Committee Project Tracking Spreadsheet

Activity	Committees	Federation Project ?	Project Description	Final deliverable (FD)	Date last updated
USP Excipient Monograph Submission Guide	Compendial Review/ Harmonization	N/A	Provide formal comment letter for the recently revised USP Excipient Monograph Submission Guide (for new and proposed revision). Comment letter will discuss inapplicability of ICH Q3A/B to excipients.	IPEC-Americas comments for the USP Excipient Monograph Submission Guide	13-Sep-23
USP EI tests/limits for naturally derived materials	Compendial Review/ Harmonization	N/A	PF47(4) USP proposed changes to alginate for Pb and As (tighten limits) although industry has provided USP with significant data available demonstrating that there is no potential for Pb or As to be present even at levels much lower than the proposed tighter limits. The PF47(4) proposal is in alignment with the USP and EP policy to maintain individual EI tests/limits in monographs in naturally derived materials. Compendial review team agreed to prepare and send a formal request to USP for an advisory panel or a roundtable (directed at monograph liaison, Catherine, Galina, Hong, Peng and chair of EI committee, Devandra) regarding how exclusions from the USP/EP policy can be made where there is significant data available demonstrating that there is no potential for EI in the material	Formal USP request for an advisory panel or roundtable for exclusions from the USP/EP policy where there is significant data available demonstrating that there is no potential for EI in the material	13-Sep-23
IPEC-PDG Working group	Compendial Review/ Harmonization	N/A	IPEC - PDG meeting monograph harmonization	On-going monograph harmonization	13-Sep-23
JECFA/Food Related Issues related	Compendial Review/ Harmonization	N/A	Monitor Food Additives issues	On-going.	13-Sep-23
Compendial Postings Monitoring	Compendial Review/ Harmonization	N/A	CRC to host a virtual monthly review of new proposed and official USP and international pharmacopeial content. As appropriate, comments will be developed and sent to relevant pharmacopoeias.	Individual comment letters listed separately in this tracking spreadsheet. An ongoing Compendial Publication tracker is maintained and updates are available	13-Sep-23

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Mutual Recognition of Pharmacopoeias	Compendial Review/ Harmonization	Y	identify and develop IPEC proposals to support pharmacopoeias going forward. This includes general chapter and excipient monograph modernization (e.g. state of-the-industry analytical methods), retrospective recognition of existing excipient monographs and prospective harmonisation of new excipient monographs	1) Industry white paper that identifies the impact of having to comply with multiple compendia on industry and the patient and how companies could use risk assessments and impact assessments to document and justify compendial compliance 2) concept paper and business plan to share with the other associations with proposal to form a broad international consortium to develop a process for collaborating on testing in order to minimize the impact of non-harmonised standards. 3) documented rationale as to why functional equivalence of pharmacopoeias should be considered.	13-Sep-23
QC lab capability survey	Compendial Review/ Harmonization	N/A	Survey to collect data from global PEC members regarding testing capabilities of excipient QC release labs, including instrumentation available and analyst expertise	share analytical capability with USP, ideally during a stakeholder forum	13-Sep-23
IPEC Significant Change Guide	Excipient Qualification	N/A	Based on feedback from the webinar to describe what was changed in the 2023 version of the IPEC Significant Change Guide, a webinar is being developed to provide training in the guide itself	IA LL Webinar on the IPEC Significant Change guide for Pharmaceutical Excipients	8-Nov-23
Update of Quality Agreement Guide	Excipient Qualification	Yes	Review the 2017 Federation Quality Agreement guide and re-issue updated version	Published revised Federation Quality Assurance guide	21-Sep-23
Emerging hot topics involving excipient supplier expectation and excipient supplier response	Excipient Qualification	N/A	Develop article on Emerging hot topics involving excipient supplier expectation and excipient supplier response	Article on Emerging Excipient hot topics	21-Sep-23
Update of TUPPs Guide	Excipient Qualification	Yes	Review the 2015 Federation TUPPS guide and re-issue updated version	Published revised Federation TUPPs guide	21-Sep-23
Update of Risk Assessment Guide	Excipient Qualification	Yes	Review the 2017 Risk Assessment Guide for possible update	Published revised Federation Risk Assessment guide	21-Sep-23
2022 IPEC Certificate of Analysis Guide	Excipient Qualification	Yes	Two concerns raised with 2022 CoA guide: o text requiring CoA date of approval to be shown on COA and o 2nd COA example for a COA that is not hand-signed, yet showing ID of the person approving the COA along with date of approval.	updated CoA guide	

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Importance of CAPA investigations and resolutions	Good Manufacturing Practice	N/A	Based on recent FDA warning letter to an excipient manufacturer, develop a webinar to include examples of recent FDA excipient inspection findings and actions, describe FDA's definition of excipients as "drug components" and review drug product/component adulteration provisions of the Food, Drug & Cosmetic Act.	IA LL Webinar entitled Why an effective CAPA system is important for excipient companies	15-Nov-23
NSF/IPEC/ANSI 363 Standard	Good Manufacturing Practice	N/A	- Ongoing monitoring of ANSI 363 changes and initiatives. - Reporting back to committee on quarterly basis.	ONGOING	21-Sep-23
EXCiPACT Standard	Good Manufacturing Practice	Yes	- Ongoing monitoring of EXCiPACT changes and initiatives. - Reporting back to committee on quarterly basis.	ONGOING	21-Sep-23
Rx-360	Good Manufacturing Practice	N/A	- Ongoing monitoring of Rx-360 changes and initiatives. - Reporting back to committee on quarterly basis. Mike Polito from Milipore Sigma current IPEC-Americas representative providing feedback to Rx-360 regarding issues that should be clarified or edited which could lead to misunderstandings.	ONGOING	21-Sep-23
Revise IPEC Stability Guide	Good Manufacturing Practice	Yes	Review previous Stability Guide revision charter and form a new team to addresss items in the previous charter that were not included in the 2022 guide revision	Published new revised Federation Stability guide	21-Sep-23
IPEC-Americas Excipient GMP Audit Guide to revised IPEC GMP Guide	Good Manufacturing Practice	TBD	Develop two audit checklists for the IPEC-PQG Excipient GMP guide, one comprised of questions and the other reminder phrases.	Published IPEC GMP Audit Guide to revised IPEC GMP Guide	21-Sep-23
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. GDP Guide members: Lisa Frame, Erica V., Luc S. with Charlotte M. - lead	Published GDP How To Guide	21-Sep-23
Third Party Audit and Certification Programmes	Good Manufacturing Practice	Yes	Update the 2015 IPEC Federation position paper on Third Party Audit and Certification Programmes	Publish updated Position paper on Third Party Audit and Certification Programmes	21-Sep-23

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Potential position paper Covering Risks of Use of Food/Cosmetic Grade Material as Excepient	Good Manufacturing Practice	N/A	Position paper to raise awareness when there is no USP or excipient grade available due to supply shortages, food/cosmetic grade only available and other circumstances that may impact the supply. position paper on what would be needed to justify using a different grade.	Education Opportunity with potential for series of articles, Webinar, IPEC Insider	21-Sep-23
Excipient GMP Auditing Workshop	Good Manufacturing Practice	N/A	In person Workshop to be held at IPEC Americas, Arlington. Workshop to includes analyzing essential elements and expectations related to excipient GMP and GDP for materials intended for use in pharmaceuticals or dietary supplements. Review of EXCiPACT Excipient GMP Certification scheme and requirements of NSF/IPEC/ANSI 363-2019.	Workshop on Excipient GMP Auditing	21-Sep-23
Comparing excipient GMPs (USP vs IPEC vs ANSI)	Good Manufacturing Practice	N/A	Once USP <1078> publishes, article comparing USP GMP vs IPEC-PQG GMP vs ANSI 363 – including expectation for notification of significant change.	Article on comparing excipient GMPs	26-May-23
Insider Membership Article	Good Manufacturing Practice	N/A	Article on "How has IPEC benefited your company, industry.",	Quarterly articles published in the IPEC Insider	26-May-23
Annex/Guidance for Parenteral Applications	Good Manufacturing Practice		The current Excipient GMP guide has a Gap in how to handle parenteral applications.	GMP Annex/Guide for Parenteral medicines	28-Sep-23
Excipient GMP 101 Webinar/Training	Good Manufacturing Practice	N/A	Regulators outside US requested short webinar on excipient GMP, but IPEC does not currently have such a webinar. Suggested to develop an Excipient GMP 101 course to provide basic excipient GMP training/overview for regulators and people new to excipients (both manufacturers and users).	Excipient GMP 101 webinar/course for management	28-Sep-23
PQRI Project: Patient Centric Dosage forms	Quality by Design	N/A	Project to focus on impurities and impact to patient safety.	PQRI Proposal	14-Sep-23
Develop PQRI Workshop proposal for ICH M9 EWG Oral Bioavailability Project – Phase II	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 support ICH M9 project	PQRI ICH M9 workshop on excipient/API Interactions	14-Sep-23

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Update definition for excipient impurities/ concomitant components	Quality by Design	Yes	Formation of a new project team, pulling together members from different committees (e.g., QbD, GMP, etc.), to better understand and define excipient impurities and concomitant components as well as develop a strategy moving forward, including potential revisions to the recently published IPEC Glossary and Composition Guide.	Updated definition for excipient impurities and concomitant components. Defined strategy to communicate (e.g., infographic), and where necessary, update IPEC documents.	14-Sep-23
Two-part T&C article on Emerging Technology and impact on excipients	Quality by Design	N/A	Emerging Technology and impact on excipients – Need for Novel Excipients and functionalities. Including excipient fundamentals-review of excipient characterization activities (two part series).	Published T&C articles	14-Sep-23
FDA meeting on additives and processing aids in pharmaceutical excipients	Quality by Design	N/A	Revive backgrounder previously developed for FDA and circle back to FDA regarding request for a meeting to discuss the importance for how to handle information pertaining to additives and process aids in drug applications	Renew FDA request for meeting on additives and process aids	14-Sep-23
PQRI workshop: Co-processed Excipients to Enhance Continuous Manufacturing	Quality by Design	N/A	• Decoupling co-processed excipients from novel excipients • EU GMP implications of co-processed excipients • “perceived” need for compendial materials to make co-processed excipients • Improved stability and properties through co-processing • Customization of co-processed excipients (instant release, continuous release, controlled release, etc.) o Use of platform concepts • Limitation of CM material feeders	PQRI workshop Planning	14-Sep-23
New Guide on Excipient Interchangeability	Quality by Design	TBD	Based on EQ committee article on Supplier Qualification, develop a position paper and/or workshop to address interchangeability of excipients for excipient users.	New Position Paper and/or workshop on Excipient Interchangeability	14-Sep-23
QbD Sampling Guide	Quality by Design	Yes	Integrate the details of the QbD Sampling Guide into the 2020 International Pharmaceutical Excipient Council Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design (QbD) Guide	Combined Guide for Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Desig and QbD Sampling	14-Sep-23

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New, more sensitive analytical technology applied to excipients	Quality by Design	N/A	To address how new, more sensitive analytical methods could impact concerns related to excipient composition, collect feedback from members on issues related to characterizing excipients using new analytical techniques (e.g., identification or new peaks due to more sensitive techniques may lead to a misconception that the excipient contains new compositional impurities). Develop position paper, including unintended consequences.	Position paper on issues related to new analytical techniques	14-Sep-23
FDA IID update	Regulatory Affairs	N/A	Support FDA clean-up and update of US FDA IID	Improved FDA IID database and process for toxicology assessments for families of similar products	13-Sep-23
CROSSFUNTIONAL TEAM - nitrosamines	Regulatory Affairs	N/A	Monitor emerging "hot topics" globally, share, as appropriate and determine whether further action is warranted	Communication (updates) and potential actions	13-Sep-23
CROSSFUNTIONAL TEAM - microplastics	Regulatory Affairs	N/A	Monitor emerging "hot topics" globally, share, as appropriate and determine whether further action is warranted	Communication (updates) and potential actions	13-Sep-23
Atypical Actives Position Paper (Revised) and FAQ	Regulatory Affairs	TBD	* Revised position paper (TBD if necessary) * Develop a FAQ to address atypical actives with regard to regulatory expectations * This may also lead to development of other documents e.g. FAQs on CEPs, DMFs etc relative to excipients * Seek opportunities to engage with regulators/industry on this topic	1) Position paper or FAQ on how regulatory issues with atypical actives might be handled 2) FAQs or other documents on related topics (relevance of CEPs, DMFs, etc) 3) External presentations to share information on atypical actives	13-Sep-23
Excipients Regulations Database project	Regulatory Affairs	Yes	IPEC Federation project to investigate the development of a regulatory database for excipients by partnering with existing companies that offer regulatory databases. The Federation developed a high level project requirement document that was shared with 2 companies being considered, Decernis and Clarivate (Cortellis).	Development of a regulatory database for excipients	13-Sep-23
TiO2, nanoparticles	Regulatory Affairs	TBD	Follow evolving TiO2 activates in France targeted at banning TiO2 from foods	Understanding of impact of TiO2 activities on pharmaceutical products/ingredients	11-Aug-23
FDA CDRH best practices for commenting	Regulatory Affairs	N/A	Incorporate CDRH guidelines into an IPEC-Americas procedure to use when developing and sending comments to any agency/organization	IPEC-Americas commenting procedure	13-Sep-23

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IQ Initiative (Novel Excipients FDA Qualification Pathway	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"	25-May-23
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	16-May-23
Develop Co-processed excipient white-paper	Scientific Affairs	N/A	IPEC-Americas to partner with IQ to prepare and publish a white paper targeted to decouple novel excipients from the definition of novel excipient, especially as related to novel chemistry	Co-processed excipient white-paper	25-Sep-23
Monitor for poorly reviewed scientific excipient articles	Scientific Affairs	N/A	Monitor literature for “peer reviewed” articles considered to be “poor science.” As appropriate, develop public comments, from IA, highlighting issues with these publications. When available, review/discuss articles/follow-up during quarterly committe meetings. Jeff Pitt/Ron Filler agreed to help lead. Consider reaching out to to academia for help in monitoring/identifying articles	ongoing monitoring and response to poorly reviewed scientific excipient articles	25-Sep-23
Excipient 101 Course	Scientific Affairs	N/A	Proposed forming an Excipient 101 Course for academia and potentially for industry workshops or webinars	Excipient 101 Course, webinar and/or workshop	25-Sep-23
Alternative Methodologies subteam activities	Scientific Affairs	N/A	Following publication of the IPEC Safety Guide for Pharmaceutical Excipients, a global sub team of Safety Guide contributors continue to monitor current and emerging trends in use/acceptance of alterntive methodologies by healthcare regulatory authorities.	Develop webinar and/or article on alternative methodologies	25-Sep-23