Committee Project Tracking Spreadsheet

Activity	Committees	Federation Project ?	Project Description	Final deliverable (FD)	Date last updated
<320> NMR – proposed new chapter: please review and provide comments	Compendial Review/ Harmonization	N/A	Develop and submit comments to USP on proposed new chapter to have a standardized methodology based on NMR to determine degrees of hydrolysis for different types of PVA materials. IA members using this method are encouraged to comment.	Letter to USP	4-Jun-25
Congratuale Fouad Atouf, newly appointed Chief Science Officer of USP	Compendial Review/ Harmonization	N/A	IPEC-Americas to develop a congratualtory letter to Fouad Atouf who was recently appointed Chief Science Officer of USP	Letter to Fouad	4-Jun-25
IPEC-PDG Working group	Compendial Review/ Harmonization	N/A	IPEC - PDG meeting monograph harmonization	On-going monograph harmonization	4-Jun-25
JECFA/Food Related Issues related	Compendial Review/ Harmonization	N/A	Monitor Food Additives issues	On-going.	4-Jun-25
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	4-Jun-25
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 harmonization of new excipient monographs. Objectives include: 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-harmonized standards. 3) documented rationale as to why functional equivalence of pharmacopoeias should be considered.	1) Industry white paper identifying industry/patient impact for requiring compliance with multiple compendia 2) concept paper and business plan to share with the other associations. 3) documented rationale as to why functional equivalence of pharmacopoeias should be considered.	26-Feb-25

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Communicate value of EIP	Excipient Qualification	N/A	Need to better promote the value of developing and using the IPEC Excipient Information Package document. Considering development of an article, white paper and/or Infographic with "tips" for how to use the IPEC guide	Publication and/or infographic	5-Jun-25
Application of <1115> to excipients	Excipient Qualification		Committee to consider developing a position paper, guide and/or tools on how to apply <1115> to excipients		5-Jun-25
Update PDA-IPEC TR 54-6 Risk Assessment for Excipient report	Excipient Qualification	Yes	Review the 2019 PDA-IPEC TR 54-6 Risk Assessment for Excipient report	Published revised PDA-IPEC Risk Assessment report	5-Jun-25
Setting specifications	Excipient Qualification		Develop a guide or annex to an existing guide for setting specifications.	Guide or Guide Annex on Setting Specifications	5-Jun-25
Differences between Excipient and Food GMPs	Excipient Qualification	N/A	position paper or guidance on the differences between Excipient and Food GMPs	Publish position paper or guidance	5-Jun-25
NSF/IPEC/ANSI 363 Standard	Good Manufacturing Practices	N/A	- Ongoing monitoring of ANSI 363 changes and initiatives. - Reporting back to committee on quarterly basis. - submit ANSI 363 Excipient GMP Standard to FDA as Voluntary Consensus Standards Related to Pharmaceutical Quality	Quarterly report to GMP Committee	5-Jun-25
EXCiPACT Standard	Good Manufacturing Practices	Yes	- Ongoing monitoring of EXCiPACT changes and initiatives. - Reporting back to committee on quarterly basis.	Quarterly report to GMP Committee	5-Jun-25
Rx-360	Good Manufacturing Practices	N/A	Placeholder for GMP committee members to voice any feedback they would like shared with RX-360	Quarterly GMP Committee discussion	5-Jun-25
Annex 1, Pharmaceutical Excipients	Good Manufacturing Practices	Yes	In January 2025 China issued final GMP regulations for excipients. Annex 1, Pharmaceutical Excipients. IPEC China reviewed, translated and compared the 2022 versions vs the 2025 version.	Comments to IPEC China on any MAJOR issue(s)	5-Jun-25
Revise IPEC Stability Guide	Good Manufacturing Practices	Yes	Review previous Stability Guide revision charter and form a new team to address items in the previous charter that were not included in the 2022 guide revision	Publish revised Federation Stability guide	5-Jun-25
IPEC-Americas Excipient GMP Audit Checklist to revised IPEC GMP Guide	Good Manufacturing Practices	TBD	Develop two audit checklists for the IPEC-PQG Excipient GMP guide, one comprised of questions and the other reminder phrases.	Pulish internal audit checklist to IPEC-PQG GMP guide for IPEC-Americas members	5-Jun-25
Comparing excipient GMPs (USP vs IPEC vs ANSI vs WHO vs Excipact)	Good Manufacturing Practices	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 Potential article for International journal of pharmaceutical excipients,	5-Jun-25

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Annex/Guidance for Parenteral Applications	Good Manufacturing Practices		The current Excipient GMP guide has a Gap in how to handle Risk assessment for parenteral, pediatric, inhalation, etc. applications.	GMP Annex/Guide for Parenteral medicines Potential article for: International journal of pharmaceutical excipients	5-Jun-25
GDP Audit guide	Good Manufacturing Practices	Yes	Update the current guide for GDP	Revised GDP Audit Guide	5-Jun-25
Bulk chemical handling guide	Good Manufacturing Practices	Yes	Develop a new IPEC Guide for bulk chemical handling	New Bulk Chemical Handling guide	5-Jun-25
EMA Q&A on co-processed excipients used in solid oral dosage forms	Quality by Design	Yes	IPEC Federation Positon paper entitled: EMA Q&A on co-processed excipients used in solid oral dosage forms. The document was developed by members of IPEC-Americas and Europe.	IPEC Federation Positon Paper on CoP	5-Jun-25
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	5-Jun-25
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	5-Jun-25
Excipient Impurities	Quality by Design	N/A	Agreed to develop another infographic in the Excipient Composition series focussed on excipient imputies.	Excipient composition infographic highlighting excipient impurities	5-Jun-25
Revision to IPEC Composition Guide for Pharmaceutical Excipients	Quality by Design	N/A	Federation has identified the IPEC Composition Guide for Pharmaceutical Excipients for update/revision in 2025. An initial review of the guide by suggested that the revision might include more substantive changes. Next steps to include sending it out to the various PECs for comment and, if necessary, formation of a small revision sub-team.		5-Jun-25

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USP ⟨1037⟩ Process Analytical Technology—Theory	Quality by Design	N/A	Review recent USP General Chapter on Process Analytical Technology - Theory and decide whether or not to prepare and submit comments to USP	Comments to USP	5-Jun-25
USP Stimuli ArticleProcess Analytical Technology I—Theory of Sampling in PAT	Quality by Design	N/A	Review recent USP Stimuli article on Process Analytical Technology - Theory of Sampling in PAT and decide whether or not to prepare and submit comments to USP	Comments to USP	5-Jun-25
USP Stimuli Article Process Analytical Technology II—Implementation of Real-Time Release Testing	Quality by Design	N/A	Review recent USP Stimuli article on Process Analytical Technology II - implementation of Real-Time Release Testing and decide whether or not to prepare and submit comments to USP	Comments to USP	5-Jun-25
New Guide on Excipient Interchangeability	Quality by Design		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	5-Jun-25
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	5-Jun-25
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	4-Jun-25
PRIME update	Regulatory Affairs	N/A	Formal letter from USP, IQ and IPEC requesting update/formal closure of PRIME program reach out to Catherine Sheehan at USP to better understand their involvement and understanding for the PRIME program	discussion with USP and potential letter to FDA	4-Jun-25
PRIME publication	Regulatory Affairs	N/A	In lieu of a formal FDA acknowledgement that the PRIME program has been canceled, IPEC-Americals to develop and publish an article providing an update on the PRIME program and current understanding of its discontinuance	Published Article	4-Jun-25

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Docket No. FDA-2025-D-0507, Replacing Color Additives in Approved or Marketed Drug Products	Regulatory Affairs	N/A	recommendations for replacing color additives in approved or marketed drug products. IA to prepare and submit comments	FDA comments to Docket No. FDA-2025-D-0507	4-Jun-25
Best Practice Guide for New Excipient	Regulatory Affairs	Yes	Develop a guide or white paper on strategy and issues with New Excipients, specifically on “degrees of novel” and how to bridge the gap on data for excipients that are not new chemical entities (not related to safety).	Published guide or white paper	4-Jun-25
Atypical Actives Advocacy	Regulatory Affairs	TBD	Proposed initatives to action in 2024: 1. Discuss topics in Latin America 2. CEP 2.0 hasn't addressed use of CEPs 3. Consider Advocacy on atypical actives	Atypical Actives Advocacy and How To Guide	4-Jun-25
Position Paper on Good Manufacturing Practices for Atypical Actives (2019)	Regulatory Affairs	Yes	Update and expand current positon paper to include references to regional regulations, where they exist	updated position paper	4-Jun-25
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	4-Jun-25
Annex 2: WHO prevention & control of nitrosamines in pharma products	Regulatory Affairs	Yes	Annex 2 is not open to direct commenting but input will be provided to WHO looking for talking points for Federation to discuss with WHO (no wordsmithing)	WHO talking points	4-Jun-25
CROSSFUNTIONAL TEAM - microparticles	Regulatory Affairs	N/A	Monitor emerging "hot topics" globally, share, as appropriate and determine whether further action is warranted	Communication (updates) and potential actions	4-Jun-25
PFAS	Regulatory Affairs	TBD	Monitor and report back on emerging PFAS regulations/requirements		4-Jun-25
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	4-Jun-25
State Regulatory Tracking document	Regulatory Affairs	TBD	Develop and maintain a spreadsheet of emerging state regulations related to excipients (e.g., PFAS, TiO2)	Living spreadsheet available to IPEC-Americas members	4-Jun-25

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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 committee meetings. Jeff Pitt/Ron Filler agreed to help lead. Consider reaching out to academia for help in monitoring/identifying articles	ongoing monitoring and response to poorly reviewed scientific excipient articles	3-Jun-25
Misinformation on safety of excipient use in drug products	Scientific Affairs	N/A	Discussed developing a Journal article reviewing misinformation trends and realities. Potentially partner with industry SME(s).	Published Article	3-Jun-25
SME Engagement/Knowledge Sharing with SAC Members	Scientific Affairs	N/A	Identify and invite industry SMEs to share knowledge on excipients used in/needed for pediatrics and/or injectables to IPEC members. Knowledge to feed into future guidance development and/or related initiatives.	Presentations at SAC 2025 meetings	3-Jun-25
Comments to FDA panel banning talc	Scientific Affairs	N/A	Letter to FDA Expert Panel on Talc. The Talc Panel concluded that talc should be banned due to the precautionary principle even though they did not cite any safety studies showing a problem with oral use of talc	FDA Letter	3-Jun-25
NAMs deep dive sub-committee	Scientific Affairs		Form a NAMs deep dive sub-committee to distill FDA NAMs Report. o Distill FDA NAMs Report and identify potential relevant items from excipient(s) evaluations. o Develop toolbox and workflow for the use of NAMS for novel excipients and/or infographic. o Potentially develop a review article on NAMs for the International Journal of Pharmaceutical Excipients. o Consider partnering/collaborating with SOT and/or other industry toxicologists to further better understand and promote the application of NAMs to novel excipients.	NAMS toolbox, review article, NAMS promotion	3-Jun-25
Guide Road map for Users	User Network	N/A	Infographic to show "road map" for users (and maybe makers, too) for applying IPEC guides and position papers	Guide Infographic for Users	9-Jun-25