A Message from the 2014 EFG Chair: Thiago Carvalho

Dear EFG members,

As I enter my chairmanship mandate at EFG, it is with great excitement that the EFG steering committee brings to you the Spring edition of our newsletter.

Several scientists interested in the topic of excipients attended our business meeting in San Antonio in November last year during the Annual Meeting. One of the topics covered was the new organizational structure of our steering committee proposed for 2014. We have Nicole Buist joining our team as the chair-elect and we also have clearer roles & responsibilities moving forward. Kevin O’Donnell is serving as our Public Affairs representative, organizing and restructuring our website and leading the newsletter edition. Kiran Vangara joins us as our Programming Coordinator, reaching out to the more than 800 EFG members throughout the world to bring together relevant scientific programming. Ping Du joins us as our student representative and will represent our focus group at the Formulation Design and Development (FDD) student committee to discuss topics relevant to students and young scientists. Ken Liljegren and Dave Schoneker continue to serve as our secretary and Regulatory Sciences representative, respectively.

To all of you: welcome and thanks for volunteering at the EFG steering committee!

We are excited that we have many interesting programming being offered to you in 2014. We started with the webinar presented by
Dr. Ajit Narang, from Bristol-Myers Squibb, on Impact of Excipients on Oral Drug Bioavailability on February 27th. Another webinar will be offered in May and we will have three excipients-related topics at our Annual Meeting in San Diego in November: one symposium, one roundtable and one sunrise session. Additional information on these events can be found on page 3 of this newsletter!

This programming offering comes to reality with work from many volunteers who have served before us and/or are still serving the EFG. With the intent to honor some of them, Kevin and Ping have seamlessly put together the bios of our past chairs and I invite you to check it out here. Of course, this focus group is only as active as our membership is engaged. So we thank those who connect with us on a monthly basis during our telecoms every last Tuesday of the month, from 12pm to 1pm EST. And, if you are considering learning more and/or contributing to foster scientific discussions in the area of pharmaceutical excipients, please join us! We welcome new ideas and have plenty of opportunities for volunteering. You can contact any of us listed in the EFG website: http://www.aaps.org/Excipients/ for more information.

We will be delighted to have you join our mission to promote understanding of quality, functionality, drug-excipient interactions and regulatory considerations of pharmaceutical excipients.

Sincerely,
Thiago Carvalho, chair.
Update on the Novel Excipients Working Group
(by Keith Horspool, Sarah Nicholson and Thiago Carvalho)

In October 2013, we published in the EFG newsletter the endorsement of the formation of the Streamlined Approval of Novel Excipients Working Group under the sponsorship of the Drug Product Leadership Group within the IQ Consortium (see here). Since then, the two sub-teams formed (Excipients of Interest & Preclinical Safety Data Package) have put together a survey that was sent out to IQ company members. The goals of this survey were i) to identify specific novel excipients that are of common interest to IQ Consortium member companies; and ii) to identify formulation issues for which the current range of commercially available excipients in approved drug products is inadequate and novel excipients are required. Based upon the survey results and consensus among member companies, the Novel Excipients Working Group may consider joint testing to produce a preclinical data package for selected excipients of mutual interest. Twenty-one IQ members responded to the survey and the anonymous results have been compiled for review and refinement by the Working Group.

On another front, a small delegation from the Novel Excipients Working Group met with the IPEC Executive Board in the beginning of December 2013, followed up by another meeting in February 2014. The focus of these meetings was to discuss the possibility of a new regulatory review route for excipients. Jointly, IQ and IPEC are developing a background document

**Novel Excipients**
- Survey results may lead group to joint testing for selected excipients of mutual interest
- New regulatory review route for excipients discussed by IQ & IPEC

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**EFG is proud to announce 3 excipient related events at the 2014 AAPS Annual Meeting:**

**Symposium:**
“Excipients as Atypical Actives in Nutraceuticals and Pharmaceuticals - Applications and Development Considerations”

**Mini-Symposium:** “Next Generation Formulation Design: Innovations in Material Selection and Functionality”

**Sunrise session:**
“The Excipient Paradox - Interaction of Solubilizing Excipients with Metabolizing Enzymes and Transporters”
on this topic for initial discussion with FDA aimed for June. In this high level document, the DMF system is suggested as basis for “approval” of novel excipients and the members will solicit ideas and comments from FDA attendees. This meeting is expected to be a kick off discussion that will shape future efforts to address the challenging long-term goal of obtaining approval of excipients independent of drug product approval.

Companies interested in participating in this initiative and/or responding to the survey are encouraged to contact their IQ or IPEC representatives. Ilse Peterson (ilse.peterson@dbr.com) can also provide further details.

The mission of the Excipients focus group is to promote understanding of excipients and their use in pharmaceutical formulations. This includes understanding of excipient quality, functionality, drug-excipient interactions and regulatory considerations. To fulfill this mission, the Excipients Focus group will develop its own relevant programming and publications as well as influence the content of AAPS annual meeting and national biotechnology conference.
Recent excipient research and development
- A list of recent publications centered on excipient research compiled by our EFG Student Representative Ping Du, a Ph.D. student at The University of Texas at Austin


Awards to Apply For

- Below are descriptions of awards associated with excipient research. This is not a complete list and the EFG encourages all readers to apply for these and other available awards/scholarships in this field.

Ralph Shangraw Memorial Award

- The Ralph Shangraw Memorial Award is to be awarded to any person who, in the opinion of the Board, has provided outstanding research contributions in the study of excipients or excipient-related technology over a number of years. The award is open to all scientists of any nationality or residence working in this field of research. Apply through the EFG website link or at http://www.ipecfoundation.org/ralph-shangraw-memorial-award

Industry Research Achievement in Excipient Technology Award

- The Foundation established the Industry Research Achievement in Excipient Technology Award to recognize individuals working in an industrial setting who have made significant contributions in the field of excipient technology. The award will be given annually to an individual working in the field of excipient technology who, in the opinion of the Board, has made a significant research contribution to the field, while working in industry. Apply through the link on the EFG website.

Other Awards

Additionally, the IPEC Foundation has Graduate Student Awards available. For details regarding qualification and application visit http://www.ipecfoundation.org/uploads/File/GraduateApplication2014.pdf

The FDD sectional also has numerous awards to apply for which can be found at http://www.aaps.org/AMAWards/#AM. The deadlines for some of these awards are in May, be sure to look online!

Deadline to apply for these awards is June 11, 2014.
Excipient Focus Group Newsletter

For more information on any of the topics in this newsletter, visit the Excipient Focus Group website at:

http://www.aaps.org/Excipients/

The 2014 Spring edition of EFG Newsletter edited by Kevin O’Donnell, Senior Chemist, The Dow Chemical Company, Midland, MI USA

American Association of Pharmaceutical Scientists

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