

Activity	Committees	Federation Project ?	Project Description	Final deliverable (FD)	Date last updated
USP Digital Standards demo	Compendial Review/ Harmonization	N/A	Janeen to reach out and invite Rich Panzer to present a demo on Digital standards during the June 2026 CRC committee meetings moved to Q4 committee meeting	Collaboration - USP	23-Sep-26
Pharmacopoeia – General Over & Current Hot Topics	Compendial Review/ Harmonization	N/A	Kathryn McCullough invited Stephen Corrigan to share his PDA presentation with CRC committee members moved to Q4 committee meeting	Presentation - IA	23-Sep-26
Appropriate use of monograph methods	Compendial Review/ Harmonization	N/A	Contract labs article drafted Q3, 2026. Correspondence intended to help USP understand that the methods used are appropriate QC lab environment. Education for what it takes for industry to use a contract lab. Wait until article/position paper published	Correspondence - USP	23-Sep-26
Education for what it takes for industry to use a contract lab	Compendial Review/ Harmonization	N/A	identified 2 articles 1) requirements for qualifying and utilizing a contract lab - Outline drafted and under review. 2) requirements to allow the use CoA data in a reduced testing program	Publication - ???	18-Sep-26
Macrogol Pharmeduropa 38.3 follow-up	Compendial Review/ Harmonization	0	Doug Muse has identified a list of items to follow-up on, including reaching out to members asking them to send supporting batch data directly to EDQM. Consider reaching out to USP to determine if they could blind and send excipient information directly to EDQM.	Correspondence - Pharmeduropa	18-Sep-26
Macrogol Pharmeduropa 38.3 follow-up	Compendial Review/ Harmonization	0	Develop and send sample request to IA and IE members	Correspondence - IPEC members	1-Oct-26
IA - Ph. Eur. Email chaing	Compendial Review/ Harmonization	0	email trail correspondence between IA and Ph. Eur.	Correspondence - Pharmeduropa	1-Oct-26
Webinar on the Need for Excipient Manufacturers to Interact with and Send Supporting Data to Pharmacopoeias	Compendial Review/ Harmonization	0	it was also suggested that this might be a good topic for a presentation or even a panel discussion at EW27. In addition, we should consider an infographic. Volunteers included J. Skutnik Wilkinson and P. Zawislak	Webinar - IPEC LL	23-Sep-26
Advancing Excipient Innovation through risk-based frameworks	Compendial Review/ Harmonization	0	Meera to represent IPEC-Americas with a novel excipient presentaton and panel discussion	Workshop - AAPS	23-Sep-26
IPEC-PDG Working group	Compendial Review/ Harmonization	N/A	IPEC-PDG meeing being planned for December 2026.	ongoing quarterly update	23-Sep-26
JECFA/Food Related Issues related	Compendial Review/ Harmonization	N/A	no comments Q3'2026 Last JECFA meeting scheduled for March 2025.	ongoing quarterly update	23-Sep-26
Compendial Postings Monitoring	Compendial Review/ Harmonization	N/A	Reviewed/discussed new postings for o excipient related monographs listed in PF 52(5) o excipient related monographs listed in Pharmeduropa Issue 38.4 Next meeting scheduled for October 11, 2026 from 1:00-2:30	ongoing quarterly update	23-Sep-26
Mutual Recognition of Pharmacopoeias	Compendial Review/ Harmonization	y	to be reviewed in Q1 '2027 with decision on disposition at that time.	White Paper Concept Paper	23-Sep-26
Application of USP GC <1115> Bioburden Control For Non Sterile Drug Substance to excipients	Excipient Qualification	N/A	Rick Jakober, Perritt Laboratories, Inc. to present at EW26 on "Microbes in Pharmaceutical Excipients - What is Objectable?". IA members working on a joint article with Rick. Target getting published in Q1 27 followed by an EW27 presentation	Presentation - IA	24-Aug-26
Acceptable Tailgate Practices including Samples	Excipient Qualification	0	IPEC to send a formal note to Janeen to ask the RIDG team if they would want to collaborate on a tailgate sample paper - that talks about why tailgate samples might be used and controls.	IPEC Position Paper	24-Aug-26
Handling of FDA Inspections	Excipient Qualification	0	Consider developing an article, position or white paper on interpretations of regulations and techniques to help Over the Counter (OTC) manufacturers as they prepare to conduct audits of their suppliers volunteers include I. Silverstein and T. Sullivan	IPEC LL Webinar IPEC Infographic EW27 Webinar or Presentation	24-Aug-26

CHPA webinar to provide overview of IPEC resources	Excipient Qualification	0	The TUPPs team to discuss this opportunity with Fred Meadows from CHPA during our next TUPPs call volunteers include: TBD	Webinar - CHPA	24-Aug-26
Raise Awareness for TUPPs	Excipient Qualification	N/A	Fred Meadows, Senior Dir, Qual Tech/Reg Affairs from CHPA joined team. Developing joint webinars for CHPA and general industry (IA LL). Plans to develop a journal article and possibly infographic volunteers include: M Santelli, D Carter, C Moreton, C Reynolds, K Ulman, D Schoneker	IPEC LL Webinar IPEC Infographic PQRI workshop	24-Aug-26
Comparison of Pharmaceutical Excipients, Non-Dietary Ingredients in Dietary Supplements, Food Additives, and GRAS Substances	Excipient Qualification	N/A	Volunteer: Meera Raghuram, Chris DeMerlis, Priscilla Zawislak, Dave Schoneker PP finalized, posted for member comments in EQ discussion board and routed for XC approval. Approved 2026 09 18. Submitted an EW27 abstract for a presentation	IPEC Position Paper	18-Sep-26
IPEC Americas and Europe Excipient Pedigree Position Paper	Excipient Qualification	Y	volunteers from IPEC-Americas include C Mclvaine, J Skutnik Wilkinson, L Sergile, K Ulman Janeen drafted a new Federation position paper which is currently routing for comment. Posted on EQ discussion board	IPEC Position Paper	24-Sep-26
2021 IA Position paper on Qualifying an Excipient Site	Excipient Qualification	N/A	volunteer to include C Mclvaine, I Silverstein, J Cansler, K Ulman PP revised/updated and sent to EQ to post in EQ discussion board 2026 09 21 for member comment by 2026 10 05.	IPEC Americas Position Paper	21-Sep-26
Using a 3rd party Distributor audits to demonstrate they meet appropriate GMPs	Excipient Qualification	N/A	volunteers: I Silverstein, D Carter, C. Mclvaine - team to develop outline by Q4' 2026 EQ meeting. Team met 2026 08 13 to discuss outline and share resources. C. Mclvaine agreed to draft something to share with the EQ members during Q3 committee meeting	Position Paper or White Paper	13-Aug-26
Revise IPEC EIP Guide	Excipient Qualification	Yes	2026 09 15 IF reviewed member comments due 9/30 (posted for IA member 8/20 in EQ Disc Board) and verified that edits were not significant. Final revised guide to Publish soon.	IPEC Guide - Revision	14-Sep-26
Update PDA-IPEC TR 54-6 Risk Assessment for Excipient report	Excipient Qualification	Yes	IPEC/PDA team recently reconvened to review the TR and the Revision of ICH Q9 R1. Team meeting every other week to go through the entire document and update, where necessary. Team chaired by Janeen and Chris M.	IPEC Guide - Revision	24-Sep-26
Update Federation Data Integrity position paper	Excipient Qualification	Yes	D Carter, I Silverstein and L Sergile, K. Ulman finalized 2026 PP edits. PP currently routing for comment by IF members (posted for IA member 9/14 in EQ disc board). Comments due to IF 10/31/2026.	IPEC Position Paper	14-Sep-26
Issues driving excipient makers to leave the market and how to discontinue products/exit market	Excipient Qualification	N/A	No activity Q3 2026 Volunteers: D. Carter, I Silverstein, C Moreton. Develop a one-page proposal and present at next meeting	Publication -	24-Sep-26
IPEC Guide on Setting Product Specifications	Excipient Qualification	N/A	Volunteers: C. Reynolds to lead, B Febbo, G Collins, T Warren, W Awad, D Carter, J Putnam, D Muse, K Ulman, P Zawislak, P Smutz IF approved as a Federation guide and sent a "New project" template to team. 2026 09 15 - Charter drafted /routed to team for review and comment.	IPEC Guide - New	15-Sep-26
NSF/IPEC/ANSI 363Excipient GMP Standard	Good Manufacturing Practices	N/A	No update Q3, 2026 For time being, NSF will continue to support the ANSI 363 Standard.	ongoing quarterly update	24-Sep-26
NSF/IPEC/ANSI 363Excipient GMP Subcommittee	Good Manufacturing Practices	N/A	- Identify project chair - Identify members Irwin provided a detailed overview of proposed changes/updates to the 2026 NSF/IPEC/ANSI 363 Excipient GMP Standard	IPEC-Americas ANSI 363 team	24-Sep-26

CDER Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	Good Manufacturing Practices	N/A	Janeen has tried to contact FDA for access to the portal, but is still waiting for their response. Janeen to re-send through the current CDER's NextGen Collaboration Portal (https://cdernextgenportal.fda.gov/s/login/?ec=302&startURL=%2Fs%2F)	Correspondence - FDA	24-Sep-26
EXCiPACT Standard	Good Manufacturing Practices	Yes	Currently concerned with some of the EXCiPACT messaging (some negative of IPEC Standard and GMPs), changes and decisions (some more aligned with API than excipient) IPEC-Americas plans to follow-up with EXCiPACT per our concerns and possibly propose a face-to-face meeting to ensure we are all aligned on GMP related activities.	ongoing quarterly update	24-Sep-26
Excipient QMS design, CAPA, NCR, Deviations, and Batch Record Review	Good Manufacturing Practices	N/A	no update Q3, 2026 'volunteers include Irwin Silverstein, Dale Carter and Mike Cassell	Webinar - IPEC LL	24-Sep-26
Revise IPEC Validation Guide	Good Manufacturing Practices	Yes	Paul Smutz, Beth Febbo and Michael Hicks reviewed for content and Irwin Silverstein reviewed content of new references to ensure they still aligned with content. No significant edits; therefore, IF currently preparing revised guide for re-issue.	IPEC Guide - Revision	14-Sep-26
2026 Position Paper on Artificial Intelligence in GMP Environments	Good Manufacturing Practices	Yes	Janeen drafted the position paper, sent to IPEC members on August 10, 2026 for review and comment September 30, 2026. Copy also sent to the IPEC Federation for comments.	IPEC Position Paper - New	10-Aug-26
Communicating the position paper on Artificial Intelligence in GMP Environments	Good Manufacturing Practices	0	Volunteers include J. Skutnick-Wilkinson, Dave Schoneker and Michael Hicks	LL Webinar EW27 Workshop IPEC Guide	24-Sep-26
Establishing Effective Stability Programs for Pharmaceutical Excipients	Good Manufacturing Practices	N/A	Priscilla worked with D. Schoneker and kim.huynhba@pharmalytik.com to prepare marketing sheet and host the webinar	IPEC-Americas - webinar for AAPS	7-Jul-26
Accelerated Stability	Good Manufacturing Practices	N/A	No activity Q3 2026. Waiting for ICH Q1 Guidance to publish. 'Need to review revisions to ICH Q1 to determine whether it already contains sufficient information. Agreed to hold until final ICH Q1 document is published in Q4' 2026	IPEC-Americas - white paper or journal article	24-Sep-26
2015 IPEC-Americas position paper entitled "Conducting Accelerated Stability on Excipients"	Good Manufacturing Practices	N/A	No activity Q3 2026. Waiting for ICH Q1 Guidance to publish, then merge with above activity. 'to be posted in GMP committee folder for review and comment	IPEC-Americas - position paper	24-Sep-26
Customer GMP Workshop - On-site	Good Manufacturing Practices	N/A	finalizing training content and slide decks	Workshop - IPEC-Americas LL	1-Sep-26
Customer GMP Workshop - On-site	Good Manufacturing Practices	N/A	finalizing training content and slide decks	Workshop - IPEC-Americas LL	1-Sep-26
Customer GMP Workshop - On-site	Good Manufacturing Practices	N/A	finalizing training content and slide decks	Workshop - IPEC-Americas LL	1-Sep-26
IPEC-Americas GMP Compliance Workshop 2027	Good Manufacturing Practices	0	General IA GMP compliance workshop	Workshop - IPEC-Americas LL	24-Sep-26
Comparing excipient GMPs (USP vs IPEC vs ANSI vs WHO vs EXCiPACT)	Good Manufacturing Practices	N/A	Reviewed and discussed several potential discrepancies between the various Excipient GMP resources Committee completed review of EXCiPACT and will be deciding whether or not to review other GMP sources. IPEC Europe has requested to be involved with this project/comparison. Suggested to include high level comparison of China Excipient GMPs.	Publication - Journal of Pharmaceutical Excipients	24-Sep-26
New GMP regulations and how they align (or not) with the principles of the IPEC-PQG GMP guide	Good Manufacturing Practices	0	Mike Polito has agreed to work with above sub-committee and Bev Stout and Roberto Mastrantonio from IPEC Europe to draft a Federation Charter for the project. Suggested to include Iain Moore from EXCiPACT	Federation Initiative	24-Sep-26

Annex/Guidance for Parenteral Applications	Good Manufacturing Practices	N/A	Need to develop a charter and to identify/prioritize Annexes that might be applicable to add to the GMP guide volunteers. K. Allen, P Zawislak, K. McCullough, J Skutnik, E Ray, L Bisharat (Chris M./Jim M.) Discussion around what annex we might want to include in Excipient GMP guide/Risk assessment Guide: Need charter and volunteer to lead. Review proposed document drafted by Chris Moreton	IPEC Guide - Revision	24-Sep-26
GDP Audit guide	Good Manufacturing Practices	Yes	IE review/update sect 7-13 and sent to IA; IA review/comments to IE; IE rev/resolve comments sent back to IA; IA responded back to IE IA review/update sect 1-6; IA sent to IE; IA waiting for IE comments	IPEC Guide - Revision	18-Sep-26
Bulk chemical handling guide	Good Manufacturing Practices	Yes	No update Q3, 2024 updated project from developing an IPEC-Americas guide to initially developing a white paper on Bulk Chemical Handling. Volunteers include: C. McIlvain and P. Andrews	IPEC-Americas white paper	24-Sep-26
FDA meeting on additives and processing aids in pharmaceutical excipients	Quality by Design	N/A	Agreed to work through USP to set-up a meeting with FDA (i.e. Pongpeerapat) to discuss excipient composition information including how best to handle additives and processing aids.	FDA meeting	24-Sep-26
PQRI workshop: Co-processed Excipients to Enhance Continuous Manufacturing	Quality by Design	N/A	Next Planning Committee Meeting scheduled for September 29, 2026. Reviewed draft plans/topics during Q3 2026 committee meeting Meeting will be both in-person and hybrid and will be held a USP headquarters	Workshop - PQRI	24-Sep-26
Excipient Composition Profile	Quality by Design	N/A	Jessica to pull team together to develop charter for the final infographic (currently working to define meeting dates). Develop outline of a flow diagram for creating and excipient composition profile	Infographic or video	24-Sep-26
New Guide on Excipient Interchangeability	Quality by Design	N/A	Jackie Welo to lead the project. Planning to start proj in October 2026. Volunteers: B Carlin, C Moreton, J Zeleznik, J Putnam, J Skutnik, D Carter, K. Beals, K. Ulman, K. Allen, A Rajabi-Siahboomi The Federation support drafting the guide but questioned whether it should be an Annex to the IPEC QoE Guide instead of a separate guide	IPEC Guide - New	24-Sep-26
Excipients used in Continuous Manufacturing	Quality by Design	TBD	no update provided in Q3 Joe Zeleznik agreed to help with project. Need to develop and get XC approval for Project Charter Currently in-process of developing an outline based on historical work	Position Paper or White Paper	24-Sep-26
FDA IID update	Regulatory Affairs	N/A	The last IID update was posted on July 23, 2026. Discussed the value of the spreadsheet to members and decided to continue to use the spreadsheet tabs to capture/monitor high level information, but discontinue creating separate tabs for individual excipients	ongoing quarterly update	23-Sep-26
US Laws, Regulations and Industry Best Practices for Excipients	Regulatory Affairs	0	presenter - Priscilla Zawislak	Webinar - IPEC LL	30-Sep-26
FDA request for comments to new proposal for Substances Generally Recognized as Safe	Regulatory Affairs	N/A	Kick off meeting held August 31 Volunteers include: T. Barrix (chair), C. Reynolds, D. Schoneker, M. Raghuram, Patel, P. Zawislak, A. Gulau, B. Sulouff, T. Wegesser, K. Ulman. Subteam currently determining the impact on pharmaceutical excipients impact on FEMA GRAS and providee feedback to FDA's specific questions. Consider reaching out to FEMA and other related org.	Correspondence - FDA	31-Aug-26

New Excipient Product Development Guide -Advancing Excipient Innovation Through Risk-Based Frameworks	Regulatory Affairs	No	sub team formed, developed various decision trees and shared with attendees at a May 4 EW26 workshop. Committee making progress on developing a framework intended to facilitate decision-making regarding feasibility, development strategy, data generation, and regulatory considerations while supporting innovation in medicinal products. Targeting completion of guide in Q4' 2026 and looking into acquiring feedback from FDA.	IPEC Guide - New	23-Sep-26
Webinar on Best Practice Guide for New Excipient	Regulatory Affairs	No	nothing new Q3, 2026 Upon completion of the guide (see above), a webinar will be developed and offered.	Webinar - IPEC LL	23-Sep-26
Update/Revise the 2019 IA U.S. Drug Master File Guide for Pharmaceutical Excipients	Regulatory Affairs	No	Project initiated to update guide to include Canadian DMF guidance and updates/requirement implemented by FDA since 2019. Team considering significant revisions and is targeting Q1 2027 for completion..Meeting held 8/7 and 8/25. Currently scheduled every 3 weeks. Continue to consider as a second step to develop a "how to" best practice guide for providing intellectual property excipient information in the various regions. Volunteers include P Zawislak, K Ulman, D Schoneker, M Raghuram, P Smutz, T White, K McCullough and J Dungan	IPEC Guide - Revision	23-Sep-26
Atypical Actives Advocacy	Regulatory Affairs	TBD	Team met 8/25/26. Team meetings currently schedule for every 3 weeks. Next meeting scheduled for October 8, 2026. Decision to first update the position paper followed by developing a new guide.	IPEC Guide - New	23-Sep-26
State Regulatory Tracking document	Regulatory Affairs	TBD	no update Q3' 2026 Maintain a spreadsheet for listing substances that states are proposing to ban. Spreadsheet to identify states, ingredients, and status of any proposal (e.g. PFAS, TiO2). BHA to be added to tracking sheet to be monitored.	ongoing quarterly update	23-Sep-26
Misinformation on safety of excipient use in drug products	Scientific Affairs	N/A	Q3' 2026, no update	Publication -	23-Sep-26
SME Engagement/Knowledge Sharing with SAC Members	Scientific Affairs	N/A	Q3, 2026 - no invited speaker but looking into inviting a speaker to the Q1 2027 meeting Survey to identify key knowledge gaps to focus SME search and line up speakers for upcoming SAC meetings in 2026	Presentation - SAC	23-Sep-26
Webinar on the Future use of NAMs in the Safety Evaluation of Novel Excipients	Scientific Affairs	N/A	Webinar volunteers include: T. Wegesser, K. Ulman, R Filler, D Schoneker, T Gorski, J Pitt Webinar: Global Perspectives on Novel Excipient Safety Evaluation and Use of NAMs - scheduled November 4 from 10-12	Webinar - IPEC LL	23-Sep-26
Publication on the Future use of NAMs in the Safety Evaluation of Novel Excipients	Scientific Affairs	N/A	volunteers: Y Li, J Pitt, K Ulman, ST Kim, T Wegesser, Y Yu Rice, C DeMerlis o Manuscript outline is under development o Kick-off meeting will be scheduled between Oct 12 and Oct 22. o Outline to be shared before the kick-off meeting o Kick-off meeting to cover scope/limitation, outline refinement, timeline, journal options, meeting frequency, and next steps for manuscript development	Publication - ???	23-Sep-26
2021 IPEC Safety Guide for Pharmaceutical Excipients	Scientific Affairs	N/A	Volunteers include: C. DeMerlis, D. Schoneker, T. Wegesser, R. Filler, K. Ulman, J. Pitt, ST Kim, Y Yu Rice Safety Guide to be updated as practical/usable resource. NAMs info added as an addendum 2021 Guide posted for comment on SAC dashboard 8/11/2026 – comments to be reviewed 2026 09 28 from 3-5 p.m.	IPEC Guide - Revision	23-Sep-26