Board of Trustees
December 7, 2016

Multiple stakeholders; **one objective.**

International Pharmaceutical Excipients Council

Collaborative solutions for excipient industry stakeholders

Financial Update

- Organization is financially stable
- High membership retention for 2016
- Increased reserves
- Opened a Fidelity Investment Account

Member dues/Membership update

- As of 12/7/2016 Total membership: 99
- 42 Makers, 15 Users, 12 Distributors
- 14 Consultants, 1 Association, 3 Scientific Org., 2 Publications, 1 Academic, 4 Academic Institution and 5 Graduate Students
- **9 New Corporate Members** for 2016: Roquette, Apotex, Pride Solutions, Perrigo, VKD Consulting, Chandra Sekhar Consulting, Drug Development Consulting, Dah Feng Capsule, DFE Pharma
- **4 New Academic Institution Members**: Appalachian, Auburn, Mississippi and New England

Overall 2016 Achievements

- **IPEC-Americas formal comments/presentations**
  - **January**
    - Partnership with CSPS Canada
    - Exhibited at IFPAC Annual Conference, Arlington, VA
    - QbD presentation at IFPAC US excipient workshop
  - **March**
    - Finalized Atypical Actives Coalition Charter
  - **April**
    - Excipient Fest, Baltimore, MD
    - IPEC-Americas 25th Anniversary Celebration
    - Comments to Health Canada guidance related to DMF
  - **May**
    - IPEC Federation - PDG meeting
    - Comments at FDA public meeting re: GDUFA Regulatory Science Initiative - Safety Assessment during Generic Drug Review
    - Exhibited at NBC Biotech, Boston, MA

Overall 2016 Achievements cont.

- **IPEC-Americas formal comments/presentations**
  - **June**
    - Comments at FDA public meeting re: OTC Monograph User Fees
    - QbD Sampling Guide webinars
  - **July**
    - Excipient Fest Asia
    - Met with ChP to discuss plans for ChP 2020 and open items from 2015
    - IPEC India conference
    - Comments submitted to FDA docket on OTC Monograph User Fees
  - **August**
    - Workshops with Sindusfarma (Brazil), SAFYBI (Argentina) and Collegio (Mexico)
    - Comments to EMA on EI Guidance
  - **September**
    - USP Excipient Stakeholder Forum presentation on Dual Use Excipients
    - EU PFI Conference on Pediatric Excipients
    - IPEC Europe - APV conference - Overview of US Regulations
    - Exhibited at PDA/FDA Conference, Bethesda, MD

Overall 2016 Achievements cont.

- **IPEC-Americas formal comments/presentations**
  - **October**
    - USP PNP Stakeholder meeting presentation on Future of Element Specific Chapters
    - Joint Compendial Industry meeting
    - Participated in ChP-USP workshop
    - QbD presentation at IFPAC Europa excipients workshop
  - **November**
    - 2 Workshops co-sponsored with AAPS at Annual Meeting – QbD for Excipients, Risk Assessment for Change Notification
    - Exhibited at AAPS, Denver, CO.
    - GPhA Fall Technical Conference presentation on e-submissions
    - PQRI USP workshop on Implementation of Elemental Impurities
    - Joint letter and backgrounder with IQ to FDA on Critical Path initiative for Novel Excipients

Overall 2016 Achievements and 2017 Goals

- 25th Anniversary Celebration – April, 26, 2016 Baltimore, MD
- Strategic Planning meeting November
  - Revised mission and vision statements
  - Established 3 major objectives for next 2 yr
    - Increase count, diversity and participation of membership
    - Expand expertise and offerings to larger medical products markets
    - Define Education and establish process and tools by which to deliver

Training Team Activities

Overall	• Renamed and re-branded Training as “Excipient Learning Lab”
Workshops	• Initiated Member-sponsored Public Workshop program – excellent results • Re-named and re-branded Excipient Auditor Workshop as “Excipient GMP Compliance for Auditors and Auditees” • Developed and delivered 3 on-site workshops (Dow Corning, Genentech, Lubrizol) • Developed and delivered 2 workshops at AAPS Annual Meeting
Webinars	• Delivered 10 fee-based and 1 free webinar • Developed and delivered 1 “customized” webinar for Dow • Proposed second customized webinar for Dow (to be delivered in 2017) • Introducing 6 (of 10) new webinars for 2017
eLearning	• Developed and delivered 2 series of eLearning courses
Training Development and Design	• Development and implementation of unique design documents for webinars, workshops and eLearning
Training Committee Infrastructure	• Re-draft of Training Committee Charter and 2015 objectives
Training Publicity	• Wrote and published series of articles (5) on eLearning in IPEC Insider
Training Marketing	• Used paid advertising (AAPS and C&E News) for eLearning
Training Administration	• Launched and implemented iCohere system for automated eLearning, webinar and webinar archive registration and purchasing • LL Staff has become expert in the use of iCohere functions and features
Training Financials	• Monthly use of Training P&L • Routine use of break-even calculator for all revenue-generating training events • Development and implementation of pricing guidelines for eLearning

Committee Updates

Quality by Design

- Published IPEC-Americas QbD Sampling Guide
- Developing QbD Primer, Pre-Filing and Post Filing Guides
- Comments prepared to FDA Draft Guidance on Comparability Protocols
- PQRI workshop on Excipient Variability planning in progress
  - Impact of Raw Materials on Continuous Manufacturing
- Initiating workshop with PQRI on continuous manufacturing

Committee Updates

Excipient Composition

- Published Co-processed Excipient Guide
- Backgrounder document for Additives in Excipients drafted to send to FDA along with a request for a meeting
- Update of 2009 Excipient Composition guide underway
- IPEC represented on USP General Notices panel
  - Draft stimuli article submitted to USP: Excipient Specific Definitions of Impurities and Concomitant Components

Committee Updates

Good Manufacturing Practices

- GMP Audit Guide revision in progress with members from IPEC-Europe
  - Aligned with EXCiPACT and NSF/IPEC/ANSI 363-2014
- GDP Guide revision drafted – sent to IPEC Europe for comments
- Atypical Actives coalition formed with IPEC-Americas, IPEC Europe, GPhA, CHPA, CRN, SOCMA-BPTF, Sindusfarma, AHPA
- Continuous Verification guide drafted - sent to IPEC Europe for review
- Data integrity - position paper drafted

Committee Updates

Excipient Qualification

- Revised QA Guide drafted jointly by IPEC-Americas and IPEC Europe
  - Addition of Manufacturer's Statement
- Risk Assessment Guide being drafted
  - Charter drafted and sent to IPEC Federation
- USP <1080> General Chapter on COAs for excipients published for comment in the PF based on the IPEC COA Guide

Committee Updates

Compendial Review and Harmonization

- Input provided to ChP monograph revisions
- Round robin study (SiO_2)
- Round robin study (pregelatinized starch)
- Provided comments to FDA Draft Guidance on Elemental Impurities
- Provided comments to EMA Draft Guidance on Elemental Impurities
- Provided comments to USP Stimuli Article on Future of Element Specific Chapters in the USP-NF
- Participated on USP Compendial Process Improvement Team and USP General Notices Project Team

Committee Updates

Regulatory Affairs

- Drug Master Files
  - Revision of Excipient Master File guide in progress
  - Comments provided to Health Canada regarding their new DMF requirements
  - Developed IPEC position on electronic DMF submissions for excipients
  - Negotiated discounts with several vendors for eCTD DMF conversions
- Inactive Ingredient Database
  - FDA clean-up of data in progress; IPEC monitoring changes and providing feedback to FDA via meetings and communications
  - Strategy for progressing the family approach based on input from the agency still pending with FDA
- Presentation at GDUFA II Workshop on OGD Excipient Safety Review
- Monitoring of China regulatory changes and provided input especially related to Excipient Bundling Review
- International task force set up with IPEC Federation to monitor global regulatory developments and respond to issues of global impact

Committee Updates

Safety

- IPEC-Americas/IQ Consortium Novel Excipient Project
  - Biomarker approach recommended as a qualification process
  - Backgrounder and request for meeting sent to FDA
- Alcohol-induced dose dumping
- Nanotechnology /Nanomaterials position paper being drafted

IPEC Foundation Awards 2016

- **Ralph Shangraw Memorial Award**
- **Abu T.M. Serajuddin, Ph.D.,** Professor of Industrial Pharmacy, Department of Pharmaceutical Sciences, College of Pharmacy & Allied Health Professions, St. John's University.
- **Emerging Researcher Award**
  Qi (Tony) Zhou, Ph.D., Assistant Professor, College of Pharmacy, Purdue University.
- **Industry Research Achievement in Excipient Technology Award**
  Sandip B. Tiwari, Ph.D., Actavis Laboratories.
- **Graduate Student Winners:**
- **Mr. Rajan Jog**, University of Connecticut
- **Ms. Laura Mosquere-Giraldo**, Purdue University, Indiana
- **Mr. Hitesh Purohit,** Purdue University, Indiana
- **Mr. Arunprasad Sivaraman**, Mercer University, Georgia
- **Ms. Hui Wang**, Queensland University of Technology, Australia.

Post Meeting Election Results

- **Chair Elect:** Janeen Skutnik
  Compliance & Standards, Biogen
- **Vice Chair for Administrative Affairs:** Bretta Lichtenhan
  Business Development Manager – Formulation & Drug Delivery
  MilliporeSigma
- **Vice Chair for Harmonization & Compendial Monograph:**
  Phyllis Walsh, Associate Director
  Merck & Company, Inc.
- **Elected Executive Committee Officers:**
  George Collins, Jr., Vice President, Vanderbilt Mineral Co.
- Heather Sturtevant, Manager, Technical Operations, J&J
- Meera Raghuram, Manager, Regulatory Affairs & Strategies
  Lubrizol Advanced Materials, Inc.