Cross-industry organizations

The Inhalation and Nasal Technology Focus Group: Evolving to meet the needs of its scientific community

Members of the INTFG

The American Association of Pharmaceutical Sciences (AAPS) Inhalation and Nasal Technology Focus Group (INTFG) has supported a number of activities this past year and several upcoming events are planned.

A presentation on MDI propellants

At the 2017 Respiratory Drug Delivery (RDD) Europe Annual meeting in France, the INTFG supported a scientific presentation by Dr. Tim Noakes and Stuart Corr from Mexichem UK, Ltd. The talk was titled "The Future of Metered Dose Inhalers and Their Propellants, Status Quo or Time for a Change?" The presentation was part of a continued presence that the INTFG has at each RDD, with an open meeting followed by a scientific presentation. The objectives are to engage as many members as possible who attend RDD and to open the group to exposure from non-INTFG members.

Supporting programming on genome editing

At the 2017 AAPS Annual Meeting, the focus group supported programming around the rapidly emerging and important topic of "Challenges and Opportunities for Gene Editing and Delivery" and recruited several speakers including Professor Cory Berkland from the University of Kansas, Dr. Hao Yin from MIT and Professor Gene Yeo from UCSD. There is significant interest in developing gene editing and inhalation delivery for the treatment of genetic diseases that manifest in the airways, such as cystic fibrosis. In recent years, several new genome-editing technologies have been developed. Of these, the zinc finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) and the CRISPR/Cas9 RNA-guided endonuclease system are the most widely described. Each of these technologies utilizes restriction enzymes to introduce a DNA double-stranded break at a targeted location with the guidance of homologous binding proteins or RNA. Such targeting is viewed as a significant advancement compared to current gene therapy methods that lack such specificity. Proof-of-concept studies have been performed to treat multiple disorders, including *in vivo* experiments in mammals and even early phase human trials. Careful consideration and investigation of delivery strategies will be required so that the therapeutic potential for gene editing is achieved. In this session, the mechanisms of these gene editing technologies and evidence of therapeutic potential was introduced. The major focus of the session was the pharmaceutical development approaches and the biological delivery obstacles.

Back to basics webinars

A major effort of the INTFG has been the development and scheduling of a "Back to Basics" webinar series focused on inhalation aerosols. This webinar series covers the fundamentals of several aspects of inhalation product science and development. For example, a webinar titled "Metered Dose Inhalers 101" to be presented by Dr. Mark Sommerville is scheduled for January 18, 2018. This webinar is intended to introduce formulation scientists, device engineers and other pharmaceutical professionals to the technical considerations needed for metered dose inhaler (MDI) development. Content will include the basics of formulation science for MDI solutions and suspensions, device design for MDI componentry (valve, can and actuator), and the ways these factors combine to influence the inhalation product performance. Insights will also be provided on recent advances in MDI formulation and device technologies and the needs these new technologies are meeting. Additional webinars in the series include "Clinically relevant *in vitro* tests for the assessment of nasally administered drug products," "INTFG Back to Basics—Nebulization" and others topics. Watch the INTFG discussion board on the AAPS website for dates.

Developing a classification system for inhaled drugs

Over the past four years, the INTFG has been working on a biopharmaceutical classification system (BCS) for inhalation drugs. As with the immediate release oral drug product BCS (the "giBCS"), a pulmonary or inhalation "iBCS" concept would guide a discovery chemist in selection of new chemical entities intended for pulmo-

nary delivery and a formulator in selection of manufacturing processes for inhalation drug product development. Also, an iBCS would contribute to an understanding of bioequivalence between products during development and commercialization. Developing a classification system for inhaled drugs could lead to a better understanding of the key *in vitro* attributes impacting product *in vivo* bioperformance by "class" of drug (or drug product). This approach could therefore lead to streamlined drug development and regulatory relief as achieved for immediate release oral products and could ultimately improve product quality control and understanding of *in vivo* product performance.

Development of an iBCS needs to be scientifically driven and must be based on an understanding of the product deposition attributes, the physicochemical properties of the drug, and the physiology of the lung; all of which depend upon the development of standardized biorelevant *in vitro* test methods for inhaled drugs. Therefore, the development of such a system needs support from the inhalation community. A project proposal to develop a classification system for inhaled drug products was recently accepted by the Product Quality Research Institute (PQRI) and will be up and running in 2018.

Encouraging student participation

In order to increase student involvement with the INTFG as well as provide content on emerging research topics, the INTFG has also planned webinars to be presented by graduate students. The first of these will be given by a past student member of the focus group's executive committee, Mandana Azimi, and will focus on her PhD research related to clinically relevant *in vitro* tests for nasally administered drug products.

Shifting from focus groups to communities

AAPS has made a strategic decision to develop "communities," which are expected to replace the current structure of AAPS focus groups, such as the INTFG. More information is available on the AAPS website regarding these changes (www.aaps.org).

Despite this pending transition, please look for the INTFG to continue to be involved in upcoming meetings from RDD to ISAM to AAPS. In addition, if you see an opportunity for the INTFG to work with you or your team on a project or scientific need, please contact Dr. Hugh Smyth, INTFG Chair (hugh.smyth@austin.utexas.edu).