IPEC Foundation Issues Awards at ACT & AAPS Meetings in November

On Monday, November 8th, during the 31st Annual Meeting of the American College of Toxicology in Baltimore Maryland, Dr. Joseph Borzelleca received the Marshall Steinberg Memorial Award for outstanding contributions in the area of safety and toxicology for excipients.

Dr. Borzelleca is a world renown toxicologist who has been involved in safety evaluations of excipients as well as food and color additives for many years. He co-authored IPEC’s Excipient Safety Evaluation Guideline with Marshall Steinberg (published in 1996) which are held in high regard by Food and Drug Administration as a basis for testing new excipients. Dr. Borzelleca was honored at the IPEC Foundation dinner with IPEC and ACT senior leaders later that evening at the Oceanaire Restaurant in Baltimore.

Pictured on the right former winner 2009 Chris DeMerlis, 2010 winner Dr. Borzelleca, and Dr. Robert Osterberg 2008.
On November 15th, during the annual meeting of the American Association of Pharmaceutical Scientists in New Orleans, Louisiana, Dr. James McGinity, professor of pharmaceutics in The University of Texas at Austin College of Pharmacy, received the $10,000 Ralph Shangraw Memorial Award for outstanding research in powder technology and the design and development of novel oral dosage forms. A formal dinner to honor Dr. McGinity and Dr. Karl Kolter, Head of R & D Pharm Ingredients, BASF SE (Germany) who received the first IPEC Foundation Award for Industry Research and Achievements in Excipient Technology took place the prior evening at Restaurant August, New Orleans. Dr. Kolter has extensive experience in industrial research which has led to the development of innovative excipients and drug delivery systems.

Four graduate students were also recognized during the dinner and AAPS formal awards ceremony: Mr. Ken K. Qian, University of Connecticut, School of Pharmacy; Ms. Maitri R. Trivedi, Long Island University; Mr. Qi (Tony) Zhou, Monash University, Parkville, Victoria, Australia; and, Ms. Archana Rawat, University of Connecticut, School of Pharmacy. The graduate students were also recognized during the Excipient Focus Group session held on Tuesday, November, 16, where they received travel scholarships of $1,000 to attend the AAPS meeting. The focus group is chaired by Thomas Farrell, Ph.D., Director, Product Development, Colorcon. Assisting with the event was R. Christian Moreton, Ph.D., Principal, FinnBrit Consulting, former Chair of IPEC–Americas (2003–2004).
Senior representatives from IPEC–Americas and NIPTE (The National Institute for Pharmaceutical Technology and Education) also met in New Orleans to discuss if a collaborative effort to encourage excipient research and pharmacy graduate and undergraduate students to consider careers in the excipient field could be achieved. NIPTE, Inc. is a not–for–profit organization dedicated to fundamental research and education in pharmaceutical product development and manufacturing.

Help the IPEC Foundation shape the future by energizing research in excipients through education and scholarship. To make a donation, please visit www.ipecfoundation.org.

Is your corporation interested in other opportunities to support the Foundation? Please consider sponsorship for the IPEC Foundation Gala Dinner to be held during the IPEC–Americas 20th Anniversary Conference in Baltimore Maryland, May 9, 2011. Contact Kim Beals, IPEC–Americas Executive Director for additional information at kim.beals@ipecamericas.org.
IPEC Federation Directors Report Progress from Fukuoka Meetings

According to initial minutes from the November 10–12 IPEC Federation Board of Directors meetings in Fukuoka, Japan, substantial progress was made in several areas important to global IPEC members. Progress also was reported from the November 11 meeting between IPEC Federation representatives and the Pharmacopeial Discussion Group. A separate report concerning that meeting appears later in this issue.

IPEC–Americas representatives in Fukuoka were four Executive Committee members: Chair Janeen Skutnik–Wilkinson of Pfizer, Chair Elect Dale Carter of JM Huber Engineered Materials, Immediate Past Chair David Schoneker of Colorcon, and Compendial Review Committee Chair Priscilla Zawislak of Ashland Aqualon Functional Ingredients.

During the Federation Board meetings, attendees agreed on changes to the Policy Manual that governs Federation activities, authorized the hiring of an accounting firm to manage Federation accounts and to arrange audits when they are needed. The Board also reviewed a draft 2011 budget and agreed that a final budget should be prepared for approval at the Federation’s 2011 Annual General Meeting. This will take place January 26 in Cannes, France.

Next year’s budget also is expected to include funding for a dedicated IPEC Federation teleconference facility, fees for accounting services, development of Federation promotional materials, and an independent audit if it could be managed by IPEC Europe’s service provider.

Participation in IPEC’s 20th Anniversary celebration was discussed, as was an initiative to “publicize” the Federation in 2011 and how its objectives and key messages can best be communicated. Input from the separate IPEC associations will be needed to produce the messages and the necessary materials for the Federation’s website and other forms of promotion.

During the three days of meetings, each regional association reported on their ongoing projects and also provided regulatory and compendial updates which affected excipient production and use. IPEC–Americas representatives reported on its current U.S. legislative goals to have third party certification of excipient GMP recognized in the absence of formal regulations for excipient manufacturing, although this appears doubtful in the near future even for food ingredient sources. In the meantime, however, there is reason to believe that FDA will continue its strict enforcement
of current GMP regulations set out in 21 CFR 210 and 211, with more attention to corporate leadership responsibility in preventing errors and control over drug components (excipients.)

Reports on the status of the NSF 363 GMP project status also were provided along with committee projects. Usage of additives during excipient manufacturing, their safety and presence in final materials and their approval for use in pharmaceutical formulation manufacturing is becoming a major global issue in the U.S., it was noted. There also is growing U.S. concern about possible use of materials thought by their manufacturer to be limited for an excipient function which instead have been discovered used as active pharmaceutical ingredients, e.g. APIs.

From Europe an update on a proposed directive on Falsified Medical Products was provided. It includes excipients and could be finalized in December. An earlier proposal to require general excipient GMP and GDP standards equivalent to those for APIs has been withdrawn, although certain categories of excipients for which API GMPs would apply are still referenced in Articles 46(f) and 47 of the proposal.

A proposal for third party accreditation of wholesale distributors has been deleted; however, it is believed that names of those who have been inspected will be publicly available. Unannounced inspections of excipient manufacturers still remains in the proposal, it was reported.

IPEC Europe committees also have projects underway, some of which involve interaction with IPEC–Americas. These include Certificates of Analysis guidance and updated Significant Change reporting guidance. In addition, development of an excipient risk assessment chart is progressing as are work in connection with the ongoing European Pediatric Initiative and compendial harmonization activity.

In Japan, JPEC has been working to revise its “Guidebook to Implementing the Self-imposed Standards of GMP for Pharmaceutical Excipients” and the Japanese Pharmaceutical Excipients (JPE) Compendium. An extensive program of excipient–related seminars also is underway.

From China a report on SFDA development of Drug Master File requirements, including those relating to excipients was provided. Details will be provided when SFDA establishes the submission process. Audit reports of raw materials suppliers will be required, it was noted, although it remains unclear whether third party audit reports will be accepted. If so, the China Pharmaceutical
Excipients Council (IPEC China) has identified a company with authority to accredit auditing companies and auditors.

Other ongoing Chinese projects involve development of information required for excipient master file submission, information needed for new or novel excipients, and for audit reports and pharmacopeial monographs.

Other Topics and Action Items

Future IPEC Federation expansion appears to be possible as a result of recent strategic partnerships established between IPEC-Americas and a professional association in Argentina, Safybi, and a similar relationship in Brazil with Sindusfarma, an association of pharmaceutical companies and suppliers, most of which are distributors.

Another possibility involves the countries of India, Pakistan and Bangladesh where a regional organization may be possible or maybe just in India initially after companies doing business there focus on their goals and needs.

Other topics discussed included:

- Need for an IPEC Federation Global Forum on Harmonization of Excipient Pharmacopeial Monographs on a Global Basis (including the emerging markets)
- A process for deciding when regional issues warrant discussion at the Federation level and topics which should be addressed globally
- The need for creation of a risk assessment analysis for excipients based on advice from regulatory groups, makers and users
- A review of priorities identified at earlier meetings of the Federation Board and their current status for possible resolution in January 2011 at Cannes or at the next series of Federation Board Meetings, June 15, 16, and 17 in Cincinnati, Ohio, USA.
PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Fukuoka, Japan 8-11 November 2010


At present, 27 of the 35 General Chapters and 41 of the 62 excipient monographs of the current work programme have been harmonised. General chapter sign-offs include Uniformity of Dosage Units (revision) and corrections to sign-off cover sheets for Extractable Volume and Particulate Matter. Excipient sign-offs include the newly-harmonized Crospovidone monograph and revisions to Lactose Anhydrous and Cellulose Acetate Phthalate. The latter revision is the outcome of PDG’s review of previously harmonised excipient monographs.

Following a meeting of experts from the three regions which took place on the Saturday preceding the PDG meetings, the general chapter on Chromatography was formally added to the PDG work programme.

Interaction with ICH Q4B

Harmonisation has been achieved on 9 of the 10 General Chapters identified by the ICH Q6A Guideline. PDG re-emphasised the importance of consistent regulatory positions on harmonised text. The sign-off of the revision to Uniformity of Dosage Units represented a resolution of the long-standing concern related to the 2% Relative Standard Deviation exemption in the harmonised Uniformity of Dosage Unit text that is not accepted by the US.

In their joint meeting, PDG provided Q4B with progress reports on a number of harmonised texts undergoing evaluation of interchangeability in response to their comments.

Other Topics

The three pharmacopoeias discussed other topics, including metal impurities and antioxidant additives in cellulosic excipients.

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation (IPEC-Americas, IPEC-Europe, IPEC-China and the Japan Excipients Council) was held on November 11, 2010. Topics, among others, included the cellulosics, propylene glycol, povidone, and silicon dioxide monographs.

PDG will hold its next meeting in June 2011 in Cincinnati, Ohio, USA.

Note for the editor: The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantations and consumer health issues.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM
Tel.: +33 (0) 3 88 41 28 15 - E-mail: caroline.letarnec@edqm.eu

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.
Chinese Pharmacopeia and Provincial Government Delegation To Visit the U.S.

During the week of December 13, a delegation of as many as 25 representatives of the Chinese Pharmacopeia and Chinese provincial government offices which regulate drug manufacturing and sale throughout China will be coming to the U.S. to meet with USP and Department of Commerce officials. The meeting at Commerce will take place on December 15 and IPEC–Americas has been asked if it is interested in participating and possibly making a presentation. IPEC, through its past Chair and principal USP representative David Schoneker of Colorcon, has expressed interest in doing both and a reply from the Department of Commerce is expected shortly. When this is received, a report to IPEC–Americas members will be provided.

According to IPEC personnel whom were present at the recent IPEC Federation and IPEC–PDG meetings in Fukuoka, Japan, a principal point of discussion there involved the need for U.S., European and Japanese government officials, pharmacopeial, pharmaceutical and excipient industry representatives who have been meeting in recent years in conjunction with International Conference on Harmonization activity to expand their future discussion with counterparts in China, India, Brazil and Russia because of their countries increasing importance in global pharmaceutical production, consumption and regulation. It would appear, therefore, that the chance to meet with Chinese representatives next month could be the first opportunity to raise that possibility and discuss the issues involved. As matters develop, reports will be provided.

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Call for Volunteers

The IPEC training team, an ad hoc committee formed in 2010 to develop and bring educational programming related to excipients to the general public, is seeking presenters for the 2011 educational training series. Experts in several different areas are needed to present on a variety of topics critical to manufacturers and users of pharmaceutical excipients. This is a great opportunity to share your knowledge about excipients to others.
interested in learning more about the field of excipients and to help advance IPEC–Americas mission. The webinars typically last about 1.5 hours with time allotted for Q & A. WebEx – the leading webinar service provider for online collaboration solutions – is the training platform provider and a rehearsal webinar is typically scheduled prior to the event.

If you would like to volunteer for one of the following three open topics, please contact Kim Beals, IPEC–Americas Executive Director at:

kim.beals@ipecamericas.org

Jan: Certificates of Analysis
Feb: Significant Change – Dave Schoneker, Director, Global Regulatory Affairs, Colorcon
Mar: Excipient Pedigree
Apr: Stability
May: Validation – Ann Van Meter, Senior Quality Systems Specialist, Dow Wolff Celluotics

Mutchler Chemical Company to Sponsor IPEC Foundation Gala Dinner Entertainment

Mutchler Chemical Company has generously agreed to sponsor the Capitol Steps, who will be providing entertainment during the IPEC–Americas Foundation Gala Dinner on Monday, May 9th, 2010 at the Renaissance Harborplace Hotel in Baltimore, Maryland. The Capitol Steps claim they “put the MOCK in Democracy” and are Americas favorite political satire group.

Other corporate sponsorship opportunities for the dinner include:

Diamond Sponsor – $7,000 – Preferred table for eight, banners and signage – full page in program
Ruby – $3,500 – Dinner for four, preferred seating, banners, signage and program recognition.

Contact Kim Beals at IPEC headquarters for additional information.
CHPA Becomes an IPEC-Americas Member

On November 16 an application for associate membership in the Pharmaceutical Industry Association category was submitted on behalf of the Consumer Healthcare Products Association (CHPA) and accepted by IPEC-Americas Executive Committee. CHPA is the U.S. industry association that represents manufacturers of non-prescription medicines and dietary supplements and, like IPEC, is involved globally in science-related pharmacopeial and regulatory matters through its members and those of related associations in other countries and regions, for example AESGP in Europe and the World Self Medication Industry (WSMI) association on a worldwide basis.

Dr. Rachael Roehrig, CHPA’s Director of Technical and Scientific Affairs has been designated its principal representative to IPEC and she plans to actively participate in future IPEC-Americas committee meetings and projects. At CHPA Dr. Roehrig provides principal staff support to both its Manufacturing Control and Scientific Affairs Committees. Since many IPEC members also hold membership in CHPA, Dr. Roehrig is well-known already to many IPEC members and will be most welcome since the two associations already cooperate on several levels. IPEC-Americas also is a CHPA associate member.

2010 Membership Update

With the addition of Consumer Healthcare Products Association in November, as noted elsewhere in this issue, IPEC-Americas membership now totals 78 – 45 full member manufacturers of excipients or finished pharmaceutical products; 1 affiliate which is a division of a full member; and 32 associates. Associate members include companies that distribute excipients for use in pharmaceuticals and dietary supplements, consultant firms that provide scientific and other services to full members, non-profit scientific research organizations, pharmaceutical industry associations and academics. The latter category includes both professors and department heads of graduate schools of pharmacy and related sciences, as well as their students. During 2010 16 new members were accepted, 4 full members and 12 associates. These are listed below.
Full Members

1. Apotex Inc. (Canada)
2. Catalent Pharma Solutions
3. Croda USA, Inc.
4. Natural Response SA (Chile)

Associate Members

1. Americhem Inc.
2. Chemistry for Life Inc.
3. Consumer Healthcare Products Association
4. Doe & Ingalls of North Carolina LLC
5. EC Knight Consulting Services LLC
6. IBS Consulting in Quality LLC
7. Maria de Lourdes Rivera
8. PFAR Consulting
9. PharmaVize NV (Belgium)
10. Radhakrishna Maroj
11. Shao Fu*
12. VWR International

*Graduate Students

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**Member Name Change-Mallinckrodt Baker is Now Avantor™ Performance Materials**

As a result of a recent transaction between Mallinckrodt Baker’s parent company Covidien and the New Mountain Capital, LLC investment group, the J.T. Baker® and Mallinckrodt® product brands are now being produced, marketed and managed by a newly formed New Mountain Capital company Avantor Performance Materials, Inc.

According to information set forth online at:


and

[http://www.avantorperformancematerials.com](http://www.avantorperformancematerials.com)

Avantor™ will operate as a stand-alone entity whose goal is to become one of the world’s leading suppliers of performance materials for use in the pharmaceutical, laboratory and microelectronic markets.

Avantor will retain IPEC–Americas membership and according to its principal member representative Juanita Garofalo, Director of Regulatory
Affairs, the only change necessary for email contact purposes is to replace “covidien.com” or “malinckrodt.com” with “avantormaterials.com”

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IPEA News: Excipient GMP Conformance Certification Program

In November, following an audit of Grace Davison’s facility in Sorocaba, Brazil, IPEA’s Certification Board agreed with the auditor’s findings and determined that the facility has earned a Certificate of Excipient GMP Conformance for excipients produced there. The certification applies to their Silicon Dioxide NF grades Syloid® 63FP and 244 FP and states:

“The excipients certified are produced in substantial conformance to the IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients 2006 through warehousing and shipment to their customers.”

This is the second certificate issued by IPEA. Two additional GMP certification audits have been completed this month for an IPEC member company. There are at least three other companies that have approached IPEA with an interest in the GMP certification program. For more information, excipient manufacturers are invited to contact ipeainc@aol.com or check the IPEA website information at:

http://www.ipeainc.com/Certification.htm

Recently there was a surge in interest in ISP excipient audit reports for excipients produced at ISP’s Calvert City and Texas City facilities, e.g., for Copovidone NF, Crospovidone NF, Pharmasolve®, and Povidone USP. For more information on reports available for purchase go to www.ipeainc.com/reports.htm.

SAVE THE DATES: April 5–7, 2010
Next (3 Day) Excipient Auditing Workshop in Arlington, VA (DC metro area)

Now Open for Registration: Go to http://www.ipeainc.com/auditingworkshop11.htm
Contact IPEA at 703–351–5266 or email: ipeainc@aol.com

Workshop Fees:
$1850 IPEC–Americas member company employees
$2250 Non members
$600 Government
This workshop offers participants training in the assessment of excipient manufacturer conformance to appropriate GMP requirements. The workshop leaders are Drs Art Falk and Irwin Silverstein. Please contact Valeria Stewart at IPEA, Inc. at 703–351–5266 or email: ipeainc@aol.com to reserve a space.

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**Important Industry Meetings**

**December 1–3**

PQRI–FDA Workshop on Process Drift: Detection Measurement, and Control in the Manufacture of Pharmaceuticals
Bethesda North Marriott Hotel
Bethesda, MD

**December 3**

USP Food Ingredient Stakeholder Forum
Rockville Headquarters
Rockville, MD
Register: [http://events.signup4.net/fisf](http://events.signup4.net/fisf)

**December 14**

Tablets & Capsules Webinar on Regulation of Excipients
12:00 PM – 2:00 PM EST       Cost: $99
Presenter John A. McCarty
Register: [https://secure.netbriefings.com/event/tabletscapsules/Live/tc1210/registercc.html](https://secure.netbriefings.com/event/tabletscapsules/Live/tc1210/registercc.html)

January 27, 2011

IPEC Europe Annual Seminar
Gray d’Albion Hotel
Cannes, France
Register: [Non-member registration form](#)
IPEC-Americas Committee Meetings - December 2010*

Monday, December 6

Membership 10am – 12pm (by invitation only)

Executive Committee 12:00pm – 5:00pm (by invitation only)
(luncheon provided)

Tuesday, December 7

Quality by Design 8:15am – 12:00pm
Lunch – 12:00 pm

Excipient Composition 1:00pm – 5:00pm
Validation Working Group 1:00pm – 5:00pm
IPEC Foundation Dinner Meeting 5:30pm – 8:30pm (by invitation only)

Wednesday, December 8

Good Manufacturing Practices 8:15am – 12:00pm
Lunch – 12:00 pm

Excipient Qualification 1:00pm – 5:00pm
Board of Trustees Dinner Meeting 5:30pm – 8:00pm

Thursday, December 9

Compendial Review 8:15am – 12:00pm
Lunch – 12:00 pm

Regulatory Affairs 1:00pm – 5:00pm

*All listed meetings will take place at the offices of IPEC–Americas legal counsel, Buchanan Ingersoll & Rooney, 1700 K Street, N.W., Washington, D.C.
IPEC 20th Anniversary Conference and ExcipientFest Americas!

The ExcipientFest planning committee has been meeting regularly to identify speakers and presenters for the educational programming for ExcipientFest, 2011, which will be held immediately following IPEC's 20th Anniversary Conference, May 9th. ExcipientFest will host over 50 exhibitors and there will be over 24 different presenters on a variety of topics critical to excipient manufacturers, distributors and finished drug makers. Mark your calendar because you won't want to miss the excitement in Baltimore Maryland's Inner Harbor May 9 – 11!