Activity	Committees	Federation Project ?	Project Description	Final deliverable (FD)	Date last updated
USP Digital Standards demo	Compendial Review/ Harmonization	N/A	USP 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	10-Jun-26
Appropriate use of monograph methods	Compendial Review/ Harmonization	N/A	Future correspondence to USP and possibly FDA on the appropriate use of monograph methods (e.g. NMR <761> and ICPMS <730>) and their claim that they are in general on-line chapters. Monographs that illustrate concerns include: dl-Lactide and Glycoside (85:15) Copolymer 23000 Hexanediyl Ester	Correspondence w USP and possibly FDA	10-Jun-26
Education for what it takes for industry to use a contract lab	Compendial Review/ Harmonization	N/A	Develop article to define all the steps and considerations necessary to select and qualify a contract lab.	article/position paper	10-Jun-26
IPEC-PDG Working group	Compendial Review/ Harmonization	N/A	IPEC - PDG meeting monograph harmonization	On-going monograph harmonization	10-Jun-26
JECFA/Food Related Issues related	Compendial Review/ Harmonization	N/A	Monitor Food Additives issues	On-going.	10-Jun-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	10-Jun-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.	10-Jun-26
Raise Awareness for TUPPs	Excipient Qualification	N/A	Based on recent concerns with users not understand TUPPs, IPEC needs to raise awareness of the TUPPS guide. Ideas include an IPEC-Americas webinar, joint webinar with CPHA, infographic, PQRI project (Chris M to follow-up).	Webinar (possibly joint with CPHA) Infographic PQRI workshop	11-Jun-26
Comparison of Pharmaceutical Excipients, Non-Dietary Ingredients in Dietary Supplements, Food Additives, and GRAS Substances	Excipient Qualification	N/A	Review position paper entitles "Comparison of Pharmaceutical Excipients, Non-Dietary Ingredients in Dietary Supplements, Food Additives, and GRAS Substances" and determine whether to complete minor updates, revise or retire	updated position paper or retire position paper	11-Jun-26
IPEC Americas and Europe Excipient Pedigree Position Paper	Excipient Qualification	Y	Federation working on a project to determine best method to communicate supply chain security and excipient pedigree. IPEC-Americas to support Federation project which will determine fate of the 2008 position paper.	TBD	11-Jun-26

2021 IA Position paper on Qualifying an Excipient Site	Excipient Qualification	N/A	Review current IPEC-Americas position paper and decide whether to update, revise or retire,	updated position paper or retire position paper	11-Jun-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	11-Jun-26
Application of USP GC <1115> Bioburden Control For Non Sterile Drug Substance to excipients	Compendial Review/ Harmonization	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 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	11-Jun-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	11-Jun-26
Update Federation Data Integrity position paper	Excipient Qualification	Yes	The Federation is looking for a sub team to review and update the 2020 Position Paper on Data Integrity. IA currently developing a policy for the use of Artificial Intelligence (AI). Intent is to include and cover AI in the updated revision of the position paper.	Revised Data Integrity Position Paper	11-Jun-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, stability samples, retain samples, customer complaints, quality agreements, supply agreements, 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 consider stimulus article for EW 2027 roundtable discussion	11-Jun-26
IPEC 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 Federation Guide on Setting Specifications	11-Jun-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	11-Jun-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	11-Jun-26
CDER Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	Good Manufacturing Practices	N/A	Re-submit the ANSI 363 Excipient 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	11-Jun-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	11-Jun-26
Excipient QMS design, CAPA, NCR, Deviations, and Batch Record Review	Good Manufacturing Practices	N/A	Per request from members, develop a webinar focused on excipient QMS design, CAPA, NCR, deviations and batch record review. Include documentation/GMP/data integrity requirements	IPEC-Americas LL Webinar	11-Jun-26
2015 IA Position Paper - Implementation-of-NSF Standard	Good Manufacturing Practices	N/A	Review position paper entitles "Implementation-of-NSF Standard" and determine whether to complete minor updates, revise or retire	updated position paper or retire position paper	11-Jun-26
2018 IA Position Paper - accreditation vs certification distinctions	Good Manufacturing Practices	N/A	Review position paper entitles "accreditation vs certification distinctions" and determine whether to complete minor updates, revise or retire	updated position paper or retire position paper	11-Jun-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	11-Jun-26
2015 IPEC-Americas position paper entitled "Conducting Accelerated Stability on Excipients"	Good Manufacturing Practices	N/A	Review position paper entitles "Conducting Accelerated Stability on Excipients" and determine whether to complete minor updates, revise or retire	updated position paper or retire position paper	11-Jun-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	25-Jun-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,	11-Jun-26
New GMP regulations and how they align (or not) with the principles of the IPEC-PQG GMP guide	Good Manufacturing Practices	0	The Federation has asked IPEC-Americas to support a Federation initiative to establish a standing group to review new GMP regulations and determine how they align (or not) with the principles of the IPEC PQG GMP guide	Standing Federation GMP Group formed	11-Jun-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	11-Jun-26
GDP Audit guide	Good Manufacturing Practices	Yes	Update the current guide for GDP	Revised GDP Audit Guide	11-Jun-26
Bulk chemical handling guide	Good Manufacturing Practices	Yes	Develop a new IPEC Guide or white paper for bulk chemical handling	New Bulk Chemical Handling white paper	11-Jun-26

Differences between Excipient and Food GMPs	Good Manufacturing Practices	N/A	position paper or white paper on the differences between Excipient and Food GMPs	Publish position paper or white paper	11-Jun-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	11-Jun-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	11-Jun-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	11-Jun-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 Guide on Excipient Interchangeability (alternative sourcing)	11-Jun-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	11-Jun-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	10-Jun-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	10-Jun-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	10-Jun-26
Update/Revise the 2019 IA U.S. Drug Master File Guide for Pharmaceutical Excipients	Regulatory Affairs	No	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 Master File Guide	10-Jun-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	10-Jun-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	10-Jun-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	10-Jun-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	10-Jun-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	IA LL Webinar on the Future use of NAMs in the Safety Evaluation of Novel Excipients	10-Jun-26

Publication on the Future use of NAMs in the Safety Evaluation of Novel Excipients	Scientific Affairs	0	Develop a publication based on the content for the two EW 26 NAMs Posters	Publication on the Future use of NAMs in the Safety Evaluation of Novel Excipients	10-Jun-26
2021 IPEC Safety Guide for Pharmaceutical Excipients	Scientific Affairs	0	Review current 2021 IPEC Safety Guide for Pharmaceutical Excipients and discuss the benefits of updating the guide and expanding information on the use of NAMS	Updated IPEC Safety Guide for Pharmaceutical Excipients	10-Jun-26
Alternative Methodologies deep 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	10-Jun-26