AAPS February Workshop “Development of Pediatric Formulations: Challenges and Opportunities”
49th AAPS Arden Conference February 24-26, 2014

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The need for pediatric pharmaceutical formulations has been growing rapidly in recent years as a result of the recognition that children are often underserved by ad-hoc compounding of adult formulations and increased regulatory incentives. Pediatric drug products can be challenging to develop due to their unique requirements and limitations.

Examples of these challenges include:
- Effects of growth and development on drug ADME,
- Poorly soluble drugs with incomplete absorption,
- Safety concerns of commonly used excipients in pediatric patients,
- Taste evaluation and masking,
- Age appropriate dosage forms and flexible dosing,
- Combination drug products for pediatric patients.

In order to address the increasing need of developing innovative age appropriate pediatric products, also driven by regulatory requirements, the pharmaceutical industry is committed to meeting pediatric patients’ needs.

Goals and Objectives
- Present current state-of-art technologies suitable for pediatric drug products
- Review technical issues including flexibility of dose titration, ease of administration and swallowing, palatability, solution stability, microbial challenges, dosing and measuring devices, considerations of a multi-phase and/or multi-use product, and packaging,
- Discuss practical development strategies to facilitate the selection of pediatric dosage forms for clinical trials and commercial manufacturing
- Discuss special considerations and issues unique to pediatric products from the regulatory agency perspective (US FDA and the EMA)
- Initiate a flow diagram/guideline for pediatric formulations development.

Travel Information
The 49th AAPS Arden Conference will be held at USP Meetings Center, only a ten minute walk from the Hilton Washington D.C./Rockville Hotel and Executive Meeting Center.

USP Meetings Center
12601 Twinbrook Parkway
Rockville, Md. 20852