

IPEC-AMERICAS NEWS

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Chair’s Note:



Summer rolls on with the blazing intensity of aluminum foil wrapped leftovers reheating in a microwave oven and IPEC–Americas member company volunteers continue to light up the phone lines. The GMP Committee is about to finish their last in a series of calls held to review and comment on the ANSI NSF 363 GMP standard. The ANSI NSF 363 working group will be reviewing these comments through the end of September with plans to publish the proposed standard for public comment late this fall. The EXCiPACT standards working group (including IPEC–Americas representatives David Klug, Dave Schoneker, Irwin Silverstein, and Dale Carter) will complete their review of the public comments on the Excipient GMP & GDP Certification Annex for ISO 9001 in August and send the final draft to the

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EXCiPACT Steering Committee (chaired by Janeen Skutnik–Wilkinson) for approval to publish in late September. The IPEC Americas Legislative Initiative member companies are meeting in Washington DC the second week of August to review the lobbying strategy (if your company is not participating in this effort there is still time join in and attend the meeting). A preparation team is meeting to start the draft of the Risk Assessment Guideline in preparation for our September face to face meetings and our Phthalates Coalition,

Elemental Impurities working group, validation guide, and visible particles group continue to hold regular conference calls. For those that may be in the process of preparing next year's budget, remember IPEC–Americas ExcipientFest in Puerto Rico April 2012

and the January 2012 IPEC Europe 20th Anniversary Conference to be held in Barcelona.

Have a great August and plan on attending our September face to face meetings in Washington DC.

Changes in FDA's Management Structure Message from the Commissioner to FDA Staff

As widely reported last week in the U.S. public press and FDA–regulated industry publications, FDA Commissioner Margaret A. Hamburg, MD has announced a reorganization of the agency's management structure in a letter to FDA staff which also included a link to the agency website where revised organization charts are displayed. To review Dr. Hamburg's letter to her staff, go to:

<http://carl1anderson.wordpress.com/2011/07/14/major-reorganization-at-fda/>

Among the most notable additions that establish a new level of management and accountability between center directors and the Office of the Commissioner are creation of new offices which will be headed by personnel whom will report directly to Commissioner Hamburg. These are the:

- Office of Medical Products and Tobacco

- Office of Global Regulatory Operations and Policy
- Office of Operations

The Medical & Tobacco Office will be headed by a new Deputy Commissioner, Dr. Stephen Spielberg, who will leave a post at Children's Mercy Hospital in Kansas City to join FDA. A pediatrician by training, Dr. Spielberg also held management positions at both Merck and Johnson & Johnson previously. Another newly appointed Deputy Commissioner, who will lead the Global Regulatory Operations and Policy Office, is Deborah Autor, who until the announcement was Director of the Office of Compliance within CDER. The third new Office, the Office of Operations, will be headed by a Chief Operating Officer. A search is underway to fill this position.

USP and FDA: Partners in Public Health

A notice in the July issue of Tablets and Capsule magazine, associate member of IPEC–Americas, reports that “The U.S. Pharmacopeial Convention (USP) and the FDA signed a 3–year cooperative R&D agreement to improve USP reference standards for the quality, identity, purity, and strength medicines. The agreement strengthens annual testing of roughly 40 chemical reference standards and promotes joint work to modernize tests and assays included in USP’s written or documentary standards, which are widely used of the development and testing of pharmaceuticals.

The partners will further develop test methods for hand–held instruments that law enforcement inspectors can use to test drug–product quality in the field.”

Acknowledgement of the FDA and USP partnerships are referenced at:

<http://www.usp.org/audiences/regulator/uspAndFda.html>



FDA & USP to Co-Sponsor Over-the-Counter Drug Substances and Drug Products Workshop

The following invitation to IPEC–Americas members is provided by Steven Paul of the United States Pharmacopeia.

“Dear Colleague:

Please plan now to participate on September 8 & 9 in the Over–the–Counter (OTC) Drug Substances and Drug Products Workshop.

This important workshop is co–sponsored by the U.S. Food and Drug Administration (FDA) and the United States Pharmacopeia (USP). Dr. Janet Woodcock, Director of the FDA Center for Drug Evaluation and Research (CDER) will keynote the event.

Mr. Scott Melville, CEO of the Consumer Healthcare Products Association (CHPA), is a featured speaker.

It is recognized that a number of widely applicable USP monographs for OTC products require modernization to incorporate current, more specific analytical techniques. USP is working with FDA and OTC manufacturers to strengthen the USP monographs for OTC ingredients and to create or strengthen the corresponding OTC dosage form monographs.

Participants in this workshop will gain an understanding of the monograph modernization initiative and the regulatory roles of USP and FDA OTC drug monographs.

The two–day workshop will also provide OTC drug manufacturers, FDA, and USP with a unique forum to discuss and explore the challenges and needs related to setting and strengthening public standards (i.e. USP monographs) for OTC drug substances and drug products. Discussions at the workshop may help shape future directions for OTC public standards.

More information, the workshop agenda, and registration for this unique opportunity are available here:
<http://www.usp.org/meetings/asMeetingIntl/rockvilleEvent.html>

The workshop venue is USP headquarters in Rockville, MD.

The workshop will be preceded by a USP Pharmacopeial Education course, “Understanding the USP Compendial Process,” which is open for registration to workshop attendees at a specially reduced rate.

For further information, please contact:

Steven Paul
Marketing Director, Pharmaceutical Industry
US Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852
301–816–8210 (voice)
301–816–8236 (fax)
STP@USP.ORG



IPEC Foundation Deadline Approaching for Shangraw & Steinberg Memorial Prize Applications

The deadline for submission of applications for the Ralph Shangraw and Marshall Steinberg Memorial Awards and separate Graduate Student awards is quickly approaching! Applications must be received by August 31, 2011.

The Ralph Shangraw Memorial Award recognizes research achievements broadly in the field of pharmaceutical excipients, and is given to any person that has provided outstanding research in the study of excipients or excipient–related technology.

The Marshall Steinberg Memorial Award rewards those individuals who have made outstanding contributions in the area of safety and toxicology for excipients.

Graduate student awards focus on recent significant contributions to formulation science and technology with excipients brought about by highly innovative research. Recipients will receive \$1,000.00 to attend the AAPS Annual Meeting and will exhibit their research during the poster session.

In 2011, the Foundation will participate in the award ceremony of the American Association of Pharmaceutical Scientists (AAPS) 2011 Annual Meeting in Washington DC, where members of the Board of Directors will present the awards to the winners. The winners of the two prestigious awards will also receive \$10,000.

(Employees of IPEC–Americas or IPEC Federation member companies are not eligible to receive monetary compensation if selected.)

For additional information about the award and to submit an application or to make a charitable donation, please visit the Foundation website at:

www.ipecfoundation.org, or contact Kim Beals, Foundation Secretary–Treasurer at kim.beals@ipecamericas.org.



Two IPEC Presentations Will Be Part Of 50th EAS Program

EAS Eastern Analytical Symposium & Exposition

According to a recent EAS news release, the 50th Anniversary Eastern Analytical Symposium and Exposition program, November 14–17 in Somerset, New Jersey, will include two IPEC–Americas member presentations.

One will be given by Christopher DeMerlis, Regulatory Affairs Manager for Colorcon and the other by Dr. Irwin Silverstein of IBS Consulting in Quality LLC, who also serves as Vice President of IPEC–Americas GMP auditing subsidiary, IPEA.

Mr. DeMerlis, Chair of IPEC–Americas Safety Committee, summarizes his presentation in the following abstract: New excipients are only approved throughout the world within new drug applications, as no independent regulatory approval process exists for new excipients. As a result, the current regulatory environment strongly discourages the development of new excipients, limiting the choices to those already used in approved drug products. In response, IPEC–Americas developed an independent safety evaluation procedure for new excipients in order that this information could be included with an NDA to support the presence of a new excipient in the product. The procedure, and its application for the safety evaluation of new excipients, will be presented.

According to Dr. Silverstein:

All components (active pharmaceutical ingredients and excipients) used in the manufacture of drug products must be produced under Good Manufacturing Practice (GMP). This presentation will provide an overview of the regulatory requirement, establish the more significant differences between GMP and ISO 9001 quality systems, and will briefly discuss the expectations the Food & Drug Administration places on the pharmaceutical manufacturer in terms of assuring their components are produced under GMP.

For more information regarding the EAS Symposium & Exposition, go to:

<http://www.eas.org>

IPEA Workshops



**3 Day Excipient Auditing Workshop in Arlington, VA (DC Metropolitan area)
October 25–27, 2011**

Register Early! This popular workshop offers participants training in the assessment of excipient manufacturer conformance to appropriate GMP

requirements. The workshop contains exercises to hone observation skills, including participation in a hands-on mock excipient GMP audit. The last workshop sold-out quickly so be sure to register early. The workshop leaders are Drs Sidney Goode and Irwin Silverstein.

Registration is now open and available on line. Go to:

<http://www.ipeainc.com/auditingworkshop11.htm>

Workshop Schedule:

Tuesday 10/25/2011 Registration first day 8:00–8:30am

Tuesday–Thursday Workshop Sessions 8:30am–4:30pm plus a networking cocktail session.

For questions about the Arlington workshop:

contact Valeria Stewart at IPEA, Inc. at 703–351–5266 or email: ipeainc@aol.com

2 ½ Day IPEA Excipient Auditing Workshop (no mock audit) October 6–8, 2011 in conjunction with FDA – Xavier Global Outsourcing Conference in Cincinnati, OH, October 2 – 5, 2011

Registration is available for this workshop. Please go to:

<http://medxu.com/goc/registration-2/>

About the Xavier Conference:

- Co-Sponsored by the FDA
- Bringing pharma (i.e., pharma, biotech, generics, OTC) together with contract organizations to not only address the dysfunction in contract relationships, but also to identify what can be done together to increase overall patient safety – including supply chain security
- focus on suppliers, but also provides an understanding of how to conduct effective audits that meet FDA and Global expectations.

For information on the Xavier Conference, including conference registration go to:

<http://medxu.com/goc/> or contact Sue Bensman at 513–745–3396 (Bensman@xavier.edu)

Important Industry Meetings

August 1–5

51st Annual Land O’Lakes Pharmaceutical Analysis Conference
“Challenges for the Analytical Laboratory: Today and tomorrow”
Devils Head Resort and Conference Center
Merrimac, Wisconsin
Register: <http://ce.pharmacy.wisc.edu/courseinfo/2011AugustLOL>

August 8–10

16th Annual GMP By The Sea
Grand Hyatt Hotel, Tampa Bay, Florida
Register: www.pharmaconference.com

August 17–18

Extension Services in Pharmacy (ESP) School of Pharmacy
The Role of CMC Quality in Ensuring Patient Safety: From Development through Commercialization
Hilton Washington, D.C./Rockville Hotel
Rockville, Maryland
Register: <http://cepharmacy.wisc.edu/courseinfo/2011safety>

September 8–9

USP Over-the-Counter (OTC) Drug Substances and Drug Product Workshop
USP Meeting Center, USP Headquarters
Rockville, Maryland
Register: www.usp.org/meetings/asMeetingIntl/rockvilleEvent.html

September 12–13

PQRI Workshop on Sample Sizes for Decision Making in New Manufacturing Paradigms
Co-sponsored by AAPS, IQ Consortium, FDA, IFPAC, and ASTM
Hyatt Regency Bethesda, Bethesda, Maryland
Register: <http://www.signmeup.com/7591> and additional information is available at www.pqri.org

September 12–14

2nd Annual West Coast Forum on Supplier Audits
“Ensure Compliance through Proper Risk Assessment, Supplier Qualification and Audit Programs”
Sponsored by Institute of Validation Technology
San Diego, California
Register: http://www.ivtevents.com/show_conference.cfm?confCode=PI11079

September 19–21

2011 PDA/FDA Joint Regulatory Conference & TRI Courses

Quality and Compliance in Today's Regulatory Enforcement Environment

Renaissance Hotel

Washington, D.C.

Register: www.pda.org/pdafda2011

September 20–21

IPA's 7th Annual: GMP Update 2011

Global Perspectives for Pharmaceutical, Biopharmaceutical and Allied Industries

Montreal, Canada

Register: <http://www.ipacanada.com/viewcourse.php?id=gmp0911mon>

October 6–7

CHPA's 2011 OTC Product Quality & Operations Workshop

Hyatt Regency Bethesda

Bethesda, Maryland

Register: www.chpa-info.org

October 22–23

AAPS Workshop – Pharmaceutical Stability Scientific and Regulatory Considerations
for Global Drug Development and Commercialization

Walter E. Washington Convention Center

Washington, D.C.

Register: www.aapspharmaceutica.com/stability

October 23–27

2011 AAPS Annual Meeting and Exposition

Walter E. Washington Convention Center

Washington, D.C.

Register: www.aapspharmaceutica.com/annualmeeting

November 14–17

2011 Eastern Analytical Symposium & Exposition

Garden State Exhibit Center

Somerset, New Jersey

Register: www.eas.org