Excipient Focus Group
March 2012

Newsletter of AAPS Excipient Focus Group

A Message from Excipient Focus Group
Chair and Chair-Elect:

Dear EFG Members,

This year, we welcomed many new members to EFG and are looking into more sign ups and contributions from the active members in achieving our shared goals. Our next members’ face-to-face meeting at NBC in San Diego is a great opportunity for you to boost our membership sign ups. We strongly encourage your involvement in EFG and suggestions for ways to serve you and our community better.

We have had already a good start in 2012 with three meetings held with good turn outs. The meetings are fixed on a monthly basis for last Monday of each month at 12:00 p.m. Please refer to the EFG message board on AAPS website or contact us for conference call information.

It is our privilege to be part of the steering committee and we strive to improve our group’s efficiency, please do not hesitate to contact us with your suggestions and thoughts on ways to excel.

EFG—Current Activities and 2012 Primary Goals

We welcomed this year, Firouz Asgarzadeh, as chair elect. The current chair, Ajit Narang, will be leading the group during 2012, until AAPS annual meeting in Chicago at which point Firouz will be taking over his responsibilities and the 2013 chair-elect will be selected through member voting.

Below are a summary of EFG goals in 2012:

- Member outreach through
  - Periodic newsletters
  - Website discussion forums
- AAPS programming influence/participation
  - Webinar/other distance learning programs
  - Influence NBC & AM programming
- Monitor and participate in excipient-related publications
  - Operational:
    - Monthly teleconference with steering committee
    - Participation in monthly teleconference and support affiliated section activities [FDD (primary section), PPB and RS (secondary sections)]

See you at: National Biotechnology Conference:

Exciipients Focus Group Face-to-Face Membership Meeting
Wednesday May 23rd
12:15 – 1:15 pm
Agenda includes:

- Introduction of EFG Leadership
- 2012 Focus Group Objectives and Activities So Far
- Opportunities for greater involvement in the focus group and networking with fellow AAPS members with similar interests.

Mission Statement

To promote understanding of excipients and their use in pharmaceutical formulations. This includes understanding of excipient quality, functionality, drug-excipient interactions and regulatory considerations.

The Excipients Focus Group is affiliated with FDD, PPB and RS Sections
http://www.aaps.org/inside/focus_groups/Excip/index.asp
Website Suggestions / Comments?
Min Wei Wei_Min@Lilly.com)
NBC—Excipient Related Topics:
- Functional Excipients for Improved Drug Delivery of Biologics
- Recent Excipient Publications!

Excipients Focus of Themed Journal

This issue provides latest advances in research and use of pharmaceutical excipients. Articles cover a broad range of topics in the utilization of novel materials and the functionality and testing of excipients.

Recent Excipient Publications!
- Reversible and pH-dependent weak drug-excipient binding does not affect oral bioavailability of high dose drugs
  J Pharm Pharmacol. 2012 Apr;64(4):553-65
- Trends in excipient safety evaluation
  Int J Toxicol. 2011 Dec;30(6):600-10
- Influence of polymeric excipient properties on crystal hydrate formation kinetics of caffeine in aqueous slurries.
- Reactive Impurities in Excipients: Profiling, Identification and Mitigation of Drug–Excipient Incompatibility
- Preparation and Characterization of a Novel Co-processed Excipient of Chitin and Crystalline Mannitol
  AAPS PharmSciTech. 11(4): 1558–1571
- Safety issues with ethanol as an excipient
- Numerical Model to Characterize the Size Increase of Combination Drug and Hygroscopic Excipient Nanoparticle Aerosols

Awards and Honors

The Ralph Shangraw Memorial Award
The Ralph Shangraw Memorial Award is awarded to any person who has provided an outstanding research in the study of excipients or excipient-related technology. The award recognizes research achievements broadly in the field of pharmaceutical excipients including but not limited to research that contributes to an understanding of the basic science underlying excipients functionally; excipient safety, including the development of test methods and standards; the development of new excipients or novel use of existing in new applications; and the development of rational compendial/regulatory standards for excipients. The award recipients will receive $10,000.

IPEC Foundation Graduate Student Awards
The IPEC Foundation is sponsoring five annual awards to acknowledge excellence in research conducted at graduate level pertaining to the field of excipients. The awards focus on recent significant contributions to formulation science and technology with excipients brought about by highly innovative research. All interested candidates engaged in their final year of graduate studies leading to Ph.D. degree (or to be awarded in the year of submission) are encouraged to apply. The awardees will receive a cash award of $1,000 and a commemorative plaque. If selected, the applicant must attend the 2011 AAPS Annual Meeting &

Current EFG Leadership

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<tr>
<th>Position</th>
<th>Name</th>
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<tbody>
<tr>
<td>Chair</td>
<td>Ajit Narang</td>
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<tr>
<td>Chair-elect</td>
<td>Firouz Asgarzadeh</td>
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<td>Past Chair</td>
<td>Thomas Farrell</td>
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<td>Secretary</td>
<td>Ken Liljegren</td>
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<td>Webinars</td>
<td>Susan Lum &amp; Chris Moreton</td>
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<td>Webmaster</td>
<td>Min Wei</td>
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<td>RS Section</td>
<td>David Schoneker</td>
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<td>Other Steering Committee members</td>
<td>Sameer Late, Jennifer L’Hote-Gaston, Allison Radwick, Otilia Koo, Yongmei Wu, Sai Boddhu, Ming Zhou, Anthony Palmieri</td>
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IPEC-Americas Forms Inactive Ingredient Database (IID) Subcommittee and works with FDA’s Office of Generic Drugs to minimum delays in ANDA submissions (Submitted by: Dave Schoneker)

On December 9th, 2011 a team of five IPEC-Americas representatives met with about 20 representatives from the US FDA’s Office of Generic Drugs (OGD) to discuss potential issues and concerns with the Inactive Ingredients Database (IID). The meeting was a huge success and resulted in a number of key actions that will significantly improve the issues that ANDA sponsors have been having related to the use of various grades of excipients and establishing an appropriate precedence of use level.

The FDA has recently posted minutes and slides from the meeting, as well as an extensive backgrounder document (which was developed by the IPEC team and given to the FDA in advance of the meeting). The minutes provide a list of the key action items from the meeting. Click on the link below to access the FDA website where the information is posted.


As a result of the meeting with the FDA in December 2011, the FDA has formed an inactive ingredient working group (IIWG) to help work on and resolve issues as well as to improve the type of information listed in the database. Several meetings between IPEC-America’s core team and OGD are planned for 2012 where the work will continue.

A second meeting occurred between IPEC-Americas IID core team and OGD’s IIWG on March 6, 2012 which was also very beneficial. During the meeting, mechanisms were discussed for how the industry can provide FDA with lists of excipient grades that should be covered by one set of safety data and that should have the same maximum potency range based on the approval of one of the grades. Additionally, discussion occurred on how industry can make better use of the “controlled correspondence” mechanism that FDA offers to ask OGD questions about things like acceptable maximum daily dose levels of excipients, etc. FDA has already updated their website to reflect these discussions at:

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm120610.htm

IPEC is forming an IID Subcommittee to work with the IPEC IID Core Team in supporting and preparing information for the quarterly meetings planned with OGD. Additionally, IPEC-America has developed a priority list of excipients that have had issues with recent IID list changes and is interested in additional information related to what excipients have been causing IID problems in getting ANDA submissions accepted for filing.

IPEC-Americas would like to get more people involved in these efforts and hopefully have additional companies become a member in IPEC Americas. Non-members may attend IPEC-Americas committee meetings as a guest for up to three meetings. Please consider coming to a meeting of the IID Subcommittee or one of our other committees to find out about the many activities our members participate in. You can’t make a difference if you are not involved in the discussions.

New Excipients Book
EFG members are working towards a multi-authored Excipients-focused book that would highlight the latest developments and address unmet needs in the current literature. Interested? Contact ajit.narang@bms.com

ICH Q3D Metal Impurities Workshop
IPEC-Americas, SOCMA (Society of Chemical Manufacturers and Affiliates, Inc.) and CHPA (Consumer Healthcare Products Association) are partnering together to offer a workshop that will discuss the ICH Q3D Metal Impurities Guideline. New limits for element impurities in drug products are being recommended that could have a DIRECT IMPACT on your business.

This workshop will offer an opportunity to confidentially share data and then have it taken back to ICH for consideration.

Register online at:
https://www.ipec-events.com/events.asp

REGISTER NOW! One week away! April 4-5, 2012
Marriott Bethesda North Hotel
5701 Marinelli Road
Bethesda, Maryland 20852
1-800-859-8003