

# CROSS-INDUSTRY Organizations

## INTFG update: iBCS Workshop and recent activities

**Bill Schachtner**

*On behalf of the AAPS Inhalation and Nasal Technology Focus Group*



The Inhalation and Nasal Technology Focus Group (INTFG) is a specialty focus group within the Formulation Design and Development (FDD) section of the American Association of Pharmaceutical Scientists (AAPS). Membership in the focus group is comprised of scientists from industry, academia and government agencies from around the world. The group's goal is to bring together scientists to discuss and disseminate information related to the advancement of the sciences required for the development and improvement of oral pulmonary inhalation and nasal drug delivery products.

### INTFG annual business meeting

The 2014 AAPS Annual Meeting was held in San Diego, CA, US, November 2-6, with the INTFG annual business meeting taking place on November 4. An update on the previous year's activities was given

and the annual elections for members to the Executive Committee were held (Table 1). Also, a preview of the idea behind and expectations for the March 2015 INTFG Workshop on an inhalation Biopharmaceutical Classification System (iBCS) was presented by Jayne Hastedt of JDP Pharma Consulting, LLC.



### INTFG iBCS Workshop

The INTFG held a workshop March 16-17, 2015 in conjunction

with the US Food and Drug Administration (FDA) and the US Pharmacopeia (USP) on the topic of an inhalation Biopharmaceutical Classification System (iBCS). The purpose of the workshop was to discuss and evaluate the issues involved in development of such a classification system for inhaled drugs. Comparisons were made with the current BCS system utilized for solid oral dosage forms, introduced in the 1990s, with the equivalent areas for pulmonary delivery of drugs. The systemic absorption of a drug substance from a dosage form is dependent primarily on three factors: the solubility properties of the drug, the permeability of the drug to the cells and the pharmacokinetics associated with the route of administration. If these properties can be well understood, the potential for correlating *in vitro* dosing to *in vivo* bioavailability may be possible.

The workshop was well attended

**Table 1**

#### Members of the 2014-2015 INTFG Executive Committee

Bill Schachtner	Chair	Lupin, Inc.
Jayne Hastedt, PhD	Vice Chair/Chair-Elect	JDP Pharma Consulting, LLC
Jeffrey Breit, PhD	Past Chair	Bend Research/Capsugel Dosage Form Solutions
Philip Kuehl, PhD	Secretary	Lovelace Respiratory Research Institute
Prabo Wijetunge, PhD	Executive Member	Novel Laboratories, Inc.
Vivek Gupta, PhD	Executive Member	Keck Graduate Institute
Goncalo Andrade, PhD	Executive Member	Hovione
Benjamin Maynor, PhD	Executive Member	Liquidia Technologies
Daniel Moraga-Espinoza	Student Member	University of Texas–Austin

and the overview and break-out sessions provided extensive discussions on the issues for each of the three areas in relation to pulmonary drug delivery. Currently, a subgroup of the presenters and mediators is in the process of writing a white paper on the workshop. Future activities are also planned to further discuss this topic.

For further information on activities of the focus group, please visit [www.aaps.org/Inhalation\\_and\\_Nasal\\_Technology/](http://www.aaps.org/Inhalation_and_Nasal_Technology/) or follow us on LinkedIn.

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## **INTFG at RDD 2015**

An INTFG business meeting was held at RDD Europe 2015 in Antibes, France on the evening of May 6. An overview of the group's activities was presented and a request was made for feedback from the membership about topics of interest for the group to champion. In addition, Dr. Gerallt Williams of Aptar delivered a presentation on "Inhaled and nasal dosage forms—Some key drug delivery device challenges." Participation was good and many discussions on the presentation and its content were held late into the evening.

## **INTFG communication efforts in 2015**

The INTFG also works to bring additional information to its membership through the use of webinars, newsletters, its AAPS website, LinkedIn account and blog postings. Previous webinars have been presented on inhalation fundamentals and nanotechnology. Future webinars are planned on: particle formation and amorphous stabilization of biologics for inhalation, pulmonary drug development and impact of new FDA guidance for generic products, and perspectives in developing inhalation products in global marketplaces. A summer newsletter from the INTFG was released in June and included articles on nasal drug delivery, inhaled antibiotics for multi-drug resistant cystic fibrosis and a short review of the iBCS Workshop. The newsletter is available on the INTFG section of the AAPS website.