Committee Accomplishments

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
2	Joint Industry Meeting 2023	Compendial Review/ Harmonization	N/A	IPEC-Americas is the host for the first Joint Industry meeting in 2023	Workshop - JIG	11-Oct-23
3	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 Positon Paper and summary of IPEC-Americas comments to FDA docket and USP implementation plans	Industry presentation - NJPQCA	17-Oct-23
4	Expectations for Sharing Excipient Composition Information	Quality by Design	N/A	develope an IPEC-Americas webinar combining excipient composition (including review of recent composition infographics) and excipient fundamentals – a review of excipient characterization activities	Webinar - IPEC-Americas	10-Oct-23
5	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 Positon Paper and summary of IPEC-Americas comments to FDA docket and USP implementation plans	Industry presentation - JIG	11-Oct-23
6	Co-Processed Excipient Presentations	Quality by Design	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	Industry presentation - IPEC Europe	28-Sep-23
7	Response to USP Responses to Comments on Stimuli Article “Understanding the Composition and Quality of Polysorbates to Strengthen USP–NF Compendial Standards”	Compendial Review/ Harmonization	N/A	Comment positively on the transparency of sharing all the stakeholder comments and USP perspective on the comments	Correspondence - USP	25-Sep-23

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8	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	Correspondence - ECHA	21-Sep-23
9	USP-NF draft PF stimuli Article entitled Proposed Definitions of Excipient Components - Revisions to 2018 Definitions	Quality by Design	N/A	review stimuli article and prepare comments/response from IPEC-Americas	Correspondence - USP	14-Sep-23
10	PharmTech Q&A on Quality of Excipients	Excipient Qualification	N/A	Develop IA response to Questions for Pharmaceutical Technology's September 2023 Ingredients Quality Feature	Publication - Pharm Tech	2-Sep-23
11	Microparticles Regulation	Regulatory Affairs	Yes	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 microplastics. Sent to XC for approval by August 25.	Miscellaneous support	30-Aug-23
12	PharmTech Q&A on Quality of Excipients	Excipient Qualification	N/A	Develop IA response to Questions for Pharmaceutical Technology's September 2023 Ingredients Quality Feature	Publication - Pharm Tech	30-Aug-23

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13	Request to Revoke Color Additive Listing for Use of Titanium Dioxide in Food	Regulatory Affairs	N/A	IPEC-Americas comments uploaded to FDA Docket 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	docket comments	30-Aug-23
14	Revise Federation position paper on supply chain security	Good Manufacturing Practice	Yes	Revised Federation position paper on supply chain security. Published on	IPEC Position Paper	30-Aug-23
15	ECHA's proposed restriction on PFAs	Regulatory Affairs		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 excipients or impurities -Medicinal products cannot be formulated without excipients -A ban on excipients or impurities will significantly impact the availability of medicines	Correspondence - ECHA	16-Aug-23

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16	Testing for Diethylene Glycol and Ethylene Glycol	Regulatory Affairs	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 comments to 2023 FDA-2023-D-1573. Also consider developing and submitting comments to USP regarding monograph updates.	Correspondence - USP	11-Aug-23
17	Co-Processe excipient guidance	Scientific Affairs	N/A	IPEC-Americas and IQ Consortium to meet with FDA to develop guidance to de-couple co-processed excipients from "novel"	Correspondence - FDA	10-Aug-23
18	Testing for Diethylene Glycol and Ethylene Glycol	Regulatory Affairs	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 comments to 2023 FDA-2023-D-1573. Also consider developing and submitting comments to USP regarding monograph updates.	Docket comments	28-Jul-23

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19	IPEC-Americas/CRS Biological Summit - Part 1	Scientific Affairs	N/A	IPEC-Americas partnered with CRS to host 2 Biological Summit workshops. Part 1 was held prior to the EW Conf and Expoon 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/2023/biologics_summit.cfm.	Workshop - EW IPEC-Americas/CRS	24-Jul-23
20	TiO2 – Importance to Pharma, The Real Safety Profile, Potential Impact of a Ban	Regulatory Affairs	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 6 different countries and is being organized by Wen Li from FDA	FDA - training	19-Jul-23
21	Response to USP PF49(3) Acetyltributyl Citrate and Histidine	Compendial Review/ Harmonization	N/A	Comments to USP proposed monographs for Acetyltributyl 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 (i.e., LC/MS)	Correspondence - USP	11-Jul-23

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22	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.	Docket comments	5-Jul-23
23	Microplastics Webinar	Regulatory Affairs	N/A	2023 IPEC-Americas webinar on EU Microplastics Regulation"	Webinar - IPEC-Americas	22-Jun-23
24	Excipient Compliance with Compendial and GMP Requirements	Good Manufacturing Practice	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.	Workshop - CfPA	14-Jun-23
25	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	Correspondence - OEHHA	14-Jun-23
26	PQRI Workshop: TiO2 Use in Pharmaceuticals – Global Regulatory and Technical Challenges	Regulatory 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 challenges of the alternatives to titanium dioxide for use in solid oral dosage forms.	Workshop - PQRI	14-Jun-23

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
27	USP Thank you for EW 2023 participation	Compendial Review/ Harmonization	N/A	Send a thank you letter to USP for their involvement in various EW 2023 activities	Correspondence - USP	7-Jun-23
28	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	Correspondence - OEHHA	1-Jun-23
29	Introduction to IPEC-Americas	Executive Committee	N/A	International Pharmaceutical Excipients Council (IPEC) Americas Introduction at in-person USP Excipients Collaborative Group Hybrid Meeting	Presentation - USP	31-May-23
30	SAFYBI W	Good Manufacturing Practice	N/A	LATAM working group to work with SAFYBI to schedule and LATAM working group webinar on 2019 Remote Auditing Webinar	Webinar - SAFYBI	31-May-23
31	WHO DRAFT 2023 Excipient GMP Guidelines	Good Manufacturing Practice	Yes	Review draft WHO excipient GMP guidelines and provide feedback to WHO via the Federation	Correspondense - WHO	26-May-23
32	FDA IPEC Excipient GMP training	Good Manufacturing Practice	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	17-May-23
33	LATAM webinar on Federation Nitrosamine position paper	Good Manufacturing Practice	N/A	LATAM working group to work with SAFYBI to schedule and LATAM working group webinar on the Federation Nitrosamine position paper –	Webinar - SAFYBI	17-May-23

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
34	A Deep Dive into Supplier Qualification	Excipient Qualification	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.	Workshop - EW Academy	15-May-23
35	De-coupling certain co-processed excipients from regulatory definition of “novel”	Scientific Affairs	N/A	IQ/IPEC-Americas presentation to justify regulatory authorities de-coupling certain co-processed excipients from their definition of "novel" excipient	Presentation - EW	15-May-23
36	EW 2023 TiO2 Discussion Panel	Regulatory Affairs	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	Presentation - EW	15-May-23
37	IPEC - Latin America Working Group - Enhancing the regional integration	Regulatory Affairs	N/A	This session aims to present the benefits to current and new IPECAmericas members joining this working group. It also aims to present an overview of various excipient regulations in Latin America.	Presentation - EW	15-May-23
38	Key new IPEC Papers and Guides: What you need to know!	Excipient World	N/A	A review of recently published and pending IPEC Position Papers and Guides.	Workshop - EW Academy	15-May-23

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
39	NAMs Regulatory Considerations & Reality Check for Pharmaceutical Excipients	Scientific 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) are used for evaluating excipient safety.	Poster - EW	15-May-23
40	IPEC-Americas/CRS Biological Summit - Part 1	Scientific Affairs	N/A	IPEC-Americas partnered with CRS to host 2 Biological Summit workshops. The first prior to the EW Conf and Expoon May 1, 2023 and Part 2 to take place as part of the CRS conference in July 2023. https://s6.goeshow.com/ipec/annual/2023/biologics_summit.cfm.	Workshop - EW IPEC-Americas/CRS	1-May-23
41	Joint IPEC-Americas/CRS workshop	Scientific Affairs	N/A	Collaborate with CRS on a joint IPEC-Americas / CRS workshops marketed as EW Academy and held as part of Excipient World 2023	Workshop - EW Academy	1-May-23
42	Supplier Qualification	Excipient Qualification	N/A	Develop and publish article in T&C based on J. Putnam 2022 EW presentation	Publication - T&C	26-Apr-23
43	CPhI TiO2 Update	Regulatory Affairs	TBD	CPhI presentation on TiO2 by Dave Schoneker	Presentation - CPhI	24-Apr-23
44	IQ Initiative (Novel Excipients FDA Qualification Pathway	Scientific Affairs	N/A	IPEC-Americas and IQ Consortium to collaborate with FDA to propose/develop new "novel excipient qualifying process."	Correspondense - FDA	11-Apr-23

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45	2023 Excipient World Conference & Expo Webinar	Excipient World	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.	Webinar - EW	4-Apr-23
46	Update of Significant Change Guide	Excipient Qualification	Yes	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.	IPEC Guide - Revision	8-Mar-23
47	Sustainability and Responsible Sourcing	Excipient Qualification	Yes	Develop and publish a Federation guide to add a fourth section to the EIP Guide covering sustainability and responsible sourcing	IPEC Guide - New	28-Feb-23
48	T&C publication on IPEC-Americas comments to USP	Compendial Review/ Harmonization	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	Publication - T&C	24-Feb-23
49	2023 Excipient World Conference & Expo Webinar	Excipient World	N/A	Join us for this exciting presentation... and walk away with a clear understanding of why this is a must-attend event!	Webinar - EW	22-Feb-23
50	FDA data inconsistencies	Regulatory Affairs	N/A	email to Susan Zuk and IID mailbox regarding IID data inconsitencies between Q2, 2022 and Q1 2023	Correspondence - FDA	14-Feb-23

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51	USP <312> Molecular Weight Determination for Alginates	Compendial Review/ Harmonization	N/A	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.	Correspondence - USP	31-Jan-23
52	IPEC-Americas Excipient GMP Audit Guide to ANSI Standard webinar	Good Manufacturing Practice	Yes	Free learning lab webinar for IPEC members on recently issued IPEC-Americas GMP Audit guide to the NSF/IPEC/ANSI 363 Standard.	Webinar - LL	25-Jan-23
53	IPEC-Americas Excipient GMP Audit Guide to ANSI Standard	Good Manufacturing Practice	Yes	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	IPEC-Americas Guide - New	22-Jan-23
54	Pharmeuropa 34.4 detetion of As and Pb	Compendial Review/ Harmonization	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 deletion is not aligned with stated EDQM policy to maintain specific EI tests for natural materials	Correspondence - EDQM	19-Dec-22
55	Joint Industry Meeting 2022	Compendial Review/ Harmonization	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	Collaboration - Joint Ind Team	8-Dec-22

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56	USP Stimuli Article “Mutagenic Impurities and Potentially Mutagenic Impurities in the USP-NF"	Compendial Review/ Harmonization	N/A	Provide IPEC-Americas comments to stimuli article published in PF48(5) regarding mutagenic impurities and potentially mutagenic Impurities in the USP-NF	Correspondence - USP	30-Nov-22
57	USP PF 48(5) GC <5.15> Definition	Compendial Review/ Harmonization	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	Correspondence - USP	28-Nov-22
58	USP PF48(5) removal of the Aspartame Acesulfame NF Monograph	Compendial Review/ Harmonization	N/A	IPEC-Americas comments to the briefing provided in PF48(5) for the removal of the Aspartame Acesulfame NF Monograph	Correspondence - USP	28-Nov-22
59	Excipient GMP Compliance Virtual Workshop	Good Manufacturing Practice	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 - IPEC-Americas LL	17-Nov-22
60	Update Stability Guide	Good Manufacturing Practice	Yes	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.)	IPEC Guide - Revision	17-Nov-22
61	USP for PF48(4) <1078> Excipient GMP re-write	Good Manufacturing Practice	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)	Correspondence - USP	17-Nov-22

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62	ICH Continuous Manufacturing (Q13)	Quality by Design	Yes	Brian C. to represent IPEC on ICH Q13 Working Group. He will provide updates/drafts from WG activities, as allowed.	Correspondence - ICH	16-Nov-22
63	Nanoparticles in excipients and their potential impact on patients and pharmaceuticals	Quality by Design	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 to the presence of nanoparticles in food additives and excipients.	Webinar - IPEC-Americas LL	8-Nov-22
64	Update of CoA Guide	Excipient Qualification	Yes	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.	IPEC Guide - Revision	3-Nov-22
65	Modernizing Excipient Technology – Need for excipients designed for purpose	EW Large team	N/A	3D Printing – Characteristics and limitations of excipients designed specifically for 3D printing	Webinar - EW	2-Nov-22
66	Supplier Oversight article	Excipient Qualification	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	Publication - BioPharm International	1-Nov-22

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67	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 languages and has presented educational workshops for several years in this region to regulators and industry associations. Some countries have established regulations for excipients, e.g. ANVISA in Brazil has regulations for excipient GMPs, while other countries' regulations do not specifically address excipients.	Webinar - IPEC-Americas LL	27-Oct-22
68	IPEC Foundation Video	Executive Committee	N/A	To provide awareness of what the Foundation does and clear information on how academia / industry might get involved.	IPEC Infographic or video	4-Oct-22
69	CPHI Podcast on Novel Excipient	Scientific Affairs	N/A	IPEC-Americas presenter (Nigel Langley) for CPHI Podcast Series: The importance of novel excipients for innovative drug development	Presentation - CPhI	2-Aug-22
70	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	Publication - Pharm Tech	2-Aug-22
71	Excipient World 2023 Video	EW Large team	N/A	To promote Excipient World participation	IPEC Infographic or video	1-Aug-22

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72	IPEC-Americas Journal of Excipients and Food Chemical	Executive Committee	N/A	IPEC-Americas sponsors and publishes a peer-reviewed quarterly journal related exclusively to excipients entitled “The Journal of Excipients and Food Chemicals”.	Publication - JEFC	1-Aug-22
73	Submit IPEC Safety Guide to FDA for recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	Scientific 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	Correspondence - FDA	1-Aug-22
74	TiO2 worshop	Regulatory Affairs	N/A	APV_IE_IA_IQ workhop entitled: The future Role of Titanium dioxide as an excipient in Pharmaceuticals	Workshop - APV_IE_IA_IQ	27-Jul-22
75	Poorly reviewed scientific excipient article IN Gastroenterology	Scientific Affairs	N/A	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	Correspondence - Gastroenterology	21-Jul-22
76	USP Response to GC <1083>	Excipient Qualification	N/A	IA comments to USP PF 48(3) Stimuli Article “USP’s Iterative Approach to Standards Development and the ‘Emerging Standards’ Concept”	Correspondence - USP	17-Jul-22
77	Document Depot Navigation Videos & Mapping pdf	Executive Committee	N/A	To improve useability of the Document Depot	IPEC Infographic or video	1-Jul-22

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78	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	Collaboration - USP	1-Jul-22
79	Excipients: Compliance with Compendial and GMP Requirements	Compendial Review/ Harmonization	N/A	IPEC-Americas and CfPA Co-Sponsor a 3 1/2-Day Virtual Course – Excipients: Compliance with Compendial and GMP Requirements	Workshop - CfPA	15-Jun-22
80	NSF Letter to clarify future support for ANSI 363 Standard	Good Manufacturing Practices	N/A	Prepare and send a letter to NSF aking about their intent to continue to support the ANSI 363 Excipient GMP Standard	Correspondence - NSF	15-Jun-22
81	Docket No. FDA-2022-N-0236 Prioritizing IID MDE and collapsing dosage forms	Regulatory Affairs	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	Docket comments	9-Jun-22
82	Excipient World Novel Excipient Discussion Panel	Scientific Affairs	No	Host a novel excipient panel discussion during the EW conference	Presentation - EW	4-Jun-22
83	T&C Article on Continuous Manufacturing	Quality by Design	N/A	Article on Switching from Batch to Continuous: Don't Forget about Formulations	Publication - T&C	1-Jun-22
84	T&C Article on Educational Opportunities Available from IPEC-Americas	Executive Committee	N/A	Article on Educational Opportunities Available from IPEC-Americas	Publication - T&C	1-Jun-22
85	T&C Article on Microplastics	Regulatory Affairs	N/A	Article on Microplastics: proposed EU regulation on Small Particles Could lead to Potentially Big regulatory implications	Publication - T&C	1-Jun-22

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86	Develop PQRI Continuous Manufacturing Workshop	Quality by Design	N/A	PQRI sponsored workshop entitled Manufacturing Excipients and API Impact on Continuous Manufacturing	Workshop - PQRI	28-May-22
87	Pending Australia TGA regulation change for their Poisons Standard	Regulatory Affairs	N/A	IPEC-Americas comments to pending Australia TGA regulation change for their Poisons Standard	Correspondence - TGA	27-May-22
88	Excipient GMP Compliance Virtual Workshop	Good Manufacturing Practices	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 - IPEC-Americas LL	26-May-22
89	Novel Excipient Pilot Program Review	Scientific Affairs	N/A	IPEC-Americas presntation on the Novel Excipient Pilot Program Review - Nigel Langley	Presentation - CPhI	17-May-22
90	Review of recently published nitrosamine position paper	Scientific Affairs	Yes	IPEC-Americas presntation at a Lhasa webinar held	Presentation - Lahas webinar	17-May-22
91	Atypical Actives - déjà vu What can be done about new regulatory concerns?	Regulatory Affairs	N/A	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?	Presentation - EW	3-May-22
92	Impact and Far Reaching Consequences of European Microplastics Regulations on Excipients and Medicinal Products	Regulatory Affairs	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 if industry does not act now.	Presentation - EW	3-May-22

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
93	Impact of the EU E171 Ban on Pharmaceuticals - IPEC & Industry Respons	Regulatory Affairs	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 pharmaceuticals. See what IPEC is doing to address this!	Presentation - EW	3-May-22
94	Improved Supply Chain Security for Distributors of Closed-Pack Pharmaceutical Excipients	Good Manufacturing Practices	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 supply chain security experts specifically for distributors of closed-pack pack pharmaceutical excipients	Presentation - EW	3-May-22
95	Sustainability -What does it mean for pharmaceutical excipients?	Excipient Qualification	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.	Presentation - EW	3-May-22

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
96	Technical Qualification of Alternate Source Excipients in Commercialized Drug Products	Excipient Qualification	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.	Presentation - EW	3-May-22
97	An Overview of Excipient Regulations and Requirements in Key Regions and Countries	Regulatory Affairs	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 since few countries have regulations specific to excipients.	Workshop - EW Academy	2-May-22
98	Elemental Impurities Implementation Status - Outcomes from PQRI Workshop and Phase 2 Collaborative Study	Scientific Affairs	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 the analytical challenges related to EI testing.	Workshop - EW Academy	2-May-22

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
99	Key new IPEC Papers and Guides: What you need to know!	Executive Committee	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 improvements and/or needs.	Workshop - EW Academy	2-May-22
100	IPEC-Americas Journal of Excipients and Food Chemical	Executive Committee	N/A	IPEC-Americas sponsors and publishes a peer-reviewed quarterly journal related exclusively to excipients entitled “The Journal of Excipients and Food Chemicals”.	Publication - JEFC	1-May-22
101	How to document to the ECHA's Proposal for an EU-wide Restriction on Intentionally Added Microplastics	Regulatory Affairs	Yes	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.	IPEC Guide - New	24-Mar-22
102	Updates and Late Breaking News: 2022 Excipient World Conference & Expo	EW Large team	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	Webinar - EW	23-Mar-22
103	IPEC-Americas 2021 Annual Report	Executive Committee	N/A	Detailed information about IPEC-Americas accomplishments in 2021	IPEC Report	16-Mar-22

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
104	Elemental Impurity	Compendial Review/ Harmonization	N/A	Support Trade Association coalition on the Rationale Implementation of Elemental Impurities	Miscellaneous support	2-Mar-22
105	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	Collaboration - USP	1-Mar-22
106	The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products	Scientific Affairs	Yes	This paper describes IPEC's position on the role of excipients when conducting N-nitrosamine nitrosamine) risk assessments for drug products.	IPEC Position Paper	1-Mar-22
107	Medicine Maker video/article on FDA Novel Excipient Review Pilot Program	Executive Committee	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 • How lack of novel excipients is holding back the potential of new therapeutic advances • Response to FDA program • Thoughts on future needs	Publication - Medicine Maker	26-Feb-22

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
108	Medicine Maker video/article on FDA Novel Excipient Review Pilot Program	Executive Committee	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 • How lack of novel excipients is holding back the potential of new therapeutic advances • Response to FDA program • Thoughts on future needs	Publication - Medicine Maker	26-Feb-22
109	Excipient World Conference & Expo 2022: Top Reasons to Attend	EW Large team	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	Webinar - EW	23-Feb-22
110	USP Response to GC <621> Chromatography	Compendial Review/ Harmonization	N/A	IA follow-up comments to USP in response to November 22 Letter regarding PF 47(6) General Chapter <621> Chromatography	Correspondence - USP	2-Feb-22
111	IPEC-Americas Journal of Excipients and Food Chemical	Executive Committee	N/A	IPEC-Americas sponsors and publishes a peer-reviewed quarterly journal related exclusively to excipients entitled "The Journal of Excipients and Food Chemicals".	Publication - JEFC	26-Jan-22
112	USP Response to GC <1083>	Excipient Qualification	N/A	IA follow-up comments to USP in response to November 22 Letter regarding PF 47(5) General Chapter <1083> Supplier Qualification	Correspondence - USP	21-Jan-22

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
113	IPEC Best Practices Guide for the Safety Evaluation of "Novel" Pharmaceutical Excipients	Scientific Affairs	N/A	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 - IPEC-Americas	20-Jan-22
114	Defining Excipient Composition	Quality by Design		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.	IPEC Infographic or video	16-Jan-22
115	IPEC-Americas 2021 Year in Review	Executive Committee	N/A	This infographic gives a high-level snapshot of our accomplishments in 2021.	IPEC Infographic or video	16-Jan-22
116	IPEC-Americas 2022 Year in Review	Executive Committee	N/A	This infographic gives a high-level snapshot of our accomplishments in 2021.	IPEC Infographic or video	16-Jan-22
117	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	Correspondence - USP	17-Dec-21
118	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	Correspondence - USP	17-Dec-21

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
119	DMF Infographic	Regulatory Affairs	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	IPEC Infographic or video	8-Dec-21
120	Excipient GMP Compliance Virtual Workshop	Good Manufacturing Practices	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 - IPEC-Americas LL	3-Dec-21
121	USP Comment on GC 312 Prospectus	Compendial Review/ Harmonization	N/A	IA comments to USP regarding General Chapter Prospectus: <312> MW of Alginates	Correspondence - USP	2-Dec-21
122	USP GC <2800> Multi Ingredient Dietary Supplements	Compendial Review/ Harmonization	N/A	Dietary Supplements should not utilize Excipients, (Food Additive) Response needed.	Correspondence - USP	1-Dec-21
123	Challenging the 'Status Quo' for Excipient Innovation in the Global Pharmaceutical Industry	Scientific Affairs	N/A	IPEC-Americas presentation at The Association for Chemistry and Economics- German Chemical Society, Germany, November 23, 2021	Industry presentation - Association for Chemistry and Economics	23-Nov-21

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
124	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 should send in comments on this proposal.	Correspondence - USP	22-Nov-21
125	Excipient GMP Certification Scheme and Certification Body Qualification	Good Manufacturing Practices	Yes	an overview for use and value of the recently published IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients.	Webinar - IPEC-Americas LL	18-Nov-21
126	Overview of Excipient Laws and Regulations in Europe	Regulatory Affairs	Yes	This webinar was intended to provide a road map for how the regulatory process in Europe works relative to the use of excipients.	Webinar - IPEC-Americas LL	16-Nov-21
127	ICH Continuous Manufacturing (Q13)	Quality by Design	Yes	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 comments	15-Nov-21
128	Overview of Excipient Laws and Regulations in US	Regulatory Affairs	Yes	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 - IPEC-Americas LL	4-Nov-21
129	Update IPEC-Americas Safety Guide	Scientific Affairs	TBD	Revise previous IPEC-Americas Guide, published in Regulatory Toxicology and Pharmacology, Volume 24, No. 2, October 1996.	IPEC Guide - New	4-Nov-21

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
130	Novel Excipient Review Pilot Program Overview and Q&A	Excipient World Academy	N/A	2021 EW Academy webinar	Webinar - EW Academy	27-Oct-21
131	USP Comment on GC 2760 Prospectus	Compendial Review/ Harmonization	N/A	IA comments to USP regarding General Chapter Prospectus: <2760> Impurities in Dietary Ingredients and Dietary Supplements	Correspondence - USP	22-Oct-21
132	PMDA general comments for G9-1-181 proposed FRC chapter	Compendial Review/ Harmonization	N/A	IA comments to PMDA regarding their proposed FRC chapter for the JP	Correspondence - PMDA	12-Oct-21
133	IPEC - Everything you need to know about excipients and more!	Executive Committee	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 for various IPEC guides and position papers	Presentation - SAFYBI	7-Oct-21
134	Docket No. FDA-2019-N-5464-0028 Center for Drug Evaluation and Research Office of New Drugs Novel Excipient Review Pilot Program	Regulatory Affairs	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	Docket comments	4-Oct-21
135	USP Comment on Monograph Sponsors	Compendial Review/ Harmonization	N/A	IA comments to USP regarding potential conflict of interest for an instrument mfg to sponsor a monograph specific to use of their anaytical equipment	Correspondence - USP	4-Oct-21
136	PharmTech article regarding FDA Novel Excipient Pilot Program	Executive Committee	N/A	PharmTech indusry interview of IA members regarding FDA Novel Excipient Review Pilot Program	Publication - Pharm Tech	30-Sep-21

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
137	PharmTech request for article on industry response to Pandemic	Executive Committee	N/A	PharmTech request for comment on an article how pharma responded during the Pandemic	Publication - Pharm Tech	30-Sep-21
138	EDQM letter related to proposed revision to the calcium acetate monographs	Compendial Review/ Harmonization	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	Correspondence - EDQM	29-Sep-21
139	Excipient Stability – Use of Expiration/ Re-evaluation Dates and Accelerated Stability	Excipient Qualification	N/A	2021 IPEC-Americas LL webinar	Webinar - IPEC-Americas LL	29-Sep-21
140	USP letter related to proposed IPA monograph revision bulletin	Compendial Review/ Harmonization	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	Correspondence - USP	24-Sep-21
141	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 9/30/21	Correspondence - EDQM	21-Sep-21

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
142	Upper Management Training	Good Manufacturing Practices	N/A	- Need for upper management 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	IPEC Infographic or video	16-Sep-21
143	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 alginates that requires specific controls.	Correspondence - USP	15-Sep-21
144	IPEC Good Distribution Practices Audit Guide	Good Manufacturing Practices	Yes	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 completion of the other guide. Prior to initiating work on this audit guide, IPEC- Americas will reach out to IPEC EU for feedback on need and to determine priority.	IPEC Guide - Revision	14-Sep-21

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
145	CPhI Annual Meeting educational pod cast	Scientific Affairs	N/A	CPHI Collaboration – Educational Programming/Pod Cast - Drug Safety and Quality. Potential topic TiO2	Presentation - CPhI	23-Aug-21
146	IPEC-Americas celebrates 30 years	Executive Committee	N/A	Article in Tablets & Capsules entitled “IPEC-Americas celebrates 30 years"	Publication - T&C	23-Aug-21
147	DPMH comments for Pediatric Drug Development Research Crowdsourcing	Regulatory Affairs	N/A	Submit comments to DPMH regarding FDA’s Pediatric Drug Development Research Crowdsourcing Challenge	Correspondence - FDA	20-Aug-21
148	Excipient World Conference & Expo: Top Reasons to Attend	Excipient World Academy	N/A	2021 EW webinar	Webinar - EW	18-Aug-21
149	Validation for Pharmaceutical Excipients Presented by The International Pharmaceutical Excipients Council	Good Manufacturing Practices	N/A	2021 IPEC-Americas LL webinar	Webinar - IPEC-Americas LL	21-Jul-21
150	CRS Annual Meeting presentation to promote new Safety Guide	Scientific Affairs	N/A	Develop presentation for on IPEC Safety Guide for CRS Annual Meeting (July 25-29, 2021).	Presentation - CPhI	17-Jul-21
151	Excipient World Conference & Expo: Top Reasons to Attend	Excipient World	N/A	2021 EW webinar	Webinar - EW	14-Jul-21
152	Excipient World Academy: Excipients & Upstream/Downstream Manufacturing Processes in Biologic Drug Products	Excipient World Academy	N/A	2021 EW Academy webinar	Webinar - EW Academy	30-Jun-21

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
153	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	Correspondence - EDQM	30-Jun-21
154	GDUFA II – IID Commitments	Regulatory Affairs	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	FDA - presentation	29-Jun-21
155	USP letter related to Maltodextrin	Compendial Review/ Harmonization	N/A	2/16/2021 - USP requested additional information, which is being gathered by member company (Perrigo)	Correspondence - USP	18-Jun-21
156	Excipient World Academy: The Importance of Excipient Functionality	Excipient World Academy	N/A	2021 EW Academy webinar	Webinar - EW Academy	9-Jun-21
157	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)	Workshop	31-May-21
158	USP Notice of Intent to revise the USP Isopropyl Alcohol monograph	Compendial Review/ Harmonization	N/A	Provide feedback to USP with regards to their notice of Intent to revise the USP Isopropyl Alcohol monograph	Correspondence - USP	27-May-21
159	ISPE-IPEC excipient QbD Guide training	Quality by Design	N/A	Partner with ISPE India to deliver training on the recent IPEC QbD guide on May 26.	Presentation - ISPE India	26-May-21

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
160	ICH Continuous Manufacturing (Q13)	Quality by Design	Yes	Brian C. to represent IPEC on ICH Q13 Working Group. He will provide updates/drafts from WG activities, as allowed.	Correspondence - ICH	18-May-21
161	Excipient World Academy: Innovations in Pharmaceutical Coating Development	Excipient World Academy		2021 EW Academy webinar	Webinar - EW Academy	12-May-21
162	FDA IPEC excipient QbD Guide training	Quality by Design	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.	Webinar Training - FDA	11-May-21
163	Recommendations for Responding to Requests from USP for Samples	Compendial Review/ Harmonization	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.	Member tool kit	7-May-21
164	Excipient GMP Compliance Virtual Workshop	Learning Lab	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 - IPEC-Americas LL	30-Apr-21
165	USP GSP GC Prospectus	Compendial Review/ Harmonization	N/A	Provide feedback to USP with regards to General Chapter <1xxx> Supplier Qualification Prospectus	Correspondence - USP	22-Apr-21
166	Excipient World Academy: Role of Excipients in Continuous Manufacturing of Solid Oral Dosage Forms	Excipient World Academy		2021 EW Academy webinar	Webinar - EW Academy	21-Apr-21

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
167	Docket No. FDA-2020-2016: Policy for Testing Alcohol (Ethanol) and Isopropyl alcohol for Methanol, Including During the Public Health Emergency (COVID-19)	Regulatory Affairs	N/A	Develop comments to Docket No. FDA -2020-D-2016.	Docket comments	16-Apr-21
168	USP letter relatd 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	Correspondence - USP	16-Apr-21
169	GDUFA II – II IID Commitments	Regulatory 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	FDA - presentation	1-Apr-21
170	USP letter related to Oleyl Oleate	Compendial Review/ Harmonization	N/A	Review proposed monograph revisions for Oleyl Oleate from PF 47(1) and provide feedback to USP	Correspondence - USP	30-Mar-21
171	USP letter related to USP GC<232> elemental impurity limits	Compendial Review/ Harmonization	N/A	Review proposed elemental Impurity limit revisions to UPS GC <232> from PF 47(1) and provide feedback to USP	Correspondence - USP	30-Mar-21
172	2020 Year end review	Executive Committee	N/A	2020 Year end review infographic	IPEC Infographic or video	22-Mar-21
173	SOT Annual Meeting Poster to promote new Safety Guide	Scientific Affairs	Yes	Develop poster for SOT Annual Meeting (March 2, 2021).	Presentation - SOT	18-Mar-21
174	Outsourced Phama article on IPEC QbD Guide	Quality by Design	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	Publication - Outsourced Pharma	10-Mar-21
175	USP endorsement of IFAC comments to USP GCs <2740>, <2800> and <2750>.	Compendial Review/ Harmonization	N/A	IPEC-Americas endorsement of IFAC's comments on proposed new GC <2740> and <2800> and proposed revision to GC <2750>	Correspondence - USP	10-Mar-21

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
176	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	Correspondence - USP	4-Mar-21
177	Outsourced Phama article on IPEC QbD Guide	Quality by Design	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	Publication - Outsourced Pharma	3-Mar-21
178	PharmTech article on Novel Excipient	Scientific Affairs	N/A	Nigel, Priscilla, Meera, Dave S, Kathy U, etc provided input to PharmTech entitled Novel Excipients Needed More Than Ever Before	Publication - Pharm Tech	2-Mar-21
179	Pharmaceutical Lactose used in oral preparations	IPEC Europe	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	IPEC Position Paper	1-Mar-21
180	GADA Meeting with CVM (FDA)	Regulatory Affairs	N/A	Deliver a presentation on CoAs during the GADA meeting with CVM	Presentation - GADA	25-Feb-21
181	Outsourced Phama article on IPEC QbD Guide	Quality by Design	N/A	Develop an article on the QbD Guide to be published as part of a CPhI Annual report. Publish as 3 part series in Outsource Pharma	Publication - Outsourced Pharma	24-Feb-21
182	Polysorbates Composition and Quality Stimuli Article PF 47(1)	Compendial Review/ Harmonization	N/A	• Biotech members may be interested • Share with CRC during Feb committee meetings	Correspondence - USP	24-Feb-21

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
183	Letter to editor of International Journal of Biological Macromolecules (IJBM) rebuttal letter	Scientific Affairs	N/A	Prepare a rebuttal letter to IJBM for article (Baran, Sulukan, Türkoğlu, et al., Is sodium carboxymethyl cellulose (CMC) really completely innocent? It may be triggering obesity, Volume 163, Pages 2465-2473). While scientifically robust, the article made claims that were not supported by their study data nor by the published literature nor by regulatory agency reviews	Publication - IJBM rebuttal	23-Feb-21
184	Microplastics Webinar Part 2 – Continued Issues and Impact on Pharmaceutical Products	Regulatory Affairs		2021 IPEC-Americas LL webinar	Webinar - IPEC-Americas LL	17-Feb-21
185	ICH Q13 update at IPEC Europe Excipient Forum	Quality by Design	N/A	Brian C. presented an update of the draft 2 ICH Q13 Guideline to the IPEC Europe Excipient Forum	Presentation - to IPEC Europe	4-Feb-21
186	ICH Continuous Manufacturing (Q13)	Quality by Design	Yes	Brian C. to represent IPEC on ICH Q13 Working Group. He will provide updates/drafts from WG activities, as allowed.	Correspondence - ICH	31-Jan-21
187	Incorporation of Pharmaceutical Excipients into a Quality-by-Design (QbD) Development Project	Quality by Design	N/A	2021 IPEC-Americas LL webinar	Webinar - IPEC-Americas LL	31-Jan-21
188	USP courtesy email notifying them of the PharmTech publication	Compendial Review/ Harmonization	N/A	send USP a courtesy email notifying them of the PharmTech Concomitant Component publication	Correspondence - USP	28-Jan-21

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
189	Pharmaceutical Technology follow-up series of articles	Quality by Design	N/A	Develop a series of 2 article to be published in Pharm Tech 1) Additives and process aids in pharmaceutical excipients 2) Concomitant components in pharmaceutical excipients	Publication - Pharm Tech	27-Jan-21
190	USP letter related to Maltodextrin	Compendial Review/ Harmonization	N/A	Review proposed revisions to Maltodextrin monograph and stimuli article from PF 46(6) and provide feedback to USP	Correspondence - USP	25-Jan-21
191	Notify USP of IPEC in-process work to revise base resource for USP <1074>	Compendial Review/ Harmonization	N/A	The IPEC-Americas 1996 article "A New Approach to the Safety Assessment of Pharmaceutical Excipients" was the basis for USP <1074> Chapter. With the current Safety Guide revision underway and with various new project being identified by USP, IPEC needs to make USP aware of our efforts to update the Guide.	Correspondence - USP	21-Jan-21
192	Options for excipient users to qualify excipient suppliers in lieu of an audit	Excipient Qualification	N/A	Develop a position paper to include options for excipient users to qualify their excipient suppliers when the supplier won't allow an audit and isn't certified to an excipient GMP standard.	IPEC Position Paper	14-Jan-21
193	Validation Guide	Good Manufacturing Practices	N/A	Develop IPEC GUIDE on Excipient Validation, including Equipment, Process, Product, Computer, Cleaning and Analytical Validation	IPEC Guide - New	14-Jan-21
194	IPEC General Glossary of Terms and Acronyms	Executive Committee	N/A	Revise and update the latest version of IPEC General Glossary of Terms and Acronyms	IPEC Guide - Revision	1-Jan-21

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
195	Qualification of Excipient Guide	Excipient Qualification	Yes	Revise and update the latest version of IPEC Excipient Qualification Guide	IPEC Guide - New	15-Dec-20
196	Efficient and Effective Virtual Audits	Excipient Qualification	N/A	Develop a Webinar on Efficient and Effective Virtual Audits. It is critical to develop/deliver now with the current issues with on-site audits due to COVID-19	Webinar - IPEC-Americas	10-Dec-20
197	Sustainability and Responsible Sourcing	Excipient Qualification	Yes	Develop and submit a charter (IA XC and Federation) to add a fourth section to the EIP Guide covering sustainability and responsible sourcing.	New project charter	10-Dec-20
198	USP request to change definition of excipient starting material	Excipient Qualification	N/A	USP requested to change the definition for excipient starting material to: Starting Material: A raw material, intermediate, or an excipient, defined as the starting point for excipient GMPs and used in the production of an excipient that is incorporated as a significant structural fragment or that is purified to meet the quality requirement for an excipient.	Correspondence - USP	10-Dec-20
199	USP comments regarding PF_46_5_NaCMC	Compendial Review/ Harmonization	N/A	Review proposed revisions to NaCMC monograph and stimuli article from PF 46(5) and provide feedback to USP	Correspondence - USP	8-Dec-20
200	USP comments regarding GC <1469> Nitrosamines	Regulatory Affairs	N/A	Develop comments to the USP proposed <1469> Nitrosamine Impurities general chapter	Correspondence - USP	3-Dec-20

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
201	USP comments regarding PF_46_5_Lactose	Compendial Review/ Harmonization	N/A	Review proposed revisions to lactose monograph and stimuli article from PF 46(5) and provide feedback to USP	Correspondence - USP	30-Nov-20
202	USP's response to comments from Stimuli Article "The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities"	Compendial Review/ Harmonization	N/A	IPEC to draft a response to USP's response to comments received for their Stimuli Article "The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities" IPEC-Americas believes there is a significant disconnect between the Expert Committee responses and the IPEC-Americas position.	Correspondence - USP	30-Nov-20
203	IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients	Good Manufacturing Practices	N/A	Provide an overview of the soon-to-be-published IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients.	Webinar - IPEC-Americas - FREE	17-Nov-20
204	IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients	Good Manufacturing Practices	N/A	Develop a guide that pharmaceutical companies can utilize to qualify Certification Bodies involved in third-party excipient GMP certification. This will further accelerate demand for excipient GMP certification audit reports from Certificate Holders.	IPEC Guide - New	12-Nov-20

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
205	Develop PQRI Workshop on Elemental Impurity	Quality by Design	N/A	PQRI workshop proposal for follow-up workshop on Elemental Impurities 1) how can we utilize results coming out of the phase 2 study 2) review how implementation of ICH Q3D is going	Workshop	10-Nov-20
206	ICH Q3D Industry Perspective and Consequences	Quality by Design	N/A	Dale Carter - PQRI Workshop presentation	Workshop presentation	9-Nov-20
207	Guideline on Incorporation of Excipients and Excipient Variability into QbD	Quality by Design	TBD	Develop IPEC GUIDE on QbD Excipients and Excipient Variability	IPEC Guide - New	3-Nov-20
208	Letter to editor of SCIENCE for article entitled "activities of drug inactive ingredients on biological targets"	Scientific Affairs	N/A	Prepare two letters to Science to refute the way that excipients were positioned in the article entitled "activities of drug inactive ingredients on biological targets" Copy FDA on rebuttal lettter	Correspondence - SCIENCE and FDA	3-Nov-20
209	Sustainability and Responsible Sourcing	Excipient Qualification	N/A	Develop and submit a charter (IA XC and Federation) to add a fourth section to the EIP Guide covering sustainability and responsible sourcing.	New project charter	1-Nov-20
210	USP comments regarding the USP Elemental Impurity roadmap	Compendial Review/ Harmonization	N/A	Determination of how to move forward with elemental specific chapters in USP-NF post <232> and <233> implementation	Correspondence - USP	26-Oct-20
211	Excipient compliance workshop	Good Manufacturing Practices	N/A	Excipient GMP Compliance Virtual Workshop, October 18-23, 2020	Workshop	18-Oct-20
212	Regulatory Requirements for Excipients used in Drugs for the India Market	Regulatory Affairs	N/A	IPEC-Americas webinar to highlight excipient regulatory requirements in India	Webinar - IPEC-Americas LL	13-Oct-20

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
213	CPhI Annual Report article on IPEC QbD Guide and launch	Quality by Design	N/A	Prepare and submit an article to CPhI for publication in their 2020 Annual Report	Publication - CPhI	12-Oct-20
214	Data Integrity	Good Manufacturing Practices	Yes	Position paper on data integrity expectations for excipient manufacturers. This is being addressed by the Federation, but the committee should stay informed and monitor that project.	IPEC Position Paper	1-Oct-20
215	Guide Navigation Resource	Good Manufacturing Practices	Yes	There are several differences between the EXCiPACT and ANSI Standards and with the IPEC-PQG GMP Guide. Work will be done to resolve differences and move towards harmonization. For now, this project is being implemented to provide members and non-members a resource to navigate the various approaches. This could be through webinars, Insider articles, white papers, etc.	IPEC White-Paper	1-Oct-20
216	Rebuttal letter to SCIENCE for article entitled "activities of drug inactive ingredients on biological targets"	Scientific Affairs	N/A	Prepare two letters to Science to refute the way that excipients were positioned in the article entitled "activities of drug inactive ingredients on biological targets"	Publication - Science	29-Sep-20
217	Vision for FDA's Inactive Ingredient Database in 2020 and Beyond	Excipient World	N/A	Excipient World webinar designed to desribe upcoming changes to US FDA IID along with how these changes will affect excipient suppliers and drug product applicants. Susan Zuk	Webinar - EW	16-Sep-20

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
218	FDA letter to Susan Zuk pertaining to Continuing issues/concerns with July 2020 posting of the IID	Regulatory Affairs	N/A	Develop and send IPEC-Americas letter to FDA regarding continuing IID issues	Correspondence - FDA	2-Sep-20
219	ECHA open comments for SEAC opinion on microplastics	Regulatory Affairs	N/A	Submit electronic comments to ECHA endorsing comments prepared and submitted by CEFIC	Correspondence - ECHA	1-Sep-20
220	Good Distribution practices and buyig through distribution	Good Manufacturing Practices	N/A	IPEC-Americas webinar to describe the who, what, when, where, how and why of excipient distributors.	Webinar - IPEC-Americas	26-Aug-20
221	Silicon Dioxide Round Robin Study-IPEC Federation	Compendial Review/ Harmonization	Yes	Independent labs perform round robin testing of various forms/sources of silicon dioxide	Project - USP	26-Aug-20
222	Docket No. FDA-2020-N-1459: Generic Drug User Fee Amendments	Regulatory Affairs	N/A	Prepare and submit comments to Docket No. FDA-2020-N-1459: Generic Drug User Fee Amendments	Docket comments	20-Aug-20
223	USP and FDA Response to Alcohol_NITR_7	Compendial Review/ Harmonization	N/A	It is important to make a distinction between impurities and concomitant components in excipients as it relates to the proposed USP Sucrose revision in PF 46(4) published July 1, 2020	Correspondence - USP	13-Aug-20
224	USP and FDA Response to Alcohol_NITR_7	Compendial Review/ Harmonization	N/A	Prepare comments/response to the USP recently published Notice of Intent to Revise (NITR), pertaining to a proposed upcoming accelerated revision to the USP Alcohol and Dehydrated Alcohol monographs	Correspondence - USP and FDA	12-Aug-20
225	FDA follow-up letter pertaining to Docket No. FDA-2019-N-5464-0001: Novel Excipient Review Program Proposal	Regulatory Affairs	N/A	Partner with IQ to prepare and send a follow-up letter to FDA pertaining to Docket No. FDA-2019-N-5464-0001: Novel Excipient Review Program Proposal	Docket comments	27-Jul-20

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
226	CHPA - Impurities in Excipients	Quality by Design	N/A	Priscilla Zawislak - CHPA Meeting presentation	Industry presentation - CHPA	23-Jul-20
227	GADA - Excipient Perspective on Elemental Impurities Excipient Qualification Initiatives	Regulatory Affairs	N/A	Dave Schoneker, quarterly GADA meeting presentation	Industry presentation - GADA	22-Jul-20
228	Novel or Not? Our Inadvertent Journey Filing a Novel Excipient	Excipient World	N/A	Excipient World webinar to describe inherent complexities to effectively identifying, defining, and characterizing a novel excipient. Kara Quinn	Webinar - EW	22-Jul-20
229	FDA Comments from IPEC-Americas at GDUFA reauthorization public meeting	Regulatory Affairs	N/A	Prepare and present proposal from IPEC-Americas for consideration during GDUFA III Negotiation	Presentation - FDA	21-Jul-20
230	Toxicology for the 21st Century: What is in the Box for Excipients?	Excipient World	N/A	Excipient World webinar to discuss revolutionary changes in how we predict human safety by assessing biological effects of chemicals in novel ways independent from the limitations associated with traditional animal-based toxicology. Dr. Thomas Hartung	Webinar - EW	8-Jul-20
231	CRS - The Need for Novel Excipient Innovation in Drug Development	Scientific Affairs	N/A	Nigel Langley, Annual CRS meeting presentation	Industry presentation - CRS	29-Jun-20
232	EDQM comments regarding Sucrose Pharmeuropa 32.2 (Reference: PA/PH/Exp. CRB/T (19) 32 ANP)	Compendial Review/ Harmonization	TBD	It is important to make a distinction between impurities and concomitant components in excipients as it relates to the proposed EDQM Sucrose revision in Pharmeuropa 32.2	Correspondence - EDQM	25-Jun-20

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
233	Key new IPEC Position Papers and Guides: What you need to know!	Excipient Qualification & Good Manufacturing Practices	N/A	IPEC-Americas webinar to highlight key position papers and guides	Webinar - IPEC-Americas - FREE	23-Jun-20
234	Clinical Relevance: Why are Enteric Coatings Failing In Vivo?	Excipient World	N/A	Excipient World webinar designed to help participants understand the underlying science behind the unpredictable in vivo performance of enteric coated formulations. Daniela Amaral Silva, PhD Candidate, University of Alberta	Webinar - EW	17-Jun-20
235	USP 1195 Proposal to modify IPEC glossary definition for excipient starting material	Excipient Qualification	N/A	Update the 2005 USP GC for Excipient Significant Change (USP <1195>) update changes <1195> to match the current 2014 IPEC Significant Change Guide	Correspondence - USP	13-Jun-20
236	Excipient Information Package	Excipient Qualification	Yes	Revise 2012 EIP guide and develop new version.	IPEC Guide - Revision	4-Jun-20
237	Update 2009 Composition Guide	Quality by Design	TBD	Update 2009 Composition Guide to reflect current analytical capabilities?	IPEC Guide - Revision	4-Jun-20
238	Ph. Eur. Nitrosamines proposal for 2034	Scientific Affairs	Yes	Subcommittee to develop comments and submit to Ph. Eur. before March31, 2020 deadline	Correspondence - EDQM	2-Jun-20
239	CDE Provisions on Review and Approval of APIs, Pharmaceutical Excipients and Package Materials	Regulatory Affairs	Yes	Prepare and submit Federation comments to CDE regarding review and approval of API, excipient and packaging materilas	Correspondence - CDE	29-May-20
240	Regulatory Requirements for Excipients used in Drugs for the China Market	Regulatory Affairs	N/A	IPEC-Americas webinar to highlight excipient regulatory requirements in China	Webinar - IPEC-Americas	20-May-20

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
241	USP letter regarding USP extentions due to restrictions resulting from issues with Covid-19	Compendial Review/ Harmonization	N/A	Prepare and submit letter to USP regarding extentions due to restrictions resulting from issues with Covid-19	Correspondence - USP	28-Apr-20
242	USP comments related to Maltol monograph	Compendial Review/ Harmonization	N/A	It is important to make a distinction between impurities and concomitant components in excipients as it relates to the proposed USP revision in PF 46(2)	Correspondence - USP	23-Apr-20
243	The Importance of Excipients in Continuous Manufacturing	Quality by Design	N/A	IPEC-Americas webinar to discuss the impact of excpients in continuous manufacturig of drug products	Webinar - IPEC-Americas	22-Apr-20
244	Letter to Janet Woodcock at FDA RE Updates to the FDA Inactive Ingredients Database	Regulatory Affairs	IPEC-Americas comments to Janet Woodcock regaring continued IID issues	Develop and send Letter to FDA regarding continued IID	Correspondence - FDA	16-Apr-20
245	Untangling the confusion about what excipient suppliers and users need to know about nitrosamines and excipients	Regulatory Affairs	N/A	IPEC-Americas webinar to define supplier comments for the IPEC-Americas nitrosamine template and user overview for how the information can be used to support questions being raised by regulatory authorities	Webinar - IPEC-Americas	7-Apr-20
246	Comparison of Requirements for Excipients, Food Additives etc.	Excipient Qualification	N/A	Develop a white-paper comparing the regulatory requirements for food additives vs excipients vs dietary supplement non dietary ingredients	IPEC White-Paper	2-Apr-20

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
247	EDQM comments regarding EDQM Application of 5.20 Elemental Impurities to update individual monographs Reference: 5.20. Elemental impurities.	Compendial Review/ Harmonization	N/A	EDQM comments regarding EDQM Application of 5.20 Elemental Impurities to update individual monographs Reference: 5.20. Elemental impurities.	Correspondence - EDQM	1-Apr-20
248	EDQM comments regarding Pharmeuropa 32.1 request for comments on revised general monograph. Substances for Pharmaceutical use (2034)	Compendial Review/ Harmonization	Yes	Prepre and submit Federation comments to EDQM regarding 32.1 request for comments on revised general monograph: Substances for Pharmaceutical use (2034)	Correspondence - EDQM	30-Mar-20
249	IPEC-PDA “model” of Quality Risk Management for Excipients	Excipient Qualification	N/A	IPEC-Americas webinar to provide an overview for the IPEC-PDA TR on quality risk management for excipients	Webinar - IPEC-Americas	25-Mar-20
250	Excipients: Compliance with Compendial and GMP Requirements Workshop	Good Manufacturing Practices	N/A	IPEC-Americas and the Center for Professional Development (March 19/20, 2020)	Workshop	19-Mar-20
251	Changes in the Global Excipient Quality and Regulatory Landscape	Executive Committee	N/A	IPEC-Americas/PDA Workshop ChP/China - Zawislak Risk Assessment - Janeen Excipient Composition - Schoneker High quality sucrose - Quinn TUPPs - Polito Novel Excipient - Langley Excipients for Biologics - Kabakoff	Workshop	4-Mar-20
252	Untangling the confusion about what excipient suppliers and users need to know about nitrosamines and excipients	Regulatory Affairs	N/A	IPEC-Americas webinar to define supplier comments for the IPEC-Americas nitrosamine template and user overview for how the information can be used to support questions being raised by regulatory authorities	Webinar - IPEC-Americas	3-Mar-20

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
253	Incorporation of Pharmaceutical Excipients into a Quality-by-Design (QbD) Development Project Guide	Quality by Design	N/A	Brian Carlin presentation at IFPAC Annual Meeting	Industry presentation - IFPAC	26-Feb-20
254	Docket No. FDA-2019-D-4447: Transdermal and Topical Delivery Systems—Product Development and Quality Considerations	Regulatory Affairs	N/A	Prepare and submit comments to open docket FDA-2019-D-4447-0001 Transdermal and Topical Delivery Systems - Product Development and Quality Considerations Guidance for Industry	Docket comments	21-Feb-20
255	Supplier-dependent excipient performance: Caveat Emptor!	Quality by Design	N/A	IPEC-Americas webinar to address the impact of multi-sourcing of excipients on the manufacture, quality, safety, and efficacy of drug products.	Webinar - IPEC-Americas	20-Feb-20
256	Animal Health Industry Association - outreach	Regulatory Affairs	N/A	Reach out to animal health (veterinary) trade associations for joint collaboration/membership.	Industry presentation - Animal Health	12-Feb-20
257	USP Call for Candidates and Volunteering at USP	Compendial Review/ Harmonization	N/A	co-sponsored by IPEC-Americas and USP. Hear current USP volunteer experts share their experience, and discuss new volunteer opportunities to contribute your expertise, network with skilled professionals in your industry & advance your career.	Webiar - joint IPEC -Americas/USP	29-Jan-20
258	Qualifying an Excipient Supplier; Alternatives to 2nd Party Site Audit	Good Manufacturing Practices	N/A	IPEC-Americas webinar to address what a pharmaceutical company should do when their excipient supplier won't allow an on-site audit.	Webinar - IPEC-Americas	22-Jan-20

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
259	Docket No. FDA-2019-N-5464-0001: Novel Excipient Review Program Proposal; Request for Information and Comments	Regulatory Affairs	N/A	Prepare and submit comments to open docket FDA-2019-N-5464 Novel Excipient Review Program Proposal; Request for Information and Comments	Docket comments	14-Jan-20
260	USP request for response to PF comments for <1195> Sig Change	Compendial Review/ Harmonization	N/A	USP letter regarding Feedback for Comments Submitted via the Pharmacopeial Forum for the Proposed Revision of <1195> Significant Change Guide for Bulk Pharmaceutical Excipients	Correspondence - USP	13-Jan-20
261	Develop IPEC-Americas white paper on Nitrosamine	Regulatory Affairs	N/A	Review and develop IPEC-Americas strategy for responding to nitrosamines		18-Dec-19
262	IPEC-Americas comments to FDA on DMF Guidance	Regulatory Affairs	N/A	Prepare and submit comments to open FDA 2019-D-3989: Draft Drug Master Files Guidance for Industry		18-Dec-19
263	IPEC-Americas comments to FDA on open docket for assessing user fees under GDUFA 2017	Regulatory Affairs	N/A	Prepare and submit comments to open docket FDA-2012-D-0880: Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 Draft Guidance		18-Dec-19
264	IPEC-PDA Risk Assessment Guide	Excipient Qualification	Yes	Part 2 of the Risk Assessment Guide targeted for users (e.g. pharma manufacturers)		18-Dec-19
265	ANVISA draft regulation on supplier assessment	Excipient Qualification	N/A	Develop IA comments to ANVISA public consultation CP No. 689, OF AUGUST 12, 2019 on supplier assessment -		11-Dec-19
266	IPEC-Americas comments to FDA on open IID docket	Regulatory Affairs	N/A	Prepare and submit comments to open FDA Draft Guidance on Using IID		10-Dec-19

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
267	IPEC-Americas follow-up with FDA on meeting requests	Regulatory Affairs		Prepare and Submit letter highlighting list of current issues that require collaboration/input from FDA to Lyndsay Hennessey Janet Woodcock.		10-Dec-19
268	USP draft Resolutions 2020-2025	Compendial Review/ Harmonization	N/A	Develop and submit excipient resolution proposals to USP for 2020-2015 cycle. Represent IPEC-Americas as USP Convention		8-Oct-19
269	2019 Joint meeting with ChP and IPEC to collaborate on joint review process	Regulatory Affairs		Joint ChP-IPEC meeting to discuss joint review process in China and how to build in more flexibility.		24-Sep-19
270	IA presentation at Xavier Combination Products Summit	Regulatory Affairs	N/A	Meera Raghuram to speak on the topic of "Successful Practices and Challenges for Supplier Partnering."		24-Sep-19
271	IA-CSPS Joint Excipient workshop	Regulatory Affairs	N/A	IA to jointly sponsor an excipient workshop in Canada with CSPS		24-Sep-19
272	IPEC-Americas comments to FDA on open USP Pending Monograph docket	Regulatory Affairs	N/A	Prepare and submitt comments to open FDA Draft Guidance on Harmonizing Compendial Standards with Drug Application Approval Using the USP Pending Monograph Process		24-Sep-19
273	IPEC-Americas presentation at EXPOFYBI 2019	Regulatory Affairs	N/A	Represent IPEC-Americas with excipient presentations at EXPOFYBI Conference in Buenos Aires (September 10-13, 2019).		24-Sep-19
274	REACH Microplastics comments	Regulatory Affairs	IA + IE	IA to collaborate with EFPIA and IPEC Europe to develop additional comments to submit to ECHA		24-Sep-19
275	Emerging regulations, business continuity planning	Regulatory Affairs	Yes	2019 RA Committee meeting proposed project 2. …. This may be a joint project with other committee(s) and possibly Rx-360		7-Jun-19

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
276	DMF FAQ	Regulatory Affairs	N/A	IPEC-Americas to prepare an FAQ to supplement the IPEC-Americas US DMF Guide for Pharmaceutical Excipients that issued in May. Use questions from July 2018 DMF Webinar as foundation for FAQ questions		29-May-19
277	Excipient elemental Impurity requests from FDA reviewers	Compendial Review/ Harmonization	N/A	Many Companies are receiving customers letters indicating errors from FDA and requesting 3 batches of excipient data and validation method/report from excipient suppliers. Most requests from global drug companies in India where Risk Assessments are insufficient. Tim McGovern (FDA) is the ICH raptor. There is a need to discuss with him the problem IPEC is seeing.		29-May-19
278	Microplastics Implications for Medicinal Products/Excipients	Regulatory Affairs		1) IPEC-Americas to develop a "Microplastics" industry statement/position paper 2) IPEC-Americas to work with IPEC Europe and/or Federation to develop IPEC comments to REACH proposal (comment period to start April 1).		29-May-19
279	Quality Considerations for Continuous Manufacturing	Quality by Design	N/A	Docket No. FDA-2019-D-0298 Quality Considerations for Continuous Manufacturing		29-May-19

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
280	USP Continuous Manufacturing Stimuli Article	Quality by Design	N/A	Review USP (Pharmacopeial) Perspective for Pharmaceutical Continuous Manufacturing Stimuli Article and provide feedback from IPEC-Americas		29-May-19
281	2019 Excipient World Continuous Manufacturing Workshop	Quality by Design	N/A	Conduct a workshop at EW on Continuous Manufacturing with a focus on material (excipient) needs designed for purpose of CM		22-May-19
282	Request meeting with FDA to discuss urgent Elemental Impurity issues	Regulatory Affairs		Some FDA reviewers are sending out INCORRECT responses to drug sponsors directing them to acquire excipient elemental impurity information from their excipient suppliers		25-Mar-19
283	DRAFT Elemental Impurities in Human Drug Products Question and Answers	Regulatory Affairs	N/A	Consistent with FDA transparency initiative and Good Guidance Practices, FDA will consider stakeholder input and suggestions for guidance development. IPEC-Americas to draft and submit an elemental impurity FAQ for and drug products and submit to FDA to consider as a guidance development.		22-Mar-19
284	ChP comments on 2020 GC on Genotoxic Impurities	Safety	Yes	IPEC to prepare and submit comments to ChP on their 2020 GC on Genotoxic Impurities		21-Mar-19
285	Identifying the Root Causes of Drug Shortages and Findings	Regulatory Affairs	N/A	Prepare and submit IPEC-Americas comments to docket entitled "Identifying the Root Causes of Drug Shortages and Findings		8-Mar-19

Committee Accomplishments

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
286	Complexity of Setting Specifications for Excipient Composition and Impurities	Quality by Design	N/A	Prepare and deliver presentations on this topic at USP Stakeholder forums and AAPS Rapid Fire Session		14-Dec-18
287	USP Stimuli article The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities	Compendial Review/ Harmonization	N/A	Prepare a response to USP Stimuli article		14-Dec-18
288	Accreditation and Certification Distinctions	Good Manufacturing Practices	N/A	Develop and post a position paper on Accreditation and Certification Distinctions		11-Dec-18
289	FDA Guidance Development proposal for excipient DMFs	Regulatory Affairs	N/A	Consistent with FDA transparency initiative and Good Guidance Practices, FDA will consider stakeholder input and suggestions for guidance development. IPEC will consider submitting IPEC guides on relevant topics for guidance document development.		5-Dec-18
290	Gluten Rebuttal to Journal Commentary	Regulatory Affairs	N/A	IPEC Comments based on Journal Commentary entitled "Making all Medications Gluten Free"		5-Dec-18
291	China Guideline for Applicability Study of Pharmaceutical Excipients	Regulatory Affairs	Yes	Provide IA comments to Federation pertaining to DRAF China Guideline. Federation to consolidate/translate PEC comments and submit to ChP by Nov 15 2018.		13-Nov-18
292	China proposed guideline for Production of Control Quality of Animal Derived Pharmaceutical Excipients	Regulatory Affairs	N/A	Provide IA comments to Federation pertaining to DRAF China Guideline. Federation to consolidate/translate PEC comments and submit to ChP by Nov 15 2018.		4-Nov-18

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
293	Training for the new USP on-line platform	Compendial Review/ Harmonization	N/A	Provide training to IPEC-Americas member on the "new on-line USP plaform"		30-Oct-18
294	Letter to FDA regarding compounding pharmacies	Regulatory Affairs	N/A	Prepare and submit LATE comments to docket FDA-2018-D-1067-0002 for Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry. Copy FDA (e.g. Lyndsay Hennessee) to try and get meeting.		18-Oct-18
295	China ChP Safety Evaluation comments	Regulatory Affairs	Yes	Review and comment on ChP No. 361 Letter on Soliciting Opinions on the Guiding Principles of the Evaluation Methods for Biosafety of Pharmaceutical Excipients		4-Oct-18
296	How to Create a Bi-Pec Guide	Excipient Qualification	Yes	Develop a process on “best practices/lessons learned/policy” on how to create a “Bi-PEC” guide. Included will be a discussion around how to communicate that a commenting period is over.		3-Oct-18
297	Rx-360 Supplier Assessment Questionnaire	Excipient Qualification	N/A	Work with Rx-360 to revise references to excipients in the Supplier Assessment Questionnaire		3-Oct-18
298	FDA guidance on Elemental Impurities	Compendial Review/ Harmonization	N/A	Waiting on Final FDA guidance		7-Aug-18
299	USP Excipient Nomenclature Workshop	Regulatory Affairs	No	Support planning and content of USP workshop entitled "What's in a Name?" Impact of Nomenclature on Excipient Quality, Drug Product Development and Labeling Compliance"		7-Aug-18

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
300	USP appeal request to postpone USP 41-NF 36 Supplement 2	Regulatory Affairs	No	Submit appeal letter to USP to postpone USP 41-NF 36 Supplement 2, GC <467> Residual Solvents from becoming official		1-Aug-18
301	IA comments on second draft of Nomenclature of pharmaceutical Excipients in China	Regulatory Affairs	Yes	Review and comment on V2 of China Nomenclature of Pharmaceutical Excipients published by CPC on May 30, 2018		20-Jul-18
302	USP Veterinary Workshop	Regulatory Affairs	No	Provide Animal Health (veterinary) community with an overview of the importance of excipients used in animal health drugs		19-Jul-18
303	DMF Guide webinar	Regulatory Affairs	No	Develop and deliver free DMF Guide webinar		18-Jul-18
304	Prepare and submit comments to USP on PF 44(3) Stimuli Article	Quality by Design	No	Reviewed and provide comments from IPEC-Americas USP excipient stimuli article from PF 44(3).		17-Jul-18
305	USP appeal request to remove UNII codes from NF monographs	Regulatory Affairs	No	Submit a request for an appeal to USP for removal of UNII Codes from USP-NF excipient monographs		9-Jul-18
306	Third-part Excipient GMP Certification article	User Network	No	Develop and publish an article on importance of Third-Party Accredited Excipient GMP Audits		28-Jun-18
307	IA comments on Dossier requirement on excipient registration in China	Regulatory Affairs	Yes	Review and prepare comments for CDE "Annex 1 Requirement on the Registration Documentation for Pharmaceutical Excipient - Draft" published June 6, 2018		21-Jun-18

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
308	Revision of IPEC DMF guide	Regulatory Affairs	N/A	A sub team has been created to work on the new guide and many conference calls have been held. A phased approach is being used where the first phase will include the US DMF requirements. Additional phases to the guide will include global registration schemes.		21-May-18
309	Additives found in excipients	Excipient Composition	No	Develop and share with FDA a list of additives commonly found in excipients		6-Apr-18
310	Co-processed Excipient Guide	Excipient Composition	BiPEC	create a new IPEC Guide pertaining to co-processed excipients		6-Apr-18
311	IPEC-Americas Presentation at GDUFA Regulatory Science Research	Regulatory Affairs	No	IPEC comments on future of excipients research, novel excipients and collaboration		6-Apr-18
312	Docket No. FDA-2017-D-6352-0001: Gluten in Drug Products and Associated Labeling Recommendations Guidance for Industry.	Regulatory Affairs	No	Provide comments to docket pertaining to Gluten in Drug Products and Associated Labeling Recommendations Guidance for Industry		19-Mar-18
313	Accredited Certification Position Paper	Quality by Design		Falsified IPEC GMP Certificates have been observed by members which appear to originate from the FDA. It is known that the US FDA does not issue any IPEC GMP certifications. Therefore, it would be beneficial if an official statement from the FDA on this matter could be issued.		6-Mar-18

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
314	Docket No. FDA-2017-D-6854: Good ANDA Submission Practices Guidance for Industry	Regulatory Affairs	No	Provide comments to docket pertaining to Good ANDA Submission Practices related to expectations for atypical actives covered under Section V and inactive ingredients covered under subsection B “Drug Product.”		5-Mar-18
315	Guidance on User Communication with Suppliers (FOR THE PARKING LOT)	Excipient Qualification	No	A guide/stimuli article or addition to the EIP guide which would discuss the communication between users and suppliers/makers. It would detail / describe which type of information should be shared between the two.		21-Feb-18
316	Quality Agreement Guide	Excipient Qualification	Yes	Revise 2009 Quality Agreement and develop new version		21-Feb-18
317	Docket No. FDA-2017-D-0759-0002: Drug Products, Including Biological Products, that Contain Nanomaterials - Guidance for Industry	Regulatory Affairs	No	Reviewed Draft Guidance and requested 1) further clarification, definition and use of terminology and references 2) harmonization of nanomaterial dimensions and terminology 3) acknowledgment that most excipients do NOT contain nanoparticles 4) exclusion for “common excipients (containing a portion of nanoparticles)” with historical precedence of safe use.		12-Jan-18

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
318	Docket No. FDA-2017-N-5092 for Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirements	Regulatory Affairs	No	Provide comments to docket (FDA-2017-N-5101) established by FDA seeking comments from interested parties to help FDA identify existing CBER regulations and related paperwork requirements that could be modified, repealed, or replaced.		6-Dec-17
319	Docket No. FDA-2017-N-5094 for "Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements.	Regulatory Affairs	No	Provide comments to docket (FDA-2017-N-5094) established by FDA seeking comments from interested parties to help FDA identify existing FSMA regulations and related paperwork requirements that could be modified, repealed, or replaced.		6-Dec-17
320	Docket No. FDA-2017-N-5101 for Review of Existing Center for Drug Evaluation and Research Regulatory and Information Collection Requirements	Regulatory Affairs	No	Provide comments to docket (FDA-2017-N-5092) established by FDA seeking comments from interested parties to help FDA identify existing CDER regulations and related paperwork requirements that could be modified, repealed, or replaced.		6-Dec-17
321	Docket No. FDA-2017-D-5846-0002: ANDA Submissions — Refuse-to-Receive Standards: Questions and Answers	Regulatory Affairs	No	IPEC-Americas reviewed the draft guidance titled, "ANDA Submissions — Refuse-to-Receive Standards Guidance: Questions and Answers and voiced strong concerns related to inactive ingredients.		4-Dec-17

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
322	Docket No. FDA-2017-N-2697 Continuous Manufacturing	Quality by Design	No	IPEC-Americas has reviewed the public docket titled, “Developing Continuous Manufacturing of Solid Dosage Products in Pharmaceutical Manufacturing,”		20-Sep-17
323	ANSI cGMP for Pharmaceutical Excipient Standard	Good Manufacturing Practices	Yes	Develop ANSI Pharmaceutical Excipient Standard		7-Jun-17
324	Article or position paper to clarify this misuse of the TUPPs guideline	Good Manufacturing Practices		There are companies misusing the TUPPS guidance for poor GMPs. Credibility of guide is questioned because of misuse. May expand guide to include “what occurs when you have an equipment failure that results in TUPPs?” Consider rewriting guide, further educating membership of the correct usage and interpretation of the TUPPs and ensuring companies have done due diligence to remove TUPPs and only when unsuccessful, deem them “unavoidable.”		7-Jun-17
325	Bi-PEC/IPEC Glossary of Terms	Excipient Qualification		review and update current 2010 IPEC-Americas Glossary and work with other PECs to make it global		7-Jun-17
326	Emerging Publications	Safety	N/A	Collect current and emerging publications, presentation, etc. on Nano-technology/Nano-materials, develop reference list and library of documents.		7-Jun-17
327	Excipient Certification Program (ECP)	Good Manufacturing Practices	Yes	Develop a paper for circulation or inclusion into the IPEC Insider to help excipient manufacturers "sell" the IPEC Certification internally.		7-Jun-17

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
328	FDASIA Atypical Actives on-going activities	Good Manufacturing Practices	Yes	work with FDASIA subcommittee to be prepared for potential meeting with FDA		7-Jun-17
329	IPEC Global Risk Assessment Strategy (RAT - Risk Assessment Team)-Part 1	Excipient Qualification	Yes	1. The initial intent was to develop a comprehensive risk assessment guide with sections covering risk assessment by excipient manufacturer (ANSI GMP and EXCiPACT), excipient user (EU FMD and others) and atypical actives. The intent now is to publish the guide in phases similar to the excipient composition guide. There is an urgent need to publish the ANSI risk assessment section and the goal is to publish it by the end of the year. IPEC Europe has already published the FMD risk guide in March 2016. 2. The phased approach to the risk assessment guide using the EQ guide as a model is as follows: I. Phase I (risk assessment for excipient maker) ii. Phase 2 (risk assessment for excipient user) iii. Phase 3 is the risk assessment required for atypical actives iv. Final phase is to bring this all together		7-Jun-17
330	IPEC Good Distribution Practices Guide update	Good Manufacturing Practices	Yes	2017 revision to the IPEC GDP Guide		7-Jun-17

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
331	Revised IPEC-PQG Excipient GMP Guide	Good Manufacturing Practices	Yes	Rewrite IPEC/PQG GMP Guide with updated information from ANSI Excipient GMP standard		7-Jun-17
332	Revisit of Stability Position Paper	Good Manufacturing Practices	Yes	Need to do more related to getting stopping the request for accelerated and “extreme” stability testing. The lack of this data is stopping product from being received in some countries and could be considered a trade barrier. It is recommended that this be take to the US Dept. of Commerce as a trade barrier.		7-Jun-17
333	Significant Change Guide	Excipient Qualification	Yes	Revise and update the 2009 version of IPEC Significant Change Guide.		7-Jun-17
334	IPEC-Americas Response to FDA Quality Metrics Guide	Regulatory Affairs		FDA issued their second DRAFT Quality Metrics Guidance		22-Mar-17
335	EMA guidance on Elemental Impurities	Compendial Review/ Harmonization		EMA Issued Final Guidance. Discussion at the June CRC meeting		20-Mar-17
336	Excipient eCTD DMF strategy for discounted conversion and submission services	Regulatory Affairs		Ongoing discussions with various suppliers and vendors on available "discounted" eCTD support available for excipient DMF holders		13-Mar-17
337	IPEC DMF Position Paper	Regulatory Affairs	No	RA committee reviewed and worked on the DMF position paper. It was approved for submission to XC in December 2016 and was approved and posted in January 2017.		13-Mar-17

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
338	Over-the-Counter Monograph User Fees: Public Meeting Friday, June 10, 2016, from 9 a.m. to 5 p.m. EDT	Regulatory Affairs		Public meeting on proposed user fees for OTC monographs (https://www.federalregister.gov/articles/2016/05/11/2016-11098/over-the-counter-monograph-user-fees-public-meeting-request-for-comments).		13-Mar-17
339	Preparation of US excipient Regulatory process flow chart	Regulatory Affairs		Description of how the regulatory produces works in the US for IPEC China		13-Mar-17
340	Response to FDA regarding family approach and IID issues	Regulatory Affairs		Response to FDA on their letter regarding IID issues, novel excipient and family approach		13-Mar-17
341	QbD Sample Guide	Quality by Design		QbD Sampling Guideline - User and supplier sections to be merged		6-Dec-16
342	WHO - Good Pharmacopoeial Practices Guide	Compendial Review/ Harmonization				1-Dec-16
343	2016 GDUFA Regulatory Science Initiatives Part 15 Public Meeting - May 20, 2016	Regulatory Affairs		Comments on the need for Science and Risk-based Excipient Safety Assessment during generic drug review – Impact on formulation quality and performance		6-Jun-16
344	Final Controlled Correspondence guidance issued by FDA	Regulatory Affairs		Requires review and team discussion on next steps and possibly approaching the agency to suggest alternate ways that excipient industry can submit information regarding IID and other relevant issues.		6-Jun-16
345	Health Canada request for comments on “Draft Guidance Document: Master Files (MFs) - Procedures and Administrative Requirements”.	Regulatory Affairs		IPEC-Americas to prepare a response to this document in time for Health Canada’s deadline of 14-Apr-2016.		6-Apr-16

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
346	Docket No. FDA-2015-21149: Request for Quality Metrics; Notice of Draft Guidance Availability and Public Meeting Public Docket http://www.regulations.gov/#!documentDetail;D=FDA-2015-D-2537-0015			need to prepare and submit comments to FDA with regards to their DRAFT Quality Metrics Guidance as it potentially impacts pharmaceutical excipients		2-Nov-15
347	FDA Final Refuse to Receive Guidance	Regulatory Affairs		IPEC Americas comments submitted to docket No. FDA-2013-D1120: ANDA Submissions — Final Guidance for Industry: Refuse-to-Receive Standards.		15-Oct-15
348	FDA guidance on providing regulatory submissions using eCTD specifications	Regulatory Affairs		Team review indicated that excipient DMFs will need to be submitted in eCTD format from May 2017 onwards. This was a change from the FDA draft guidance which excluded excipient DMFs.		15-Oct-15
349	FDA PDF Specs Guidance issued	Regulatory Affairs		Revision of IPEC Americas Position Paper on PDF specs issued in 2014.		15-Oct-15
350	IPEC Americas Position Paper	Regulatory Affairs		Position paper on IID status, critical issues and next steps		15-Oct-15
351	IPEC Americas written comments on open FDA Docket on July 2015 PDUFA public meeting	Regulatory Affairs		IPEC Americas written comments to docket No FDA-2010-N-0128.		15-Oct-15
352	IPEC Americas written comments to open FDA Docket on June 2015 GDUFA public meeting	Regulatory Affairs		IPEC Americas written comments submitted to docket No FDA-2012-N-0882.		15-Oct-15
353	IPEC testimony at FDA public meeting seeking input on the reauthorization of the Generic Drug User Fee Act (2012) (GDUFA).	Regulatory Affairs		Preparation and presentation of IPEC-Americas Inactive Ingredient Proposals for Consideration during GDUFA Negotiations at the GDUFA public meeting.		15-Oct-15

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
354	IPEC testimony at PDUFA Reauthorization public meeting	Regulatory Affairs		Preparation and presentation of IPEC Americas testimony at the PDUFA reauthorization public meeting.		15-Oct-15
355	July 30 meeting with FDA	Regulatory Affairs		Discussion and presentation to agency on Toxicology/safety utilizing a family approach		15-Oct-15
356	Letter to FDA (Janet Woodcock)	Regulatory Affairs		GpHA/IPEC letter to Janet woodcock requesting a meeting to discuss IID (e-mail sent by Lisa Tan GpHA)		15-Oct-15
357	Request clarification from FDA on requirement for excipient DMFs to be submitted electronically	Regulatory Affairs		Questions drafted and sent to FDA (Art Shaw and FDA specified mail box). FDA response was reviewed and shared with committee members at the September meetings.		15-Oct-15
358	Review of IID issues related to the August 12, 2015 update	Regulatory Affairs		Compilation and submission of urgent issues to the agency related to August 2015 IID update.		15-Oct-15
359	September 18 meeting with FDA	Regulatory Affairs		Review of all discussions with FDA since 2011 and compilation of historical IID issues/status and future plans/timelines.		15-Oct-15

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
360	FDA Docket seeking public comments on how they might enhance the utility and usability of the Inactive Ingredient Database	Regulatory Affairs		• Work on generating a letter with IPEC comments ongoing • Draft letter to be sent to IPEC Americas member companies for input • Communication sent to IPEC Federation members asking for member input and encouraging direct submission of comments to docket.		12-Oct-15
361	Acid Leach/PQRI workshop;	Safety		Propose a project/program to PQRI for a multi day/multi functional (tox, analytical, USP, FDA, mfg., etc.) workshop to promote an EI workshop focused on methods and the analytical/toxicological impact of acid leach vs. total digestion		1-Apr-15
362	IPEC-Americas comments for Final FDA Guidance on ANDA Refuse to Receive	Regulatory Affairs				6-Feb-15
363	Addressing US Import issues	Regulatory Affairs		Address current issues companies are currently experiencing when importing excipients into the US.		4-Dec-14
364	Nano technology/Nano-materials LIBRARY	Safety		Collect current and emerging publications, presentation, etc. on Nano-technology/Nano-materials, develop reference list and library of documents.		23-Oct-14
365	Global Ingredient Archival System (GinAS) Project	Regulatory Affairs		Help communicate and support the FDA/NIH/global regulatory GInAS initiative		11-Jun-14

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
366	FDA Portable Document Format (PDF) Specifications	Regulatory Affairs		We need to clarify with the FDA on what PDF attachments to regulatory filings (NDAs, INDs or ANDAs) are impacted by this guidance. Also, IPEC Americas will issue a position paper with input with FDA.		1-Jun-14
367	DMF Workshop at ExcipientFest	Regulatory Affairs		IPEC-Americas to host DMF workshop at 2014 ExcipientFest Americas		28-May-14
368	FDA public hearing on Over-the-counter drugs	Regulatory Affairs		IPEC to submit request to speak at the meeting on supporting FDA efforts and request future meeting to discuss 1) clarity around the quality standards used for the excipients in OTC products and 2) handling atypical actives.		28-May-14
369	IPEC Comments on ANDA Refuse to Receive Guidance	Regulatory Affairs		Submission of comments to FDA docket (FDA-2013-D-1120)		3-Mar-14
370	Phthalate response to EMA draft guideline	Safety		EMA draft “Guideline on the use of phthalates as excipients in human medicinal products” issued in February 2013 and small team agreed to publish phthalate article and submit comments to EMA		28-Feb-14
371	Support publication of FDA 2012 EI study/data	Compendial Review/ Harmonization		Work with John Kauffman and Gang Li at FDA Research labs to substantiate their work and publish an article in Pharmaceutical Science		24-Jan-14

Committee Accomplishments

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
372	FDASIA Atypical Actives on-going activities	Regulatory Affairs		1) Update the Federation position paper on Atypical Actives. 2) Conduct poll for IPEC members who manufacture excipient(s) used as "Atypical Active(s)" to identify concerns or questions they are currently receiving from their customers based on updates/changes to the regulatory environment. DONE		18-Dec-13
373	Gluten Bill	Safety		Developing IPEC response on proposed gluten bill for excipients used in human drugs and long term engagement on this issue. Engaging the US S		13-Dec-13
374	Article for Tablets and Capsules	Regulatory Affairs		Develop and article based on FDASIA letters to FDA and target for publication in Tablets and Capsules		2-Dec-13
375	FDA QbD Workshop	Quality by Design		Joint FDA OGD and IPEC-Americas QbD Workshop		16-Oct-13
376	Technically Unavoidable Particles Profile (TUPP) Guide	Good Manufacturing Practices		Develop IPEC TUPP GUIDE		18-Sep-13
377	FDA OGD training materials and session	Quality by Design		Finalize training materials for FDA OGD and deliver training to new reviewers		13-Sep-13
378	FDASIA FDA Letter on Atypical Actives	Regulatory Affairs		Prepare letter to send to the FDA pertaining to IPEC-Americas interpretation and offer for support on FDASIA Title 3 implementation for "atypical actives"		13-Sep-13

Committee Accomplishments

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
379	FDASIA FDA letter on Nano-technology	Regulatory Affairs		Prepare letter to send to the FDA pertaining to IPEC-Americas interpretation and offer for support on FDASIA Title 11, Section 1126 pertaining to nanotechnology		13-Sep-13
380	FDASIA FDA letter on Supply Chain Security	Regulatory Affairs		Prepare letter to send to the FDA pertaining to IPEC-Americas interpretation and offer for support on FDASIA Title 7 pertaining to supply chain security		13-Sep-13
381	Response to USP General notice on Elemental Impurities	Compendial Review/ Harmonization		IPEC member companies & EI Coalition need to respond to USP EI General Notice regarding elemental impurities USP General Notices -		13-Sep-13
382	USP Excipient Stakeholder Forum	Compendial Review/ Harmonization		IPEC-Americas asked to chair USP Stakeholder Forum		13-Sep-13
383	Brazil/Argentina GMP Workshops	Good Manufacturing Practices		To provided excipient training to ANVISA (Brazilian regulators) and Sindusfarma (industry organization in Brazil)		26-Aug-13
384	Coalition letter to USP	Compendial Review/ Harmonization		Comments to USP regarding the General Notices Section 5.60.30 Elemental Impurities in USP and NF Articles in the Pharmacopoeial Forum, Vol. 39(1) [Jan.-Feb. 2013]		13-May-13
385	DOE/Design/Space/Control Strategy Checklist	Quality by Design		Create checklist of DOE/Design Space/Control Strategy		1-May-13
386	Gutter Oil PharmTech article	Excipient Qualification		Article in PharmTech entitled “Supply Chain Security Requires Standardized Excipient Information“		29-Jan-13