IPEC-AMERICAS NEWS

August 2011

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Chair's Note:

With August behind us we look forward to our fall face to face committee meetings September 26 – 29 in Washington DC. A planning committee has been formed to develop the educational program for ExcipientFest 2012 in Puerto Rico (led by committee chair Alexa Smith of Colorcon). On the day before ExcipientFest, IPEC will provide a workshop based on our popular webinars. An IPEC Foundation fundraising gala dinner also will be held on the night before ExcipientFest. Several sponsorship opportunities are available for the IPEC Foundation Dinner, providing an excellent way to show your company cares about research in the excipient field. Combining our Regulatory Affairs Conference with ExcipientFest built the perfect venue to focus on the excipient science and regulatory topics.

INSIDE THIS ISSUE

I hope all IPEC member companies will be represented in Puerto Rico.

The IPEC member company representatives attending our legislative initiative strategy meeting participated in a lively discussion of IPEC's US congressional efforts and plans. Excipients have risen to forefront of pharmaceutical safety legislation and Congress is expected to act within the next 12 months. IPEC's legislative initiative helps provide a balanced voice from excipient

users and makers that will produce effective legislation. A review of our legislative initiative will be provided during our general update meeting on Wednesday September 28th.

Don't miss out on our fall meetings and your opportunity to get involved in IPEC committee work. Meeting times, location and travel tips can be found on our website at: www.ipecamericas.org

FDA News

According to recent press reports and agency contacts, an extensive list of FDA recommendations related to needed user fees and its 2013 Fiscal Year budget have been completed and are ready for discussion with Congress. In today's world, user fees received from drug and medical device companies are essential to FDA in order to supplement its budget, particularly since budget appropriations have failed to grow in recent years despite the added responsibilities assigned to FDA in connection with needed foreign inspections and other global supply chain security issues. A rapidly aging scientific staff which is beginning to seek retirement also is a major problem that is expected to increase substantially in the years ahead – largely because of the time and costs involved in obtaining and training qualified replacements.

As a result, an immediate concern for FDA involves the expiration in September 2012 of both Prescription Drug User Fee Act (PDUFA) and the Medical Device user Fee Amendments (MDUFA) and the fact that new legislation will be required for FDA to continue to collect user fees in connection with product applications and related services. Development of a generic drug user fee program acceptable to industry also was critical, reports indicated, but this seems to have been achieved according to a meeting last week. That also will require legislative approval, along with a similar system for approving follow-up formulations of biologic drug products, which currently is under discussion between agency and industry personnel.

The next steps are up to Congress, which involves:

- approval of FDA's Fiscal Year 2012 budget which begins October 1, 2011;
- approval of user fees payable by industry in order to speed up product approval applications and for other services beneficial to involved companies; and

- recognition by Congress that FDA must have the funding necessary to properly perform its assigned responsibilities which are needed in order to adequately protect the health of the American public!

Let's get started. Congress!

IPEC-Americas Committee Goals for 2011 – Status Report

EXCIPIENT QUALIFICATION

- Completed revision of the 2000 IPEC Certificate of Analysis Guide for Pharmaceutical Excipients with IPEC Europe and are awaiting FDA comments before publishing

- An update of the 2009 Excipient Information Package, Template and User Guide is under development by an EQ subcommittee

- Committee members are assisting FDA in development of comprehensive screening technology capable to establish a spectral library for pharmaceutical excipients to help improve global supply chain security of drug components

- Has begun planning for consultation with an IPEC Europe committee to develop IPEC guidance based on IPEC-Americas 2009 Significant Change Guide for Bulk Pharmaceutical Excipients

IPEC-Americas Submits Comments Regarding Draft Nanotechnology Guidance

Following below are comments filed August 17 in response to draft FDA guidance labeled "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology." In its comments, which are signed by IPEC-Americas Vice Chair David Schoneker of Colorcon, IPEC supported comments submitted separately by the Consumer Healthcare Products Association (CHPA) and outlined key issues of particular importance to

IPEC-Americas members. FDA also was urged to work with regulatory authorities in other regions "… to gain agreement on a similar approach to handling nanomaterials…"

"Association Background

IPEC-Americas is a regional pharmaceutical industry trade association headquartered in Arlington, Virginia. Many of its member companies are U.S. based and manufacture either finished drug products or components used in such products for various purposes, and therefore are substantially affected by the subject guidance.

IPEC-Americas appreciates the opportunity to provide these comments. IPEC-Americas commends the Food and Drug Administration for the development of this important guidance document. Clear guidance regarding the application of nanotechnology and nanomaterials is certainly needed and this draft guidance document will initiate a good scientific discussion throughout the industry to help develop good approaches for handling these materials in the future.

Support for CHPA Comments

IPEC-Americas has reviewed the attached comments which were submitted by the Consumer Healthcare Products Association (CHPA) and IPEC supports the comments made by CHPA in their submission. The points discussed in their letter are of concern to IPEC-Americas members as well and IPEC recommends that FDA carefully consider and incorporate the CHPA comments in the revised guidance which will be finalized.

Key Issues for IPEC Americas

Of particular concern is the need for clearer guidance regarding how to handle particles between 100nm and 1 micron. Common pharmaceutical ingredients exist with a long history of use that should not be considered as "engineered nanomaterials" or as agglomerates of nanomaterials. However, they may have particles whose size falls within this range. These materials have been used in drug products safely for decades and there is no need for additional safety data to support the use of these materials. IPEC recommends that this be clearly described in the revised guidance document before it is finalized.

Due to the global nature of the pharmaceutical industry, it will be very important for the FDA to work with regulatory agencies in other major regions to gain agreement on a similar approach to handling nanomaterials in all regions. Otherwise, it will be difficult for global companies to fully take advantage of the concepts this guidance provides.

Hopefully, through FDA's involvement in ICH and WHO, harmonization of requirements in other regions to match those outlined in this guidance document can be achieved.

Thank you for the opportunity to comment on the guidance document. We look forward to the publication of the final version in the near future."

EDQM News – August 2011

The following notices of possible interest to IPEC-Americas members were included in this month's issue of EDQM News. Subscriptions to the update are available through infopub@edqm.pheur.org

The EDQM signed a trilateral Memorandum of Understanding (MoU) with the State Administration of Traditional Chinese Medicine of the People's Republic of China (SATCM) and its National Key Institute of TCM Quality Control (NKI-TCM). More information: http://www.edqm.eu/en/Whats-new-525.html

Certification
Monthly Report of Activities (July 2011): http://www.edqm.eu/en/News-and-General-Information-164.html

New applications forms for new applications and revisions/renewals applicable from 1 September: http://www.edqm.eu/en/News-and-General-Information-164.html

Expert Meeting: "Indicators of the quality of pharmaceutical care", 10 December 2010: http://www.edqm.eu/en/Quality-and-Safety-Standards-in-Pharmaceutical-Practices-Pharmaceutical-Care-1244.html

Expert Meeting: "Impact of traditional Chinese medicine on pharmaceutical practices in Europe" 28 October 2010: http://www.edqm.eu/en/Quality-and-Safety-Standards-in-Pharmaceutical-Practices-amp-Pharmaceutical-Care-1244.html

Pharmeuropa 23.3 July 2011
This issue is now available to order.
More information:
https://www.edqm.eu/store/liste.php?categ=2&PHPSESSID=d1077c9ba2efe3d4055ab058ef853518

IPEA Workshops

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

Register Now, class is half full! 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
- The October agenda has a heavy 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)

New Webinar Training Schedule – September thru December

We are excited to announce our new set of training webinars! Four educational modules covering a variety of topics critical to manufacturers and users of pharmaceutical excipients will feature industry professionals and experts as presenters.

Tuesday, September 20: **Quality Agreements**

Defining Quality Agreements, General Provisions, and Key Quality Elements

Presenter: Alexa Smith, Regulatory Services Manager, Colorcon

Tuesday, October 25: **Good Manufacturing Practices (GMP)**
Global Regulations - How they are applied to excipients and GMP for excipients, Understand and Review various global guidelines, IPEC GMP, ICHQ7, WHO GMPs & GDPs ANSI and EXCiPACT highlights.

Presenter: Dale Carter, Global Quality Director, Silica, JM Huber, Engineered Materials

Tuesday, November 8: **Excipient Auditing**

How IPEC Guidance Documents and the Excipient Information Package (EIP) Relate to the Supplier Audit Process

Presenter: Dale Carter, Global Quality Director, Silica, JM Huber, Engineered Materials

Tuesday, December 20: **3rd Party GMP Certification**
Preparation and maintenance - IPEA, EXCiPACT review

Presenters: Dale's Carter, Global Quality Director, Silica, JM Huber, Engineered Materials and Dr. Irwin B. Silverstein, Vice President and Chief Operating Officer, IPEA, and President of IBS Consulting in Quality LLC

All webinars will take place from 11:00 AM – 1:00 PM Eastern Time and utilize the WebEx training platform.

Registration Fees: **Discounts offered for participation in all 4 modules:**

$275 IPEC-Americas Member Company Employees

$500 Non Members

One session price:

$75 IPEC-Americas Member Company Employees

$150 Non Members

REGISTER: www.IPEC-Events.com

IPEC-Americas Committee Meeting Schedule
For September
All meetings are held in the offices of
Buchanan Ingersoll & Rooney PC
1700 K Street, N.W., Suite 300, Washington, D.C.

Monday, September 26

Executive Committee	11:00am – 5:00pm
Luncheon Provided	

Tuesday, September 27

Quality by Design	8:15am – 12:00pm
Validation Working Group	8:00am – 12:00pm
EIP Working Group	9:00am – 12:00pm
Shared Luncheon	
Excipient Composition	1:00pm – 5:00pm

Wednesday, September 28

Good Manufacturing Practices	8:15am – 12:00pm
Shared Luncheon	
Excipient Qualification	1:00pm – 5:00pm
General Update	5:30pm – 7:30pm
Dinner Provided	

Thursday, September 29

NSF Excipients Standard (tentative)	8:00am – 5:00pm
Compendial Review/Harmonization	8:15am – 12:00pm
Shared luncheon	
Regulatory Affairs/Safety	1:00pm – 5:00pm

Speakers and Topics

Pulmonary drug metabolism, clearance, and absorption
Staffan Edsbacker, AstraZeneca, Sweden

Low cost inhalation technologies designed for use in the developing world
Anthony Hickey, University of North Carolina, U.S.A.

Overcoming lung clearance mechanisms for controlled release drug delivery
Hugh Smyth, University of Texas, U.S.A.

Controlled transport for pulmonary drug delivery
Jennifer Fiegel, University of Iowa, U.S.A.

Excipient selection, biomaterials, and biocompatibility in pulmonary drug delivery
Paul Myrdal/Aliyah Sheth, University of Arizona, U.S.A.

Particle engineering technologies for pulmonary drug delivery
Cory Berkland, University of Kansas, U.S.A.

In vitro performance testing for pulmonary drug delivery
Jason McConville, University of Texas, U.S.A.

Regulatory issues and challenges relating to pulmonary products
Gur Jai Pal Singh, Axar Pharmaceuticals, U.S.A.

Pulmonary Drug Delivery: future prospects based on lessons learned
John Patton, Dance Pharmaceuticals, U.S.A.

Take advantage of a world class opportunity to learn from the best and network with colleagues. Early registration deadline is September 9. To learn more and register, visit:
www.controlledreleasesociety.org/meetings/Pages/DevelopingPharmaceuticalProducts.aspx

Sponsorships

Sponsorship opportunities are available as well. Contact Deborah Woodard at +1.651.994.3817 or dwoodard@scioc.org to become a workshop sponsor.

Register early and save money

Early registration ends September 9, 2011. Registration is $995 on or before that date, $1,095 after. To register for this workshop, visit the AAPS and CRS workshop website.

This workshop is cosponsored by AAPS and CRS and will be held immediately prior to the 2011 AAPS Annual Meeting.

Other Important Industry Meetings

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 11-12
3rd Annual Great Lakes cGMP & Regulatory Science Forum
University of Illinois at Chicago (UIC Forum) College of Pharmacy
Chicago, IL
Register: http://www.regonline.com/register/checkin.aspx?eventid=932206

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