IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
IPEC-PDG Working group	**Compendial Review/Harmonization**		Hold technical meetings with PDG on as needed basis/meet yearly with PDG	On-going monograph harmonization	13-Sep-13
JECFA/Food Related Issues related to Mg Stearate	**Compendial Review/Harmonization**		To support EFSA (European Food Safety Authority) need for Mg stearate exposure data, where used, what products it's used in, etc., work with IPEC makers & users of Mg stearate to gather necessary Mg stearate information.		13-Sep-13
Support Elemental Impurity Coalition	**Compendial Review/Harmonization**		Support Trade Association coalition on the Rationale Implementation of Elemental Impurities	Rationale implementation of Global Elemental Impurity requirements for pharmaceutical excipients	13-Sep-13
USP Monograph Modernization Project	**Compendial Review/Harmonization**		An update on the modernization project. 1. PF 41(3) May. Lecithin revision. 2. PF 41(4) July/August. 3 monographs: chlorobutanol, eucalyptus oil, PEG 3350. USP received comments from the FDA and the public and the comments were published. 3. Four new stage 6 notices were published on the USP website.		28-Sep-15

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IPEC Excipient Data Base	**Compendial Review/Harmonization**		The IPEC Excipient Data base is an Incomplete database. During the 3Q 2015 a project to obtain a listing of all excipient in USP and Ph. Eur. will be started. Phyllis will discuss with USP. USP to provide list of USP and NF excipients to IPEC. Company names will be added to each excipient on the list; companies can then be notified on requests for revision or if revisions are proposed/ new monographs. Companies should also add excipients not listed.		
PQRI Excipient Variability Project	**Compendial Review/Harmonization**		A survey was sent out on the impact of excipient variability. Larry Block organized the survey.		28-Sep-15
Pharmaceutical Excipient Elemental Impurities Database POLL	**Compendial Review/Harmonization**				
Support publication of FDA 2012 EI study/data	**Compendial Review/Harmonization**		Work with John Kauffman and Gang Li at FDA Research labs to substantiate their work and publish an article in Pharmaceutical Science	Scientific article on Elemental Impurities in excipients published in peer reviewed journal	24-Jan-14
Guidance on User Comminication with Suppliers (FOR THE PARKING LOT)	**Excipient Qualification**		A guide/stimuli article or addition to the EIP guide which would discuss the communication between users and suppliers/makers. It would detail / describe which type of information should be shared between the two.	TBD	4-Mar-14

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
Excipient Information Package	**Excipient Qualification**	**Yes**	Revise 2012 EIP guide and develop new version.	Revised EIP Guide published as Federation Guide.	2-Oct-15
Quality Agreement Guide	**Excipient Qualification**	**Yes**	Revise 2009 Quality Agreement and develop new version	Revised and updated version of Quality Agreement Guide as Federation Guide.	2-Oct-15
Significant Change Guide	**Excipient Qualification**	**Yes**	Revise and update the 2009 version of IPEC Significant Change Guide.	To publish 2014 IPEC Significant Change Guide (ideally as a Federation guide, and at the least a "bi-PEC guide)	2-Oct-15
How to Creat a Bi-Pec Guide	**Excipient Qualification**	**Yes**	Develop a process on “best practices/lessons learned/policy” on how to create a “Bi-PEC” guide. Included will be a discussion around how to communicate that a commenting period is over.	Protocol	2-Oct-15

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
IPEC Global Risk Assessment Strategy (RAT - Risk Assessment Team)	**Excipient Qualification**	**Yes**	To develop a risk assessment guide which would include 1) guidance on conducting manufacturer's internal risk assessment for GMP (EXCiPACT, NSF/IPEC 363), and 2) risk assessment from users perspective (IPEC Europe). The guide may also cover risk assessment for atypical actives, decision making for significant changes etc.	IPEC Americas will provide to IPEC Federation- the following content for the risk assessment guidance document: • Process including methodologies and tool box for conducting risk assessment • How-to chapters on internal risk assessment from excipient manufacturers perspective • How-to chapters on internal risk assessment from excipient users perspective	1-Oct-15
Excipient Qualification Guide (PARKING LOT)	**Excipient Qualification**	**Yes**	Revise and update the latest version of IPEC Excipient Qualification Guide	To publish an IPEC Excipient Qualification Guide (ideally as a Federation guide, and at the least a "bi-PEC guide)	30-Sep-14
Update to USP	**Excipient Qualification**		Ensuring the process by which our guides are updated in the USP General Chapeters is periodically reviewed	Updated USP General Chapters to align with our recently published	2-Oct-15
Bi-PEC/IPEC Glossary of Terms	**Executive Committee**		review and update current 2010 IPEC-Americas Glossary and work with other PECs to make it global	IPEC Federation Glossary of Terms	5-Mar-14

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
ANSI cGMP for Pharmaceutical Excipient Standard	**Good Manufacturing Practice**		Develop ANSI Pharmaceutical Excipient Standard	Approved ANSI Pharmaceutical Excipient Standard	13-Sep-13
FDASIA Atypical Actives on-going activities	**Good Manufacturing Practice**		work with FDASIA subcommittee to be prepared for potential meeting with FDA	Tool chest of discussion items pertaining to atypical actives for requested FDA meeting	13-Sep-13
Revised IPEC-PQG Excipient GMP Guide	**Good Manufacturing Practice**		Rewrite IPEC/PQG GMP Guide with updated information from ANSI Excipient GMP standard	Revised IPEC-PQG Excipient GMP Guide	13-Sep-13
Validation Guide	**Good Manufacturing Practice**		Develop IPEC GUIDE on Excipient Validation, including Equipment, Process, Product, Computer, Cleaning and Analytical Validation	Published IPEC GUIDE on Excipient Validation	13-Sep-13
Technically Unavoidable Particles Profile (TUPP)	**Good Manufacturing Practice**		Develop IPEC TUPP GUIDE	Published IPEC TUPP GUIDE	18-Sep-13

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
Additives found in excipients	**Quality by Design Product Development**		Develop and share with FDA a list of additives commonly found in excipients	Share list of additives commonly found in excipients with FDA	22-Oct-14
Co-processed Excipient Guide	**Quality by Design Product Development**		create a new IPEC Guide pertaining to co-processed excipients	Published IPEC Co-processed Excipient Guide	22-Oct-14
Guideline on Incorporation of Excipients and Excipient Variability into QbD	**Quality by Design Product Development**		Develop IPEC GUIDE on QbD Excipients and Excipient Variability	Published Federation IPEC GUIDE on QbD Excipients and Excipient Variability	28-Sep-15

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
QbD Sample Guide	**Quality by Design Product Development**		QbD Sampling Guideline - User and supplier sections to be merged	Published IPEC QbD Sampling Guide	28-Sep-15
FDA Final Refuse to Receive Guidance	**Regulatory**		IPEC Americas comments submitted to docket No. FDA-2013-D1120: ANDA Submissions — Final Guidance for Industry: Refuse-to-Receive Standards.	IPEC Comments	15-Oct-15
Letter to FDA (Janet Woodcock)	**Regulatory**		GpHA/IPEC letter to Janet woodcock requesting a meeting to discuss IID (e-mail sent by Lisa Tan GpHA)	Letter to FDA	15-Oct-15
IPEC Americas Position Paper	**Regulatory**		Position paper on IID status, critical issues and next steps	Position Paper	15-Oct-15

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
Revision of IPEC DMF guide	**Regulatory**		A sub team has been created to work on the new guide and many conference calls have been held. The DMF guide is being revised to include both DMF and excipient registration schemes globally.	IPED DMF and Global Registration Guide	15-Oct-15
FDA guidance on providing regulatory submissions using eCTD specifications	**Regulatory**		Team review indicated that excipient DMFs will need to be submitted in eCTD format from May 2017 onwards. This was a change from the FDA draft guidance which excluded excipient DMFs.	Review Guide and develop strategy	15-Oct-15
IPEC testimony at GDUFA Reauthorization public meeting	**Regulatory**		Preparation and presentation of IPEC-Americas Inactive Ingredient Proposals for Consideration during GDUFA Negotiations at the GDUFA public	Testimony at FDA public meeting	15-Oct-15
Request clarification from FDA on requirement for excipient DMFs to be submitted electronically	**Regulatory**		Questions drafted and sent to FDA (Art Shaw and FDA specified mail box). FDA response was reviewed and shared with committee members at the September meetings.	E-mail to FDA and DMF question box	15-Oct-15

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
IPEC Americas written comments on GDUFA reauthorization	**Regulatory**		IPEC Americas written comments submitted to docket No FDA-2012-N-0882.	IPEC Comments	15-Oct-15
IPEC testimony at PDUFA Reauthorization public meeting	**Regulatory**		Preparation and presentation of IPEC Americas testimony at the PDUFA reauthorization public meeting.	Testimony at FDA public meeting	15-Oct-15
FDA PDF Specs Guidance issued	**Regulatory**		Revision of IPEC Americas Position Paper on PDF specs issued in 2014.	Revision of Position paper	15-Oct-15
July 30 meeting with FDA	**Regulatory**		Discussion and presentation to agency on Toxicology/safety utilizing a family approach	FDA meeting	15-Oct-15
IPEC Americas written comments on PDUFA reauthorization	**Regulatory**		IPEC Americas written comments to docket No FDA-2010-N-0128.	IPEC Comments	15-Oct-15

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
Review of IID issues related to the August 12, 2015 update	**Regulatory**		Compilation and submission of urgent issues to the agency related to August 2015 IID update.	Urgent IID Issues Documentation	15-Oct-15
Excipient eCTD DMF strategy	**Regulatory**		Ongoing discussions with Antoinette Azevedo on eCTD strategy and development of guidance to be included in the IPEC DMF guide.	Documentation in DMF guide	15-Oct-15
September 18 meeting with FDA	**Regulatory**		Review of all discussions with FDA since 2011 and compilation of historical IID issues/status and future plans/timelines.	FDA meeting	15-Oct-15
Final Controlled Correspondence guidance	**Regulatory**		Requires review and team discussion on next steps and possibly approaching the	Review and planning next steps	15-Oct-15
FDA Docket seeking public comments on how they might enhance the utility and usability of the Inactive Ingredient	**Regulatory**		• Work on generating a letter with IPEC comments ongoing • Draft letter to be sent to IPEC Americas member companies for input • Communication sent to IPEC	IPEC Comments	15-Oct-15
Global Ingredient Archival System (GinAS) Project	**Regulatory**		Help communicate and support the FDA/NIH/global regulatory GInAS innitiative	functional Global ingredient identification database with reviewed/reliable ingredient information	3-Mar-14
Addressing US Import issues	**Regulatory**		Address current issues companies are currently experiencing when importing excipients into the US.	Response from FDA on Import hold letter. IPEC-Americas would like the opportunity to connect with the appropriate resources at FDA in order to allow both parties to openly communicate and collaborate on this topic.	4-Dec-14

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
FDA IID update	**Regulatory**		Support FDA clean-up and update of US FDA IID	Improved FDA IID database and process for toxicology assessments for families of similar products	28-May-14
Revise IPEC Master File Guide	**Regulatory**		Update content/instructions and format/granularity. Target working with FDA to define their current and future needs (e.g. electronic filing, format/granularity, etc)	Revised IPEC Master File Guide. Work on draft prior to september meeting. Target date is end of 2014.	28-May-14
FDA Portable Document Format (PDF) Specifications	**Regulatory**		We need to clarify with the FDA on what PDF attachments to regulatory filings (NDAs, INDs or ANDAs) are impacted by this guidance. Also, IPEC Americas will issue a position paper with inpu with FDA.	IPEC position paper clarifying FDA's requirement and applicabiltiy to excipient documents	28-May-14
Acid Leach/PQRI workshop;	**Safety**		Propose a project/program to PQRI for a multi day/multi functional (tox,	scheduled multi day/multi functional workshop	27-Feb-14
Steinberg Award for Foundation	**Safety**		develop a branding/marketing plan for the award	sustainable plan for delivering the Marshall Steinberg Award	27-Feb-14
Form a Novel Excipient sub-committee projects	**Safety**		Define members to work in an IPEC-Americas Novel Excipient subcommittee, formalize team and develop mission	Sub-committee and projects identified, mission / charter developed	28-Feb-14
IQ Initiative;	**Safety**		The sub-group continues work with the IQ Consortium. The group presented at the PDUFA and GDUFA meetings with		28-Sep-15

IPEC-Americas Ongoing Projects

Project name	Committees	Possible Federation Project	Description	Final deliverable	Last Updated-DATE
Stimuli article on novel excipient solutions for drug delivery	**Safety**		Develop and publish stimuli article on benefits of using NOVEL EXCIPIENTS in drug applications	Stimuli Article on Novel Excipients	28-Feb-14
Alcohol Induced Dosage Dumping	**Safety**		Safety Committee to provide a response to next steps		28-Sep-15
Gluten in Medicines Petition	**Safety**		after initial review of the petition and the most recent FDA response, there does not appear to be a need for further action however, Jeff recommends another IPEC member/company with impacted product also weigh in on the		18-Sep-15
Nano technology/nano-materials subteam	**Safety**		April Hernandez updated that relevant global documents are now available in the IPEC Americas Nano Technology library		28-Sep-15