Activity	Committees	Federation Project ?	Project Description	Final deliverable (FD)	Date last updated
USP Digital Standards demo	Compendial Review/ Harmonization	N/A	USP is is evolving how Digital Documentary Standards (dDS): machine-readable versions of USP/NF monographs and methods — standard clauses, tests, and specifications are coded for systems rather than human reading. For this activity IPEC-A will invite Rich Panzer from USP to present a demo on USP Digital standards	USP Demo on Digital Standards	6-Mar-26
IPEC-PDG Working group	Compendial Review/ Harmonization	N/A	IPEC - PDG meeting monograph harmonization	On-going monograph harmonization	4-Mar-26
JECFA/Food Related Issues related	Compendial Review/ Harmonization	N/A	Monitor Food Additives issues	On-going.	4-Mar-26
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-Mar-26
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.	4-Mar-26
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-Mar-26
Using a 3rd party Distributor audits to demonstrate they meet appropriate GMPs	Excipient Qualification	N/A	The article should describe the current problem for distributors in assuring their excipient suppliers meeting appropriate GMPs. The article should address qualification of third party auditors, provision for report review and comment by the auditee, report confidentiality and ownership, use of the audit report by the excipient manufacturer (if allowed), and inclusion of CAPA from the auditee.	Published article, position or white paper	5-Mar-26
Application of USP GC <1115> Bioburden Control For Non Sterile Drug Substance to excipients	Excipient Qualification	N/A	The current Excipient GMP guide has a Gap in how to handle Risk assessment for parenteral, pediatric, inhalation, etc. applications. It is important to understand what specific requirement might exist for excipients used in these products.	SME Presentation on application of USP GC <1115> to excipients	5-Mar-26
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	5-Mar-26

Revise IPEC EIP Guide	Excipient Qualification	Yes	The current version of the IPEC EIP guide is now 5 years old and on the Federation list to be updated in 2025. Need to update guide and incorporate EIP Part IV into same document as EIP Part I - III.	Publish revised Federation EIP guide	5-Mar-26
EIP User Guide and Template, Part IV : Sustainability Overview, V1 2023	Excipient Qualification	Yes	Need to incorporate Part IV of the EIP into the Part I - III revision. Prior to adding it, need to have Sustainability SMEs review 2023 EIP Part VI and determine of significant edits are necessary	Revisions to EIP Part IV and incorporation into EIP Part I - III Revision	5-Mar-26
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-Mar-26
Update Federation Data Integrity position paper	Excipient Qualification	Yes	The Federation is looking for a subteam to review and update the 2020 Position Paper on Data Integrity. IA currently developing a policy for the use of Artifical Inteligence (AI). Intent is to include and cover AI in the updated revision of the position paper.	Revised Data Integrity Position Paper	5-Mar-26
Issues driving excipient makers to leave the market and how to discontinue products/exit market	Excipient Qualification	N/A	Develop article to stimulate interest. Go through a decommissioning process, removal of DMF, customer notification, security stock, customer notification, etc. Need to understand how important the product is or the impact the excipient is within the market space.	Published article, position or white paper	5-Mar-26
IPEC-Americas Guide on Setting Product Specifications	Excipient Qualification	N/A	Develop a guide for how to set specs for non-compendial excipients and for compendial excipients when additional customer requirements/specs are needed. Describe process/steps to create specs - how to ensure patient safety - existing, new excipients, mfgs vs. sales specs - apply process capabilities but excludes limits and tests, use sound statistical knowledge - capture key quality attributes and/or stability indicating parameters - define requirements for prod stewardship/regulatory - define needs for internal specs (proprietary) vs. external specs - intended to be regional (USP/NF)	IPEC-Americas Guide on Setting Specifications	5-Mar-26
NSF/IPEC/ANSI 363Excipient GMP 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-Mar-26
NSF/IPEC/ANSI 363Excipient GMP Subcommittee	Good Manufacturing Practices	N/A	Identify an IPEC-Americas sub team to review and provide ongoing support to the ANSI 363 Standard including: • Update to address differences identified by the GMP Comparison team • Add clause on data integrity • Revise to align with the updated ISO 9001 standard • Identify an ANSI Standards Writing Body to replace NSF, if possible	Continue to maintain and update NSF/IPEC/ANSI 363Excipient GMP Standard	5-Mar-26
CDER Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	Good Manufacturing Practices	N/A	Re-submit the ANSI 363 Sexcipient GMP Standard to FDA for consideration as an FDA Reference Standard for excipient GMPs. The previous request was uploaded into the designated FDA CDER portal in May 2024; however, to date no FDA response has been received. The committee discussed and agreed to re-send based on the current FDA organization	ANSI 363 Excipient GMP Standard recognized by FDA as a voluntary consensus standard	5-Mar-26
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-Mar-26
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-Mar-26

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-Mar-26
Key Revisions to IPEC Stability Guide, Version 3	Good Manufacturing Practices	Yes	This webinar will focus on key revisions made in the recently re-issued IPEC Stability Guide for Pharmaceutical Excipients, Version 3.	IPEC Webinar on Stability Guide Revisions	5-Mar-26
Accelerated Stability	Good Manufacturing Practices	N/A	Consider developing a white paper or journal article on the theory and scientific justification for accelerated stability - To include references for where theory came from	Publish white paper or Journal article	5-Mar-26
Excipient GMP Compliance Workshop	Good Manufacturing Practices	N/A	workshop to include Status of ANSI Standards Writing Body search for ANSI 363 Impact of draft update to ISO 9001 on GMP standards and guide Joint IPEC Excipient GMP auditing and EXCiPACT auditor training. Compliance with excipient GMP/GDP is important to everyone (not just auditors) inv	Excipient GMP Compliance Workshop - in person	5-Mar-26
Is IPEC-PQG GMP up to the task of being the foundational GMP for excipients worldwide?	Good Manufacturing Practices	N/A	The existing GMPs from WHO, Brazil and latterly China are different to IPEC-PQG GMP in that there is more demanding requirements, and these are more like API or event full drug product GMPs.	EW 26 Presentation	5-Mar-26
Revision to GMP Certification Scheme and Certification Body Qualification Guide	Good Manufacturing Practices	Yes	Review previous version which is now 5 years old and re-issue with updates	Publish revised Federation GMP Certification Scheme and Certification Body Qualification Guide	5-Mar-26
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-Mar-26
Annex/Guidance for Parenteral Applications	Good Manufacturing Practices	N/A	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-Mar-26
GDP Audit guide	Good Manufacturing Practices	Yes	Update the current guide for GDP	Revised GDP Audit Guide	5-Mar-26
Bulk chemical handling guide	Good Manufacturing Practices	Yes	Develop a new IPEC Guide for bulk chemical handling	New Bulk Chemical Handling guide	5-Mar-26
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	5-Mar-26
FDA Docket No. FDA-2026-N-0809 - Comments on Industry Scale-Up and Post approval Changes	Quality by Design	0	Identify IA sub team, review current documents, prepare IPEC-Americas comments to Docket No. FDA-2026-N-0809 request for Public Comments on Possible Revisions to Guidances for Industry Scale-Up and Post approval Changes.	IA comments to FDA Docket No. FDA–2026-N-0809	5-Mar-26
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-Mar-26
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-Mar-26

From Powder to Product: Excipient Impact on Advanced Manufacturing	Quality by Design	N/A	This workshop will explore how excipient selection and variability impact process design, control strategies, and product quality in both batch and continuous systems.	EW 26 Workshop	5-Mar-26
Excipient Impurities, Contaminants, & Adulterants.	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	5-Mar-26
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	5-Mar-26
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	5-Mar-26
Key Revisions to IPEC Composition Guide, V 3	Quality by Design	N/A	This webinar will focus on key revisions made in the revised IPEC Composition Guide for Pharmaceutical Excipients, Version 3.	IPEC-Americas Learning Lab webinar	5-Mar-26
New Guide on Excipient Interchangeability	Quality by Design	N/A	Based on EQ committee article on Supplier Qualification (https://www.tabletscapsules.com/3641-Technical-Articles/597455-Re-Sourcing-Qualifying-Excipient-Vendors-Can-Strengthen-Supply-Chain/?arev=true), develop a new IPEC-Americas Guide on Excipient Interchangeability	New IPEC-Americas Guide on Excipient Interchangeability	5-Mar-26
Excipients used in Continuous Manufacturing	Quality by Design	TBD	Develop position paper or white paper on how best to use excipients in continuous manufacturing.	Published Position Paper or White Paper	5-Mar-26
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-Mar-26
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-Mar-26
New Excipient Product Development Guide -Advancing Excipient Innovation Through Risk-Based Frameworks	Regulatory Affairs	No	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-Mar-26
EW 26 workshop entitled "Risk Based Framework for Development of New Excipient Products and USP’s Novel Excipient Emerging Standards Approach to Meet Stakeholder Needs:	Regulatory Affairs	0	workshop to include roundtable on new excipient product development (including risk assessment, feasibility, and regulatory pathways) and presentations focusing on novel excipients or new chemical entities. USP will outline key challenges in incorporating novel excipients into drug formulations, conducting safety assessments, and share insights into emerging standards and iterative strategies supporting novel excipients. Session will also explore pathways to overcome barriers to adopting novel excipients in innovative therapeutics and advanced formulations	EW 26 Workshop	24-Feb-26
Webinar on Best Practice Guide for New Excipient	Regulatory Affairs	No	Develop a webinar to review the IPEC-Americas Best Practice Guide for New Excipients	IA webinar on Best Practice Guide for New Excipients	24-Feb-26

Update/Revise the 2019 IPEC-Americas U.S. Drug Master File Guide for Pharmaceutical Excipients	Regulatory Affairs	0	Review the current guide and determine whether or not to expand the scope of the guide to best practices for providing confidential excipient information in the various regions	Updated IA DMF Guide	4-Mar-26
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	4-Mar-26
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 Atypical Actives position paper	4-Mar-26
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-Mar-26
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-Mar-26
Risk Based Framework for Development of New Excipient Products and USP's Novel Excipient Emerging Standards Approach to Meet Stakeholder Needs	Regulatory Affairs	N/A	Part 1 - new excipient product development – including risk assessment, feasibility, and regulatory pathways Part 2 - focus on novel excipients or new chemical entities	EW 26 Workshop	4-Mar-26
PFAS	Regulatory Affairs	TBD	Monitor and report back on emerging PFAS regulations/requirements	0	4-Mar-26
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-Mar-26
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-Mar-26
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	3-Mar-26
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-Mar-26
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-Mar-26
Talc Survey to support FDA Talc 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	3-Mar-26
Driving Innovation Through Regulatory Evolution: Global Perspectives on Novel Excipients and New Approach Methodologies (NAMs)	Scientific Affairs	N/A	Build on recent initiatives such as the FDA's new drug development programs, OECD's guideline updates, ICCVAM's framework for validation of NAMs, and ECHA's acceptance of NAM-based assessments to emphasize the value of these science-based approaches conferring greater human safety	IPEC-Americas NAMS Poster 1 for EW 2026	24-Feb-26
Scientific Challenges in Developing Novel Excipients: Leveraging NAMs, AI, and Machine Learning to Overcome Barriers	Scientific Affairs	N/A	With all the emerging activities occurring in the alternative methodologies and AI space, sub team to develop a poster entitled "Scientific Challenges in Developing Novel Excipients"	IPEC-Americas NAMS Poster 2 for EW 2026	3-Mar-26

Webinar on the Future use of NAMs in the Safety Evaluation of Novel Excipients	Scientific Affairs	N/A	building off of the two posters for EW 26, sub team members will present information on the future use of NAMS in the safety evaluation of novel excipients	IPEC-Americas Webinar on the Future use of NAMs in the Safety Evaluation of Novel Excipients	3-Mar-26
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	3-Mar-26
Biologics Summit: Bridging Excipient Standards with Raw and Starting Materials in Biologics	Executive Committee	N/A	highlight the growing intersection between excipient management and the raw and starting materials community within biologics and advanced therapies. The session will explore how IAs' organizational framework and resources can be extended to support this evolving space.	EW 26 Workshop	0-Jan-00