

IPEC-AMERICAS NEWS

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Chair’s Update 2010 Board of Trustees Meeting



Four major reports were provided by Chair Janeen Skutnik-Wilkinson in her December 8 annual report to IPEC-Americas members. These reviewed:

- IPEC-Americas Strategic Plan and Priorities;
- 2010 Accomplishments
- IPEC Federation progress; and
- Status of the Legislative Initiative

All are summarized in an informative set of PowerPoint slides which are available for reviewing and downloading from IPEC-Americas website at:

<http://ipecamericas.org/content/board-trustees-update-december-2010>

As IPEC-Americas members themselves are aware, 2010 is likely to be remembered generally as a year in which

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progress was achieved in a number of areas.

These involved the development and production of training initiatives, membership gains, issuance of new IPEC guidance and the updating of others, as well as completion of a technology upgrade to spread the IPEC message more broadly. More is planned for 2011, thanks to IPEC-Americas leadership and the more than 200 member company employees who actively participate on seven IPEC committees and three current working groups.

Executive Committee Election Results

Four open Executive Committee positions for two–year terms beginning January 1, 2011 and ending December 31, 2012 were filled through election during the 2010 Annual Board of Trustees meeting on December 8 in Washington, D.C.

Chair Elect: David B. Klug
Senior Manager, Supplier Audit
sanofi–aventis U.S.

Vice Chair for Science & Regulatory Policy: David R. Schoneker
Director, Global Regulatory Affairs
Coloron

Elected Executive Committee Members (2): John Giannone
Business Manager
Cognis Corporation

Priscilla S. Zawislak
Global Regulatory Affairs Manager
Ashland Aqualon Functional Ingredients
Ashland, Inc.

Executive Committee to Expand in 2011 Four New Vice Chairs to be Added

During its meeting on December 6, IPEC–Americas Executive Committee agreed to expand itself to 13 members by adding 4 new Vice Chairs to manage member involvement and staff support in areas dealing with:

- Administrative Affairs
- Harmonization & Compendial Relations
- User Relations
- Membership

The change will bring the total of Vice Chairs to 6, since Vice Chair positions in the Industry Relations and Science and Regulatory Policy areas already exist.

Elections for terms of office on a staggered basis for the new Vice Chair positions are expected to be held early next year. Thus IPEC–Americas full members who presently are active in one or more operating committees and who wish more day–to–day involvement for their companies regarding

excipient regulatory and compendial issues are urged to offer their names as candidates as soon as possible by email to ipecamer@aol.com

Following below is the current Executive Committee roster for 2011 as the result of the December 8 elections and pending elections for the different offices.

For more information go to IPEC–Americas website at <http://ipecamericas.org/content/board-trustees-update-december-2010>

to review the slides explaining the Executive Committee changes contained in the December 8 Annual Report.

**2011
Executive Committee
(as of 12/8/10)**

Chair: William Dale Carter J.M. Huber Engineered Materials	Thru December 31, 2012 then becomes Immediate Past Chair for 2 years
Chair Elect: David B. Klug sanofi–aventis U.S.	Thru December 31, 2012 then assumes Chair position for 2 years
Vice Chair for Science & Regulatory Policy: David R. Schoneker Coloron	Thru December 31, 2012, 1 st term; then eligible for a 3 year term Beginning January 1, 2013 and ending December 21, 2015
Vice Chair for Industrial Relations: Richard Green CP Kelco	Thru December 31, 2011 (office changes name in 2012)
Elected Executive Committee Members (limited to 2 two year terms): Eric Berg, Amgen, Inc. John Giannone, Cognis Ann Van Meter, Dow Wolff Cellulosics Priscilla Zawislak, Ashland, Inc.	Thru December 31, 2011, 1 st term Thru December 31, 2012, 1 st term Thru December 31, 2011, 1 st term Thru December 31, 2012, 2 nd term

Immediate Past Chair: Thru December 31, 2012
Janeen Skutnik–Wilkinson
Pfizer Inc.

IPEA Liaison: (non–voting position)
Arthur J. Falk, Ph.D.
IPEA

Pending Election During 2011

January, 2011

Vice Chair for Administrative Affairs for a 3 year term ending December 31, 2013; eligible for a 2nd term.

Vice Chair for Harmonization and Compendial Relations for a 3 year term ending December 31, 2013; eligible for a 2nd term.

Vice Chair for User Relations for an initial 2 year term ending December 31, 2012; then eligible for a 3 year term beginning January 1, 2013 and ending December 31, 2015.

Vice Chair for Membership for an initial 1 year term ending December 31, 2011; then eligible for a 3 year term beginning January 1, 2012 and ending December 31, 2014.
(As noted below)

December 2011

Vice Chair for Maker/Distributor Relations for a 3 year term beginning January 1, 2012 and ending December 31, 2014; eligible for a second term.

Vice Chair for Membership for a 3 year term beginning January 1, 2012 and ending December 31, 2014

Two elected Executive Committee member positions, each for a 2 year term beginning January 1, 2012 and ending December 31, 2013.



IPEC-Americas 2011 Web-Based Training

IPEC–Americas is pleased to announce the second series of educational webinars beginning February, 2011. The five educational modules will cover a variety of topics critical to manufacturers and users of pharmaceutical excipients and will feature industry professionals and experts as presenters.

Session Topics to include:

February 15: Significant Change – Dave Schoneker, Director Global Regulatory Affairs, Colorcon

March 15: Certificates of Analysis – John Giannone, Business Manager, Cognis Corporation

April 12: Excipient Pedigree – Linda Herzog, Marketing Director, Asahi Kasei America

May 17: Stability – Phillip Merrell Ph.D., Technical Marketing Manager, Jost Chemical Company

June 21: Validation – Ann Van Meter, Senior Quality Systems Specialist, Dow Wolff Cellulosics

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

Best Value – Sign up for all five sessions and save hundreds!

Register NOW at www.ipec-events.com



China Pharmacopeia Delegation Receives IPEC Positions on Harmonization, GMP and Supply Chain Security

IPEC–Americas, along with representatives of other U.S.–based pharmaceutical, dietary–supplement, natural and herbal product associations, was an invited participant in a December 15 workshop

hosted by the U.S. Department of Commerce for a 25 person China Pharmacopeia delegation that also included an SFDA officer and drug control officials from Chinese provinces.

Its purpose had two parts. The first was to provide China with information on U.S. regulation of dietary supplements and health food products. The second involved reports on the impact of globalization on the pharmaceutical industry and ongoing efforts for cooperation against counterfeit medicines and how they can be prevented.

IPEC's participant was past Chair David Schoneker of Colorcon who made two presentations during the all-day workshop. One was delivered as part of the dietary supplement portion and the second concerned "Control of Excipients for Use in Pharmaceutical Products" as a U.S. pharmaceutical industry participant. Here Mr. Schoneker explained IPEC and its purpose, our participation in the pharmacopeial harmonization process and the growing need in the global pharmaceutical industry for improved good manufacturing practices standards and supply chain security controls, particularly since so few regulations around the world "... describe appropriate GMP and technical controls for Excipients."

Mr. Schoneker then went on to explain how IPEC guidance was developed to fill the different voids and concluded by saying:

- "It is CRITICAL only to use ingredients in drug formulations from high quality, reliable suppliers who meet appropriate GMPs and have good change notification programs in place
- Global Pharmacopeial Compliance must include requirements for appropriate GMP
- No longer is it acceptable to use ingredients from suppliers simply based on specification compliance and cost!!!"

Copies of slides used by Mr. Schoneker in both presentations are available to IPEC–Americas members. Please contact Tammy Kramer in the IPEC office by requesting them from Tammy.Kramer@ipeamericas.org

Monthly Supply Chain Security Telecons To Resume in January

This is to announce that regular monthly Supply Chain Security teleconferences for IPEC–Americas members will resume Friday, January 7 at 11 am. They focus on current supply chain issues that involve pharmaceutical excipients and

product security matters. If you have not participated in prior telecons but would like to join them, please contact ipekamer@aol.com for a 2011 schedule and other information.

IPEC-Americas 20th Anniversary Conference

Planning has begun for IPEC–Americas 20th Anniversary Conference which will be held Monday, May 9, 2011 – immediately preceding ExcipientFest 2011, at the [Renaissance Inner Harbor Hotel](#) in Baltimore Maryland. An opening night reception is planned for Sunday, May 8th and the one–day conference will consist of sessions focusing on:

- The history and evolution of IPEC;
- How IPEC's collaboration efforts have benefited other organizations and what's needed for the future ;
- IPEC's strategic direction – interactive session
- The IPEC Federation and Global Concerns

One of the highlights of the conference will be the IPEC Foundation Gala to Benefit Excipient Research and Education on Monday evening. The Gala Dinner will be the first of its kind and proceeds from the event will support the Foundation's mission, which is "to promote research

and education related to excipients". The evening's entertainment will be the "Capitol Steps" America's favorite political Satire group, sponsored by Mutchler Inc.

Other sponsorships are available, please contact Kim Beals at the IPEC office if you are interested in sponsoring or co-sponsoring an event.

kim.beals@ipecamerica.org

Diamond – \$7,000.00 – Table for eight, banners and signage – full page in program

Ruby – \$3,500.00 – Dinner for four, preferred seating, banners, signage and program recognition.

Emerald – \$1,500.00 – Dinner for two, preferred seating, signage, and program recognition.

[Registration for the IPEC–Americas 20th Anniversary Conference is now open!](http://www.ipecevents.com)

www.ipecevents.com



Other News For and About Members

CHPA Board Picks New Chair

During a recent meeting of the Consumer Healthcare Products Association Board of Directors, the Board selected Paul L. Sturman of Pfizer as CHPA's next Chair. Mr. Sturman is President and General Manager of Pfizer Consumer Healthcare. He will assume the chairmanship in March, during CHPA's Annual Executive Conference in Florida. CHPA is an IPEC–Americas associate member and IPEC–Americas holds the same membership in CHPA.

Asahi Kasei Becomes IPEC–Americas Latest Member

In December Asahi Kasei America, Inc. became IPEC–Americas 79th member. Headquartered in New York City, the U.S. division of the major Japanese excipient producer supplies microcrystalline cellulose, pregelatinized starch, croscarmellose sodium, and trehalose

products to the U.S. market. Linda Herzog, the company's regional Marketing Director, has been designated Asahi Kasei's IPEC–Americas member representative.

HHS Semiannual Regulatory Agenda Link

"The purpose of the Agenda is to encourage more effective public participation in the regulatory process, and HHS invites all interested members of the public to comment on the rulemaking actions included in this issuance of the Agenda." 75FR243, p79764, Dec. 20, 2010

<http://edocket.access.gpo.gov/2010/pdf/2010-30444.pdf>



Important Industry Meetings

January 10

ASQ Northeast Pharmaceutical GMP/Quality Conference
Somerset Holiday Inn, Somerset, New Jersey

Register: <http://neqc2011.eventbrite.com/?ref=eivte>

January 27, 2011

IPEC Europe Annual Seminar

Gray d'Albion Hotel

Cannes, France

Register: [Non-member registration form](#)

March 9–10

PDA/FDA Atypical Actives Workshop

Coming Together to Develop Solutions

Hyatt Regency Bethesda, Bethesda, MD

Register: www.pda.org/atypicalactives2011