Committee Project Tracking Spreadsheet

Project name	Committees	Federation Project ?	Project Description	Final deliverable (FD)	Date last updated
Future of Element-Specific Chapters in the USP-NF	Compendial Review/ Harmonization	N/A	Determination of how to move forward with elemental specific chapters in USP-NF post <232> and <233> implementation	USP determination and implmentation of element specific chapters in USP-NF	6/8/2020
IPEC-PDG Working group	Compendial Review/ Harmonization	N/A	IPEC - PDG meeting monograph harmonization	On-going monograph harmonization	6/8/2020
JECFA/Food Related Issues related	Compendial Review/ Harmonization	N/A	Monitor Food Additives issues	on going	6/8/2020
Silicon Dioxide Round Robin Study- IPEC Federation	Compendial Review/ Harmonization	Yes	Independent labs perform round robin testing of various forms/sources of silicon dioxide	Round Robin Test results complete and report issued	3/19/2020
Support Elemental Impurity Coalition	Compendial Review/ Harmonization	N/A	Support Trade Association coalition on the Rationale Implementation of Elemental Impurities	Rationale implementation of Global Elemental Impurity requirements for pharmaceutical excipients- on going	6/8/2020
USP Monograph Modernization Project	Compendial Review/ Harmonization	N/A	IPEC working with USP to modernize monographs. USP currently has unequal API vs NF excipient monographs. The issue is related to	modernized monographs	6/8/2020
USP request to change definition of excpient starting material	Compendial Review/ Harmonization	N/A	USP requested to change the definition for excipient starting material to: Starting Material: A raw material, intermediate,	Decision by IPEC Federation regarding definition for excipient starting material	6/10/2020
Qualification of Excipient Guide	Excipient Qualification	Yes	Revise and update the latest version of IPEC Excipient Qualification Guide	To publish an IPEC Excipient Qualification Guide as a Federation guide	6/4/2020
Options for excipient users to qualify excipient suppliers in lieu of an audit	Excipient Qualification	N/A	Develop a position paper to include options for excipient users to qualify their excipient suppliers when the supplier won't allow an audit	Position paper on supplier qualification w/o excipient GMP audit Possibly publish in Pharm Tech. Presentation	6/4/2020
Sustainability and Responsible Sourcing	Excipient Qualification	Yes	Develop and submit a charter (IA XC and Federation) to add a fourth section to the EIP Guide covering sustainability and responsible	Approved project charter	6/4/2020
Update to USP	Executive Committee	N/A	Ensuring the process by which our guides are updated in the USP General Chapters is periodically reviewed	Updated USP General Chapters to align with our recently published	2/21/2018
NSF/IPEC/ANSI 363 Standard	Good Manufacturing Practice	N/A	- Ongoing monitoring of ANSI 363 changes and initiatives. - Reporting back to committee on quarterly	ONGOING	6/4/2020
EXCiPACT Standard	Good Manufacturing Practice	Yes	- Ongoing monitoring of EXCiPACT changes and initiatives. - Reporting back to committee on quarterly	ONGOING	6/4/2020

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Rx-360	Good Manufacturing Practice	N/A	- Ongoing monitoring of Rx-360 changes and initiatives. - Reporting back to committee on quarterly	ONGOING Currently providing feedback to Rx-360 regarding issues that should be clarified or	6/4/2020
IPEC-PQG Excipient GMP How To 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	Revise IPEC-PQG Guide	6/4/2020
IPEC GMP Audit Guide	Good Manufacturing Practice	Yes	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	10/4/2018
Data Integrity	Good Manufacturing Practice	Yes	Position paper on data integrity expectations for excipient manufacturers. This is being addressed by the Federation, but	IPEC Federation Position Paper on Data Integrity	6/4/2020
Guide Navigation Resource	Good Manufacturing Practice	Yes	There are several differences between the EXCiPACT and ANSI Standards and with the IPEC-PQG GMP Guide. Work will be done to resolve	Provide information on various approaches to IPEC members and non-members.	6/4/2020
Validation Guide	Good Manufacturing Practice	Yes	Develop IPEC GUIDE on Excipient Validation, including Equipment, Process, Product, Computer, Cleaning and Analytical Validation	Published IPEC GUIDE on Excipient Validation	6/4/2020
Upper Management Training	Good Manufacturing Practice	N/A	- Need for upper management commitment to GMP - Need for training to engage upper	Infographic created Volunteers: Irwin S., George C., Mike C., Luke G., Jessica C., and Danielle G. or Dora M. from	6/4/2020
IPEC Good Distribution Practices Audit Guide	Good Manufacturing Practice	Yes	This guide will draw from applicable sections of the ANSI 363 standard which apply to distributors and is intended be a reference guide	New GDP Audit Guide	6/4/2020
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	Publish a GDP How To Guide GDP Guide members: Lisa Frame, Erica V.,	6/4/2020
Develop PQRI Workshop on Elemental Impurity	Quality by Design		PQRI workshop proposal for follow-up workshop on Elemental Impurities 1) how can we utilize results coming out of the	Hold PQRI EI Workshop on Elemental Impurity.	6/4/2020
Develop PQRI Continuous Manufacturing Workshop	Quality by Design	N/A	PQRI workshop proposal for API and excipient impact on continuous manufacturing	PQRI CM Workshop held Volunteers: L. Tocce, G. Collins, C. Moore	12/11/2019
Develop PQRI Workshop proposal for ICH M9 EWG Oral Bioavailability Project	Quality by Design	N/A	ICH M9 EWG next meets in autumn. Dave Schoneker proposed IPEC work with PQRI on a workshop to gather information needed to	PQRI ICH M9 workshop on excipient/API Interactions	12/11/2019
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	6/4/2020

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ICH Continuous Manufacturing (Q13)	Quality by Design	Yes	Brian C. to represent IPEC on ICH Q13 Working Group. He will provide updates/drafts from WG activities, as allowed.	ICH Q13 CM Guideline	6/4/2020
Pharmaceutical Technology follow-up series of articles	Quality by Design	N/A	Develop a series of 2 article to be published in Pharm Tech 1) Additives and process aids in pharmaceutical	articles published in Pharmaceutical Technology	6/4/2020
Type V DMF Status	Regulatory Affairs	N/A	Request FDA variance for CTD structure for Type V DMFs	FDA variance granted	6/3/2020
Compound Pharmacy Association – outreach	Regulatory Affairs	N/A	Reach out to compounding pharmacy trade associations for joint collaboration/membership.	Collaboration/membership with compound pharmacy organizations/personnel	6/3/2020
Highlight excipient information on US Laws, regulations and industry	Regulatory Affairs	N/A	IPEC-Americas is currently developing some short briefs, infomercials and fact sheets highlighting basic regulations on excipients (where	Short briefs, infomercials, fact sheets and documentation to communicate the value IPEC-Americas brings	6/7/2019
Explore membership expansion into combination products	Regulatory Affairs	N/A	Explore expanding IPEC membership to companies producing combination products. Priscilla to contact someone at Dow. Irwin S.	Feasibility for expanded IPEC membership	12/10/2019
Export certificates/ certificates to foreign governments/ certificates	Regulatory Affairs	N/A	2019 RA Committee meeting proposed project 3	Review/update white paper on “export certificates” with new export certificates/ certificates to foreign governments/	6/3/2020
FDA IID update	Regulatory Affairs		Support FDA clean-up and update of US FDA IID	Improved FDA IID database and process for toxicology assessments for families of similar products	6/3/2020
Health Canada Atypical Actives List	Regulatory Affairs	N/A	Action item to update HC Atypical Actives list carried over from 2017.		6/3/2020
Emerging regulatory Hot Topics	Regulatory Affairs	N/A	Monitor emerging "hot topics" globally, share, as appropriate and determine whether further action is warranted	Communication (updates) and potential actions	6/3/2020
Global regulatory requirements for excipients	Regulatory Affairs	Yes	Project to find the regulatory requirements for Excipient in different countries	A definitive report on the stability study methods and expiry date on excipients	6/3/2020
IQ Initiative	Scientific Affairs	N/A	IPEC-Americas and IQ Consortium to collaborate with FDA to propose/develop new "novel excipient qualifying process."	FDA supported "novel excipient qualification process"	6/2/2020
TiO2, nanoparticles	Scientific Affairs	TBD	Follow evolving TiO2 activates in France targeted at banning TiO2 from foods	Understanding of impact of TiO2 activities on pharmaceutical products/ingredients	6/2/2020

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Update IPEC-Americas Safety Guide	Scientific Affairs	TBD	Revise previous IPEC-Americas Guide, published in Regulatory Toxicology and Pharmacology, Volume 24, No. 2, October 1996.	An updated guide for the types of safety testing needed for a product approval	6/2/2020
PQRI Project on polymeric chain length on absorption	Scientific Affairs	N/A	Support PQRI project to address polymer absorption based on molecular chain length.	Publication on how to address absorption based on molecular chain length	5/30/2019

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