Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
2	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	IPEC-Americas comments submitted to USP for their notice of Intent to revise the USP Isopropyl Alcohol monograph	5/27/2021
3	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.	IPEC presentation for ISPE on QbD: Product Development and Life-cycle Management	5/26/2021
4	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.	FDA training on IPEC excipient QbD Guide completed	5/11/2021
5	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.	Recommendations for Responding to Requests from USP for Samples	5/7/2021
6	USP GSP GC Prospectus	Compendial Review/ Harmonization	N/A	Provide feedback to USP with regards to General Chapter <1xxx> Supplier Qualification Prospectus	IPEC-Americas comments submitted to USP for GC <1xxx> Supplier Qualification Prospectus	4/22/2021
7	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.	Submit comments to Docket No. FDA-2020-D-2016.	4/16/2021
8	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	Follow-up comments to USP for Feb 11 & 12 Open Forum	4/16/2021
9	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	IPEC-Americas comments submitted to USP for GC <232> EI limit revisions in PF 47 (1)	3/30/2021

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
10	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	IPEC-Americas comments submitted to USP for Oleyl Oleate monograph revisions in PF 47 (1)	3/30/2021
11	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	Part 3 of QbD Guide article published in Outsourced Pharma	3/10/2021
12	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>	USP notification of endorsement of IFAC comments	3/10/2021
13	USP comments related to Glucose, Liquid PF 47(1)	Compendial Review/ Harmonization	N/A	Review proposed revisions to glucose, liquid monograph from PF 47(1) and provide feedback to USP	IPEC-Americas comments submitted to USP for proposed glucose, liquid monograph revisions in PF 47 (1)	3/4/2021
14	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	Part 2 of QbD Guide article published in Outsourced Pharma	3/3/2021
15	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	Published PharmTech article on Novel excipient review process	3/2/2021
16	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	Position paper on Pharmaceutical Lactose used in oral preparations is a low-risk excipient published	3/1/2021

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
17	GADA Meeting with CVM (FDA)	Regulatory Affairs	N/A	Deliver a presentation on CoAs during the GADA meeting with CVM	Present on IPEC and CoAs at GADA-CVM meeting	2/25/2021
18	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	Part 1 of QbD Guide article published in Outsourced Pharma	2/24/2021
19	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	shared with CRC committee members	2/24/2021
20	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	Rebuttal letter/comments submitted to IJBM for article by Baran, Sulukan, Türkoğlu, et al.	2/23/2021
21	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	ICH Q13 Presentation to IPEC Europe Excipient Forum	2/4/2021
22	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	USP notification email to Catherine S, John G and Hong W.	1/28/2021
23	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	articles published in Pharmaceutical Technology (both on-line and in print)	1/27/2021

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
24	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	IPEC comments submitted to USP for proposed Maltodextrin monograph revisions in PF 46 (6)	1/25/2021
25	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	Send official notification to USP of IPEC's efforts to update the IPEC Safety Assessment of Pharmaceutical Excipients	1/21/2021
26	Validation Guide	Good Manufacturing Practices	N/A	Develop IPEC GUIDE on Excipient Validation, including Equipment, Process, Product, Computer, Cleaning and Analytical Validation	Published new IPEC GUIDE on Excipient Validation	1/14/2021
27	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.	Position paper "Qualifying an Excipient Manufacturing Site" Possibly publish in Pharm Tech. Presentation at NJPQCA, IA Webinar, EW workshop	1/14/2021
28	Guideline on Incorporation of Excipients and Excipient Variability into QbD	Quality by Design	TBD	Develop IPEC GUIDE on QbD Excipients and Excipient Variability	Published Federation IPEC GUIDE on QbD Excipients and Excipient Variability	1/7/2021
29	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	To publish version 2 of IPEC General Glossary of Terms and Acronyms	1/1/2021
30	Qualification of Excipient Guide	Excipient Qualification	Yes	Revise and update the latest version of IPEC Excipient Qualification Guide	To publish an IPEC Excipient Qualification Guide as a Federation guide	12/15/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
31	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 on Efficient and Effective Virtual Audits	12/10/2020
32	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.	Approved project charter	12/10/2020
33	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.	Decision by IPEC Federation regarding definition for excipient starting material	12/10/2020
34	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	IPEC comments submitted to USP for proposed NaCMC monograph revisions in PF 46 (5)	12/8/2020
35	USP comments regarding GC <1469> Nitrosamines	Regulatory Affairs	N/A	Develop comments to the USP proposed <1469> Nitrosamine Impurities general chapter	Comments to USP for <1469> Nitrosamines	12/3/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
36	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	Send USP IPEC-Americas response to their response to Stimuli Article response.	11/30/2020
37	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	IPEC comments submitted to USP for proposed lactose monograph revisions in PF 46 (5)	11/30/2020
38	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	11/17/2020
39	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.	Published Federation IPEC Guide on Qualifying Certification Scheme and Certification Bodies	11/12/2020
40	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	Hold PQRI EI Workshop on Elemental Impurity.	11/10/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
41	ICH Q3D Industry Perspective and Consequences	Quality by Design	N/A	Dale Carter - PQRI Workshop presentation	PQRI Workshop presentation from IPEC-Americas	11/9/2020
42	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	1) letter to editor critiquing their poor peer review/process 2) rebuttal letter (published in Science) on positioning of excipients as bad actors 3) copy rebuttal letter to FDA as sponsor of project	11/3/2020
43	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.	Approved project charter consider adding new project to develop the guide	11/1/2020
44	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	Comments to USP Roadmap for Addressing Element-Specific Chapters	10/26/2020
45	Excipient compliance workshop	Good Manufacturing Practices	N/A	Excipient GMP Compliance Virtual Workshop, October 18-23, 2020	IPEC-Americas Workshop	10/18/2020
46	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	10/13/2020
47	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	Artilce for publishing in CPhI Annual Report for 2020	10/12/2020
48	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 Federation Position Paper on Data Integrity	10/1/2020

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49	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.	Provide information on various approaches to IPEC members and non-members.	10/1/2020
50	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"	1) letter to editor critiquing their poor peer review/process 2) rebuttal letter (published in Science) on positioning of excipients as bad actors	9/29/2020
51	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	Excipient World webinar	9/16/2020
52	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	IPEC-Americas letter to FDA regarding continuing IID issues	9/2/2020
53	ECHA open comments for SEAC opinion on microplastics	Regulatory Affairs	N/A	Submit electronic comments to ECHA endorsing comments prepared and submitted by CEFIC	IPEC-Americas electronic endorsement of Cefic's input to SEAC's opinion	9/1/2020
54	Silicon Dioxide Round Robin Study-IPEC Federation	Compendial Review/ Harmonization	Yes	Independent labs perform round robin testing of various forms/sources of silicon dioxide	Round Robin Test results complete and report issued	8/26/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
55	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	8/26/2020
56	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	IA comments prepared, approved and submitted to FDA docket by Aug 20, 2020	8/20/2020
57	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	IPEC comments submitted to USP for proposed Sucrose monograph revisions in PF 46 (4)	8/13/2020
58	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	IPEC comments submitted to USP & FDA for Alcohol monograph revision NITR	8/12/2020
59	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	Joint IPEC/IQ letter finalized, approved and sent	7/27/2020
60	CHPA - Impurities in Excipients	Quality by Design	N/A	Priscilla Zawislak - CHPA Meeting presentation	CHPA Meeting presentation	7/23/2020
61	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	Excipient World webinar	7/22/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
62	GADA - Excipient Perspective on Elemental Impurities Excipient Qualification Initiatives	Regulatory Affairs	N/A	Dave Schoneker, quarterly GADA meeting presentation	quarterly GADA meeting presentation	7/22/2020
63	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	Present IA GDUFA III negotiation proposal at FDA public meeting	7/21/2020
64	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	Excipient World webinar	7/8/2020
65	CRS - The Need for Novel Excipient Innovation in Drug Development	Scientific Affairs	N/A	Nigel Langley, Annual CRS meeting presentation	Annual CRS Conference presentation	6/29/2020
66	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	IPEC comments submitted to EDQM for proposed Sucrose monograph revisions	6/25/2020
67	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	6/23/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
68	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	Excipient World webinar	6/17/2020
69	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	Updated USP GC <1195>	6/13/2020
70	Update 2009 Composition Guide	Quality by Design	TBD	Update 2009 Composition Guide to reflect current analytical capabilities?	Publish updated IPEC Composition Guide	6/4/2020
71	Excipient Information Package	Excipient Qualification	Yes	Revise 2012 EIP guide and develop new version.	Revised EIP Guide published as Federation Guide.	6/4/2020
72	Ph. Eur. Nitrosamines proposal for 2034	Scientific Affairs	Yes	Subcommittee to develop comments and submit to Ph. Eur. before March31, 2020 deadline	IPEC comments sent to EDQM on proposed changes in 2034	6/2/2020
73	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	Federation comments to CDE regarding review and approval of API, excipient and packaging materilas	5/29/2020
74	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	5/20/2020
75	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	Letter to USP regarding extentions due to restrictions resulting from issues with Covid-19	4/28/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
76	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)	IPEC comments submitted to USP for proposed Maltol monograph revisions Re: Maltol – PF 46(2)	4/23/2020
77	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	4/22/2020
78	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	Letter to FDA regarding continued IID	4/16/2020
79	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	4/7/2020
80	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-Americas White-Paper comparing regulatory requirements for excipients vs food additives .	4/2/2020
81	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.	IPEC-Americas comments submitted to EDQM	4/1/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
82	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)	Federation comments to EDQM regarding 32.1 request for comments on revised general monograph: Substances for Pharmaceutical use (2034)	3/30/2020
83	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	3/25/2020
84	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)	IPEC-Americas/CfPA Workshop	3/19/2020
85	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	IPEC-Americas/PDA Workshop	3/4/2020
86	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	3/3/2020
87	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	IFPAC Conference presentation from IPEC-Americas	2/26/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
88	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	IA comments submitted to Docket No. FDA-2019-D-4447-0001 Transdermal and Topical Delivery Systems - Product Development and Quality Considerations	2/21/2020
89	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	2/20/2020
90	Animal Health Industry Association - outreach	Regulatory Affairs	N/A	Reach out to animal health (veterinary) trade associations for joint collaboration/membership.	Collaboration/membership with animal health (veterinary) organizations/personnel	2/12/2020
91	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	1/29/2020
92	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	1/22/2020
93	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	IA comments submitted to Docket No. FDA-2019-N-5464 Novel Excipient Review Program Proposal; Request for Information and Comments	1/14/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
94	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	IPEC-Americas response to USP for proposed <1195> revisions	1/13/2020
95	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	IA comments submitted to Docket No. FDA-2019-D-3989: Draft Drug Master Files Guidance for Industry	12/18/2019
96	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	IA comments submitted to Docket No. FDA-2012-D-0880: Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 Draft Guidance	12/18/2019
97	Develop IPEC-Americas white paper on Nitrosamine	Regulatory Affairs	N/A	Review and develop IPEC-Americas strategy for responding to nitrosamines	IPEC-Americas Risk Assessment Template for Nitrosamines	12/18/2019
98	IPEC-PDA Risk Assessment Guide	Excipient Qualification	Yes	Part 2 of the Risk Assessment Guide targeted for users (e.g. pharma manufacturers)	Publish PDA-IPEC RA Guide for users	12/18/2019
99	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 -	IA submit comments to: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=49395 for ANVISA CP No. 689	12/11/2019
100	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.	Letter to Lyndsay Hennessey Janet Woodcock and potential follow-up meetings	12/10/2019
101	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	IA comments submitted to Docket No. FDA-2019-D-2397: Draft Guidance for Industry on Using the Inactive Ingredient Database	12/10/2019

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
102	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	Two IPEC-Americas 2020-2025 excipient resolutions presented at USP Convention 1) Quality Standards for Dietary Supplements and Their Ingredients 2) Develop a Framework for Non-Standard Excipient Monographs	10/8/2019
103	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.	Joint meeting between ChP and IPEC	9/24/2019
104	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).	Presentations by PZ and DS at EXPOFYBI 2019	9/24/2019
105	REACH Microplastics comments	Regulatory Affairs	IA + IE	IA to collaborate with EFPIA and IPEC Europe to develop additional comments to submit to ECHA	Submit additional IA/IE joint microplastics comments to ECHA	9/24/2019
106	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."	IA presentation delivered at Xavier Combination Product Summit	9/24/2019
107	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	IA comments submitted to open FDA Draft Guidance on Harmonizing Compendial Standards with Drug Application Approval Using the USP Pending Monograph Process	9/24/2019
108	IA-CSPS Joint Excipient workshop	Regulatory Affairs	N/A	IA to jointly sponsor an excipient workshop in Canada with CSPS	hold workshop, including sevearl speakers from IA	9/24/2019

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
109	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	IPEC Federation published position paper on supply chain security in Q2'2019 https://ipecamericas.org/sites/default/files/20190129-if-pp-supply-chain-security-final-1558601418.pdf	6/7/2019
110	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.	IPEC letter to FDA (Tim McGovern & Danae Christodoulou) requesting an urgent meeting with FDA.	5/29/2019
111	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	IPEC-Americas comments to USP on CM Stimuli Article	5/29/2019
112	Quality Considerations for Continuous Manufacturing	Quality by Design	N/A	Docket No. FDA-2019-D-0298 Quality Considerations for Continuous Manufacturing	IPEC-Americas comments submitted to open FDA docket FDA-2019-D-0298	5/29/2019
113	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	IPEC-Americas US DMF FAQ finalized and published on IPEC-Americas website	5/29/2019

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
114	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).	Position Paper on Microplastics and IPEC comments to REACH proposal	5/29/2019
115	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	EW Workshop	5/22/2019
116	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	Send Letter (request) to FDA and schedule meeting with FDA	3/25/2019
117	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.	Submit DRAFT Elemental Impurities in Human Drug Products Question and Answers to FDA for consideration as a guidance	3/22/2019
118	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	comments finalized, approved and submitted to ChP	3/21/2019

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	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
119	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	Comments finalized, approved and submitted to FDA	3/8/2019
120	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	Presentation made at USP fall PNP (Oct 2018) and Excipient (Dec 2018) Stakeholder Forums.	12/14/2018
121	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	USP response to USP	12/14/2018
122	Accreditation and Certification Distinctions	Good Manufacturing Practices	N/A	Develop and post a position paper on Accreditation and Certification Distinctions	Position Paper on Accreditation and Certification Distinctions	12/11/2018
123	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.	Submitted letter and draft Guideline on 11/30/2018 (comment tracking number: 1k2-96ug-6tw3).	12/5/2018
124	Gluten Rebuttal to Journal Commentary	Regulatory Affairs	N/A	IPEC Comments based on Journal Commentary entitled "Making all Medications Gluten Free"	Updated to publishing gluten article in Tablets and Capsules	12/5/2018
125	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.	IA comments sent to Federation	11/13/2018

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
126	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.	IA comments sent to Federation	11/4/2018
127	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"	WebEx trainig provided	10/30/2018
128	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.	IA comments uploaded into Docket FDA-2018-D-1067-0002. FDA (Lyndsay H.) cc'd on docket response	10/18/2018
129	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	IA comments to IPEC Federation to be included with Federation comments	10/4/2018
130	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.	Internal Flow Chart of Best Practices	10/3/2018
131	Rx-360 Supplier Assessment Questionnaire	Excipient Qualification	N/A	Work with Rx-360 to revise references to excipients in the Supplier Assessment Questionnaire	Revised Rx-360 Supplier Assessment Questionnaire.	10/3/2018

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
132	FDA guidance on Elemental Impurities	Compendial Review/ Harmonization	N/A	Waiting on Final FDA guidance	completed	8/7/2018
133	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"	USP Workshop and IPEC-Americas presentations 1) Excipient Industry Perspective on Excipient Nomenclature 2) Case Study 2 - Silicone	8/7/2018
134	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	Appeal letter sent to USP from 1) IPEC-Americas 2) CHPA 3) CRN 4) IFAC	8/1/2018
135	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	IA comments to IPEC Federation to be included with Federation comments	7/20/2018
136	USP Veterinary Workshop	Regulatory Affairs	No	Provide Animal Health (veterinary) community with an overview of the importance of excipients used in animal health drugs	Presentation from IPEC-Americas entitled "Quality and Safety of Inactive Ingredients- Critical for Animal Health Drug Products "	7/19/2018
137	DMF Guide webinar	Regulatory Affairs	No	Develop and deliver free DMF Guide webinar	IPEC-Americas U.S. Drug Master File Guide for Pharmaceutical Excipients Webinar	7/18/2018
138	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).	Formal comments to USP on PF 44(3) Stimuli Article “The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities”	7/17/2018

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
139	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	Appeal letter sent to USP from IPEC-Americas	7/9/2018
140	Third-part Excipient GMP Certification article	User Network	No	Develop and publish an article on importance of Third-Party Accredited Excipient GMP Audits	Article published in Pharm Tech	6/28/2018
141	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	IA comments to IPEC Federation to be included with Federation comments	6/21/2018
142	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.	IPEC DMF Guide: Phase I - US DMF	5/21/2018
143	Additives found in excipients	Excipient Composition	No	Develop and share with FDA a list of additives commonly found in excipients	Provide FDA with list of additives commonly found in excipients	4/6/2018
144	Co-processed Excipient Guide	Excipient Composition	BiPEC	create a new IPEC Guide pertaining to co-processed excipients	Published IPEC Co-processed Excipient Guide	4/6/2018
145	IPEC-Americas Presentation at GDUFA Regulatory Science Research	Regulatory Affairs	No	IPEC comments on future of excipients research, novel excipients and collaboration	5/3/2017 for presentation; June 2, 2017 for comments	4/6/2018
146	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	IPEC-Americas comments uploaded to FDA Docket folder	3/19/2018

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
147	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.	Petition FDA to include statement on their website and/or write an IPEC position paper regarding accredited certification programs. https://ipecamericas.org/news/ipec-americas-publishes-position-paper-accreditation-and-certification-distinctions	3/6/2018
148	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.”	IPEC-Americas comments uploaded to FDA Docket folder	3/5/2018
149	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.	EQ mtg notes from 02/26/14 proposed better guidance on what users should communicate suppliers pertaining to excipient use (e.g. share more “non-confidential” information on how a material is used). Guide to describe what type of information to share. Could include as part of EIP or as supplement/reference to the guide.	2/21/2018
150	Quality Agreement Guide	Excipient Qualification	Yes	Revise 2009 Quality Agreement and develop new version	Revised and updated version of Quality Agreement Guide as Federation Guide.	2/21/2018

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
151	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.	IPEC-Americas comments uploaded to FDA Docket folder	1/12/2018
152	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.	IPEC-Americas comments uploaded to FDA Docket folder	12/6/2017
153	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.	IPEC-Americas comments uploaded to FDA Docket folder	12/6/2017

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
154	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.	IPEC-Americas comments uploaded to FDA Docket folder	12/6/2017
155	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.	IPEC-Americas comments uploaded to FDA Docket folder	12/4/2017
156	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,"	IPEC-Americas comments uploaded to FDA Docket folder	9/20/2017
157	Significant Change Guide	Excipient Qualification	Yes	Revise and update the 2009 version of IPEC Significant Change Guide.	To publish 2014 IPEC Significant Change Guide (ideally as a Federation guide, and at the least a "bi-PEC guide)	6/7/2017

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
158	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	IPEC Americas will provide to IPEC Federation- the following content for the risk assessment guidance document: • Process including methodologies and tool box for conducting risk assessment • How-to chapters on internal risk assessment from excipient manufacturers perspective • How-to chapters on internal risk assessment from excipient users perspective	6/7/2017
159	ANSI cGMP for Pharmaceutical Excipient Standard	Good Manufacturing Practices	Yes	Develop ANSI Pharmaceutical Excipient Standard	Approved ANSI Pharmaceutical Excipient Standard	6/7/2017

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
160	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.	Sell sheet to promote IPEC certification	6/7/2017
161	FDASIA Atypical Actives on-going activities	Good Manufacturing Practices	Yes	work with FDASIA subcommittee to be prepared for potential meeting with FDA	Tool chest of discussion items pertaining to atypical actives for requested FDA meeting	6/7/2017
162	Revised IPEC-PQG Excipient GMP Guide	Good Manufacturing Practices	Yes	Rewrite IPEC/PQG GMP Guide with updated information from ANSI Excipient GMP standard	Revised IPEC-PQG Excipient GMP Guide	6/7/2017
163	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.	Publish IPEC-Americas Position Paper on Conducting Accelerated Stability on Excipients	6/7/2017

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
164	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."	TUPPS Position paper to clarify potential misuse of Guide	6/7/2017
165	IPEC Good Distribution Practices Guide update	Good Manufacturing Practices	Yes	2017 revision to the IPEC GDP Guide	IPEC Excipient GDP Guide update	6/7/2017
166	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	IPEC Federation Glossary of Terms	6/7/2017
167	Emerging Publications	Safety	N/A	Collect current and emerging publications, presentation, etc. on Nano-technology/Nano-materials, develop reference list and library of documents.	1) IPEC Americas team identified to monitor for Nano-technology/Nano-material information. 2) IPEC-Americas library established to store information (documents, presentations, etc.) on Nano-technology/Nano-materials. 3) list of referenced materials developed	6/7/2017

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
168	IPEC-Americas Response to FDA Quality Metrics Guide	Regulatory Affairs		FDA issued their second DRAFT Quality Metrics Guidance	The Regulatory Affairs committee will prepare comments to submit to the open docket for the draft QM Guidance.	3/22/2017
169	EMA guidance on Elemental Impurities	Compendial Review/ Harmonization		EMA Issued Final Guidance. Discussion at the June CRC meeting	Complete	3/20/2017
170	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	Discounted eCTD excipient DMF support and training awareness	3/13/2017
171	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).	presentation/public comments	3/13/2017
172	Preparation of US excipient Regulatory process flow chart	Regulatory Affairs		Description of how the regulatory produces works in the US for IPEC China	April/May 2017	3/13/2017
173	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.	IPEC-Americas published a position paper on Jan. 4, 2017, on the utility of drug master files (DMFs).	3/13/2017
174	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	Send letter/comments to Kathleen Uhl at FDA	3/13/2017
175	QbD Sample Guide	Quality by Design		QbD Sampling Guideline - User and supplier sections to be merged	Published IPEC QbD Sampling Guide	12/6/2016

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
176	WHO - Good Pharmacopoeial Practices Guide	Compendial Review/ Harmonization			Complete	12/1/2016
177	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	presentation/public comments	6/6/2016
178	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.	FDA Comments/follow-up	6/6/2016
179	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.	IPEC-Americas Response to Health Canada Draft Guidance Document: Master Files (MFs) - Procedures and Administrative Requirements	4/6/2016
180	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	IPEC-Americas Comments to open FDA Docket on Quality Metrics Draft Guidance	11/2/2015
181	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.	IPEC Comments	10/15/2015

Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
182	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)	Letter to FDA	10/15/2015
183	IPEC Americas Position Paper	Regulatory Affairs		Position paper on IID status, critical issues and next steps	Position Paper	10/15/2015
184	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.	Review Guide and develop strategy	10/15/2015
185	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.	IPEC-Americas Presented on Two Key Excipient Topics on behalf of IPEC-Americas at 2015 June GDUFA Reauthorization public meeting http://multibriefs.com/briefs/ipec/GDUFA_Article_R.pdf	10/15/2015
186	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.	E-mail to FDA and DMF question box	10/15/2015
187	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.	IPEC-Americas prepared and submitted comments to open docket for GDUFA reauthorization public meeting	10/15/2015

Committee Accomplishments

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
188	IPEC testimony at PDUFA Reauthorization public meeting	Regulatory Affairs		Preparation and presentation of IPEC Americas testimony at the PDUFA reauthorization public meeting.	Dave Schoneker presented comments on behalf of IPEC-Americas during the July 2015 FDA public meeting with comments centering on review and qualification of novel excipients.	10/15/2015
189	FDA PDF Specs Guidance issued	Regulatory Affairs		Revision of IPEC Americas Position Paper on PDF specs issued in 2014.	Revision of Position paper	10/15/2015
190	July 30 meeting with FDA	Regulatory Affairs		Discussion and presentation to agency on Toxicology/safety utilizing a family approach	FDA meeting	10/15/2015
191	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.	IPEC-Americas prepared and submitted to the FDA docket on PDUFA Re-authorization with detailed written comments that describe the need for an independent FDA safety review/qualification process for novel excipients outside of the normal drug approval process.	10/15/2015
192	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.	Urgent IID Issues Documentation	10/15/2015
193	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.	FDA meeting	10/15/2015

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
194	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.	IPEC Comments to Docket No. FDA-2015-20556: Technical Document for Using the Inactive Ingredient Database; Establishment of a Public Docket http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-2986-0001	10/12/2015
195	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	PQRI/USP Workshop on Elemental Impurity Requirements in a Global Environment – Next Steps?	4/1/2015
196	IPEC-Americas comments for Final FDA Guidance on ANDA Refuse to Receive	Regulatory Affairs				2/6/2015
197	Addressing US Import issues	Regulatory Affairs		Address current issues companies are currently experiencing when importing excipients into the US.	Response from FDA on Import hold letter. IPEC-Americas would like the opportunity to connect with the appropriate resources at FDA in order to allow both parties to openly communicate and collaborate on this topic.	12/4/2014

Committee Accomplishments

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198	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.	1) IPEC Americas team identified to monitor for Nano-technology/Nano-material information. 2) IPEC-Americas library established to store information (documents, presentations, etc.) on Nano-technology/Nano-materials. 3) list of referenced materials developed	10/23/2014
199	Global Ingredient Archival System (GinAS) Project	Regulatory Affairs		Help communicate and support the FDA/NIH/global regulatory GInAS initiative	functional Global ingredient identification database with reviewed/reliable ingredient information	6/11/2014
200	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.	IPEC position paper clarifying FDA's requirement and applicability to excipient documents	6/1/2014
201	DMF Workshop at ExcipientFest	Regulatory Affairs		IPEC-Americas to host DMF workshop at 2014 ExcipientFest Americas	DMF workshop - complete	5/28/2014
202	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.	Representative from IPEC-Americas to speak at FDA public meeting on OTC drugs Complete	5/28/2014
203	IPEC Comments on ANDA Refuse to Receive Guidance	Regulatory Affairs		Submission of comments to FDA docket (FDA-2013-D-1120)	Comment letter	3/3/2014

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204	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	Published article on phthalates and comments to EMA	2/28/2014
205	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	Scientific article on Elemental Impurities in excipients published in peer reviewed journal	1/24/2014
206	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	The regulatory team will consider developing and posting an FAQ based on questions/comments from poll	12/18/2013
207	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	Response to senate bill and longer term advocacy/engagement on this issue	12/13/2013
208	Article for Tablets and Capsules	Regulatory Affairs		Develop and article based on FDASIA letters to FDA and target for publication in Tablets and Capsules	Published Article in Tablets and Capsules	12/2/2013
209	FDA QbD Workshop	Quality by Design		Joint FDA OGD and IPEC-Americas QbD Workshop	Workshop scheduled and delivered October 16 and 21, 2013	10/16/2013