

CROSS-INDUSTRY Organizations

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

Samiran De
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).

Executive committee

The current executive committee of the INTFG, elected at the 2011 AAPS Annual Meeting in Washington DC, is shown in Table 1. In 2011, the INTFG modified the focus group by-laws to allow for the election of a student member to the executive committee.

Lectures at RDD Europe 2011

At the 2011 Respiratory Drug Delivery (RDD) Europe conference in Berlin, INTFG organized two evening lectures on the topic of “Dramatically improving adherence in respiratory medicine—The next breakthrough in therapy.” The speakers for the two lectures were John Pritchard of Phillips Respironics who presented “Adherence — Can patients stick to treatment regimes?” and Garth Sutherland of Nexus6, Ltd.

who presented “Adherence monitoring in respiratory drug delivery: Why do it and who will pay for it?”

2011 Annual Fall Symposium

Scientific talks and poster presentations for the 2011 Annual INTFG Fall Symposium were on the subject of “Delivery of biologics through the lung: Challenges and opportunities.” Presenters for the symposium were:

- Masahiro Sakagami of Virginia Commonwealth University who presented “Towards improved systemic delivery of macromolecular drugs through the lung: What limits their absorption and what should be controlled?”
- Ramesh Kashi of Merck & Co. who presented “Challenges in the development of stable protein formulations for lung delivery;”
- Diane Griffin of John Hopkins Bloomberg School of Public Health who presented “Successful respiratory immunizations with dry powder live-attenuated measles virus vaccine in rhesus macaques;” and
- Homayoun Shams of University of Texas Health Science Center at Tyler

who presented “Using aerosolization to prevent influenza infections.”

AAPS/INTFG webinars

An AAPS webinar on “Accelerating device and drug development for inhalables” by Stefan Steigerwald of Sympatec was held on October 20, 2011. This presentation was the first part of a three-series webinar on particle characterization techniques for inhalables. Fundamentals of laser diffraction technique, use of laser diffraction during development, and correlations between laser diffraction and cascade impaction were presented during the webinar. A series of INTFG AAPS webinars, on topics such as solid analytical techniques and powder flow characterization, are currently being organized.

2011 AAPS Annual Meeting events

A mini-symposium on “Bioequivalence considerations for alternative dosage form modified release products” was hosted by INTFG at the 2011 AAPS Annual Meeting. Presenters on inhalation topics for the symposium were Partha Roy of the US FDA who presented “Bioavailability challenges for ophthalmic and inhalation drug products: A regulatory perspective” and Steve Horhota of Boehringer Ingelheim who presented “Bioequivalence of inhaled products: The scientific and regulatory dilemmas.”

Plans for 2012

For 2012, INTFG-sponsored activities include an evening business meeting and technical talk by Hugh Smyth of The University of Texas at Austin on “Controlling respiratory drug delivery: Dispersion, release, and transport.” This is scheduled at

Table 1

The current INTFG executive committee

Samiran De, Ph.D.	Chair	Next Breath, LLC.
Sai Chamarthy, Ph.D.	Vice Chair	Merck & Co.
Jason Ehrick, Ph.D.	Past Chair	Merck & Co.
Bill Schachtner, B.S.	Secretary	PPD, Inc.
Prabo Wijetunge, Ph.D.	Executive Member	MicroDose Therapeutx
Jeff Breit, Ph.D.	Executive Member	Bend Research
James Butz, Ph.D.	Executive Member	Merck & Co.
Guenther Hochhaus, Ph.D.	Executive Member	University of Florida
Tammy Shen	Student Member	University of North Carolina

the Respiratory Drug Delivery Conference in Phoenix, AZ on Tuesday, May 15. The presentation will focus on recent, innovative research findings that have challenged existing theories on powder dispersion in respiratory drug delivery. In addition, recently-emerging findings on drug transport in the airways will be presented and discussed in terms of nanoparticle delivery systems and nanotoxicology.

INTFG will host a sunrise session at the 2012 AAPS Annual Meeting at Chicago, IL on October 17 entitled "Defining critical quality attributes for combination products." Justin Pennington (Merck & Co.), Gerallt Williams (Aptar Pharma) and Prasad Peri (US FDA) are the invited speakers for this session. This session will highlight the unique analytical challenges encountered during the development of inhaled fixed dose combination products.

At the Annual Meeting, on October 18, INTFG will host another session entitled "Correlating *in vitro* and *in vivo* lung deposition of pulmonary formulations: Pharmacokinetic and regulatory perspectives." The invited speakers are Warren Finlay of the University of Alberta, Julie Suman of Next Breath, LLC, Neil Miller of GlaxoSmithKline and Dennis O'Conner of Boehringer Ingelheim. This session will focus on a mechanistic correlation between measured *in vitro* formulation characteristics or *in silico* predictions with observed *in vivo* behavior towards an acceptable bioequivalence standard for a pulmonary dosage form.

Become involved

Information about the INTFG, presentations from past meetings and upcoming events can be found on its website: http://www.aaps.org/Sections_and_Groups/Focus_Groups/Inhalation_and_Nasal_Technology/. In addition, the INTFG has a LinkedIn group that provides event updates, scientific discussions and job postings.