Cross-Industry Organizations

INTFG to support three sessions at 2016 AAPS Annual Meeting

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On behalf of the AAPS Inhalation and Nasal Technology Focus Group

The 2016 American Association of Pharmaceutical Sciences (AAPS) Annual Meeting is fast approaching and will be held November 13-17 in Denver, CO, US. This year's program promises to include a range of scientific topics and discussions relevant to pharmaceutical scientists, formulators, chemists and regulatory officials across the world.

The AAPS Inhalation and Nasal Technology Focus Group (INTFG) is excited to be supporting three sessions that will be included within the meeting. A brief description of each session is provided below. Please mark your calendars and try to attend these presentations.

The Lipinski Rule of 5 for alternative routes of administration: Dialogue and debate

The systemic absorption and distribution of the drug substance from a dosage form is dependent primarily upon the physicochemical properties of the drug, the dose administered, and the permeability and pharmacokinetics associated with the route of administration. An approach for classifying orally administered drugs based on a macroscopic assessment of gastrointestinal permeability and aqueous solubility was first introduced in the 1990s. Even though this Biopharmaceutical Classification System (BCS) has been revised over the ensuing years, its goal has remained the same: to provide a basis for correlating *in vitro* drug product dissolution to *in vivo* bioavailability assuming that drug dissolution, drug dose and GI permeability are the attributes dictating the rate and extent of drug absorption via the oral route of administration.

In contrast, drugs delivered via inhalation devices are deposited within the complex and diverse architecture of the human lung, rather than being swallowed for absorption in and distribution from the gastrointestinal tract. Drug deposition within the lung and the dose to the lung are primarily influenced by the inhalation device design, aerodynamic particle size and distribution of the dispersed product, fluid mechanics and the way the patient interacts with the drug delivery device. Although an inhalation drug classification system has not been established to date, at least one paper has been published on this topic. For inhaled drug products, the development of a classification system that combines the physicochemical properties of the drug, the critical quality attributes of the product and the biology of the lung is the first step in understanding the role of *in vitro* performance parameters on *in vivo* product performance.

The session "Lipinski Rule of 5 for alternative routes of administration: Dialogue and debate" is a continuation of the inhalation BCS (iBCS) discussion initiated at the AAPS/FDA/USP workshop held in Baltimore, MD, US in 2015 and is sponsored by the AAPS Inhalation and Nasal Technology Focus Group (INTFG). The session is designed to be a scientific "point/counter-point" discussion focused on whether an inhalation classification system is more aligned with a BCS or Lipinski Rule of 5 approach. The findings at this session will further support development of a pulmonary drug classification model. The session will include two speakers: Gordon Amidon ("Impact on ADME properties on oral drug delivery") and Chris Edwards ("Pulmonary drugs—Physicochemical properties"). The session will be held on Tuesday, November 15, 10:00 AM - 12:00 PM.

3D-printed drug delivery systems

The United States Food and Drug Administration (FDA) recently characterized personalized medicine as "the tailoring of medical treatment to the individual characteristics, needs and preferences of a patient during all stages of care, including prevention, diagnosis, treatment, and follow-up." Three dimensional (3D) printing has the potential to play a role in achieving this and is a growing technology. It has been used in the manufacture of the oral drug Spritam (levetiracetam) (Aprecia Pharmaceuticals) for the treatment of epileptic seizures, recently approved by the FDA. This indicates that future, broader deployment within the pharmaceutical industry is possible.

To provide a fundamental overview of the technology, a sunrise session titled "3D-printed drug delivery systems" will be on held on November 17, 7:30-8:45 AM. Two speakers, Didier Lefebvre from Abbvie and Clive Roberts from The University of Nottingham, will give presentations with specific emphasis on principles of 3D-printed dosage forms, commercial opportunities and hurdles. This session couples with a symposium titled "A new chapter in pharmaceutical technology: 3D-printing for solid oral dosage forms" on the same day to give meeting attendees detailed insight into this exciting development in pharmaceutical technology.

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Dissolution testing for controlled release products

In order to increase patient compliance and provide better control for chronically administered therapeutic agents, long-term drug delivery systems are being developed. The challenge associated with the design and development of such systems is multifaceted. For instance, confirming the actual release rate of long-term delivery systems is costly and time-consuming but it is a critical quality attribute for such a product. However, since the long-term release data can take several months to obtain, the quality control (QC) product release specification for the dissolution attribute typically only contains a fraction of the actual drug release profile. Therefore, a shorter, discriminating dissolution method is generally utilized to release the drug product. The INTFG is co-sponsoring a symposium that will focus on the challenge associated with development of discriminating, short-term, QC dissolution test methods and their correlation with the actual release rate profiles.

The symposium "Dissolution testing for controlled release products" will include three speakers: H. Thomas Karnes from VCU, Juergen Siepmann from the University of Lille and Jeff Kindig from Liquidia. They will speak on a range of topics, from relationships between functional drug release and QC-based test methods to mathematical modeling of diffusion data or dissolution testing for depot/implant devices. This session will be held on Wednesday, November 16, 1:20-3:40 PM.

INTFG annual business meeting

In addition to these scientific sessions, the INTFG will be holding its annual business meeting on Tuesday, November 15, 4:00-5:00 PM in Room 405/406 of the Colorado Convention Center. The meeting will summarize the INTFG's work throughout the past year, provide a scientific talk in the area of inhalation and nasal drug delivery and include the election of new members to the INTFG executive committee.

We look forward to seeing everyone at the 2016 AAPS annual meeting and encourage you to get involved in INTFG! For more information, visit the INTFG website at: http://www.aaps.org/Inhalation_and_Nasal_Technology and the annual meeting website: http://www.aaps.org/annualmeeting.