

IPEC-AMERICAS NEWS

IPEC-Americas, Inc., 1655 North Fort Myer Drive, Suite 700, Arlington, VA 22209
 www.ipecamerica.org, email: ipecamer@aol.com, Tel: 703-875-2127

IPEC-Americas and Rx-360 Participate in Supply Chain Security Roundtable for Pharmaceutical Technology

As reported in the cover story of Pharmaceutical Technology magazine's November 2009 issue, "representatives from industry, standard-setting bodies and regulatory organizations" participated in a recorded roundtable discussion in September to review and discuss global pharmaceutical supply chain concerns. Participating were: IPEC-Americas Chair Janeen Skutnik, Director of Quality & Regulatory Policy at Pfizer; Martin Van Trieste, Vice President of Quality at Amgen and interim Director of Rx-360; Susan Schniepp, Javelin Pharmaceuticals Vice President of Quality (who served as moderator); Dr. Tom Buggy, International Quality Manager at DSM Anti-Infectives in the Netherlands and a member of the European Chemical Industry Council's API Committee (APIC); and Dr. Susanne Keitel, Director of the European Directorate for the Quality of Medicines and Healthcare (EDQM).

Full audio transcripts are available on the magazine's website at this link:

INSIDE THIS ISSUE

IPEC-Americas and Rx-360 Participate in Supply Chain Security Roundtable.....	1-4
IPEC New Excipient Safety Evaluation Webinar Attracts Wide Audience!.....	4 & 5
IPEC Foundation Awards Several Financial Prizes at Recent ACT and AAPS Meetings.....	5 & 6
CoA Guide Revision Project - Member Participation Invited.....	6 & 7
What's New? The IPEC Novel Excipient Safety Evaluation Procedure Article.....	7
IPEC-Americas to Sponsor On-line Open Journal....	8
2010 Annual IPEC Europe Seminar.....	9
Important Industry Meetings.....	10
IPEC-Americas Committee Meetings.....	10

<http://pharmtech.findpharma.com/pharmtech/Top+Story+PT/Special-Supply-Chain-Podcast-Series/ArticleStandard/Article/detail/636866?contextCategoryId=48560>

Condensed versions are reprinted in the November issue. For example, in hers, Ms. Skutnik pointed out that IPEC's focus for over 15 years has been on developing needed voluntary industry guidance in lieu of specific regulations applicable to excipients; all, she noted, "focusing on the safety and security of pharmaceutical supply chain." In addition to developing

excipient current good manufacturing and distribution practices (cGMP & GDP) guidance, IPEC also has produced quality agreement templates which can be used by pharmaceutical manufacturers with their excipient suppliers, e.g., manufacturers, reproducers, repackagers, and distributors. IPEC also has developed excipient qualification guidance, Ms. Skutnik noted, which lays out what is important both from the perspective of an excipient manufacturers as well as the excipient user.

Auditing is another important part of supply chain security for excipients, she added, and companies doing or having audits performed for them also need to ask questions about subcontractors and assure themselves that suppliers have their own qualification systems. Third-party auditing through a company such as IPEA, an IPEC–Americas subsidiary, also can be useful, she noted, and concluded by saying: “We (IPEC) really are trying to work together with the key parties to ensure the safety and security of excipients.”

In his segment Mr. Van Trieste reviewed events which led to formation of the RX-360 Consortium in December 2008 and which now has more than 25 members. These include pharmaceutical and biotechnology companies such as Amgen, their suppliers, different professional

organizations, as well as industry associations like IPEC–Americas, the latter as non-voting observers. RX-360’s intention, he stated, was not to duplicate or compete with organizations like IPEC, but rather to “collaborate” with them on supply chain matters “to reduce patient risk”.

RX-360 has four functions, he continued. “First, we are adopting standards and best practices” and noted that consortium members would be reviewing available supply chain security standards to see which worked best and how they might be improved.

“Second, RX-360 will conduct supply chain surveillance,” acting as a clearing house for reporting of suspicious occurrences and for dissemination of that information. Once information has been evaluated, development of solutions to prevent similar situations from occurring in the future might be possible.

“Third, we will develop technology to prevent or detect adulteration.” This will involve working with research organizations so that tampering within the supply chain can be detected more easily.

The last role for consortium members, Mr. Van Trieste said, involves development of “a process for sharing

audit information.” While it still will be a member’s responsibility to accept a supplier according to its own procedures and product requirements, it is believed that sharing of audits “should reduce the number of audits at common suppliers.” What suppliers will be asked for in return, he concluded, “...is to allow RX-360 to conduct longer, more thorough audits that not only cover GMP but that also look at environmental health and safety, risk management, supply chain security and other activities.”

As a member of the European Chemical Industry Council’s API Committee Audit Program Task Force, Mr. Buggy stated that his organization fully recognized “the importance of supplier qualification as an effective quality system to approve new suppliers and to periodically evaluate suppliers and manufacturers for ongoing manufacture.” He added that his committee (APIC), was developing such guidance which was due to be published in November.

A key element of supplier qualification, he continued, was “the on-site audit” and when one considered those requirements on a global basis for the pharmaceutical industry the burden was “overpowering”. In response APIC created a third-party auditing program which includes sharing of reports. This is acceptable to European

authorities, provided certain principles are maintained, which he then outlined.

APIC API auditors also must be certified, Mr. Buggy noted, and must sign confidentiality agreements. GMP compliance is assessed on the basis of the ICH Q7 guidelines and an important element of the APIC program is that it follows European authorities’ guidance for third-party audits.

Dr. Keitel also focused on need for certification standards and sharing of inspection information during her report. She began with an outline of EDQM’s API certification of suitability (CEP) program that began in 1994 and noted that inspections of API manufacturing sites and their processes were added 3 years later – as the result of a European Commission mandate.

Inspections follow European Union rules and are conducted usually by inspectors from EDQM and national European authorities. As such they are conducted on a risk-based selection basis posted on the EMEA web site.

Today, Dr. Keitel continued, a majority of inspections take place outside Europe, primarily in India and China, and results have shown a need for closer monitoring. In 2008, for example, 28 on site

inspections were conducted by EDQM and local inspectorates, resulting in 16 CEP suspensions. From January to June of 2009, 8 suspensions followed 17 inspections. In each case, the local competent authority was fully informed. Consequently, Dr. Keitel noted, EDQM supports an EMEA pilot program to exchange API inspection information with both FDA and Australia's Therapeutic Goods Administration or TGA. Although EDQM shares its information, lack of mutual recognition agreements will make it impossible to take regulatory action solely based on information received from outside partners. Such information, however, could be used as part of the site

selection process for future inspections.

She concluded by pointing out that a planned revision of European pharmaceutical legislation, e.g., the EU Pharmaceutical Package, is likely to require auditing and accreditation of auditors by national authorities. EDQM supports "this (as) a move into the right direction."

As noted earlier, the full transcript of the roundtable program moderated by Susan Schniepp is available on PharmTech.com.

IPEC New Excipient Safety Evaluation Webinar Attracts Wide Audience!

Over 135 individuals registered for the first IPEC–Americas webinar, which took place on November 18th. Although only 77 of those who registered were on-line for the WebEx based event, it is expected that the webinar reached even higher numbers since many viewers had indicated that groups of people would be participating at their offices and in corporate board rooms.

The webinar was hosted and moderated by Christopher DeMerlis, Regulatory Affairs Manager, Colorcon, and featured three other speakers, Dr. Bruce Kerwin,

Scientific Director, Amgen, Inc., Dr. Elaine V. Knight, Research Fellow, Global Preclinical Development, Johnson & Johnson Pharmaceutical Research & Development LLC and Dr. Robert Osterberg, Senior Consultant, Pharmacology/Toxicology, Aclairo PDG, Inc.

The webinar discussed the excipient review process; the role of the New Excipient Evaluation Committee; and how the procedure can help excipient manufacturers and pharmaceutical companies expedite the use of new

excipients to solve drug development problems and minimize regulatory risk. If you are interested in receiving copies of the slides from the webinar, please contact Kim Beals, IPEC–Americas Executive Director at ipecamer@aol.com. The webinar will be available for future viewing from the IPEC–Americas website. For information about the IPEC New Excipient Safety Evaluation Procedure, contact:

Robert E. Osterberg, RPh, PhD, Fellow–ATS
Senior Consultant,
Pharmacology/Toxicology
Aclairo PDG Inc.
1950 Old Gallows Rd., Suite 300
Vienna, VA 22182
ph–703–506–6760 ext 302
fax–703–506–0142
cell–301–518–1493
ROsterberg@aclairo.com

IPEC Foundation Awards Several Financial Prizes at Recent ACT and AAPS Meetings

During the November 1–3 ACT (American College of Toxicology) meeting in Palms Springs, California, the IPEC Foundation awarded the Marshall Steinberg Memorial Prize to Christopher DeMerlis, Regulatory Affairs Manager, Colorcon and Jay M. Goldring, Ph.D., Director, Regulatory Affairs, L’Oreal Company. The two individuals shared the award for their efforts to create a rational, practical system to address the current lack of regulatory targets in the excipient development process. The awards were presented during the ACT Awards Luncheon on Nov 1 to Chris and Jay by IPEC–Americas Chair, Janeen Skutnik and Robert G. Pinco, IPEC Foundation Chairman.

IPEC congratulates Chris and Jay for all their efforts!



One week later, in Los Angeles, California at the AAPS Annual Meeting, the IPEC Foundation awarded five Graduate Student Awards and the Ralph Shangraw Memorial Prize during the official AAPS Awards Ceremony. With almost 8,000 attendees present, the five Graduate Students: Diana Sperger (Kansas), Raimondo Ho (Imperial College, London), Michiel Van Speybroeck (Leuven, Belgium), Sudhir Verma (Connecticut) and Jhon Rojas Camargo (Iowa) received recognition on stage. Next, Professor Robin Bogner (Connecticut) received her Shangraw Prize from the President of AAPS, Pat DeLuca.

During the Excipient Focus Group meeting the following day, R. Christian Moreton, Ph.D., former Chair of IPEC–Americas, introduced the graduate students and presented them with \$1000.00 checks. Professor Bogner also had an opportunity to speak. Foundation ribbons were placed on all of the Graduate Students posters at their Poster Session which immediately followed the Excipient Focus Group event.



Pat DeLuca and Professor Robin Bogner

The mission of the IPEC Foundation is to educate the public and professionals on the importance of excipients. The Foundation awards prizes, scholarships and grants to support development of excipients in cutting-edge research on pharmaceuticals and biotechnology products.

To make a donation to the IPEC Foundation, or to find out more about applying for a foundation prize, please visit the Foundation website at www.ipefoundation.org.

CoA Guide Revision Project - Member Participation Invited

On December 10, 2009, IPEC–Americas' Excipient Qualification committee will continue its revision work on the Certificate of Analysis Guide for Bulk

Pharmaceutical Excipients, which was initially published almost ten years ago in 2000. With this revision we intend to address a core supply chain security topic

and will include among other possible enhancements, a new expectation that the original manufacturer be disclosed on Certificates of Analysis and periodic authentication by the excipient user. To ensure that the revised Guide takes into consideration your company's input, please plan to participate in the December 10th meeting. Our vision is that the revised guide will be applicable

worldwide as an IPEC Federation document.

Kind regards,

David B Klug, MS
U.S. Quality & Compliance
sanofi–aventis U.S. LLC
Chair, Excipient Qualification Committee

What's New? The IPEC Novel Excipient Safety Evaluation Procedure Article

In case you may have missed it, a reprint of the November 2009 Pharmaceutical Technology position paper on IPEC's novel excipient safety evaluation procedure is, with the magazine's permission, available on the IPEC–Americas website at www.ipecamericas.org in the "What's New" section. Jointly authored by current Safety Committee Chair Christopher DeMerlis of Colorcon; former Committee Chair Dr. Jay Goldring now with L'Oreal; Dr. Ranga Velagaleti of BASF; Dr. William Brock of Brock Scientific Consulting, and Dr. Robert Osterberg of Aclairo PDG, the article closely details the tiered toxicology testing approach contained in

the procedure and recommended by IPEC as an independent way to evaluate a novel excipient's safety for pharmaceutical use apart from a formal new drug approval procedure. According to the authors, all of whom have been intimately involved in the procedure's development, testing, implementation, and evaluation process, the tired process will enable an excipient sponsor to create a program in cooperation with the sponsor of a new drug formulation that is designed to avoid safety-related surprises.

It is well worth reading and considering.

IPEC-Americas to Sponsor On-line Open Journal

IPEC–Americas has agreed to sponsor a peer reviewed scientific journal which will be dedicated to excipients. This journal will be an on–line open–access journal published by IPEC, titled the Journal of Excipients and Food Chemicals (JEFC). JEFC will publish research articles, research reports, technical notes, scientific commentaries, news, views and review articles related to the physical, chemical biological, biotechnological,

clinical and socioeconomic–pharmacoeconomic as well as regulatory aspects of pharmaceutical excipients and food chemicals.

The scope of the journal is to offer a unique forum for the discussion and communication of research, reviews or commentary related exclusively to excipient materials. It is hoped that the journal will be launched by the second quarter of 2010.

2010 Annual IPEC Europe Seminar - January 28, 2010, Gray d'Albion Hotel Cannes, France

Provisional Program

“Taking Excipients into the Next Decade”

Keynote Address:

Pharmacopoeias in the 21st Century

Dr. Susanne Keitel

Director, European Directorate for the

Quality of Medicines and Healthcare (EDQM)

Session on Supply Chain Issues:

Supply Chain Security

Dr. Cornelia Nopitsch–Mai

Member, EMEA Quality Working Party

Chair, EDQM Technical Advisory Board

Challenges of Compliance

Dr. Bernd Renger
Chair, European Qualified Person
Association

Excipient Certification

Dr. Iain Moore
Coordinator, Excipient Certification
Project

Session on Quality by Design:**QbD: Regulator Perspective**

Mr. Ian Thrussell
MHRA GMP Inspector

QbD: Industry Perspective

Dr. Prabir Basu
Director, National Institute for
Pharmaceutical Technology and Education

Session on Risk Management:**ICH Q9**

Mr. Jacques Morenas
Assistant Director, AFSSAPS

Q9: Industry Perspective

Pharmaceutical Quality Group
Speaker to be confirmed

Important Industry Meetings

December 15–16

*Product Quality Research Institute (PQRI) Conference
On Advancing Drug Product Quality and Development*

Hilton Executive Meeting Center

Rockville, MD

Register: 703–248–4719 or by email to pennv@pqri.org

IPEC–Americas Committee Meetings

December 8

Executive Committee (by invitation only)

12:00 PM – 5:30 PM

December 9

Quality by Design/ Product Development

8:15 AM – 12:00 PM

–Luncheon –

Excipient Composition Working Group

1:00 PM – 5:00 PM

IPEC Foundation Meeting/Dinner

(by invitation only)

5:30 PM – 8:30 PM

December 10

Good Manufacturing Practices

8:15 AM – 12:00 PM

–Luncheon –

Excipient Qualification

1:00 PM – 5:00 PM

Board of Trustees Meeting/Dinner

5:30 PM – 8:30 PM

December 11

Compendial Review/Harmonization

8:15AM – 12:00PM

–Luncheon–

Regulatory Affairs

1:00 PM – 5:00PM

Reminder: All committee and working group meetings are held in the offices of IPEC–Americas outside legal counsel, Buchanan Ingersoll & Rooney PC, 1700 K Street, Suite 300, N.W., Washington, D.C. Since the building is security–protected, names of expected meeting attendees must be provided in advance to security personnel. Thus, if you are attending a listed meeting for the first time, please provide your name at least a day before the event by email to jean.rodgers@bipc.com