excipient technical, regulatory, and processing topics that provide excellent opportunities for a person with three or so years of industry experience to get involved, contribute and learn. Supervisors, manufacturing or quality support staff, and mid level managers from our member companies may be looking to expand their knowledge and accept some additional responsibility. Working with people from other organizations through involvement in IPEC committees brings a refreshing and reassuring sense to your day to day job and what you learn from listening as the gurus in our industry give examples and share their reasoning brings a wealth of understanding back into your company. For the betterment of their company and the future of IPEC, I extend an invitation for all our member companies to think of IPEC as a development opportunity for their employees. Active involvement in IPEC provides great returns on the time invested. It's hard to describe the sense of assurance you get while in discussions with customers, suppliers or regulators you refer to an IPEC guide that you participated in creating. So please continue to send us your anxious and eager employees who wish to expand their knowledge and careers.

W. Dale Carter
IPEC Chairman

General Update as of February 24

As customary during the quarterly series of scheduled IPEC-Americas Committee meetings, a general update session is usually held one evening for members who come to D.C. that week, with live meeting access provided for those unable to attend. In February, the first 2011 General Update took place on Thursday the 24th, following an Excipient Qualification Committee meeting. 24 IPEC members were represented and 7 others participated through the live meeting. Presentations were provided by current Chair Dale Carter (J.M. Huber Engineered Materials) and Past Chair David Schoneker (Colorcon). During his summary Mr. Carter reported concerning the newly-established Executive Committee structure and responsibilities of the four new Vice Chairs. He also introduced two other new Executive Committee members, Dr. Nigel Langley of BASF and Ms. Gwyn Murdoch of Eli Lilly & Co., who were appointed to fill the unexpired terms

of members elected to new Vice Chair offices. Other reports delivered by Mr. Carter involved

- Ongoing projects with the U.S. Food and Drug Administration;
- Recently completed and future training webinars;
- The upcoming IPEC-Americas 20th Anniversary Conference and ExcipientFest programs;
- The ongoing federal legislative initiative;
- status of the Excipact ISO 9001 Excipient GMP annex
- expected benefits of Excipact GMP and GDP certification to suppliers, users, and ultimately patients; and
- an update on IPEA's progress.

Mr. Schoneker followed with a report on the upcoming March 9&10 PDA-FDA Conference on Atypical Actives which he and Immediate Past Chair Janeen Skutnik-Wilkinson of Pfizer are both co-chairing and presenting information from an excipient maker and a user's standpoint. He reviewed legal issues involved, which were confirmed by legal counsel present, and also mentioned IPEC's initial concepts for how to deal with the current issues. All this would be fully covered during the March 9-10 conference, he added, by both U.S. and European government and industry speakers.

Mr. Schoneker concluded the session by previewing the program for IPEC-Americas 20th Anniversary Conference on May 9 in Baltimore, Maryland. This deals with what is needed for achieving "Total Excipient Control (TEC)" and developing its needed "tools for managing excipient quality." Accomplishing this, he continued, would involve "The Next Decade for IPEC" and will represent "IPEC's challenge for the future!!!"

Copies of Both Mr. Carter's and Mr. Shonekers PowerPoint slides are available at http://ipecamericas.org/content/general-update-slides

Excipient Qualification Subcommittee to Cooperate with FDA's Effort to Develop Comprehensive Screening of Pharmaceutical Excipients

During its February 24th meeting following a presentation by Dr. Lucinda Buhse of FDA, Excipient Qualification Committee members agreed to form a subcommittee to assist the Division of Pharmaceutical Analysis (DPA) within CDER to develop a comprehensive library of pharmaceutical excipient samples that would be useful in helping FDA to develop its rapid screening capability on several

levels. Its purpose would be to assist in the surveillance of raw materials and finished products through rapid screening techniques to better identify materials in need of more in depth analysis in order to prevent counterfeit, contaminated and mislabeled substances from entering the market and causing harm.

The subcommittee will be headed by Dr. Philip Merrell, Technical Marketing Manager of Jost Chemical Company and will work directly with Dr. Buhse, Director of DPA, and other Division members to learn more about the project and how IPEC members can assist in providing samples through Material Transfer Agreements. As the project continues, additional information will be provided to IPEC-Americas members.

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

2011 PDA/FDA Atypical Actives Workshop – Parenteral Drug Association

The challenges of Atypical Actives has not been openly discussed and debated by the industry or regulators – here's your chance to discuss Atypical Actives at this workshop, March 9-10, 2011, Bethesda, Maryland.

The Opening Plenary Session at this workshop will set the stage for the challenges of using a material typically known as an excipient in a formulation as an Active Pharmaceutical Ingredient (API). This issue has significant implications from regulatory, quality, legal, sourcing and liability perspectives. The issue has not been adequately addressed in the past but is now becoming a hot topic as companies spend more time understanding their materials, function in their formulations and supply chain.

Presentations by Janeen Skutnik-Wilkinson, Director, Quality and Regulatory Policy, Pfizer, Inc. and David Schoneker, Director, Global RA, Colorcon.

For additional information on the workshop and to view the current detailed agenda listing the speakers, etc., please go to the following website:

http://www.pda.org/atypicalactives2011

PDA Parenteral Drug Association — *Connecting People, Science and Regulation®*

IPEC-Americas Upcoming Strategic Planning Meeting

IPEC-Americas Executive Committee and Committee Chairs have been invited to attend a Strategic Planning session in Newport, Rhode Island, March 21 – 23, 2011. The goal of the meeting is to review the current strategic plan, (mission, vision and core objectives) and to confirm its validity. The attendees will also prioritize strategic initiatives and identify any new or missing topics or areas of concern.

Once these tasks have been accomplished, the group will break out into small workgroups and will work on the key strategic initiatives to develop action items and work plans for the future. This will in turn result in objectives and a roadmap of ways to achieve them. Many of the action items will then be tasked to committees and sub committees to focus on during the upcoming year.

IPEC-Americas Committees Report 2010 Accomplishments and 2011 Goals

During the past week in Washington, D.C., members of 6 of IPEC-Americas 8 active standing committee's and 3 of their current working groups met to review their 2010 progress and to begin working to accomplish their 2011 goals. Currently more than 200 employees of IPEC-Americas 78 members regularly participate in at least one of the committees and working groups that meet on a quarterly basis and others follow by telephone or live meeting.

This level of participation, IPEC-Americas committee chairs and other leaders believe, is largely responsible for the committees' accomplishments over the 20 years of IPEC-Americas existence.

To review IPEC-Americas Committees 2010 Accomplishments and 2011 Goals reported thus far, go to: http://ipecamericas.org/content/ipec-americas-committees-goals-and-projects

2011 IPEC-Americas Executive Committee

As a result of February elections for three of the four new Vice Chair positions, coupled with appointment of two members to fill the remaining terms of two other Committee vacancies, IPEC-Americas Executive Committee now has twelve of its thirteen authorized positions filled. An election to fill the last office, Vice Chair for User Relations is expected shortly, once candidates come forward and are qualified by the Nominating Committee. In the interim, here are the present members and their terms of office:

Chair thru December 2012	William Dale Carter J.M. Huber Engineered Materials
Chair Elect thru December 2012	David Klug sanofi-aventis U.S.
Vice Chair for Administrative Affairs thru December 2013	John Giannone Cognis Corporation
Vice Chair for Harmonization and Compendial Monographs thru December 2013	Priscilla Zawislak Ashland Aqualon Functional Ingredients
Vice Chair for Industrial Relations thru December 2011	Rick Green CP Kelco
Vice Chair for Membership thru December 2011	Marc Fages BASF Corporation
Vice Chair for Science & Regulatory Policy thru December 2012	David Schoneker Colorcon
Vice Chair for User Relations thru December 2012	VACANT

Elected Executive Committee Members (4)

thru December 2011	Eric Berg Amgen, Inc.
thru December 2011	Ann Van Meter Dow Wolff Cellulosics
thru December 2012	Nigel Langley, Ph.D. BASF Corporation
thru December 2012	Gwyn Murdoch Eli Lilly & Company
Immediate Past Chair thru December 2012	Janeen Skutnik-Wilkinson Pfizer, Inc.
IPEA Liaison (non-voting)	Arthur Falk, Ph.D. IPEA Inc.

IPEC-Americas 20th Anniversary Conference Program Developments!

The 20th Anniversary conference program is nearing its final stages of development as additional speakers are confirmed!

Welcoming Remarks - Dale Carter, IPEC Chairman, Global Quality Director -Silica, J.M. Huber, Engineered Materials (session moderator).

How to Combine TEC Elements - Dave Schoneker, Director Global Regulatory Affairs, Colorcon

1. Introduction of TEC Concept
2. What is TEC and Why is it Important?
3. How all the Guides Fit Together

FDA Perspective on Excipients - Rick Friedman, Director of the Division of Manufacturing and Product Quality, Office of Compliance, FDA - invited

Total Cost of Ownership - Industry Speaker

- How much Does Your Excipient Really Cost"
- How TEC Reduces Financial Risk

Lawsuits and Liability - Ted Sullivan, Esq., Buchanan, Ingersoll & Rooney PC

IPEC Federation - Patricia Rafidison, IPEC Federation Chair, Quality and Regulatory Affairs Life Sciences,
Dow Corning (France) and **Janeen Skutnik-Wilkinson,** IPEC Federation Vice Chair, IPEC-AmericasImmediate Past Chair, Director, Quality & Regulatory Policy, Pfizer, Inc.

<u>Afternoon Session</u>

Distribution Services - Dwight Mutchler, Vice President, Mutchler, Inc., Pharmaceutical Ingredients

- Formulation services; lab services; growing markets
- Different kind of Excipient Control
- What are you being asked to do?

Contract Manufacturing - Industry Speaker

Marshall Steinberg Tribute

ROI: An Excipient Manufacturing Investment - Nigel Langley, Ph.D., MBA, Head Technical Sales, BASF

- Why Invest in Your Excipient Market?
- Know Your Market!

Emerging International Issues

- **Beam Suffolk,** IPEC Europe Chair
- **Dr. Keiji Kijima,** Secretary-General, IPEC Japan
- **Daniel Liu**, Chair, IPEC-China – invited
- **Jair Calixto**, Director of Sindusfarma

Presentation of lunch results and wrap up.

Reception and the IPEC Foundation Gala Dinner
Recognition Ceremony and entertainment provided by:
***The Capitol Steps – Americas Favorite Political Satire Group*!**

The Conference will be held at the Renaissance Harborplace Hotel, in Baltimore, Maryland, and immediately precedes ExcipientFest Americas! Be sure to plan on staying on in Baltimore to participate in the industry's premier exposition and educational event!

BOOK YOUR ROOM NOW – ExcipientFest Hotels Always Sell Out Take Advantage of the Preferred Rate of $179

The Renaissance Baltimore Harborplace Hotel showcases a new distinctive design featuring modern urban sophistication. The hotel's recently renovated 586 guestrooms and 34 suites have been revived with unprecedented comfort and include new amenities including flat panel televisions, iPod docking stations and improved high-speed Internet connectivity. Discover a four-diamond jewel among downtown Baltimore hotels, situated just steps from the area's most unique sights and attractions. Enjoy premier access to the world-famous Inner Harbor, home to the Baltimore Aquarium, the Maryland Science Center, and 120 dining and shopping options. Experience the rich culture of Charm City in a vibrant location sure to delight you at this waterfront hotel in Baltimore. For hotel accommodations at the Renaissance Harborplace Hotel call 1-800-535-1201 and use Group Code: xipxipa
ExcipientFest rates: $179 per night from May 7th through May 14th.
Deadline: April 9th, 2011 or until rooms last.

IPEC 20th Anniversary Gala Dinner Sponsorships!

IPEC-Americas wishes to extend appreciation to the organizations that have offered sponsorship for the 20th Anniversary Gala Dinner! It is through the support of corporate sponsorships that enables IPEC-Americas to focus its resources on promoting its mission.

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Mutchler Inc.
PHARMACEUTICAL INGREDIENTS

Sponsors of "The Capitol Steps" Americas Favorite Political Satire Group!

Other sponsorships are still available for the Gala Dinner and the Conference.
Gala Dinner Sponsorships: Sponsorships for the Gala Dinner will benefit the IPEC Foundation, whose mission is to promote research and education realted to excipients. The drugs of tomorrow cannot be developed with yesterday's excipients and processes: Energize research in excipients by supporting the IPEC Foundation!

Diamond - $7,000 - Preferred table for eight, banners and signature- full page in program
Ruby - $3,500 - Dinner for four, preferred seating, banners, signage and program recognition.

Conference sponsorships:
Breakfast: $1,000.00
Coffee breaks: $500.00 (two available)
Luncheon: $1,500.00

Sponsorships are an excellent opportunity for your company to support IPEC-Americas programs and activities and to gain visibility and recognition by conference attendees and individuals from FDA and USP. For additional information, please contact Kim Beals, Executive Director at kim.beals@ipecamericas.org .

Announcement: IPEC-Americas Good Distribution Practices Audit Guide for North American Distribution of Pharmaceutical Excipients (2011) is now available for free downloading from the website at: http://ipecamericas.org

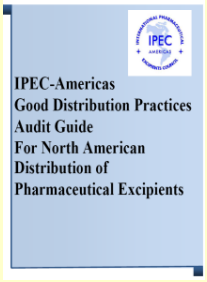
INSIDE IPEC-AMERICAS

The Guide replaces IPEC-Americas GMP Audit Guideline for Distribution of Bulk Pharmaceutical Excipients (2000) and is intended to assist companies which perform audits of excipient distributors and suppliers along their supply chain. It should be used in conjunction with the IPEC Good Distribution Practices Guide for Pharmaceutical Excipients (2006).

The new IPEC-Americas Guide is the result of a 2-year effort by 69 Good Manufacturing Practices Committee (GMP) participants from 47 IPEC-Americas members.

A special article on the Guide and its range of usefulness will appear in the March 2011 issue of Pharmaceutical Technology magazine, published by Advanstar Communications.

The article is authored by Dr. Irwin Silverstein of IBS Consulting in Quality LLC and will appear as a special Inside IPEC-Americas column provided by Pharmaceutical Technology editors. Both the magazine and IBS are IPEC-Americas associate members and Dr. Silverstein also serves as Vice President and Chief Operating Officer of International Pharmaceutical Excipient Auditing Inc. (IPEA), an independently-operated IPEC-Americas subsidiary.



News from IPEC-Americas Members

The following information was derived from recent press releases and other public announcements. Such notices are always welcome by email to ipecamer@aol.com to share with other IPEC members.

Lubrizol Advanced Materials, Inc. has opened an application and business center in Mumbai, India which includes a pharmaceutical laboratory and a technical center to provide services and training to company clients in the region. The Advanced Materials unit includes pharmaceutical ingredients, personal care materials, engineered polymers and coatings.

Catalent Pharma Solutions and Nuron Biotech have signed an agreement relating to formulation and supply of a proprietary recombinant human interferon beta compound (NU100) which Nuron presently is planning to take into Phase III clinical trials in 2011 and is being developed for treatment of multiple sclerosis. Pursuant to the agreement, NU100 will be produced at Catalent's facility in Brussels, Belgium, where the injectable product will be formulated, filled, and packaged in a prefilled syringe.

IPEC-Americas 2011 Web-Based Training

There is still time to register for the five educational webinars covering a variety of topics critical to manufacturers and users of pharmaceutical excipients that will feature industry professionals and experts as presenters.

Best Value – Sign up for all five sessions and save hundreds! Or sign up for only the ones you're interested in.

Register NOW at www.ipec-events.com

February 15: Significant Change –
How to understand and evaluate changes involving the manufacture of pharmaceutical excipients and when reporting is needed.

Presenter: Dave Schoneker, Director Global Regulatory Affairs, Colorcon

(You will receive the link to watch this presentation)

March 15: Certificates of Analysis –
Overview of IPEC's revised guideline based upon changing regulatory requirements.

Presenter: John Giannone, Business Development Manager, Cognis Corporation

April 12: Excipient Pedigree –
Why and how an understanding of the supply chain history of excipients is critical to the safety of drug products.

Presenter: Linda Herzog, Marketing Director, Asahi Kasei America

May 17: Stability –
Methods and rationale for determining excipient stability; IPEC's common sense scientific approach to stability studies for excipients stored and transported via uncontrolled conditions.

Presenter: Philip Merrell Ph.D., Technical Marketing Manager, Jost Chemical Co.

June 21: Validation –
Learn about IPEC's needed validation guideline on manufacturing processes, analytic methods and cleaning.

Presenter: Ann Van Meter, Senior Quality Systems Specialist, Dow Wolff Celluosics

Pricing: Discounts offered for participation in all five modules

$275.00 for members of IPEC-Americas Member Companies - $500.00 for Non-members.

Interested in one specific topic? Sign up for one session!

$75 for IPEC-Americas Member Company Employees $150 for Non-members

IPEA Workshop

Validation Workshop in Arlington, VA on April 7-8, 2011. This workshop consists of two half day sessions and will take place at the close of the **Excipient Auditing Workshop**, so you may register for both classes if you choose.

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.

The workshop leader is Sidney A. Goode, PharmD.

Workshop Schedule:

Thursday, April 7
Registration from 12:00-1:00pm
1/2 day Workshop Session: 1:00-4:30pm

Friday, April 8
1/2 day Workshop Session: 8:30am-12:00pm

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 collection of data
- Interpretation and analysis of the data
- Management of changes
- Addressing re-validation
- Writing the final report

Register now by going to this link: http://www.ipeainc.com/ValidationWorkshop.htm

For questions about either workshop: please contact Valeria Stewart at IPEA, Inc. at 703-351-5266 or email: ipeainc@aol.com

Important Industry Meetings

March 9-10

PDA/FDA Atypical Actives Workshop
Coming Together to Develop Solutions
Hyatt Regency Bethesda, Bethesda, MD
Register: www.pda.org/atypicalactives2011

March 10-12

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

March 14-17

35th International FDA/University of Georgia College of Pharmacy
Good manufacturing Practices Conference: GMP's – Spotlighting GMP Enforcement
The Georgia Center, The University of Georgia Conference Center and Hotel
Athens, Georgia
Register: http://www.GeorgiaCenter.uga.edu/conferences

March 29-31

INTERPHEX 2011 Innovation & Intelligence & Passion
Jacob K. Javits Center
New York, New York
Register: www.INTERPHEX.com

April 11-15

2011 PDA Annual Meeting
Harnessing the Power of Knowledge to Drive World Class Science and Technology
JW Marriott San Antonio Hill Country Hotel
San Antonio, Texas
Register: www.pda.org/annual2011

May 9

IPEC-Americas 20th Anniversary Conference
Renaissance Harborplace Hotel
Baltimore, Maryland
Register: http://ipecamericas.org/content/ipec-americas-20th-anniversary-conference

May 10-11

EXCIPIENTFEST Americas
The Excipient Industry's Best Expo for Regulatory Science and Sourcing Education
Renaissance Harborplace Hotel
Baltimore, Maryland
Register: http://www.excipientfest.com/

May 5-6

2011 CHPA Regulatory and Scientific Conference
Consumer Healthcare: Designing a Blueprint for Success
Hyatt Regency Hotel
Bethesda, Maryland
Register: www.chpa-info.org