

CROSS-INDUSTRY Organizations

An update from the AAPS Inhalation and Nasal Technology Focus Group (INTFG)

Jeffrey Breit

On behalf of the 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). The group's goal is bringing together scientists focused on nasal or pulmonary delivery of therapeutic compounds in order to disseminate the state-of-the-art in the field. Industrial, academic and government scientists actively participate in INTFG activities to ensure a robust and current approach to understanding the science and application of nasal and pulmonary drug delivery technologies. Topics of interest to the INTFG evolve to address current medical needs and areas of scientific interest in the industry. These topics include, but are not limited to, excipient/formulation selection and analytical technologies, as well as novel delivery and device technologies. The current Executive Committee (EC) of the INTFG, elected at the 2012 AAPS Annual Meeting, is shown in Table 1.

2012 AAPS Annual Meeting INTFG events

Scientific talks and poster presentations were hosted by the INTFG at the 2012 Annual INTFG Fall Symposium. A sunrise session was held, entitled "Defining Critical

Attributes for Combination Products." Speakers were Justin Pennington (Merck & Co.), Gerallt Williams (Aptar Pharma) and Prasad Peri (US Food and Drug Administration (FDA)). This session highlighted the unique analytical challenges encountered during the development of inhaled fixed-dose combination products.

INTFG also hosted a symposium at the 2012 AAPS Annual Meeting entitled "Correlating *In Vitro* and *In Vivo* Lung Deposition of Pulmonary Formulations: Pharmacokinetic and Regulatory Perspectives." Presenters were Warren Finlay of the University of Alberta, Julie Suman of Next Breath, LLC, Neil Miller of GlaxoSmithKline and Dennis O'Conner of Boehringer Ingelheim. The session focused on

a mechanistic correlation between measured *in vitro* formulation characteristics and *in silico* predictions with observed *in vivo* behavior towards an acceptable bioequivalence standard for a pulmonary dosage form.

INTFG at RDD Europe 2013 in Berlin

An INTFG business meeting will be held at RDD Europe in May. INTFG affairs will be discussed and a short scientific presentation will be delivered. Guenther Hochhaus, an INTFG EC member from the University of Florida, will present a talk entitled "Pulmonary Bioequivalence: Is There Any News?" The meeting will take place on Wednesday, May 22, 7:00-8:00 P.M. Those interested in

Table 1

Members of the INTFG Executive Committee

Sai Chamarthy, Ph.D.	Chair	Merck & Co.
Jeffrey Breit, Ph.D.	Vice Chair	Bend Research, Inc.
Samiran De, Ph.D.	Past Chair	Next Breath, LLC
Bill Schachtner, B.S.	Secretary	PPD, Inc.
Guenther Hochhaus, Ph.D.	Executive Member	University of Florida
James Butz, Ph.D.	Executive Member	Meril, Inc.
Reinhard Vehring	Executive Member	University of Calgary
Phillip Kuehl, Ph.D.	Executive Member	Lovelace Respiratory Research Institute
Tammy Shen, Ph.D.	Student Member	University of North Carolina

learning about INTFG activities or pulmonary bioequivalence are welcome to attend.

2013 Fall activities

2013 activities will include a joint workshop of the INTFG, the US FDA, the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) and the US Pharmacopeia (USP). The workshop is entitled “Inhaled Drug Products: Current Practices and the Future of *In Vitro* Testing Technologies and Regulation.” It will be held September 9-10, 2013, at the USP Meetings Center in Rockville, MD, US. (www.aaps.org/IDP/). This meeting will replace the INTFG’s regular fall meeting for 2013.

Roundtable discussions at the 2013 AAPS Annual Meeting

In the fall of 2013, at the AAPS Annual Meeting in San Antonio, TX, US, speakers from the INTFG will participate in two roundtable discussions. Guenther Hochhaus will present at the roundtable entitled “Global Clinical Regulatory Requirements for Inhalation Products.” The other presentation will be held in conjunction with the Ocular and Transdermal Focus Group and be entitled “Biopharmaceutical Considerations in Selecting Non-Oral Drug Candidates: Ocular, Pulmonary and Transdermal.”

AAPS/INTFG webinars

The INTFG’s goal is to present two seminars every year on an inhalation-focused topic. The webinar this spring, presented by John Yin of Freeman Technology, will be entitled “Quality by Design in Powder Processing: Quantifying One’s Powder-Processing Experience.” Information will be emailed to INTFG members and posted on the INTFG’s LinkedIn website.

For further information

The focus group is also preparing its spring newsletter, which will be distributed through the AAPS INTFG member email list and be posted on the LinkedIn site. For updates on the INTFG’s activities throughout the year, scientific discussions and job postings, please check the focus group’s LinkedIn site or contact members of the group’s executive committee. Information about INTFG presentations from past meetings and upcoming events can be found on its website: www.aaps.org/Inhalation_and_Nasal_Technology/.

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www.inhalationmag.com