Activity	Committees	Federation Project ?	Project Description	Final deliverable (FD)	Date last updated
2023 Excipient Request for Revision Guideline, Updated in 2025	Compendial Review/ Harmonization	N/A	IPEC-Americas submitted comments Q2 2023 re: USP excipient monograph revision request from Hong/Jenny. USP recently published an update so we compared our 2023 comments vs their revised monograph then followed-up with Hong regarding our concerns	Response to USP email	26-Sep-25
IPEC-PDG Working group	Compendial Review/ Harmonization	N/A	IPEC - PDG meeting monograph harmonization	On-going monograph harmonization	17-Sep-25
JECFA/Food Related Issues related	Compendial Review/ Harmonization	N/A	Monitor Food Additives issues	On-going.	17-Sep-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	17-Sep-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.	17-Sep-25
Risk Assessment How To - Practical Application of Guides and Tools	Excipient Qualification	N/A	Deliver targeted instruction on excipient risk assessment methodologies, tools, and best practices for industry professionals. Case-based examples to illustrate practical applications.	ELL webinar on Risk Assessment How To - Practical Application of Guides and Tools	10-Sep-25
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	18-Sep-25
Application of <1115> to excipients	Excipient Qualification	0	The current Excipient GMP guide has a Gap in how to handle Risk assessment for parenteral, pediatric, inhalation, etc. applications.	0	18-Sep-25
Revise IPEC QoE Guide	Excipient Qualification	Yes	The current version of the IPEC QoE guide is now 5 years old and on the Federation list to be updated in 2025	Publish revised Federation QoE guide	18-Sep-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	18-Sep-25
Setting specifications	Excipient Qualification	0	Develop a guide or annex to an existing guide for setting specifications.	Guide or Guide Annex on Setting Specifications	18-Sep-25
Excipient GMP Differences, Risk Assessment, and Audit Findings	Good Manufacturing Practices	N/A	Provide an overview of similarities and differences between published excipient GMPs as well as suggestions on risk assessment strategies to support excipient GMP implementation and documentation.	ELL webinar on Excipient GMP Differences, Risk Assessment, and Audit Findings	10-Sep-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	18-Sep-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	18-Sep-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	18-Sep-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)	18-Sep-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	18-Sep-25
Revision to IPEC GMP Audit Guide	Good Manufacturing Practices	yes	Revise the retired IPEC GMP Audit guide to align with the most current IPEC-PQG Excipient GMP Guide	Revised GMP Audit Guide	18-Sep-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,	18-Sep-25
Annex/Guidance for Parenteral Applications	Good Manufacturing Practices	0	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	18-Sep-25
Bulk chemical handling guide	Good Manufacturing Practices	Yes	Develop a new IPEC Guide for bulk chemical handling	New Bulk Chemical Handling guide	18-Sep-25
Differences between Excipient and Food GMPs	Good Manufacturing Practices	N/A	position paper or guidance on the differences between Excipient and Food GMPs	Publish position paper or guidance	18-Sep-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	18-Sep-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	18-Sep-25
Excipient Impurities	Quality by Design	N/A	Agreed to develop another infographic in the Excipient Composition series focused on excipient impurities	Excipient composition infographic highlighting excipient impurities	18-Sep-25
Excipient Composition Profile	Quality by Design	N/A	Discussed developing a final infographic in the Excipient composition series focused on developing an excipient composition profile	Infographic showing things to consider in developing an excipient composition profile	18-Sep-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.	Publish revised Federation Composition guide	18-Sep-25
New Guide on Excipient Interchangeability	Quality by Design	N/A	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	18-Sep-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	18-Sep-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	17-Sep-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	17-Sep-25
PRIME publication	Regulatory Affairs	N/A	In lieu of a formal FDA acknowledgement that the PRIME program has been canceled, IPEC-Americas to develop and publish an article providing an update on the PRIME program and current understanding of its discontinuance	Published Article	16-Jul-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	17-Sep-25
Atypical Actives Advocacy	Regulatory Affairs	TBD	Proposed initiatives 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	17-Sep-25
Position Paper on Good Manufacturing Practices for Atypical Actives (2019)	Regulatory Affairs	Yes	Update and expand current position paper to include references to regional regulations, where they exist	updated position paper	17-Sep-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	17-Sep-25
Excipient-Related Challenges of N-Nitrosamine Impurities	Regulatory Affairs	N/A	Invited speaker at SAAMnow 2025 Fall Workshop Oct 1 and 2, 2025 to speak on Excipient Related Challenges of N-nitrosamine impurities	Presentation on Nitrosamine Impurities at SAAMnow 2025 fall workshop	17-Sep-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	17-Sep-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	17-Sep-25
PFAS	Regulatory Affairs	TBD	Monitor and report back on emerging PFAS regulations/requirements	0	17-Sep-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	17-Sep-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	17-Sep-25
Misinformation on safety of excipient use in drug products	Scientific Affairs	N/A	Discussed developing an OpEd/Consumer article + review (technical) article reviewing misinformation trends and realities. Potentially partner with industry SME(s).	Published Consumer/Op-ed Article	16-Sep-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	16-Sep-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	16-Sep-25
Talc Survey to support FDA Talk letter	Scientific Affairs	N/A	Survey to talc makers and users on what it would take to replace talc in both OTC and Rx products. Obtain number of approved drug products in the US using talc. Discuss costs and timing for reformulation. Potential drug shortages can occur. References for approved drug product: DailyMed NLM database.	IPEC-Americas Talc survey results	16-Sep-25
Alternative Methodologies poster for EW 2026	Scientific Affairs	N/A	With all the emerging activities occurring in the alternative methodologies and AI space, subteam to develop a poster entitled "Future Use of NAMs in the Safety Evaluation of Novel Excipients"	IPEC-Americas Alternative Methodologies poster for EW 2026	16-Sep-25
Talc Poster for EW 2026	Scientific Affairs	N/A	Use talc survey results to develop a poster for EW describing what it would take to replace talc in both OTC and Rx products	IPEC-Americas Talc poster for EW 2026	8-Sep-25
Alternative Methodologies dive sub-committee	Scientific Affairs	N/A	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	16-Sep-25