The IPEC-Americas September Committee Meetings

IPEC-Americas members and invited guests met from September 19th through the 21st at IPEC-Americas headquarters in Arlington, VA. Highlights of the meetings cover a broad range of issues related to excipients, many which are described below. If these issues are important to you and your company, you should consider becoming involved in IPEC-Americas, so you can have…a source for reliable regulatory information; a structure for industry collaboration; a seat at the table to discuss issues impacting your business; and a system for education and to stay current on industry developments.

CRC (Compendial Review)

USP is still planning to add UNII numbers to excipient monographs. IPEC-Americas is planning to provide feedback to USP regarding this plan. USP and IPEC Federation members provided a review of the recent PDG meeting for monograph harmonization & USP provided updates on other excipient monograph modernization projects. Industry input is still needed regarding specific metals in excipient monographs. Can USP’s existing process be modified to support monograph development for novel excipients - discussion.
RA (Regulatory Affairs)

Global Regulatory Topics:
- Novel excipients strategy
- Status of atypical actives coalition
- Strategy for approaching FDA with Excipient Issues
- Update on China’s new regulatory framework for excipients

Update on IPEC Master File Guide
- Completion of IPEC DMF guide
- Discussion of IPEC DMF guide with FDA
- Plan on approaching FDA for CTD format exemption for Type V DMFs

GMP (Good Manufacturing Practices)

EXCiPACT
- Rx-360 white paper
- IPEC certification and guide navigation resource
- IPEC GMP Audit Guide
- IPEC-PQG Excipient GMP How To Guide
- IPEC GDP Audit Guide
- Data Integrity Position Paper
- IPEC Validation Guide

EQ (Excipient Qualification)

Volunteers for EIP guide update committee
- Status of QA guide
- Webinar Topics
- Member Engagement

QbD (Quality by Design/Product Development) and EC (Excipient Composition)

Letter to FDA: Docket No. FDA-2017-N-2697 (Developing Continuous Manufacturing of Solid Dosage Products in Pharmaceutical Manufacturing)
Letter to FDA: “Additives and Residual Processing Aids in Excipients”
Pharmaceutical Technology Article: The Real Complexity with Excipient Composition
ICH M9 Oral Bioavailability Project
Guideline on Incorporation of Excipients and Excipient Variability into QbD

Safety

Update on IPEC-Americas/IQ Consortium Novel Excipient Project
- Regulatory Committee guideline collaboration

Users Network

Feedback/discussion on “Certification” Webinar
- Consider organizing survey to identify unmet needs/issues with excipients
- Interaction with other pharmaceutical industry trade organizations