Committee Project Tracking Spreadsheet

Project name	Committees	Federation Project ?	Project Description	Final deliverable (FD)	Date last updated
IPEC-PDG Working group	Compendial Review/Harmonization		PDG meeting hosted by European Pharmacopoeia on May 25-26, 2016 in Strasbourg, France	On-going monograph harmonization	4/6/2018
JECFA/Food Related Issues related to Mg Stearate	Compendial Review/Harmonization		IFAC and USFDA met in January. Food additive GMP leading to FDA guidance.	on going	4/6/2018
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- on going	4/6/2018
USP Monograph Modernization Project	Compendial Review/Harmonization		IPEC sees unequal Monographs in USP with APIs vs NF with excipients. Testing is Not the issue. The degree of GMP is the important detail.		4/6/2018
Silicon Dioxide Round Robin Study- IPEC Federation	Compendial Review/Harmonization	Yes	Test kits sent out to participating laboratories in mid-February. 31 total samples were submitted. Target date for completion of laboratory work is May 31. Target date for completion of data analysis is August 30.	On going	4/6/2018
IPEC Excipient Good Documentation Practices Guide update	Compendial Review/Harmonization		Ask for volunteers for write a “How to Good Documentation Guide.”	IPEC Excipient GDP Guide update	6/7/2017
Future of Element-Specific Chapters in the USP-NF	Compendial Review/Harmonization		The listing of materials priority was completed. It will be sent to all IPEC CRC members for review. Kahkashan Zaidi from USP explained the USP process to receive historical data on specific metals. The list will be divided into priorities. IPEC insider will be used to request data on the material and the requesting data to be provided directly to USP. Also we will request information through the IPEC Federation.		4/6/2018
FDA guidance on Elemental Impurities	Compendial Review/Harmonization		Waiting on Final FDA guidance	on going	4/6/2018

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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.	On Hold waiting on list from USP.	4/6/2018
Excipient Information Package	Excipient Qualification	Yes	Revise 2012 EIP guide and develop new version.	Revised EIP Guide published as Federation Guide.	2/21/2018
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.	Internal Flow Chart of Best Practices	2/21/2018
Excipient Qualification Guide	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)	2/21/2018
Risk Assessment Guide-Part 2	Excipient Qualification	Yes	IPEC Europe to develop Part 2 of the Risk Assessment Guide Lead by IPEC Europe targeted for users (e.g. pharma manufacturers)	Publication of IPEC Global Risk Assessment Guide, Part 2 “Risk Assessment for Users”	2/21/2018
Update to USP	Executive Committee	N/A	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	2/21/2018
ANSI 363 Standard	Good Manufacturing Practice		- Ongoing monitoring of ANSI 363 changes and initatives. - Reporting back to committee on quarterly basis.	ONGOING	3/6/2018
EXCiPACT Standard	Good Manufacturing Practice		- Ongoing monitoring of EXCiPACT changes and initatives. - Reporting back to committee on quarterly basis.	ONGOING Currently providing comments back to EXCiPACT for inclusion into the revised Standard	3/6/2018

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Rx-360 White Paper	Good Manufacturing Practice		- Ongoing monitoring of Rx-360 changes and initatives. - Reporting back to committee on quarterly basis.	ONGOING Currently providing feedback to Rx-360 regarding issues that should be clarified or edited which could lead to misunderstandings. Team Members: Priscilla Zawislak and George Collins	6/7/2017
Guide Navigation Resource	Good Manufacturing Practice		There are several differences between the EXCiPACT and ANSI Standards and with the IPEC-PQG GMP Guide. Work will be done to resolve differences and move towards harmonization. For now, this project is being implemented to provide members and non-members a resource to navigate the various approaches. This could be through webinars, Insider articles, white papers, etc.	Provide information on various approaches to IPEC members and non-members. Team members include Linda Herzog, Irwin Silverstein, Chris Moreton, David Klug, Sidney Goode, Dale Carter, and Ann Van Meter.	3/6/2018
Accredited Certification Position Paper	Quality by Design		Falsified IPEC GMP Certificates have been observed by members which appear to originate from the FDA. It is known that the US FDA does not issue any IPEC GMP certifications. Therefore, it would be beneficial if an official statement from the FDA on this matter could be issued.	Petition FDA to include statement on their website and/or write an IPEC position paper regarding accredited certification programs.	3/6/2018
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	3/6/2018
IPEC GMP Audit Guide	Good Manufacturing Practice		Update audit guide to align with ANSI 363 Standard.	Guide revision issued which can be used by auditors and manufacturers when performing audits to the ANSI Standard	2/14/2018
IPEC-PQG Excipient GMP Guide	Good Manufacturing Practice	Yes	Revised in 2017. Next revision will align with the ISO 9001:2015 and may include development of the how-to guide (see other project listing). IPEC Federation leading revision. Volunteers from different PECs have been added to team. Work to start in 2018	Revise IPEC-PQG Guide	3/6/2018

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IPEC Good Distribution Practices How To Guide	Good Manufacturing Practice	Yes	The GDP Guide was revised in 2017. For next revision, this guide would be updated to include information on how to implement the requirements. Need to prioritize this project based on resources. On hold for now.	Publish a GDP How To Guide	3/6/2018
IPEC Good Distribution Practices Audit Guide	Good Manufacturing Practice		This guide will draw from applicable sections of the ANSI 363 standard which apply to distributors and is intended be a reference guide for auditors. However, given the status of the IPEC GDP Guide as stated above, this audit guide will be put on hold until completion of the other guide. Prior to initiating work on this audit guide, IPEC- Americas will reach out to IPEC EU for feedback on need and to determine priority.	New GDP Audit Guide	3/6/2018
Data Integrity	Good Manufacturing Practice	Yes	Position paper on data integrity expectations for excipient manufacturers. This is being addressed by the Federation, but the committee should stay informed and monitor that project.	Monitor Federation project and stay informed on subject. May need to incorporate into guides.	3/6/2018
Guideline on Incorporation of Excipients and Excipient Variability into QbD	Quality by Design	TBD	Develop IPEC GUIDE on QbD Excipients and Excipient Variability	Published Federation IPEC GUIDE on QbD Excipients and Excipient Variability	2/21/2018
Update 2009 Composition Guide	Quality by Design	TBD	Update 2009 Composition Guide to reflect current analytical capabilities?	Publish updatedIPEC Composition Guide	2/21/2018
PQRI Excipient Variability Project	Quality by Design		A survey was sent out on the impact of excipient variability. Larry Block organized the survey.		9/28/2015
Develop PQRI Workshop proposal for ICH M9 EWG Oral Bioavailability Project – Phase II	Quality by Design		ICH M9 EWG next meets in autumn. Dave Schoneker proposed IPEC work with PQRI on a workshop to gather information needed to support ICH M9 project	PQRI ICH M9 workshop	2/21/2018
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	4/6/2018

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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. A phased approach is being used where the first phase will include the US DMF requirements. Additional phases to the guide will include global registration schemes.	IPEC DMF Guide: Phase I - US DMF	4/6/2018
List of IPEC-Americas FDA discussions	Regulatory		Prepare and Submit list of current issues that require collaboration/input from FDA to Lyndsay Hennessey	Letter to Lyndsay Hennessey and pontial follow-up meetings	4/6/2018
Glutten Rebuttal to Journal Commentary	Regulatory	N/A	IPEC Comments to Journal Commentary entitled "Making all Medications Gluten Free"	Journal Rebuttal	4/6/2018
Steinberg Award for Foundation	Safety	N/A	Develop a branding/marketing plan for the award	sustainable plan for delivering the Marshall Steinberg Award	2/22/2018
IQ Initiative	Safety	N/A	IPEC-Americas and IQ Consortium to collaborate with FDA to propose/develop new "novel excipient qualifition process."	FDA supported "novel excipient qualification process"	2/22/2018
Stimuli article on novel excipient solutions for drug delivery	Safety	N/A	Develop and publish stimuli article on benefits of using NOVEL EXCIPIENTS in drug applications	Stimuli Article on Novel Excipients	2/22/2018

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Emerging Publications	Safety	N/A	Collect current and emerging publications, presentation, etc on nano-technology/nano-materials, develop reference list and library of documents.	1) IPEC Americas team identified to monitor for nano-technology/nano-material information. 2) IPEC-Americas library established to store information (documents, presentations, etc) on nano-technology/nano-materials. 3) list of referenced materials developed	6/7/2017
Position Paper on Nanomaterials	Safety	N/A		Sub-team identified and a mission statement developed	6/7/2017

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