Project name	Committees	Possible Federation Activity	Description	Final deliverable	DATE COMPLETED
USP GC Prospectus <1068> Excipient Composition and Organic Impurities	Executive Committee	N/A	IPEC-Americas Comments to General Chapter Prospectus <1068> Excipient Composition, GN 5.20.10 Added Substances in Official Substances and request for Advisory Panel for Additives and Process Aids	Comments from IA to USP	23-Mar-26
FDA Docket No. FDA–2025-D-2275 - Comment on Draft ICH M4Q (R2)	Good Manufacturing Practices	N/A	prepare IPEC-Americas comments to Docket No. FDA–2025-D-2275: M4Q(R2) The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality; International Council for Harmonisation; Draft Guidance for Industry. Comments not	IA comments to FDA Docket No. FDA–2025-D-2275	23-Mar-26
IPEC-Americas 2025 Annual Report	Compendial Review/ Harmonization	N/A	Detailed information about IPEC-Americas accomplishments in 2025	2025 Annual Report	20-Mar-26
IPEC-Americas 2025 Year in Review	Good Manufacturing Practices	Yes	This infographic gives a high-level snapshot of our accomplishments in 2025.	Infographic on IA 2025 accomplishment	4-Mar-26
Meet and greet with new USP management/staff	Compendial Review/ Harmonization	Yes	After the Dec 9 & 11 USP stakeholder's forum, a small team of IPEC-Americas attendees met to debrief and discuss possible next steps. The group is interested in setting up a meet and greet with Faoud, and possibly others at USP, i.e., Catherine Sheehan	Meeting between IPEC-Americas and USP staff	2-Mar-26
Advisory Panel with USP on additives and processs aids	Compendial Review/ Harmonization	N/A	Develop a formal comment letter requesting an Expert Advisory Panel be fomed to address the gaps and GN ommision of additives and process aids	Formation of USP Panel	4-Mar-26
Clarification of Definitions and Non-Applicability Regarding the Regulations of Active Ingredients Classified as Atypical Actives	Regulatory Affairs	N/A	This position paper aims to clarify the definitions and non-applicability of CADIFA (Letter of Adequacy of the Active Pharmaceutical Ingredient Dossier defined by ANVISA) and CBPF (Good Manufacturing Practices (GMP) certification issued by ANVISA) regarding	LATAM Position Paper on Atypical Actives	4-Mar-26
Webinar on new How-To guide entitled Best Practices for European Microparticles Restrictions.	LATAM	N/A	the IPEC Microparticles Task Force develop a How-To guide entitled Best Practices for European Microparticles Restrictions.	Federation webinar to introduce to guide	4-Mar-26

Invitation to Trade Associations to collaborate on talc response	Excipient Qualification	N/A	Letter to trade association inviting them to collaborate with other trade parties to discuss how we might address various issues related to the use of talc in drug products	Letter to trade association for talc collaboration	27-Jan-26
USP GC Prospectus <1068> Excipient Composition and Organic Impurities	Regulatory Affairs	YES	IPEC-Americas comments to USP regarding excipient composition and orgainic impurities prospectus	Comments from IA to USP	25-Nov-25
Annex 1, Pharmaceutical Excipients	Regulatory Affairs	N/A	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.	For Members Only - China Excipient GMP and the IPEC-PQG GMP Guide: Q&A	19-Dec-25
IPEC Best Practices for European REACH Restriction on Synthetic Polymer Microparticles	Regulatory Affairs	N/A	the IPEC Microparticles Task Force develop a How-To guide entitled Best Practices for European Microparticles Restrictions.	Published IPEC guide	30-Dec-25
IPEC Best Practices for European REACH Restriction on Synthetic Polymer Microparticles	Compendial Review/ Harmonization	Yes	the IPEC Microparticles Task Force develop a How-To guide entitled Best Practices for European Microparticles Restrictions.	Published IPEC guide	19-Dec-25
Excipient Composition	Compendial Review/ Harmonization	N/A	Presented on Excipient Composition by Priscilla Zawizlak at the USP Excipient Stakeholders Forum in December	presntation at USP Excipient Stakeholders Forum	9-Dec-25
The Future of Excipients is in Your Hands	Compendial Review/ Harmonization	N/A	This infographic provides an overview of the hot topics IPEC-Americas is tracking.	Infographic on IA Hot topics The future of excipients is in your hands!	21-Nov-25
Excipient GMP Differences, Risk Assessment, and Audit Findings	Regulatory Affairs	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	11-Nov-25
USP GC Prospectus <1068> Excipient Composition and Organic Impurities	Executive Committee	N/A	IPEC-Americas comments to USP regarding excipient composition and orgainic impurities prospectus	Comments from IA to USP	7-Nov-25

Annex 1, Pharmaceutical Excipients	Regulatory Affairs	N/A	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.	Federation comments sent to IPEC China for MAJOR issue(s)	7-Nov-25
Excipient Composition	Executive Committee	N/A	Presented on Excipient Composition by Priscilla Zawizlak at the Joint Industry Group Meeting November 2025	Presentation at 2025 Joint Industry Group meeting	5-Nov-25
USP Advanced Analytical Technologies for Excipients	Executive Committee	N/A	presentation on USP Advanced Analytical Technologies for Excipients by Priscilla Zawizlak at the Joint Industry Group Meeting November 2025	Presentation at 2025 Joint Industry Group meeting	5-Nov-25
Evolving TiO2 and Synthetic Color Legislation — Current Status and Potential Impact on Pharmaceuticals	Executive Committee	N/A	Several global regulatory authorities reviewed the 2021 EFSA opinion and available science relevant to food uses of TiO2, including data generated after the EFSA opinion and concluded that TiO2 was safe as a food additive and should not be banned for such use.	ELL webinar on TiO2 and Color additives	5-Nov-25
Clarification of Definitions and Non-Applicability Regarding the Regulations of Active Ingredients Classified as Atypical Actives	Good Manufacturing Practices	Yes	Atypical actives is an important topic in LATAM especially in Brazil. Brazil has some specific regulations for APIs where it's important to distinguish atypical actives from these. Questions have come up as to whether these regulations would apply to excipients	LATAM position paper for atypical actives	5-Nov-25
Risk Assessment How To - Practical Application of Guides and Tools	Quality by Design	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	23-Oct-25
IPEC Questionnaire for Excipient Nitrosamines Risk Evaluation	Regulatory Affairs	N/A	This tool assists excipient manufacturers in collecting data in a standardised format to support drug product manufacturers in assessing the risk of nitrosamine impurities. First issued in 2023, the IPEC Questionnaire has been updated to	Publish new IPEC Questionnaire for Excipient Nitrosamines Risk Evaluation	22-Oct-25
TiO2 and Synthetic Color Status - Potential Impact on Pharmaceuticals	Regulatory Affairs	N/A	Invited panelist to speak on emerging threats at the AAM GRx+Biosims Conference in Rockville	Presentation at AAM GRx+Biosims Conference in Rockville	15-Oct-25
Excipient-Related Challenges of N-Nitrosamine Impurities	Quality by Design	Yes	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	2-Oct-25

Excipient Composition	Executive Committee	N/A	Meeting held in Tokyo Oct 1, 2025. Federation presented on Excipient Composition	presntation at PDG meeting in Tokyo	1-Oct-25
USP-NF General Chapter <1029> Good Documentation Practices and Data Integrity	User Network	N/A	Review the proposed General Chapter <1029> Good Documentation Practices and Data Integrity and provide comments to USP.	Comments to USP	29-Sep-25
Congratulate Fouad Atouf, newly appointed Chief Science Officer of USP	Good Manufacturing Practices	TBD	IPEC-Americas to develop a congratulatory letter to Fouad Atouf who was recently appointed Chief Science Officer of USP	Letter to Fouad	22-Sep-25
Docket No. DOJ-OLP-2025-0169 Request for Info on State Laws Having Signif Adv Effects on National Economy or Interstate Commerce	Scientific Affairs	N/A	DOJ Request for Info on State Laws Having Significant Adverse Effects on National Economy or Significant Adverse Effects on Interstate Commerce	DOJ comments to Docket No. DOJ-OLP-2025-0169	15-Sep-25
Supplier Communication: Interaction of User and Manufacturer	Executive Committee	N/A	Day 3: All About Supplier Communication: Interaction of User and Manufacturer •Supplier Qualification Slides •Quality Agreement Slides •EIP Slides	LATAM ELL webinar on Supplier communications	11-Sep-25
Navigating Regulatory Filings: Where, When, How	Quality by Design	N/A	Overview of known regional requirements for excipients * Regulatory – excipient regulations * Pharmacopoeial * Registration/license requirements * Special labeling/shelf-life	ELL webinar on regional excipient regulations	10-Sep-25
Measurement and Maintenance of Excipient Standards	Regulatory Affairs	N/A	Day 2: Measurement and Maintenance of Excipient Standards •Audit Slides •Certificate of Analysis Slides •Significant Change Slides	LATAM ELL webinar on Excipient Standards	10-Sep-25
Setting Excipients Standards	Regulatory Affairs	N/A	Day 1: Setting Excipients Standards •GMP Slides •GDP Slides	LATAM ELL webinar on Setting Excipient Standards	9-Sep-25
LATAM WG Excipient 101 Webinar	Compendial Review/ Harmonization	N/A	Excipient 101 training, introduction to excipients. Webinar provided foundational info on excipients with a focus on: > Definitions > Regulatory Considerations	LATAM ELL webinar on Excipient 101	7-Aug-25

ICH Q1 guideline on stability testing	Compendial Review/ Harmonization	N/A	Draft comments to ICH Q1 guideline on stability testing of drug substances and drug products - Step 2b IPEC Federation Comments from IPEC-Americas and consolidate with Federation comments before submitting to EMA	Submit ICH Q1, Step 2 comments to EMA	30-Jul-25
USP ⟨1037⟩ Process Analytical Technology—Theory	Compendial Review/ Harmonization	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	30-Jul-25
Docket No. FDA-2025-D-0507, Replacing Color Additives in Approved or Marketed Drug Products	Executive Committee	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	22-Jul-25
PRIME FDA letter	Strategic Team 3	N/A	FDA Commissioner's National Priority Voucher Program (CNPVP) is as an opportunity to bring up innovative excipients into the current regulatory priorities. Prepare and send an introductory letter to FDA from IPEC highlighting that incorporation of	Comments sent to FDA Commissioner Markay	16-Jul-25
EMA Q&A on co-processed excipients used in solid oral dosage forms	Good Manufacturing Practices	N/A	IPEC Federation Position 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 Position Paper on CoP	25-Jun-25
IPEC-Americas International Journal of Pharmaceutical Excipients	Regulatory Affairs	N/A	IPEC-Americas International Journal of Pharmaceutical Excipients; Q2 2025 Edition Published	Journal publication	25-Jun-25
Guide Road map for Users	Excipient Qualification	Yes	Infographic to show "road map" for users (and maybe makers, too) for applying IPEC guides and position papers	Guide Infographic for Users	25-Jun-25
IPEC-Americas Excipient GMP Audit Checklist to revised IPEC GMP Guide	Regulatory Affairs	N/A	Develop two audit checklists for the IPEC-PQG Excipient GMP guide, one comprised of questions and the other reminder phrases.	Checklist for Federation to use in development of a revised IPEC GMP Audit guide	5-Jun-25
SME Engagement/Knowledge Sharing with SAC Members	Quality by Design	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.	Presentations at Q2 SAC 2025 meetings	3-Jun-25

EW25 Experts Panel: Addressing Misinformation Insights and Strategies	Executive Committee	N/A	panel of experts to discuss the impact of misinformation on public health	EW 2025 Panel discussion	14-May-25
Excipients in Quality Risk Management of Pharmaceutical Products	Quality by Design	N/A	Complex systems are characterized by unpredictable emergent behaviours which can confound risk analyses and control strategies, leading to sudden product failures. Quality Risk Management per ICH Q9(R1) is a necessary but insufficient requirement	EW 2025 Presentation	14-May-25
Excipient Innovation Roundtable: Strategies in Development of New Excipient Products	Executive Committee	N/A	Featured key stakeholders to provide their insight on strategies for introduction of new excipient products.	EW 2025 Round Table	13-May-25
European Decisions Impacting Excipients	Good Manufacturing Practices	Yes	roundtable session to discuss the regulatory environment in Europe and its implications for excipient manufacturers and users. Indludes current issues and regulatory challenges with the implementation of new regulations for:	EW 2025 Round Table	13-May-25
QC lab capability survey	Compendial Review/ Harmonization	N/A	Share results from QC Lab Capability Survey	EW 25 Poster	13-May-25
State of the Industry – QC Laboratories Instrument Survey	Scientific Affairs	N/A	The purpose was to determine the current "State of the Industry" for QC laboratory Instrumentation and Equipment, specifically barriers that may be encountered preventing stakeholders from evaluating new or revised procedures published in the	EW 2025 Poster	13-May-25
QC lab capability survey	Quality by Design	Yes	Survey to collect data from global PEC members regarding testing capabilities of excipient QC release labs, including instrumentation available and analyst expertise	share analytical capability with USP, ideally during a stakeholder forum	13-May-25
Biologics Summit: Advances in Cell and Gene Therapy	Executive Committee	N/A	workshop focusing on the latest advancements in cell and gene therapy. Feature insightful presentations and a dynamic panel discussion, providing a comprehensive overview of current trends, challenges, and future directions in the field	EW 2025 Conference Workshop	12-May-25
Excipients 101 Workshop	Executive Committee	N/A	Covered the essential regulatory, quality and formulation aspects of common excipients used in orgal solid dosage forms.	EW 2025 Conference Workshop	12-May-25

IPEC Good Distribution Practices Guide for Pharmaceutical Excipients Update	Executive Committee	N/A	overview of the significant updates and overview and enhancements made to the recently published IPEC GDP How-To guide.	EW 2025 Conference Workshop	12-May-25
The Increased Relevance of Excipients in the Pharmaceutical Industry	Good Manufacturing Practice	N/A	Presentaton for CPhI NA - scheduled for delivery on May 21, 2025	CPhI presentaton during NA Conference	7-May-25
Update of Risk Assessment Guide	Regulatory Affairs	N/A	Review the 2017 Risk Assessment Guide for possible update	Published revised Federation Risk Assessment guide	6-May-25
Department of Commerce Docket No. 25041-0065 RE Pharmaceutical & Pharmaceutical Ingredients	Regulatory Affairs	N/A	IPEC-Americas comments to Bureau of Industry and Security, U.S. Department of Commerce Docket No. 25041-0065 (XRIN 0694-XC120): Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and	Submitted docket comments	6-May-25
Excipients in QbD - Basic Concepts and Guide Revisions	Scientific Affairs	N/A	This webinar reviewed the impact of the IPEC QbD guide on product development and life-cycle management. Included: > The impact of excipient variability on product performance > critical material attributes	IPEC-Americas LL webinar on QbD	25-Mar-25
2025 Excipient World Event Overview	Compendial Review/ Harmonization	N/A	Late Breaking News: 2025 Excipient World Conference & Expo announcements!	EW webinar to promote conference and expo	19-Mar-25
Presentation at IFPAC	Quality by Design	Yes	IPEC-Americas presentation on excipients used for continuous manufacturing for 2025 IFPAC Conference	Presentation at IFPAC	5-Mar-25
Medicine Maker video/article on FDA Novel Excipient Review Pilot Program	Compendial Review/ Harmonization	N/A	IPEC and IQ WG / Novel excipients (Roundtable w Steph Sutton asking quests of WG members) Discussion points: • The importance of novel excipients and the pharma industry's needs in this area	Medicine Maker article on FDA Novel Excipient Review Pilot Program	1-Mar-22
Third Party Audit and Certification Programmed	Regulatory Affairs	N/A	Update the 2015 IPEC Federation position paper on Third Party Audit and Certification Programmes	Publish updated Position paper on Third Party Audit and Certification Programmes	27-Feb-25

USP innovation and customer centric solutions	Excipient Qualification	N/A	Richard Panzer, Senior Digital Product Manager and Marilyn Espinal, Senior Marketing Leader, Product & Growth Strategy spoke on ensuring innovation and customer centric solutions for USP	USP Presentation to CRC	26-Feb-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.	Presentations at Q1 SAC 2025 meetings	25-Feb-25
QbD Sampling Guide	Good Manufacturing Practices	Yes	Integrate the details of the QbD Sampling Guide into the 2020 International Pharmaceutical Excipient Council Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design (QbD) Guide	Combined Guide for Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design	25-Feb-25
IPEC-Americas 2024 Annual Report	Good Manufacturing Practices	N/A	Detailed information about IPEC-Americas accomplishments in 2024	2024 Annual Report	20-Feb-25
IPEC-Americas 2024 Year in Review	Good Manufacturing Practice	N/A	This infographic gives a high-level snapshot of our accomplishments in 2024.	Infographic on IA 2024 accomplishment	20-Feb-25
2025 Excipient World Event Overview	Excipient Qualification	N/A	Late Breaking News: 2025 Excipient World Conference & Expo announcements!	EW webinar to promote conference and expo	12-Feb-25
IPEC GDP Guide for Pharmaceutical Excipients	Good Manufacturing Practices	N/A	the IPEC GDP) Guide was revised and republished (Version 3) as a “how to” Guide in October 2024. Tne webinar will provide a high-level overview of the guide while highlighting significant changes between version 2 and version 3	ELL webinar on revised IPEC GDP Guide	30-Jan-25
FDA Docket Number: FDA-2024-N-4821	Good Manufacturing Practices	N/A	Docket Number: FDA-2024-N-4821 relative to Best Practices for FDA Communication with Interested Parties	Docket Comments Submitted	27-Jan-25
ECHA - Consultation on the implementation of the reporting requirements of the REACH restriction on microplastics	Excipient Qualification	N/A	ECHA has launched a consultation to seek comments on a proposal for reporting of estimated emissions of SPM (synthetic polymer microparticles) for certain derogated uses from REACH restriction on microplastics (Entry 78 of Annex XVII)	Comments to ECHA	3-Jan-25

SME Engagement/Knowledge Sharing with SAC Members	Strat Team 3	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.	Presentations at SAC 2024 meetings	3-Dec-24
New USP Flavor Monograph for Distilled Lime Oil	Regulatory Affairs	N/A	talk with Flavor RX to determine any comments or concerns that they might have regarding USP proposing a new monograph for distilled lime oil or any other potential monograph for flavors.	USP letter	30-Nov-24
EMA Q&A regarding co-processed excipients used in solid oral dosage forms H and V	Strat Team 3	N/A	IPEC-Americas intent to develop both high-level and detailed comments, to first share/discuss with IPEC Europe then submit to EMA, regarding their concerns which include, but not limited to, the Q&A potential misunderstanding of co-processed excipient fundamentals	comments to EMA on their Co-processed excipient Q&A	26-Nov-24
QC Laboratory Instrument Survey presentation	Quality by Design	Yes	Provide summary of QC lab survey results at 2024 Compendial Joint Industry Group meeting hosted by PDA on November 20-21st	Presentations at JIG meeting	20-Nov-24
IPEC-Americas LATAM Working Group Seminar 2024	Excipient Qualification	Yes	2024 IPEC-Americas LATAM Working Group Seminar, which will present a "Panorama and Update on Nitrosamines, Atypical Actives, and GMP for Excipients" and feature presenters from the United States, Brazil, and Mexico	LATAM Seminar	19-Nov-24
Quality Management Maturity	Compendial Review/ Harmonization	N/A	Based on 2023 ELL webinar survey, intited Jason Kerr from Moderna to give an ELL webeinar on the FDA QMM program	ELL webinar on FDA QMM	6-Nov-24
Alternative Methodologies sub team activities	Compendial Review/ Harmonization	N/A	Following publication of the IPEC Safety Guide for Pharmaceutical Excipients, a global sub team of Safety Guide contributors continue to monitor current and emerging trends in use/acceptance of alternative methodologies by healthcare regulatory	Develop webinar and/or article on alternative methodologies	30-Oct-24
IPEC Good Distribution Practices How To Guide	Compendial Review/ Harmonization	Y	The GDP Guide was revised in 2017. For next revision, this guide would be updated to include information on how to implement the requirements. Need to prioritize this project based on resources. On hold for now. GDP Guide members: Lisa Frame, Erica	Published GDP How To Guide	17-Oct-24
USP GC <1078> Excipient GMP re-write	Good Manufacturing Practices	N/A	USP GC <1078> Excipient GMP revisions have now been completed and the final version is scheduled to be published in December 2024. Sub team to review previous version vs revised version (and USP response to comments received on first revision) for any concerns/issues	IA review of revised USP <1078> Excipient GMPs	16-Oct-24

Excipient GMP 101 Webinar/Training	Quality by Design	N/A	Regulators outside US requested short webinar on excipient GMP, but IPEC does not currently have such a webinar. Suggested to develop an Excipient GMP 101 course to provide basic excipient GMP training/overview for regulators and people new to excipients (both	Excipient GMP 101 webinar/course for management	9-Oct-24
Excipient Excellence: The Power of Excipient Grade Selection	Strat Team 3	N/A	CPHI Europe(Milan) panel discussion on Excipient Excellence: The Power of Excipient Grade Selection"	Panel discussion at CPHI Europe	9-Oct-24
Excipient GMP 101 Webinar/Training	Strat Team 3	N/A	Regulators outside US requested short webinar on excipient GMP, but IPEC does not currently have such a webinar. Suggested to develop an Excipient GMP 101 course to provide basic excipient GMP training/overview for regulators and people new to excipients (both	Excipient GMP 101 webinar/course for management	1-Oct-24
Excipient GMP Compliance Workshop	Strat Team 3	N/A	Compliance with excipient GMP/GDP is important to everyone involved in the manufacture, distribution or use of excipients. This workshop includes analyzing essential elements and expectations related to excipient GMP/GDP for materials intended for use	Workshop held	20-Sep-24
PharmTech cover story on "Excipient Quaity"	Quality by Design	N/A	Publication based on PharmTech video interview (with Felicity Thomas) on the importace of excipient grade.	Pharmaceutical Technology article - published	10-Sep-24
Insider Articles on our Library of IPEC Guides and Postion Papers	0	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 15 - Hot Topics involving excipients (e.g., nitrosamines, TiO2, microplastics, etc.)	9-Aug-24
CLH proposal on silicon dioxide	Quality by Design	N/A	Prepare comments from IA to European Chemicals Agency (ECHA) in response to the Dutch Competent Authority's request (RIVM) for the harmonized classification of silicon dioxide, specifically Synthetic Amorphous Silica (SAS), as Specific Target Organ Toxicity-	On-line comment submission to ECHA	8-Aug-24
Insider Articles on our Library of IPEC Guides and Postion Papers	Regulatory Affairs	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 14 - Regional excipient laws, regulations, and guidelines.	23-Jul-24
Update definition for excipient impurities/ concomitant components	Quality by Design	N/A	Diverse project team (e.g., QbD, GMP, etc.), to better define excipient impurities and concomitant components and develop a strategy moving forward, including revisions to IPEC Glossary and guides, as appropriate	Updated definition for excipient impurities and concomitant components. Defined strategy to communicate (e.g.	15-Jul-24

2022 IPEC Certificate of Analysis Guide	Executive Committee	N/A	Two concerns raised with 2022 CoA guide: o text requiring CoA date of approval to be shown on COA and o 2nd COA example for a COA that is not hand-signed, yet showing ID of the person approving the COA along with	updated CoA guide	12-Jul-24
USP proposed Resolution Concepts	Executive Committee	N/A	Prepare IPEC-Americas comments/support for proposed resolutions for the USP 2025-2030 Convention cycle	Submit IPEC-Americas comments on proposed resolutions for the USP 2025-2030 Convention cycle	29-Jun-24
USP Draft Proposed Bylaw Amendments	Strategic Team 3	N/A	Prepare IPEC-Americas comments/support for changes to bylaws for the USP 2025-2030 Convention cycle	Submit IPEC-Americas comment for changes to bylaws for the USP 2025-2030 Convention cycle	29-Jun-24
ChP GC <0251>	Regulatory Affairs	N/A	Review the revised ChP <0251> chapter on Pharmaceutical Excipients and provide feedback from IA to the Federation by June 30, 2024	IA comments sent to Federation	28-Jun-24
Excipients: Compliance with Compendial and GMP Requirements	Good Manufacturing Practices	N/A	The International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) and Cobblestone have developed a comprehensive accredited course. The training includes an introduction to pharmacopeias, with an emphasis on the USP-NF and Ph. Eur.	Joint Course delivered	18-Jun-24
Article on excipient considerations to ensure a robust CM process operation	Compendial Review/ Harmonization	N/A	Develop article to examine the key information needed for excipients and their potential impact on CM processes. Focus on information from presentations during PQRI Workshop entitled “Managing Excipient and API Impact on Continuous Manufacturing”	Article published in PharmTech	13-Jun-24
Insider Articles on our Library of IPEC Guides and Postion Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 13- Excipient Master Files	12-Jun-24
Insider Articles on our Library of IPEC Guides and Postion Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 12- supply chain considerations for pharmaceutical excipients	29-May-24
Insider Articles on our Library of IPEC Guides and Postion Papers	Excipient World	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 11- Excipient User Quality by Design and Continuous Manufacturing activities	15-May-24

Alternative Analytical Procedures for Excipient Quality Control Testing	Strat Team 3	N/A	covers the use of alternative procedures to demonstrate equivalency to compendial procedures	EW 2024 Conference Presentation	15-May-24
Commercial Drug Product Formulation Development Road Map Using IPEC Excipient Guides	Strat team 3	N/A	This workshop demonstrated how the IPEC Papers and Guides can accelerate the use of excipients during the development and commercialization of new drugs. IPEC guides can help drug development teams avoid pitfalls that could delay development and	EW 2024 Conference Workshop	14-May-24
3D Printing: Emerging Technologies and Functionality of Polymeric Excipients in Drug Product Development	Regulatory Affairs	N/A	Covered key functionality of polymeric excipients and their utility in 3D Printing in drug development. Particular focus was given to hot melt extrusion and extruded filaments suitable for optimizing 3D Printing.	EW 2024 Conference Workshop	14-May-24
Titanium Dioxide Industry Updates	Strat Team 3	N/A	A collaborative team of experts from IQ, IPEC-Americas and IPEC Europe have combined their efforts to provide an overview of ongoing activities retated to TiO2. The presentation included a brief background and summary, a look at the use of TiO2 in pharmaceutical	EW 2024 Conference Presentation	14-May-24
Expectations for Developing and Sharing Excipient Composition Information	Regulatory Affairs	N/A	Provides an understanding of the fundamental sources and types of components that might be present in an excipient, offer best practices for characterizing an excipient composition profile and discuss potential analytical variabilities and limitations. In addition	EW 2024 Conference Presentation	14-May-24
Exploring Today's Excipient Landscape: Trends, Risks and Regulations	Compendial Review/ Harmonization	N/A	Panel discussion on perspectives from USP, IA and IE regarding trends in political and consumer pressure challenging science based regulatory agency decisions.	EW 2024 Conference Panel Discussion	14-May-24
Biologics Summit: Breakthroughs in Drug Delivery and Medical Devices	Regulatory Affairs	Yes	Set of industry presentations on 1) The role of excipients in drug delivery CQAs of Drug Coated Balloons 2) Microneedles for drug and vaccine delivery 3) Liquid Embolic System for the treatment of stroke	EW 2024 Conference Workshop	13-May-24
Excipients 101 Workshop	Excipient World	N/A	Covered the essential regulatory, quality and formulation aspects of common excipients used in orgal solid dosage forms.	EW 2024 Conference Workshop	13-May-24
Global Impact of PFAS Regulatory Restriction on Excipients	Excipient Qualification	Yes	Review of PFAS regulations and restrictions based on EU proposed restrictions on their use and undesirable toxicological and ecotoxicological properties	EW 2024 Conference Presentation	13-May-24

CDER Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	Excipient Qualification	Yes	Submit the ANSI 363 Standard to FDA for consideration as an FDA Reference Standard for excipient GMPs	ANSI 363 Excipient GMP Standard recognized by FDA as a voluntary consensus standard	7-May-24
PF 50(2) Proposed Revisions to USP GN	Executive Committee	N/A	A team of CRC members has been formed to prepare comments regarding the proposed revisions to USP General Notices posted in PF 50(2). •Minor clarifications in 3.10 Applicability of Standards •Addition of new 5.15 Definition	IA comments to USP GN proposal	29-Apr-24
Insider Articles on our Library of IPEC Guides and Postion Papers	Quality by Design	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 10 - Excipient Qualification	17-Apr-24
Insider Articles on our Library of IPEC Guides and Postion Papers	Scientific Affairs	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 9 - Excipient Qualification	3-Apr-24
2024 Excipient World Conference & Expo Webinar	Regulatory Affairs	N/A	Late Breaking News: 2024 Excipient World Conference & Expo. Join us for special announcements! We have an exciting line-up of guest speakers who will share new details about what to expect this May.	EW webinar to promote conference and expo	20-Mar-24
Insider Articles on our Library of IPEC Guides and Postion Papers	Excipient Qualification	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 8 - Excipient Qualification	20-Mar-24
Insider Membership Article #1	Strat Team 3	N/A	Article on "How has IPEC benefited your company, industry.",	Quarterly articles published in the IPEC Insider	20-Mar-24
Excipient Considerations in the Development and Approval of Animal Drug Products	Excipient Qualification	N/A	IPEC-Americas/GADA co-sponsored webinar on excipients considerations in the development and approval of animal drug products	Webinar	12-Mar-24
Insider Articles on our Library of IPEC Guides and Postion Papers	Compendial Review/ Harmonization	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 7 - Excipient GDP and GDP Audit Guides	7-Mar-24

FDA Docket No. FDA–2023-N-5653	Quality by Design	N/A	IPEC-Americas comments uploaded to FDA Docket No. FDA–2023-N-5653: Draft Report and Plan on Best Practices for Guidance	IA comments to FDA Docket No. FDA-20230N-5653	4-Mar-24
USP for <470> Determination of Diethylene Glycol and Ethylene Glycol in Polyethylene	Good Manufacturing Practices	N/A	IPEC-Americas comments to USP for <470> Determination of Diethylene Glycol and Ethylene Glycol in Polyethylene	IA comments for USP <470>	29-Feb-24
The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products	Excipient Qualification	N/A	Revised IPEC Federation positon paper entitled "The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products"	Revised IPEC position paper published	27-Feb-24
2024 Excipient 4World Conference & Expo Webinar	Compendial Review/ Harmonization	N/A	Late Breaking News: 2024 Excipient World Conference & Expo. Join us for special announcements! We have an exciting line-up of guest speakers who will share new details about what to expect this May.	EW webinar to promote conference and expo	21-Feb-24
Update of Quality Agreement Guide	Executive Committee	N/A	Review the 2017 Federation Quality Agreement guide and re-issue updated version	Published revised Federation Quality Agreement guide	21-Feb-24
Update of TUPPs Guide	Compendial Review/ Harmonization	N/A	Review the 2015 Federation TUPPS guide and re-issue updated version	Published revised Federation TUPPs guide	5-Feb-24
IPEC-Americas 2023 Year in Review	Regulatory Affairs	N/A	This infographic gives a high-level snapshot of our accomplishments in 2023.	Infographic on IA 2023 accomplishment	24-Jan-24
PQRI Workshop TiO2 Position Paper	Compendial Review/ Harmonization	N/A	PQRI TiO2 Workshop Organizing Committee/speakers position paper providing an overview of the information presented and ideas discussed during breakout sessions related to TiO2 safety and the challenges of using TiO2 alternatives in	TiO2 position paper completed and published	22-Jan-24
OEHHA reassessment of Ethylene Oxide	Regulatory Affairs	N/A	Prepare seconds set of written comments from IPEC-Americas makers and/or users of EtO for TITLE 27, CALIFORNIA CODE OF REGULATIONS, AMENDMENT TO SECTION 25705	IPEC-Americas comments to OEHHA	19-Jan-24

Potential Impact of the EU TiO2 Food Ban	Quality by Design	N/A	. This webinar will focus on the actual safety situation with TiO2, the potential use of TiO2-free coatings and the associated challenges being faced by the industry, regulators and patients, if TiO2 were to be banned in pharmaceutical applications	IA LL Webinar on TiO2	17-Jan-24
PharmTech video on Excipient Grade	Good Manufacturing Practices	N/A	PharmTech video interview (with Felicity Thomas, European/Senior Editor – Pharmaceutical Technology Group) on the importace of excipient grade. To be used as part of the PharmTech Drug Digest video series	Pharmaceutical Technology Video interview (with 5 IPEC-Americas members) - published	8-Jan-24
Insider Articles on our Library of IPEC Guides and Postion Papers	Quality by Design	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 6 - Risk Assessment for Excipients	1-Jan-24
Emerging hot topics involving excipient supplier expectation and excipient supplier response	Compendial Review/ Harmonization	N/A	Develop article on Emerging hot topics involving excipient supplier expectation and excipient supplier response	Insider series "DID YOU KNOW" highlighting IPEC resources	14-Dec-23
USP <317> ICP-OES Testing for Sodium Hydroxide and Potassium Hydroxide	Regulatory Affairs	N/A	Provide thank you to USP for publishing the General Chapter Prospectus on <317>ICP OES Testing for Sodium Hydroxide and Potassium Hydroxide	IPEC-Americas comments for GP <317>	14-Dec-23
USP-NF draft PF stimuli Article entitled Proposed Definitions of Excipient Components - Revisions to 2018 Definitions	Regulatory Affairs	N/A	review stimuli article and prepare comments/response from IPEC-Americas	Comments to USP regarding stimuli article	28-Nov-23
Importance of CAPA investigations and resolutions	Excipient Qualification	N/A	Based on recent FDA warning letter to an excipient manufacturer, develop a webinar to include examples of recent FDA excipient inspection findings and actions, describe FDA's definition of excipients as "drug components" and review drug product/component	IA LL Webinar entitled Why an effective CAPA system is important for excipient companies	15-Nov-23
IPEC Significant Change Guide	Regulatory Affairs	Yes	Based on feedback from the webinar to describe what was changed in the 2023 version of the IPEC Significant Change Guide, a webinar is being developed to provide training in the guide itself	IA LL Webinar on the IPEC Significant Change guide for Pharmaceutical Excipients	8-Nov-23
USP Hard Capsule monograph revisions	Good Manufacturing Practices	Yes	Provide formal comment letter for PF49(5) Hard Gelatin Capsules, Hard Hypromellose Capsules, and Hard Pullulan Capsules	IPEC-Americas comments for the hard capsule monograph revisions	29-Oct-23

What to Expect From Your IPEC-Americas Meetings	Regulatory Affairs	N/A	New infographic on What to Expect From Your IPEC-Americas Meetings	IPEC-Americas Infographic	18-Oct-23
USP Excipient Monograph Submission Guide	Regulatory Affairs	0	Provide formal comment letter for the recently revised USP Excipient Monograph Submission Guide (for new and proposed revision). Comment letter will discuss inapplicability of ICH Q3A/B to excipients.	IPEC-Americas comments for the USP Excipient Monograph Submission Guide	18-Oct-23
Excipient Supply Chain Challenges: EG/DEG	Regulatory Affairs	N/A	Presentation involving supply chain challenges and best practices for controlling for DEG/EG, review of IPEC Federation Position Paper and summary of IPEC-Americas comments to FDA docket and USP implementation plans	Presentation at NJPQCA meeting October 17, 2023	17-Oct-23
Joint Industry Meeting 2023	Scientific Affairs	N/A	IPEC-Americas is the host for the first Joint Industry meeting in 2023	Host first Joint Industry Meeting in 2023	11-Oct-23
Excipient Supply Chain Challenges: EG/DEG	Regulatory Affairs	N/A	Presentation involving supply chain challenges and best practices for controlling for DEG/EG, review of IPEC Federation Position Paper and summary of IPEC-Americas comments to FDA docket and USP implementation plans	Presentation at Joint Industry Group meeting on Oct. 11, 2023	11-Oct-23
Expectations for Sharing Excipient Composition Information	Scientific Affairs	N/A	developed an IPEC-Americas webinar combining excipient composition (including review of recent composition infographics) and excipient fundamentals – a review of excipient characterization activities	IPEC-Americas webinar	10-Oct-23
Excipient GMP Auditing Workshop	Regulatory Affairs	N/A	In person Workshop to be held at IPEC Americas, Arlington. Workshop to includes analyzing essential elements and expectations related to excipient GMP and GDP for materials intended for use in pharmaceuticals or dietary supplements	Workshop on Excipient GMP Auditing	5-Oct-23
Co-Processed Excipient Presentations	Compendial Review/ Harmonization	N/A	Dave to give an update presentation on Co-Processed Excipients and the FDA letters sent from IPEC-Americas at IPEC Europe-APV Conference	IPEC-Americas presentation "How FDA's PRIME program will support future Novel Excipient Development –	28-Sep-23
Response to USP Responses to Comments on Stimuli Article "Understanding the Composition and Quality of Polysorbates to Strengthen USP–NF	Regulatory Affairs	N/A	Comment positively on the transparency of sharing all the stakeholder comments and USP perspective on the comments	IPEC-Americas letter to USP	25-Sep-23

PFAS Position Paper	Regulatory Affairs	N/A	PQRI drafted a Position Paper on PFAS that IPEC-Americas provided excipient feedback/comments on and all member organizations (including IPEC) have been asked to formally endorse the document prior to submitting the responses to ECHA	IPEC-Americas endorsement of PQRI PFAS position paper to ECHA	21-Sep-23
FDA CDRH best practices for commenting	Regulatory Affairs	N/A	Incorporate CDRH guidelines into an IPEC-Americas procedure to use when developing and sending comments to any agency/organization	IPEC-Americas commenting procedure	13-Sep-23
PharmTech Q&A on Quality of Excipients	Good Manufacturing Practices	N/A	Develop IA response to Questions for Pharmaceutical Technology's September 2023 Ingredients Quality Feature	IA comments incorporated into Pharmaceutical Technology's September 2023 Ingredients Quality Feature	2-Sep-23
Microparticles Regulation	Scientific Affairs	N/A	IPEC-Americas Website posting recommending to member companies to wait until more information is available from the European regulators before providing specific information to users or creating the instructions for use and disposal of materials classified as	IPEC-Americas Website posting for providing specific information to users or creating the instructions for	30-Aug-23
Revise Federation position paper on supply chain security	Compendial Review/ Harmonization	N/A	Revised Federation position paper on supply chain security. Published on	Revised position paper published	30-Aug-23
Request to Revoke Color Additive Listing for Use of Titanium Dioxide in Food	Good Manufacturing Practices	N/A	IPEC-Americas comments uploaded to FDA Docket No. FDA-2023-C-1487: Filing of Color Additive Petition from Environmental Defense Fund, et al.; Request to Revoke Color Additive Listing for Use of Titanium Dioxide in Food	IPEC-Americas comments uploaded to FDA Docket No. FDA-2023-C-1487 https://www.regulations.gov/comment	30-Aug-23
ECHA's proposed restriction on PFAs	Executive Committee	N/A	IA to prepare a response to ECHA's proposed restriction on PFAs. Letter to include the following discussion points: -A request for a full derogation on the entire medicinal product. -Currently the proposed derogation only applies to API's but do not include	Letter submitted to ECHA's proposed restriction on PFAs	16-Aug-23
Testing for Diethylene Glycol and Ethylene Glycol	Good Manufacturing Practices	Yes	Follow the updates on the FDA Final guidance "Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol" and submit docket	Submit docket comments to USP on how to implement DEG/EG testing described in Docket 2023 FDA-	11-Aug-23
Co-Processed excipient guidance	Good Manufacturing Practices	N/A	IPEC-Americas and IQ Consortium to meet with FDA to develop guidance to de-couple co-processed excipients from "novel"	FDA meeting to discuss guidance on co-processed excipients	10-Aug-23

Testing for Diethylene Glycol and Ethylene Glycol	Good Manufacturing Practices	N/A	Follow the updates on the FDA Final guidance "Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol" and submit docket	Submit docket comments to FDA for Docket 2023 FDA-2023-D-1573 and potential comments to USP	28-Jul-23
IPEC-Americas/CRS Biological Summit - Part 1	Excipient Qualification	N/A	IPEC-Americas partnered with CRS to host 2 Biological Summit workshops. Part 1 was held prior to the EW Conf and Expo on May 1, 2023 and Part 2 was held July 24 as part of the CRS conference in July 2023. https://s6.goeshow.com/ipec/annual/20	EW 2023 Conference Workshop	24-Jul-23
TiO2 – Importance to Pharma, The Real Safety Profile, Potential Impact of a Ban	Excipient World	N/A	Following the PQRI TiO2 workshop, Dave Schoneker was invited by Wenlei Jiang (Senior Advisor for Innovation and Strategic Outreach, ORS, OGD, FDA) to speak on Ti02 at a July 19 FDA IPRP Nanomedicine Working Group meeting. The meeting includes 42 regulators from	Presentation on TiO2 to FDA IPRP Nanomedicine Working Group	19-Jul-23
Response to USP PF49(3) Acetyl tributyl Citrate and Histidine	Scientific Affairs	N/A	Comments to USP proposed monographs for Acetyl tributyl citrate (revised) and Histidine (new) posted lacking briefing information lacked rationale for impurity limits or description of value/need for advanced analytical technique being employed	IPEC-Americas letter to USP for proposed monographs for Acetyl tributyl citrate (revised) and Histidine (new)	11-Jul-23
FDA Docket FDA-2023-N-1585	Regulatory Affairs	N/A	Volunteers solicited to develop and comments to be submitted on FDA Docket FDA-2023-N-1585 on "Identification, Assessment, and Control of Nitrosamine Drug Substance-Related Impurities in Human Drug Products" if there is committee interest	IPEC-Americas comments uploaded to FDA Docket FDA-2023-N-1585 Nitrosamine	5-Jul-23
Microplastics Webinar	Regulatory Affairs	N/A	2023 IPEC-Americas webinar on EU Microplastics Regulation"	2023 IPEC-Americas webinar	22-Jun-23
PQRI Workshop: TiO2 Use in Pharmaceuticals – Global Regulatory and Technical Challenges	Scientific Affairs	N/A	The Workshop will be a hybrid event (in-person and virtual). The objective of the workshop is to bring together material suppliers, the pharmaceutical industry, and regulatory experts to discuss the impact removing titanium dioxide would have along with the benefits and	PQRI hybrid workshop – TiO2 Use in Pharmaceuticals – Global Regulatory and Technical Challenges	14-Jun-23
Excipient Compliance with Compendial and GMP Requirements	Scientific Affairs	N/A	Comprehensive 12-hour, accredited training, based on collaboration between IPEC-Americas/CfPA, which includes an introduction to the pharmacopoeias, with an emphasis on the USP-NF and Ph. Eur.	Center for Professional Advancement Joint Workshop (CfPA) "Excipients: Compliance with Compendial and	14-Jun-23
OEHHA reassessment of Ethylene Oxide	Scientific Affairs	N/A	Prepare written comments from IPEC-Americas makers and/or users of EtO for TITLE 27, CALIFORNIA CODE OF REGULATIONS, AMENDMENT TO SECTION 25705	IPEC-Americas comments to OEHHA	14-Jun-23

USP Thank you for EW 2023 participation	Excipient Qualification	N/A	Send a thank you letter to USP for their involvement in various EW 2023 activities	IPEC-Americas letter to USP	7-Jun-23
SAFYBI W	Regulatory Affairs	TBD	LATAM working group to work with SAFYBI to schedule and LATAM working group webinar on 2019 Remote Auditing Webinar	LATAM working group SAFYI webinar on IPEC-Americas Remote Audit webinar	31-May-23
Introduction to IPEC-Americas	Scientific Affairs	N/A	International Pharmaceutical Excipients Council (IPEC) Americas Introduction at in-person USP Excipients Collaborative Group Hybrid Meeting	USP Excipients Collaborative Group presentation on IPEC-Americas	31-May-23
WHO DRAFT 2023 Excipient GMP Guidelines	0	Yes	Review draft WHO excipient GMP guidelines and provide feedback to WHO via the Federation	Review and comments on draft WHO 2023 Excipient GMP from IA to Federation	26-May-23
LATAM webinar on Federation Nitrosamine position paper	Excipient World	N/A	LATAM working group to work with SAFYBI to schedule and LATAM working group webinar on the Federation Nitrosamine position paper –	LATAM working group SAFYI webinar on IPEC Nitrosamine position paper	17-May-23
FDA IPEC Excipient GMP training	Excipient Qualification	N/A	Rick Friedman (FDA) organizing IPEC-Americas training for FDA personnel regarding QMS expectations at excipient firms focusing on ANSI 363 excipient GMPs.	FDA training on QMS expectations at excipient firms 2 x 3 hour sessions for 90-130 FDA personnel	17-May-23
A Deep Dive into Supplier Qualification	Executive Committee	N/A	Review and discussion of applicable guidance, considerations for risk assessment and supplier qualification stages. In addition, share information on recent examples of counterfeit and adulterated excipients.	EW 2023 Conference Workshop	15-May-23
Key new IPEC Papers and Guides: What you need to know!	Excipient Qualification	Yes	A review of recently published and pending IPEC Position Papers and Guides.	EW 2023 Conference Workshop	15-May-23
De-coupling certain co-processed excipients from regulatory definition of “novel”	Excipient Qualification	Yes	IQ/IPEC-Americas presentation to justify regulatory authorities de-coupling certain co-processed excipients from their definition of "novel" excipient	EW 2023 Conference presentation	15-May-23

EW 2023 TiO2 Discussion Panel	Compendial Review/ Harmonization	N/A	During this session the panelists will address the overall nanoparticles issue in Europe including a potential ban of TiO2 in pharmaceuticals as well as discuss on-going industry advocacy to prevent a ban from happening	EW 2023 Pannel	15-May-23
IPEC - Latin America Working Group - Enhancing the regional integration	Excipient World	N/A	This session aims to present the benefits to current and new IPEC-Americas members joining this working group. It also aims to present an overview of various excipient regulations in Latin America.	EW 2023 Conference presentation	15-May-23
NAMs Regulatory Considerations & Reality Check for Pharmaceutical Excipients	Regulatory Affairs	N/A	Poster includes results from data mining a US FDA database to compilea list of excipients usedin approved biological,vaccines, cellular and gene therapy products and results from an IPEC-America survey to identify where and how alternative methods (or NAMs)	EW 2023 Conference poster	15-May-23
IPEC-Americas/CRS Biological Summit - Part 1	Compendial Review/ Harmonization	N/A	IPEC-Americas partnered with CRS to host 2 Biological Summit workshops. The first prior to the EW Conf and Expo on May 1, 2023 and Part 2 to take place as part of the CRS conference in July 2023. https://s6.goeshow.com/ipec/annual/20	EW 2023 Conference Workshop	1-May-23
Joint IPEC-Americas/CRS workshop	Good Manufacturing Practices	Yes	Collaborate with CRS on a joint IPEC-Americas / CRS workshops marketed as EW Academy and held as part of Excipient World 2023	Joint IPEC-Americas/CRS workshop at EW 2023	1-May-23
Supplier Qualification	Executive Committee	N/A	Develop and publish article in T&C based on J. Putnam 2022 EW presentation	T&C article on Supplier Qualification	26-Apr-23
CPhI TiO2 Update	Good Manufacturing Practices	Yes	CPhI presentation on TiO2 by Dave Schoneker	CPhI TiO2 presentation from IPEC-Americas	24-Apr-23
IQ Initiative (Novel Excipients FDA Qualification Pathway	Compendial Review/ Harmonization	N/A	IPEC-Americas and IQ Consortium to collaborate with FDA to propose/develop new "novel excipient qualifying process."	FDA supported "novel excipient qualification process"	11-Apr-23
New Section - Best Practices for Communicating Excipient Sustainability Information to Excipient Users	Compendial Review/ Harmonization	N/A	The presenters spoke about the recently published IPEC Excipient Information Package User Guide and Template, Part IV: Sustainability.	IPEC-Americas webinar	5-Apr-23

2023 Excipient World Conference & Expo Webinar	Compendial Review/ Harmonization	N/A	Late Breaking News: 2023 Excipient World Conference & Expo. Join us for special announcements! We have an exciting line-up of guest speakers who will share new details about what to expect this May.	EW webinar to promote conference and expo	4-Apr-23
Revised IPEC Significant Change Guide	Compendial Review/ Harmonization	N/A	The presenters provided an overview of the recently re-issued IPEC Significant Change Guide for Pharmaceutical Excipients	IPEC-Americas webinar	23-Mar-23
IPEC-Americas 2022 Annual Report	Compendial Review/ Harmonization	N/A	Detailed information about IPEC-Americas accomplishments in 2022	13-page pdf report	16-Mar-23
Update of Significant Change Guide	Good Manufacturing Practices	N/A	Develop Federation charter and update the 2015 IPEC Significant Change Guide. This update/revision has been approved by the Federation for a formal project in 2021.	Published revised Federation Significant Change guide	8-Mar-23
Sustainability and Responsible Sourcing	Good Manufacturing Practices	Yes	Develop and publish a Federation guide to add a fourth section to the EIP Guide covering sustainability and responsible sourcing	Published Federation guide covering sustainability and responsible sourcing	28-Feb-23
T&C publication on IPEC-Americas comments to USP	Good Manufacturing Practices	N/A	Prepare an article for the Tablet and Capsules excipient issue summarizing our USP comments over that 18 months or so, starting with maltol comments Share compiled information with the CPPQ group to help analyze the trends in USP responses to stakeholder input	Publish excipient article in Tablets and Capsules "Excipient Issue" WINTER 2022.	24-Feb-23
2023 Excipient World Conference & Expo Webinar	Quality by Design	Yes	Join us for this exciting presentation... and walk away with a clear understanding of why this is a must-attend event!	EW webinar to promote conference and expo	22-Feb-23
FDA data inconsistencies	Quality by Design	N/A	email to Susan Zuk and IID mailbox regarding IID data inconsistencies between Q2, 2022 and Q1 2023	email to FDA/IID mailbox	14-Feb-23
USP <312> Molecular Weight Determination for Alginates	Excipient Qualification	Yes	Provide IPEC-Americas comments for the new proposed General Chapter <312> stating concerns about the relevancy and applicability of SEC and MWD procedures for characterization and compendial standards for alginates.	IPEC-Americas comments for the new proposed General Chapter <312>	31-Jan-23

IPEC-Americas Excipient GMP Audit Guide to ANSI Standard webinar	EW Large team	N/A	Free learning lab webinar for IPEC members on recently issued IPEC-Americas GMP Audit guide to the NSF/IPEC/ANSI 363 Standard.	Held IPEC-Americas webinar on IA GMP Audit Guide to NSF/IPEC/ANSI 363 Standard	25-Jan-23
IPEC-Americas 2022 Year in Review	Excipient Qualification	N/A	This infographic gives a high-level snapshot of our accomplishments in 2022.	Infographic on IA 2022 accomplishment	25-Jan-23
IPEC-Americas Excipient GMP Audit Guide to ANSI Standard	Executive Committee	N/A	Develop a GMP Audit guide to the NSF/IPEC/ANSI 363 Standard. This guide could then be used as a foundation for the current IPEC GMP Audit guide which has been on-hold since 2018	Published IPEC GMP Audit Guide to NSF/IPEC/ANSI 363 Standard	22-Jan-23
Pharmeuropa 34.4 deletion of As and Pb	Regulatory Affairs	N/A	IPEC-Americas comments to EDQM for deletion of As and Pb tests from monographs for Magnesium trisilicate hydrate, Aluminum oxide, hydrated, Aluminum magnesium silicate, Aluminum sodium silicate, and Magnesium peroxide. Concerns that	Comments to EDQM regarding Pharmeuropa 34.4 deletion of As and Pb for certain monographs	19-Dec-22
Joint Industry Meeting 2022	Executive Committee	N/A	IPEC-Americas is the host for this year's joint industry meeting which has traditionally followed the Fall USP P/NP Stakeholder forum	Host the Joint Industry Meeting for 2022	8-Dec-22
USP Stimuli Article "Mutagenic Impurities and Potentially Mutagenic Impurities in the USP-NF"	Quality by Design	N/A	Provide IPEC-Americas comments to stimuli article published in PF48(5) regarding mutagenic impurities and potentially mutagenic Impurities in the USP-NF	Comments to USP	30-Nov-22
USP PF 48(5) GC <5.15> Definition	Scientific Affairs	N/A	IPEC-Americas comments for the revised General Notices and requirements as posted in PF 48(5) to include new section 5.15 Definition	Comments to USP regarding PF 48(5) to new section 5.15 Definition	28-Nov-22
USP PF48(5) removal of the Aspartame Acesulfame NF Monograph	Executive Committee	N/A	IPEC-Americas comments to the briefing provided in PF48(5) for the removal of the Aspartame Acesulfame NF Monograph	Comments to USP regarding PF48(5) removal of the Aspartame Acesulfame NF Monograph	28-Nov-22
Excipient GMP Compliance Virtual Workshop	EW Large team	N/A	Compliance with excipient GMP/GDP. This workshop includes analyzing essential elements and expectations related to excipient GMP/GDPs for materials intended for use in pharmaceuticals or dietary supplements.	IPEC-Americas Excipient GMP Auditing Workshop	17-Nov-22

Update Stability Guide	Scientific Affairs	N/A	Develop Federation charter to update current IPEC Stability Guide (2010) and revise guide to include stability gaps not covered in 2010 guide (e.g. expiration and/or use-by dates, temperature zones/regions, etc.)	Published revised Federation Stability guide	17-Nov-22
USP for PF48(4) <1078> Excipient GMP re-write	Regulatory Affairs	N/A	IPEC-Americas sub-team to review the proposed PF48(4) revision of USP <1078> Excipient GMP and prepare/submit comments to USP by comment deadline (9/30/2022)	Comments to USP for PF48(4) <1078> Excipient GMP re-write	17-Nov-22
ICH Continuous Manufacturing (Q13)	Scientific Affairs	N/A	Brian C. to represent IPEC on ICH Q13 Working Group. He will provide updates/drafts from WG activities, as allowed.	ICH Q13 CM Guideline	16-Nov-22
Nanoparticles in excipients and their potential impact on patients and pharmaceuticals	Excipient Qualification	N/A	Nanomaterial continues to be a hot topic among regulatory agencies globally. The recent ban on TiO2 (E171) as a food additive in Europe has highlighted the need to have a comprehensive understanding of the global regulatory environment related	IPEC-Americas webinar	8-Nov-22
Update of CoA Guide	Executive Committee	N/A	Develop Federation charter and update the 2013 IPEC CoA Guide. This update/revision has been approved by the Federation for a formal project in 2021.	Published revised Federation CoA guide	3-Nov-22
Modernizing Excipient Technology – Need for excipients designed for purpose	Compendial Review/ Harmonization	N/A	3D Printing – Characteristics and limitations of excipients designed specifically for 3D printing	0	2-Nov-22
Supplier Oversight article	Compendial Review/ Harmonization	N/A	Susan Haigney, Managing Editor, PharmTech is writing an article on supplier oversight and best practices for certificates of analysis for PharmTech's and BioPharm's November issues. IPEC-Americas was asked to respond to 8 questions for the article	BioPharm International article entitled "The Role of CoAs in Supplier Oversight"	1-Nov-22
A Seat at the table	Good Manufacturing Practices	N/A	this infographic shows the various HOT topics that are covered during meetings	IPEC-Americas Infographic	1-Nov-22
Excipient Requirements in Latin America	Regulatory Affairs	N/A	This webinar is intended to provide a summary of the current regulatory situation for excipients in Latin America and possible future developments. IPEC-Americas has been working with our partners in Latin America to have IPEC guidelines translated into local	IPEC-Americas webinar	27-Oct-22

IPEC Foundation Video	Scientific Affairs	No	To provide awareness of what the Foundation does and clear information on how academia / industry might get involved.	1-min animated video	4-Oct-22
Excipient Variability article	Quality by Design	N/A	Develop an article for T&C on Impact of supplier excipient composition variability on drug products/drug product formulations	Published article in Pharm Tech	2-Aug-22
CPHI Podcast on Novel Excipient	Executive Committee	N/A	IPEC-Americas presenter (Nigel Langley) for CPHI Podcast Series: The importance of novel excipients for innovative drug development	Episode 32 • 2nd August 2022 • CPhI Podcast Series: The importance of novel excipients for innovative drug development	2-Aug-22
IPEC-Americas Journal of Excipients and Food Chemical	Regulatory Affairs	N/A	IPEC-Americas sponsors and publishes a peer-reviewed quarterly journal related exclusively to excipients entitled "The Journal of Excipients and Food Chemicals".	Vol. 13, Issue 2, 2022	1-Aug-22
Excipient World 2023 Video	Quality by Design	N/A	To promote Excipient World participation	1-minute video	1-Aug-22
Submit IPEC Safety Guide to FDA for recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	Regulatory Affairs	N/A	Consistent with 21 CFR § 10.115 (Good Guidance Practices), consider submitting the recently published IPEC Safety Guide to FDA as part of CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	FDA cover letter and Safety guide submitted to FDA	1-Aug-22
TiO2 workshop	Good Manufacturing Practices	N/A	APV_IE_IA_IQ workshop entitled: The future Role of Titanium dioxide as an excipient in Pharmaceuticals	Workshop held	27-Jul-22
Poorly reviewed scientific excipient article IN Gastroenterology	Scientific Affairs	Yes	Standing topic to discuss emerging excipient "peer reviewed" articles considered to be "poor science." Intent would be to develop public comments, from IPEC-Americas, highlighting issues with these publications	ongoing monitoring and response to poorly reviewed scientific excipient articles	21-Jul-22
USP Response to GC <1083>	Scientific Affairs	N/A	IA comments to USP PF 48(3) Stimuli Article "USP's Iterative Approach to Standards Development and the 'Emerging Standards' Concept"	comments to USP for USP's Iterative Approach	17-Jul-22

Document Depot Navigation Videos & Mapping pdf	Regulatory Affairs	N/A	To improve useability of the Document Depot	1-minute video and 1-page pdf	1-Jul-22
Face-to-face meeting between USP and IPEC-Americas	Regulatory Affairs	N/A	Seek to improving relationship between USP and IPEC-Americas via face-to-face interaction between USP leadership and IPEC chair, IPEC executive administrator and IPEC liaison to USP	Increased opportunities for collaboration with USP	1-Jul-22
Excipients: Compliance with Compendial and GMP Requirements	Regulatory Affairs	N/A	IPEC-Americas and CfPA Co-Sponsor a 3 1/2-Day Virtual Course – Excipients: Compliance with Compendial and GMP Requirements	Training course developed and held	15-Jun-22
NSF Letter to clarify future support for ANSI 363 Standard	Good Manufacturing Practices	N/A	Prepare and send a letter to NSF asking about their intent to continue to support the ANSI 363 Excipient GMP Standard	Submit letter to NSF	15-Jun-22
Docket No. FDA-2022-N-0236 Prioritizing IID MDE and collapsing dosage forms	Excipient Qualification	N/A	Prepare and send a Docket comments for FDA-2022-N-0236 Prioritizing IID MDE and collapsing dosage forms, with copy to Susan Zuk	Submit comments to Docket No. FDA-2022-N-0236 Prioritizing IID MDE and collapsing dosage forms	9-Jun-22
Excipient World Novel Excipient Discussion Panel	Excipient Qualification	N/A	Host a novel excipient panel discussion during the EW conference	panel discussion	4-Jun-22
T&C Article on Continuous Manufacturing	Regulatory Affairs	N/A	Article on Switching from Batch to Continuous: Don't Forget about Formulations	T&C article Excipients and Continuous Manufacturing	1-Jun-22
T&C Article on Educational Opportunities Available from IPEC-Americas	Scientific Affairs	N/A	Article on Educational Opportunities Available from IPEC-Americas	T&C article Keeping up to Date with Excipients	1-Jun-22
T&C Article on Microplastics	Executive Committee	N/A	Article on Microplastics: proposed EU regulation on Small Particles Could lead to Potentially Big regulatory implications	T&C article Eye on Excipients	1-Jun-22

Develop PQRI Continuous Manufacturing Workshop	Executive Committee	N/A	PQRI sponsored workshop entitled Manufacturing Excipients and API Impact on Continuous Manufacturing	PQRI CM Workshop scheduled and executed	28-May-22
Pending Australia TGA regulation change for their Poisons Standard	Regulatory Affairs	Yes	IPEC-Americas comments to pending Australia TGA regulation change for their Poisons Standard	Comments to TGA on proposed change to poison control regulation	27-May-22
Excipient GMP Compliance Virtual Workshop	EW Large team	N/A	Compliance with excipient GMP/GDP. This workshop includes analyzing essential elements and expectations related to excipient GMP/GDPs for materials intended for use in pharmaceuticals or dietary supplements.	IPEC-Americas Workshop	26-May-22
Review of recently published nitrosamine position paper	Executive Committee	N/A	IPEC-Americas presentation at a Lhasa webinar held	Lhasa webinar presentation on IPEC nitrosamine position paper	17-May-22
Novel Excipient Pilot Program Review	Compendial Review/ Harmonization	N/A	IPEC-Americas presentation on the Novel Excipient Pilot Program Review - Nigel Langley	CPhI Novel Excipient Pilot Program Review presentation	17-May-22
Atypical Actives - déjà vu What can be done about new regulatory concerns?	Scientific Affairs	Yes	Regulatory agencies are issuing deficiencies and rejecting sponsors' drug applications that use excipients as atypical actives. Why, what are the issues, what can industry do?	0	3-May-22
Impact and Far Reaching Consequences of European Microplastics Regulations on Excipients and Medicinal Products	Compendial Review/ Harmonization	N/A	The European Chemicals Agency (ECHA) is moving forward with proposed restrictions on the use of microplastics in products used in various market segments – including medicinal products. ECHA's proposed regulations may lead to far reaching future impacts	0	3-May-22
Impact of the EU E171 Ban on Pharmaceuticals - IPEC & Industry Response	Executive Committee	N/A	Titanium Dioxide (also known as E171) has recently been banned for use in foods and dietary supplements in Europe. A three-year period has been granted for the EMA and the pharmaceutical industry to assess the impact of a potential ban in	0	3-May-22
Improved Supply Chain Security for Distributors of Closed-Pack Pharmaceutical Excipients	Executive Committee	N/A	Third-party GDP certification of pharmaceutical excipient distributors has been available since 2012. A new, innovative, third-party GDP standard will soon be available to improve the safety and security of pharma excipient supply worldwide. It was designed by industry	0	3-May-22

Sustainability -What does it mean for pharmaceutical excipients?	EW Large team	N/A	Sustainability is in the news everywhere, we hear about “transitioning to a carbon net zero world” which will impact all industry sectors. Join us in an interactive discussion on sustainability and what we as can do as excipient suppliers and users	0	3-May-22
Technical Qualification of Alternate Source Excipients in Commercialized Drug Products	Compendial Review/ Harmonization	N/A	This presentation seeks to highlight the complexity of the evaluation and qualification of alternate sources of excipients in already commercialized drug products, which requires much more than comparing specifications.	0	3-May-22
An Overview of Excipient Regulations and Requirements in Key Regions and Countries	Executive Committee	N/A	provide an overview of excipient regulations and requirements in key regions and countries outside of the US such as Europe, Canada, India, Brazil/other LATAM countries, China and a few other Asian countries. This information is often difficult to find	EW Academy workshop	2-May-22
Elemental Impurities Implementation Status - Outcomes from PQRI Workshop and Phase 2 Collaborative Study	Excipient Qualification	N/A	summarize and update information presented at the 4th PQRI Workshop on Elemental Impurities including the current status of global implementation of the ICH Q3D Guideline and the results and implications of a PQRI Collaborative Study which investigated a number of	EW Academy workshop	2-May-22
Key new IPEC Papers and Guides: What you need to know!	Scientific Affairs	N/A	focus on a review of recently published and impending IPEC Position Papers and Guides. The interactive workshop will be designed with breakout sessions to facilitate audience participation and feedback. It will also include group discussion on ideas for future	EW Academy workshop	2-May-22
IPEC-Americas Journal of Excipients and Food Chemical	Quality by Design	0	IPEC-Americas sponsors and publishes a peer-reviewed quarterly journal related exclusively to excipients entitled “The Journal of Excipients and Food Chemicals”.	Vol. 13, Issue 1, 2022	1-May-22
How to document to the ECHA's Proposal for an EU-wide Restriction on Intentionally Added Microplastics	Executive Committee	N/A	IA and IE summary of the core elements of the restriction proposal and intends to provide guidance for excipient manufacturers and users on how to prepare for compliance with the current proposed restriction.	Published guide	24-Mar-22
Updates and Late Breaking News: 2022 Excipient World Conference & Expo	Compendial Review/ Harmonization	N/A	Still on the fence about whether to come to Excipient World 2022? Join us for this exciting presentation... and walk away with a clear understanding of why this is a must-attend event	Excipient World webinar	23-Mar-22
IPEC-Americas 2021 Annual Report	Compendial Review/ Harmonization	N/A	Detailed information about IPEC-Americas accomplishments in 2021	13-page pdf report	16-Mar-22

Elemental Impurity	Regulatory Affairs	N/A	Support Trade Association coalition on the Rationale Implementation of Elemental Impurities	Rationale implementation of Global EI requirements for pharmaceutical excipients	2-Mar-22
The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products	Good Manufacturing Practices	N/A	This paper describes IPEC's position on the role of excipients when conducting N-nitrosamine nitrosamine) risk assessments for drug products.	Position Paper published	1-Mar-22
Face-to-face meeting between USP and IPEC-Americas	Compendial Review/ Harmonization	N/A	Seek to improving relationship between USP and IPEC-Americas via face-to-face interaction between USP leadership and IPEC chair, IPEC executive administrator and IPEC liaison to USP	Increased opportunities for collaboration with USP	1-Mar-22
Medicine Maker video/article on FDA Novel Excipient Review Pilot Program	Compendial Review/ Harmonization	N/A	IPEC and IQ WG / Novel excipients (Roundtable w Steph Sutton asking quests of WG members) Discussion points: • The importance of novel excipients and the pharma industry's needs in this area	Medicine Maker article on FDA Novel Excipient Review Pilot Program	26-Feb-22
Medicine Maker video/article on FDA Novel Excipient Review Pilot Program	Scientific Affairs	N/A	IPEC and IQ WG / Novel excipients (Roundtable w Steph Sutton asking quests of WG members) Discussion points: • The importance of novel excipients and the pharma industry's needs in this area	Medicine Maker video on FDA Novel Excipient Review Pilot Program	26-Feb-22
Excipient World Conference & Expo 2022: Top Reasons to Attend	Excipient Qualification	N/A	a comprehensive overview of Excipient World 2022... and walk away with a clear understanding of why you should attend this in-person event! Reconnect with colleagues and friends at the Gaylord Palms Resort & Convention Center, Kissimmee, FL	Excipient World webinar	23-Feb-22
USP Response to GC <621> Chromatography	Good Manufacturing Practices	Yes	IA follow-up comments to USP in response to November 22 Letter regarding PF 47(6) General Chapter <621> Chromatography	Follow-up response to USP for GC <621> Chromatography	2-Feb-22
IPEC-Americas Journal of Excipients and Food Chemical	Regulatory Affairs	Yes	IPEC-Americas sponsors and publishes a peer-reviewed quarterly journal related exclusively to excipients entitled "The Journal of Excipients and Food Chemicals".	Q4 2021 Edition Published	26-Jan-22
USP Response to GC <1083>	Quality by Design	Yes	IA follow-up comments to USP in response to November 22 Letter regarding PF 47(5) General Chapter <1083> Supplier Qualification	Follow-up response to USP for GC <1083>	21-Jan-22

IPEC Best Practices Guide for the Safety Evaluation of “Novel” Pharmaceutical Excipients	Regulatory Affairs	Yes	During this webinar, participants will learn how the guide evolved from articles published by IPEC-Americas and IPEC Europe in 1996 and 1997, respectively, to the current content, topics and safety practice recommendations	Webinar on IPEC Safety Guide for pharmaceutical excipients	20-Jan-22
Defining Excipient Composition	Scientific Affairs	TBD	This infographic is the first in a series of Excipient Composition infographics. It gives an overview of how starting materials become bulk finished excipients, as well as, lists materials that may be found in a finished excipient.	Infographic on excipient composition	16-Jan-22
IPEC-Americas 2021 Year in Review	Excipient World Academy	N/A	This infographic gives a high-level snapshot of our accomplishments in 2021.	Infographic on IA 2021 accomplishment	16-Jan-22
Maltol Appeal	Compendial Review/ Harmonization	N/A	IPEC-Americas formal appeal petition to USP for changes to Maltol, NF monograph published to be effective May 1, 2022	Repeal of the changes to Maltol, NF monograph published to be effective May 1, 2022	17-Dec-21
Maltol postponement	Compendial Review/ Harmonization	N/A	IPEC-Americas postponement request to USP for changes to Maltol, NF monograph published to be effective May 1, 2022	Request for postponement of the changes to Maltol, NF monograph published to be effective May 1	17-Dec-21
DMF Infographic	Executive Committee	N/A	Primary purpose of infographic is to clear up misconceptions that DMF: - is mandatory for DP application review - is mandatory regulatory requirement for supplier - dossier can be shared by FDA with other regulatory bodies	Infographic on DMF misconceptions	8-Dec-21
Excipient GMP Compliance Virtual Workshop	Regulatory Affairs	N/A	Compliance with excipient GMP/GDP. This workshop includes analyzing essential elements and expectations related to excipient GMP/GDPs for materials intended for use in pharmaceuticals or dietary supplements.	Workshop held Nov 29-Dec 3, 2021	3-Dec-21
USP Comment on GC 312 Prospectus	Compendial Review/ Harmonization	N/A	IA comments to USP regarding General Chapter Prospectus: <312> MW of Alginates	Comments to USP for GC 312 Prospectus	2-Dec-21
USP GC <2800> Multi Ingredient Dietary Supplements	Executive Committee	N/A	Dietary Supplements should not utilize Excipients, (Food Additive) Response needed.	Comments to USP per proposed revision to GC <2800>	1-Dec-21

Challenging the 'Status Quo' for Excipient Innovation in the Global Pharmaceutical Industry	Executive Committee	N/A	IPEC-Americas presentation at The Association for Chemistry and Economics- German Chemical Society, Germany, November 23, 2021	presentation to The Association for Chemistry and Economics- German Chemical Society	23-Nov-21
USP PF posting of revision to GC <1083> Supplier Qualification	Excipient Qualification	N/A	PF posting of revision to USP GC <1083> Supplier Qualification is proposed to be revised from "Good Distribution Practices" to "Supplier Qualification" and describe how drug product manufacturers should qualify their suppliers. It was agreed that IPEC	Comments to USP per proposed revision to GC <1083>	22-Nov-21
Excipient GMP Certification Scheme and Certification Body Qualification	Compendial Review/ Harmonization	N/A	an overview for use and value of the recently published IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients.	Webinar	18-Nov-21
Overview of Excipient Laws and Regulations in Europe	Compendial Review/ Harmonization	N/A	This webinar was intended to provide a road map for how the regulatory process in Europe works relative to the use of excipients.	Webinar	16-Nov-21
ICH Continuous Manufacturing (Q13)	Compendial Review/ Harmonization	N/A	FDA opened Docket FDA-2021-D-1047 ICH Q13 CM Oct 14, 2021 for comments to the ICH Q13 Step 2 document. IPEC-Americas commented to the open docket	Docket FDA-2021-D-1047 ICH Q13 Continuous Manufacturing	15-Nov-21
Overview of Excipient Laws and Regulations in US	Good Manufacturing Practices	N/A	2 part (Oct 20 & Nov 4) webinar intended to provide a road map for how the regulatory process in US works relative to the use of excipients.	Webinar	4-Nov-21
Update IPEC-Americas Safety Guide	Compendial Review/ Harmonization	N/A	Revise previous IPEC-Americas Guide, published in Regulatory Toxicology and Pharmacology, Volume 24, No. 2, October 1996.	An updated guide for the types of safety testing needed for a product approval	4-Nov-21
Novel Excipient Review Pilot Program Overview and Q&A	Good Manufacturing Practices	Yes	2021 EW Academy webinar	Webinar	27-Oct-21
USP Comment on GC 2760 Prospectus	Executive Committee	N/A	IA comments to USP regarding General Chapter Prospectus: <2760> Impurities in Dietary Ingredients and Dietary Supplements	Comments to USP for GC 2760 Prospectus	22-Oct-21

PMDA general comments for G9-1-181 proposed FRC chapter	Scientific Affairs	N/A	IA comments to PMDA regarding their proposed FRC chapter for the JP	Comment letter & form to PMDA for proposed FRC chapter G9-1-181	12-Oct-21
IPEC - Everything you need to know about excipients and more!	Regulatory Affairs	N/A	Develop a seminar for SAFYBI (Argentina Association of Industrial Pharmacy and Biochemistry) that provided background for the IPEC organization, Excipient Learning Lab, Excipient World Conference & Expo and Excipient World Academy as well as a general overview	Seminar delivered in Spanish to SAFYBI members	7-Oct-21
Docket No. FDA-2019-N-5464-0028 Center for Drug Evaluation and Research Office of New Drugs Novel Excipient Review Pilot Program	Excipient World Academy	N/A	Develop comments to Docket No. FDA-2019-N-5464-0028 Center for Drug Evaluation and Research Office of New Drugs Novel Excipient Review Pilot Program	Submit comments to Docket No. FDA-2019-N-5464-0028	4-Oct-21
USP Comment on Monograph Sponsors	Good Manufacturing Practices	N/A	IA comments to USP regarding potential conflict of interest for an instrument mfg. to sponsor a monograph specific to use of their analytical equipment	Comments to USP for potential monograph sponsor conflict of interest	4-Oct-21
PharmTech article regarding FDA Novel Excipient Pilot Program	Scientific Affairs	N/A	PharmTech industry interview of IA members regarding FDA Novel Excipient Review Pilot Program	Published PharmTech article entitled Great Expectations for Excipients	30-Sep-21
PharmTech request for article on industry response to Pandemic	Excipient World	N/A	PharmTech request for comment on an article how pharma responded during the Pandemic	Published PharmTech article on Industry Organizations Assist Pharma During the Pandemic and	30-Sep-21
Excipient Stability – Use of Expiration/ Re-evaluation Dates and Accelerated Stability	Excipient World Academy	N/A	2021 IPEC-Americas LL webinar	Webinar	29-Sep-21
EDQM letter related to proposed revision to the calcium acetate monographs	Regulatory Affairs	N/A	Prepare letter to EDQM in response to proposed revisions to the calcium acetate monograph posted in Pharmeuropa 33.3, regarding introduction of FRC. The comment deadline for Pharmeuropa 33.3 is 9/30/21	Follow-up comments to EDQM proposed revisions to the calcium acetate monograph	29-Sep-21
USP letter related to proposed IPA monograph revision bulletin	Regulatory Affairs	N/A	Prepare/send USP comments from IA regarding USP IPA monograph revision bulletin addition of the Limit of Methanol as an ID test. The revised monograph is to become effective 2/1/22	Follow-up comments to USP for proposed IPA monograph revision bulletin	24-Sep-21

EDQM letter related to proposed revision to the hydroxypropyl starch and pregelatinized hydroxypropyl starch monographs	Compendial Review/ Harmonization	N/A	Prepare letter to EDQM in response to proposed revisions to the hydroxypropyl starch and pregelatinized hydroxypropyl starch monographs revision posted in Pharmeuropa 33.3, regarding introduction of FRC. The comment deadline for Pharmeuropa 33.3 is	Follow-up comments to EDQM proposed the hydroxypropyl starch and pregelatinized hydroxypropyl	21-Sep-21
Upper Management Training	Excipient World Academy	N/A	commitment to GMP - Need for training to engage upper management - Training should capture their attention: - This is how you stay out of jail. - This is how you avoid costly claims	Infographic on upper management responsibilities available	16-Sep-21
USP letter related to Alginate monograph revisions	Compendial Review/ Harmonization	N/A	Prepare/send USP comments from IA regarding USP PF 47 (4) proposal to lower the current limits for Alginic Acid, Potassium Alginate, and Sodium Alginate rather than remove individual element specifications. IA is not aware of any specific risk for Pb and As in	Follow-up comments to USP for proposed Alginic Acid, Potassium Alginate, and Sodium Alginate	15-Sep-21
IPEC Good Distribution Practices Audit Guide	Compendial Review/ Harmonization	N/A	This guide will draw from applicable sections of the ANSI 363 standard which apply to distributors and is intended be a reference guide for auditors. However, given the status of the IPEC GDP Guide as stated above, this audit guide will be put on hold until	New GDP Audit Guide	14-Sep-21
IPEC-Americas celebrates 30 years	Quality by Design	N/A	Article in Tablets & Capsules entitled “IPEC-Americas celebrates 30 years"	Article published in T&C	23-Aug-21
CPhI Annual Meeting educational pod cast	Quality by Design	Yes	CPHI Collaboration – Educational Programming/Pod Cast - Drug Safety and Quality. Potential topic TiO2	IPEC-Americas CPhI TiO2 podcast	23-Aug-21
DPMH comments for Pediatric Drug Development Research Crowdsourcing	Excipient World Academy	0	Submit comments to DPMH regarding FDA’s Pediatric Drug Development Research Crowdsourcing Challenge	DPMH comments uploaded	20-Aug-21
Excipient World Conference & Expo: Top Reasons to Attend	Quality by Design	N/A	2021 EW webinar	Webinar	18-Aug-21
Validation for Pharmaceutical Excipients Presented by The International Pharmaceutical Excipients Council	Compendial Review/ Harmonization	N/A	2021 IPEC-Americas LL webinar	Webinar	21-Jul-21

CRS Annual Meeting presentation to promote new Safety Guide	Learning Lab	N/A	Develop presentation for on IPEC Safety Guide for CRS Annual Meeting (July 25-29, 2021).	IPEC Safety Guide presentation at 2021 CRS Annual Meeting	17-Jul-21
Excipient World Conference & Expo: Top Reasons to Attend	Compendial Review/ Harmonization	N/A	2021 EW webinar	Webinar	14-Jul-21
Excipient World Academy: Excipients & Upstream/Downstream Manufacturing Processes in Biologic Drug Products	Excipient World Academy	0	2021 EW Academy webinar	Webinar	30-Jun-21
Pharmeuropa 33.2 Pharmaceutical Preparations and Substances for Pharmaceutical Use GC	Regulatory Affairs	N/A	The Nitrosamine Cross Functional Team developed comments to the Pharmeuropa 33.2 Pharmaceutical Preparations (Reference: PA/PH/SG (21) 5 ANP) and Substances for Pharmaceutical Use (Reference: PA/PH/SG (21) 4 ANP) general chapters	Letter to EDQM	30-Jun-21
GDUFA II – IID Commitments	Compendial Review/ Harmonization	N/A	IA invited to GDUFA III negotiation meeting with pharma industry on June 29 to continue discussion with FDA on Industry prioritization of IID excipients/grades	IPEC Presentation update on Industry prioritization of IID excipients/grades	29-Jun-21
USP letter related to Maltodextrin	Regulatory Affairs	N/A	2/16/2021 - USP requested additional information, which is being gathered by member company (Perrigo)	Follow-up comments to USP for proposed Maltodextrin monograph revisions in PF 46 (6)	18-Jun-21
Excipient World Academy: The Importance of Excipient Functionality	Compendial Review/ Harmonization	N/A	2021 EW Academy webinar	Webinar	9-Jun-21
Excipients: Compliance with Compendial and GMP Requirements Workshop	Compendial Review/ Harmonization	N/A	IPEC-Americas and the Center for Professional Development - CfPA Virtual Workshop Collaboration – Excipients: Compliance with Compendial and GMP Requirements (cfpa.com)	IPEC-Americas/CfPA Workshop	31-May-21
USP Notice of Intent to revise the USP Isopropyl Alcohol monograph	Executive Committee	N/A	Provide feedback to USP with regards to their notice of Intent to revise the USP Isopropyl Alcohol monograph	IPEC-Americas comments submitted to USP for their notice of Intent to revise the USP Isopropyl Alcohol monograph	27-May-21

ISPE-IPEC excipient QbD Guide training	Scientific Affairs	Yes	Partner with ISPE India to deliver training on the recent IPEC QbD guide on May 26.	IPEC presentation for ISPE on QbD: Product Development and Life-cycle Management	26-May-21
ICH Continuous Manufacturing (Q13)	Quality by Design	N/A	Brian C. to represent IPEC on ICH Q13 Working Group. He will provide updates/drafts from WG activities, as allowed.	ICH Q13 CM Guideline	18-May-21
Excipient World Academy: Innovations in Pharmaceutical Coating Development	Compendial Review/ Harmonization	N/A	2021 EW Academy webinar	Webinar	12-May-21
FDA IPEC excipient QbD Guide training	Compendial Review/ Harmonization	N/A	J. Medwid/J. Parker at FDA organizing IPEC excipient QbD Guide training for FDA for May 11, 2021 from 10:00-12:00.	FDA training on IPEC excipient QbD Guide completed	11-May-21
Recommendations for Responding to Requests from USP for Samples	Quality by Design	N/A	The USP CFT to develop "Recommendations for Responding to Requests from USP for Samples", to provide member companies with things to consider when USP contacts them for samples.	Recommendations for Responding to Requests from USP for Samples	7-May-21
Excipient GMP Compliance Virtual Workshop	Scientific Affairs	N/A	Compliance with excipient GMP/GDP. This workshop includes analyzing essential elements and expectations related to excipient GMP/GDPs for materials intended for use in pharmaceuticals or dietary supplements.	Workshop held April 26-30	30-Apr-21
USP GSP GC Prospectus	IPEC Europe	N/A	Provide feedback to USP with regards to General Chapter <1xxx> Supplier Qualification Prospectus	IPEC-Americas comments submitted to USP for GC <1xxx> Supplier Qualification Prospectus	22-Apr-21
Excipient World Academy: Role of Excipients in Continuous Manufacturing of Solid Oral Dosage Forms	Regulatory Affairs	N/A	2021 EW Academy webinar	Webinar	21-Apr-21
Docket No. FDA-2020-2016: Policy for Testing Alcohol (Ethanol) and Isopropyl alcohol for Methanol, Including During the Public Health Emergency (COVID-19)	Quality by Design	N/A	Develop comments to Docket No. FDA - 2020-D-2016.	Submit comments to Docket No. FDA-2020-D-2016.	16-Apr-21

USP letter related to the USP Open Forum held Feb 11 & 12, 2021	Compendial Review/ Harmonization	N/A	Provide feedback to USP with regards to follow-up requests pertaining to the USP open forum Feb 11 & 12, 2021	Follow-up comments to USP for Feb 11 & 12 Open Forum	16-Apr-21
GDUFA II – II IID Commitments	Scientific Affairs	N/A	IA invited to GDUFA III meeting with pharma industry on April 1 to discuss how the FDA might be able to better meeting required IID enhancements	IPEC Presentation update on status of GDUFA II IID commitments	1-Apr-21
USP letter related to Oleyl Oleate	Regulatory Affairs	0	Review proposed monograph revisions for Oleyl Oleate from PF 47(1) and provide feedback to USP	IPEC-Americas comments submitted to USP for Oleyl Oleate monograph revisions in PF 47 (1)	30-Mar-21
USP letter related to USP GC<232> elemental impurity limits	Quality by Design	N/A	Review proposed elemental Impurity limit revisions to UPS GC <232> from PF 47(1) and provide feedback to USP	IPEC-Americas comments submitted to USP for GC <232> EI limit revisions in PF 47 (1)	30-Mar-21
2020 Year end review	Quality by Design	N/A	2020 Year end review infographic	Infographic on 2020 year end review	22-Mar-21
SOT Annual Meeting Poster to promote new Safety Guide	Quality by Design	Yes	Develop poster for SOT Annual Meeting (March 2, 2021).	SOT Poster presented at 2021 SOT Annual Meeting	18-Mar-21
Outsourced Pharma article on IPEC QbD Guide	Compendial Review/ Harmonization	N/A	Develop and article on the QbD Guide to be published as part of a CPhI Annual report. The paper was also broken into 3 parts and published in Outsource Pharma	Part 3 of QbD Guide article published in Outsourced Pharma	10-Mar-21
USP endorsement of IFAC comments to USP GCs <2740>, <2800> and <2750>.	Quality by Design	N/A	IPEC-Americas endorsement of IFAC's comments on proposed new GC <2740> and <2800> and proposed revision to GC <2750>	USP notification of endorsement of IFAC comments	10-Mar-21
USP comments related to Glucose, Liquid PF 47(1)	Compendial Review/ Harmonization	N/A	Review proposed revisions to glucose, liquid monograph from PF 47(1) and provide feedback to USP	IPEC-Americas comments submitted to USP for proposed glucose, liquid monograph revisions in PF 47	4-Mar-21

Outsourced Pharma article on IPEC QbD Guide	Compendial Review/ Harmonization	N/A	Develop and article on the QbD Guide to be published as part of a CPhI Annual report. The paper was also broken into 3 parts and published in Outsource Pharma	Part 2 of QbD Guide article published in Outsourced Pharma	3-Mar-21
PharmTech article on Novel Excipient	Excipient Qualification	N/A	Nigel, Priscilla, Meera, Dave S, Kathy U, etc. provided input to PharmTech entitled Novel Excipients Needed More Than Ever Before	Published PharmTech article on Novel excipient review process	2-Mar-21
Pharmaceutical Lactose used in oral preparations	Good Manufacturing Practices	N/A	Develop and publish a position paper on Pharmaceutical Lactose used in oral preparations is a low-risk excipient Possibly publish in Pharm Tech. Presentation at NJPQCA, IA Webinar, EW workshop	Position paper on Pharmaceutical Lactose used in oral preparations is a low-risk excipient published	1-Mar-21
GADA Meeting with CVM (FDA)	Executive Committee	N/A	Deliver a presentation on CoAs during the GADA meeting with CVM	Present on IPEC and CoAs at GADA-CVM meeting	25-Feb-21