

**PQRI Coordinated Workshop with RDD 2010 Florida on
*Role of Pharmacokinetics in Establishing Bioequivalence for Orally Inhaled Drug Products***

**OMNI Orlando Resort at ChampionsGate
Orlando, Florida
April 29 - 30, 2010**

Goals and Objectives of Workshop

To evaluate the current state of knowledge and identify gaps in information for the potential application of pharmacokinetics (PK) as a key approach in establishing bioequivalence of local delivery OIPs, addressing the power of the PK approach to detect differences in product performance in comparison with in-vitro and PD/clinical studies.

Background

Currently, the Food and Drug Administration (FDA) requires in-vitro, pharmacokinetic (PK), and pharmacodynamic (PD)/clinical studies for demonstrating BE, whether for the approval of multisource OIPs or for development/post-approval changes for innovator OIPs. The sensitivity to detect differences in product performance generally decreases as we move from in vitro testing to PD measurements. The greatest challenge in following this approach with some OIPs (particularly inhaled corticosteroids) is the demonstration of dose response in PD studies, without which the bioassay has no value in the determination of BE. Thus, there is an urgent need to establish a less burdensome approach for demonstrating BE of OIPs. This workshop will serve as a platform for discussing the feasibility of PK approach as a main tool to establish local BE for OIPs. If successful, the suggested approach (*in vitro* plus PK) will be applied to a broad range of drugs, with the ability to detect differences in product performance regardless of dose response on PD endpoints and mode of action of drugs.

Workshop Format

This one and a half day event will start on the morning of April 29 (coordinated and presented in conjunction with RDD 2010) with a series of podium presentations followed by a panel discussion. On April 30, the PQRI portion of the workshop will include a presentation of case studies using the PK approach followed by breakout sessions with focused discussions on selected topics. These breakout sessions will be repeated again in the afternoon of April 30. A list of proposed breakout topics includes:

- ***PK and Lung Deposition***
- ***PK and In Vitro Assessment***
- ***PK and PD Relationships***
- ***Effective PK Study Designs***

Registration and hotel information are available at <http://www.rddonline.com/rdd2010>. Additional workshop information can also be found at www.pqri.org or contact Vicki Penn at pennv@pqri.org