May 2011

IPEC-Americas News

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

Chair's Note:

I am still feeling the excitement and awe from our 20th Anniversary Conference and IPEC Foundation Gala dinner. Listening to speakers from IPEC Japan, Europe, China, the IPEC Federation, and Sindusfarma, I realized IPEC had risen to its prominence as a global leader for Excipients. Our introduction of the "Total Excipient Control" concept and following related presentations really delivered the why, what and how for excipient control. The video tape of our founding father Lou Blecher gave us all a glimpse at the beginning of IPEC, with stories repeated during breaks from the attendees who were a part of the original IPEC meetings. The IPEC Foundation Gala dinner started with the presentation of the Lou Blecher Lifetime Achievement Award to Jerry Halperin for his support of IPEC during his years with USP.

As the evening continued our whole history weaved together into a tight knit blanket of accolades as each of the past chairs gave a brief commentary on their predecessor. Joe Borzelleca's commentary on his memories of Marshall Steinberg completed the history of IPEC. The icing on the cake came with the side splitting hilarious performance by the Capitol Steps. We plan to continue the IPEC Foundation Gala Dinner on the night before ExcipientFest as a fundraiser to support the awards and scholarships designed to promote research and development in the Excipient realm. Please include the Foundation dinner in your future ExcipientFest plans.

Inside This Issue

Chair's Note: 1-3
IPEC-Americas General Update: May 2011.....4
ExcipientFest Americas Sets Attendance Record..5
Jerome Halperin Receives the IPEC Foundation Louis Blecher Lifetime Achievement Award.....5-6
NESEP Webinar Recording Available.....6-7
Press Announcement: FDA to Make Enforcement and Compliance Activities Accessible Online.....7
European Union Council Adopts Directive on Falsified Medicines.....7-8
Ashland Inc. to Buy ISP.....9
Avantor Performance Materials t Acquire Polish Company POCH S.A. 9
IPEA Workshops.....10
Important Industry Meetings 11-12

We ended May with another full week of productive committee meetings. This work will spill over into the summer as IPEC sub-committees and working groups move forward on projects. The ANSI NSF 363 Excipient GMP certification standard and the Excipact Excipient GMP/GDP certification standard are both out for comment in June. The Visible Particle working group has telecons scheduled as does the newly formed Excipient Risk Guideline working group.

Dave Schoneker is leading a coalition to comment and provide direction on the USP Elemental Impurities Chapter.

Dr. Keiji Kijima, David Schoneker, Dale Carter

Dale Carter and Rick Green

Also plan to attend the PDA/FDA Supply Chain Conference on June 6-7th which has many IPEC speakers presenting the excipient side of supply chain issues. The IPEC Federation and PDG working group are meeting in Cincinnati June 13 - 16th for compendia harmonization and as a Federation meeting with topics to include the Excipact launch and funding. Our Legislative Initiative team is planning a strategy session to review our goals and legislative priorities. If your company did not participate there is still time to join the group.

Thanks again to all who participated in our full month of activities this May. Have a safe summer and check the IPEC Americas Website for updates on summer telecons.

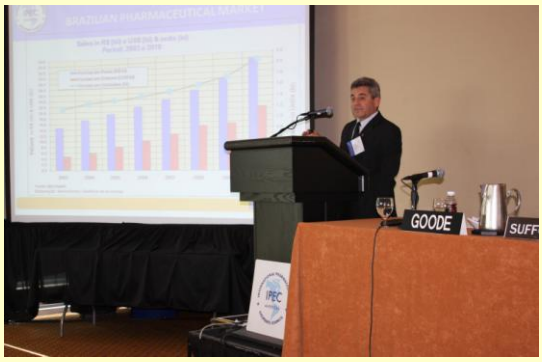
Sidney Goode, Dwight Mutchler, Susan Schniepp, Nigel Langley

The Working Luncheon

Ann Van Meter and Janeen Skutnik-Wilkinson

Alan Mercill, Valeria Stewart, Linda Herzog, Marileni Payano and Beam Suffolk

Alexa Smith



Speaker: Jair Calixto

David Schoneker, Janeen Skutnik-Wilkinson, Chris Moreton, and Art Falk at the Gala Dinner

The Capitol Steps

Rani Maloney, Sue Schniepp, Phil Merrell, Janeen Skutnik- Wilkinson, Beam Suffolk, Patricia Rafidison

IPEC-Americas General Update: May 2011

As noted on the slides linked below, which were presented to IPEC-Americas members on May 25 following a full day of committee meetings, there was a lot to report – apart from the 20th Anniversary Conference and ExcipientFest!

For example, ongoing committee activities, which includes:

Quality by Design – excipient variability guidance
Excipient Composition – visible particle issues
Good Manufacturing Practice – the ANSI 363 project, EXCIPACT, risk assessment
Excipient Qualification – updated COA guidance and FDA's spectral library project
Compendial Review – elemental impurities
Regulatory Affairs – IIG – IID issues
Safety – the new excipient safety evaluation procedure

- FDA's request for IPEC-Americas members to provide information to include in FDA's Spectral Library of excipients is designed to add a layer of difficulty for anyone trying to infiltrate a material supply chain and is well worth considering!
- A report on the current situation in Japan and products sourced from there
- Planning for upcoming IPEC Federation meetings in mid-June in Cincinnati, Ohio
- The June 6-7 PDA/FDA Pharmaceutical supply Chain Conference
- The ongoing IPEC Legislative Initiative and its goals
- A summary of a special Strategic Planning meeting in Rhode Island and its recommendation for assessment of IPEC's value to member companies and individuals:
  - What IPEC does well;
  - Where we need to improve or add; and
  - next steps

This led to a report on Elemental Impurities and "Excipient Realities" whose slides deserve careful reading since the issues involved are likely to affect all IPEC and IPEC-Americas members worldwide for months and years to come.

A summary of current IPEC plans and proposals also is provided which, as noted above, are expected to be major discussion topics in future Compendial Review/Harmonization Committee meetings.

To view and download the May 25 General Update slides, go to:

http://ipecamericas.org/content/general-update-slides

ExcipientFest Americas Sets Attendance Record

According to final numbers, 530 persons took part in the May 10-11 2011 ExcipientFest Americas event which was held for the first time on the U.S. mainland in Baltimore, Maryland. This set an attendance record in its eleven year history which has come to be recognized as the global excipient industry's best EXPO for education relating to current excipient science, regulatory issues and sourcing.

Because of a prior commitment, the April 24-25, 2012 ExcipientFest Americas program will return to the Ritz Carlton Hotel and Conference Center in San Juan, Puerto Rico. After that, however, it is planned to return ExcipientFest to the mainland, either at the Renaissance in Baltimore, site of the 2011 program, or possibly at a location closer to Washington, D.C. This will be determined later by the ExcipientFest team.

In the meantime, begin planning now for 2012 and keep monitoring excipientfest.com for program and registration details.

IPEC-Americas Staff at ExcipientFest
Valeria Stewart, Tammy Kramer, Alan Mercill, Kim Beals

ExcipientFest Asia will take place at the InterContinental Beijing Beichen, Beijing China June 19-20, 2012

Jerome Halperin Receives the IPEC Foundation Louis Blecher Lifetime Achievement Award

During the May 9 Gala Dinner Celebration in Baltimore, Maryland, Rear Admiral Jerome Halperin was awarded the IPEC Foundation's Louis Blecher Lifetime Achievement Award. This award recognizes individuals who have, during their lifetime, made substantial intellectual contributions to the field of excipients. Jerry, as he is fondly referred to by his friends and colleagues, was a Sloan Fellow at MIT; received a Masters of Public Health at John's Hopkins; and received numerous honorary degrees and honors including the prestigious Remington Honor Medal.

In late 1990, Jerry Halperin, who was CEO of the United States Pharmacopia at the time, hosted a wine and cheese reception at a world meeting of the USP, European Pharmacopeia and the Japanese Pharmacopeia in Orlando, Florida, a gathering that led to formation of IPEC in 1991. Jerry was very supportive of IPEC in the early years as the PDG organization became deeply involved in Global Pharmacopeial Harmonization and continued to work closely with IPEC for many subsequent years.

Rear Admiral Jerry Halperin has had a very distinguished career including 25 years at USPHS which he concluded as Deputy Director in FDA's Bureau of Drugs.

The first IPEC Foundation Lifetime Achievement Award was given to Lou Blecher, the Founder of IPEC, and was later named after him.

Dale Carter, Jerry Halperin, Bob Pinco

NESEP Webinar Recording Available

Throughout the world, new or novel excipients are only approved within new drug applications, and no independent regulatory approval process exists for new excipient's, new uses, or levels of an excipients use – apart from a new drug approval process. Because of this, in 2007, IPEC-Americas Safety Committee developed a novel excipient evaluation process to help reduce the cost and uncertainty related to use of novel excipients in pharmaceutical formulations; thereby encouraging their use in drug development programs and encouraging drug formulation innovation.

This led to an expanded and adaptable procedure and process which is now used by committees appointed and administered by Aclairo PDG, Inc. Its goal is to provide an independent evaluation of safety and regulatory data relating to a proposed new excipient use in a future regulatory filing. The process is designed and intended to mirror that of regulatory agencies, beginning with the U.S. Food and Drug Administration, thereby providing confidence to pharmaceutical manufacturers that the excipient will be found acceptable in their submitted formulations.

If you are interested in learning more about the procedure and want to view the November 23, 2010 Webinar featuring Christopher DeMerlis, Regulatory Affairs Manager, Colorcon; Elaine V. Knight, Ph.D, Interdisciplinary Scientist and Toxicologist, National Institute of Health; and Robert Osterberg, Ph.D., Senior Consultant, Pharmacology/ Toxicology, Aclairo PDG, Inc., Please contact: Kim Beals in the IPEC office (kim.beals@ipecamericas.org). A link will be forwarded for you to view the WebEx webinar recording.

Press Announcement: FDA to Make Enforcement and Compliance Activities Online

According to a May 26 notice from FDA's press office and posted on the agency website at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm256875.htm

FDA has established a new Web portal with a searchable database relating to:

FDAs Transparency Initiative;
an Inspection database; and
Information about FDA compliance and enforcement actions

FDA U.S. Food and Drug Administration

European Union Council Adopts Directive on Falsified Medicines

According to a report from IPEC Europe, the Council of the European Union adopted the Directive on Falsified Medicines on Friday, May 27. The Directive as adopted will be published in the Official Journal of the European Union and will take effect 20 days following publication.

Under European Union rules, member states will have 18 months to transpose the directive into their national law.

As referenced in the IPEC Europe report prepared by Elena Micelli, Scientific and Regulatory Advisor:

"...the main points concerning excipients referred to:

- **Definition of excipient**: An excipient is defined as: "Any constituent of a medicinal product other than the active substance and packaging material."

- **GMP guidances for excipients**: The holder of the manufacturing authorisation shall ensure that the excipients are suitable for use in medicinal products by verifying the appropriate good manufacturing practice on the basis of a formalised risk assessment in accordance with the applicable guidelines. Accordingly the Commission shall adopt Guidelines on the formalised risk assessment for verification of the appropriate good manufacturing practice for excipients.

- **Inspections**: It was agreed that "Manufacturers, located in the European Union or in third countries, and wholesale distributors of medicinal products shall be subject to repeated inspections. The competent authority shall have a system of supervision including by inspections at an appropriate frequency based on risk, at the premises of the manufacturers, importers, or distributors of active substances, located on their territory, and effective follow up thereof.

Whenever it considers that there are grounds for suspecting non-compliance with the legal requirements laid down in this Directive […] the competent authority may carry out inspections at the premises of: […] (b) manufacturers or importers of excipients. […] inspections shall be carried out by officials representing the competent authority who shall be empowered to: (a) inspect the manufacturing or commercial establishments of manufacturers of medicinal products, of active substances or excipients, and any laboratories employed by the holder of the manufacturing authorization to carry out checks […]".

A copy of the Falsified Medicine Directive also is available on the European Union website at http://eur-lex.europa.eu/en/index.htm

Ashland Inc. to Buy ISP

According to a May 31 news release, Ashland, Inc. the parent company of IPEC-Americas member Ashland Aqualon Functional Ingredients, has agreed to purchase International Specialty Products, Inc. The sale, which will require U.S. and European Union regulatory approval because of the chemical markets involved, is expected to be finalized before the end of 2011. ISP, based in Wayne, New Jersey, and with other facilities in the USA and the United Kingdom, also is an IPEC-Americas member.

Avantor Performance Materials to Acquire Polish Company POCH S.A.

According to a May 6 news release, Avantor Performance Materials announced an agreement to purchase the Polish-based chemical and laboratory equipment company, POCH S.A.. The step is part of Avantor's current plan to expand its global markets and to move into new ones where possible. Completion of the sale will be dependent upon obtaining clearance from the government competition authority in Poland.

Once the sale is finalized, it is expected that an early benefit to Avantor will result from POCH's marketing of Avantor product lines along with POCH's materials in POCH's established distribution channels in Poland and throughout Eastern Europe.

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 not yet available for this workshop. A link will be posted on the IPEA web site once it becomes available.

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)

Important Industry Meetings

June 6-7

2011 PDA Pharmaceutical Supply Chain Conference
Bethesda North Marriott Hotel and Conference Center
Bethesda, Maryland
Register: http://www.pda.org/MainMenuCategory/GlobalEventCalendarandRegistration/2011-PDA-Pharmaceutical-Ingredient-Supply-Chain-Workshop.aspx

June 15-16

NIPTE Research Conference – Critical Path Research for Pharmaceutical
Process Scale-Up and Stability
The Universities at Shady Grove Conference Center
Rockville, Maryland
Register: www.nipte.org

June 19-23

Drug Information Association (DIA) 47th Annual Meeting
Convergence of Science, Medicine and Health
McCormick Place West
Chicago, Illinois
Register: www.diahome.org/registerDIA2011

June 20-21

The NIPTE 13th Annual FDA and the Current Challenges of GMPs Conference
Hyatt Regency Bethesda
Bethesda, MD
Register: www.pharmaconference.com

July 31-August 5

43rd Annual IUPAC World Chemistry Conference
organized by the Colegio de Quimicos de Puerto Rico
Puerto Rico Convention Center
San Juan, Puerto Rico
Register: www.iupac2011.org

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

September 12-13

PQRI Workshop on Sample Sizes for Discussion Making in New Manufacturing Paradigms
Co-sponsored by AAPS & IQ Consortium
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

October 6-7

CHPA's 2011 OTC Product Quality & Operations Workshop
Hyatt Regency Bethesda
Bethesda, Maryland
Register: www.chpa-info.org