Workshop on Leachables and Extractables

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PQRI L&E

FDA, industry and academia collaborating to develop science and data-based approaches to a critical aspect of orally inhaled and nasal drug products (OINDP)

Background

- Issuance of draft/final guidances for OINDP provided impetus for industry discussions on L&E testing
- Those early discussions led to desire to extend discussions to regulators and wider scientific community

Background

- PQRI ideal forum for these discussions and consensus-building
- Proposal to develop thresholds and examine best practices for L&E in OINDP submitted to PQRI
- Working Group formed in 2001, consisting of chemists and toxicologists from FDA, industry and academia

Background

- Working Group developed a hypothesis and step-wise plan to investigate per established PQRI process
- Work plan approved by PQRI DPTC and Steering Committee – April 2002
- Toxicologists and chemists formed sub-groups

Background

- Toxicologists: acquired data through extensive literature and database searches and analyses
- Chemists: acquired data by conducting extractions studies and placebo leachables study
    - Materials and laboratory work provided voluntarily

Background

- Developed draft recommendations, “Safety Thresholds and Best Practices for Leachables and Extractables Testing in Orally Inhaled and Nasal Drug Products.”
- Science and data-based recommendations to PQRI and FDA. Not a policy/regulatory document

Review and Comment Period

- Document currently in draft form, under review by PQRI member organizations
- Workshop to provide venue for obtaining comments/questions from stakeholders outside of PQRI
- Comments from PQRI and Workshop to be reviewed for incorporation into second draft

Review and Comment Period

- Second draft to be resubmitted for PQRI review
- Final document to be submitted to FDA for consideration as support of regulatory documents
- Working group to publish in peer-reviewed journals

Workshop

Day 1

- Context and background to L&E in OINDP
- Plenary lecture on development of safety thresholds
- Overview of recommendations
- Discussion session on safety

Workshop

Day 2

- Discussion session on best practices
- Perspectives from FDA participants
- Panel discussion
- Closing presentation

Workshop

- Purpose of workshop is to explain recommendations, discuss questions on recommendations, and collect comments on recommendations

Workshop

- Encourage questions from attendees and constructive dialogue with working group members
- Encourage questions/comments to be submitted after workshop as well (send to lnagao@gcd.com)