Committee Accomplishments

	A	B	C	D	E	F
1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
2	Letter to editor of SCIENCE for article entitled "activities of drug inactive	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	1) letter to editor critiquing their poor peer review/process 2) rebuttal letter (published in	11/3/2020
3	Comments to USP on 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
4	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
5	Develop PQRI Workshop on Elemental Impurity	Quality by Design		PQRI workshop proposal for follow-up workshop on Elemental Impurities	Hold PQRI EI Workshop on Elemental Impurity.	11/10/2020
6	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
7	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	Approved project charter	12/10/2020
8	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	Decision by IPEC Federation regarding definition for excipient starting material	12/10/2020

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
9	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	12/14/2020
10	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
11	Future of Element-Specific Chapters in the USP-NF	Compendial Review/ Harmonization	N/A	Determination of how to move forward with elemental specific chapters in USP-NF post <232> and <233>	Comments to USP Roadmap for Addressing Element-Specific	10/23/2020
12	USP letter related to 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
13	USP letter related to 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	12/9/2020
14	Validation Guide	Good Manufacturing Practice	N/A	Develop IPEC GUIDE on Excipient Validation, including Equipment, Process, Product, Computer, Cleaning and Analytical Validation	Published new IPEC GUIDE on Excipient Validation	12/30/2020
15	Options for excipient users to qualify excipient	Excipient Qualification	N/A	Develop a position paper to include options for excipient users to qualify their excipient suppliers when the	Position paper "Qualifying an Excipient Manufacturing Site"	12/30/2020
16	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	12/30/2020

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17	IPEC GMP Certification Scheme and Certification	Good Manufacturing Practice	N/A	Provide an overview of the soon-to-be-published IPEC GMP Certification Scheme and Certification Body	Webinar - IPEC-Americas	11/17/2020
18	IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients	Good Manufacturing Practice	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
19	ICH Q3D Industry Perspective and	Quality by Design	N/A	Dale Carter - PQRI Workshop presentation	PQRI Workshop presentation from IPEC-Americas	11/9/2020
20	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
21	Excipient compliance workshop	Good Manufacturing Practice	N/A	Excipient GMP Compliance Virtual Workshop, October 18-23, 2020	IPEC-Americas Workshop	10/18/2020
22	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
23	CPhI Annual Report article on IPEC QbD Guide and	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
24	Data Integrity	Good Manufacturing Practice	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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25	Guide Navigation Resource	Good Manufacturing Practice	Yes	There are several differences between the EXCiPACT and ANSI Standards and with the IPEC-PQG GMP Guide.	Provide information on various approaches to IPEC members and	10/1/2020
26	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
27	Vision for FDA's Inactive Ingredient Database in	Excipient World	N/A	Excipient World webinar designed to desribe upcoming changes to US FDA IID along with how these changes will	Excipient World webinar	9/16/2020
28	ECHA open comments for SEAC opinion on microplastics	Regulatory Affairs	N/A	Submit electronic comments to ECHA endorsing comments prepared and submitted by CEFIC	electronic comments submitted	9/1/2020
29	Silicon Dioxide Round Robin Study- IPEC	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
30	Good Distribution practices and buyig through distribution	Good Manufacturing Practice	N/A	IPEC-Americas webinar to describe the who, what, when, where, how and why of excipient distributors.	Webinar - IPEC-Americas	8/26/2020
31	Docket No. FDA-2020-N-1459: Generic Drug User	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	8/20/2020
32	USP comments related to Sucrose 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 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

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33	USP & FDA comments related Alcohol_NITR	Compendial Review/ Harmonization	N/A	Prepare comments/response to the USP recently published Notice of Intent to Revise (NITR), pertaining to	IPEC comments submitted to USP & FDA for Alcohol monograph	8/12/2020
34	Follow-up letter to FDA Docket No. FDA-2019-N-5464-0001	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
35	CHPA - Impurities in Excipients	Quality by Design	N/A	Priscilla Zawislak - CHPA Meeting presentation	CHPA Meeting presentation	7/23/2020
36	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
37	GADA - Excipient Perspective on	Regulatory Affairs	N/A	Dave Schoneker, quarterly GADA meeting presentation	quarterly GADA meeting presentation	7/22/2020
38	Generic Drug User Fee Amendments (GDUFA) of 2017 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
39	Toxicology for the 21st Century: What is in the Box	Excipient World	N/A	Excipient World webinar to discuss revolutionary changes in how we predict human safety by assessing	Excipient World webinar	7/8/2020
40	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

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
41	EDQM comments related to Sucrose monograph	Compendial Review/Harmonizatio	TBD	It is important to make a distinction between impurities and concomitant components in excipients as it relates	IPEC comments submitted to EDQM for proposed Sucrose	6/25/2020
42	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
43	Clinical Relevance: Why are Enteric Coatings Failing In	Excipient World	N/A	Excipient World webinar designed to help participants understand the underlying science behind the	Excipient World webinar	6/17/2020
44	USP General Chapter Update: Significant Change for Excipients	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>	6/10/2020
45	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
46	Excipient Information Package	Excipient Qualification	Yes	Revise 2012 EIP guide and develop new version.	Revised EIP Guide published as Federation Guide.	6/4/2020
47	EDQM Application of 5.20 Elemental Impurities to	Compendial Review/Harmonizatio	N/A	EDQM comments regarding EDQM Application of 5.20 Elemental Impurities to update individual monographs	IPEC-Americas comments submitted to EDQM	6/2/2020
48	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

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49	Regulatory Requirements for Excipients used in Drugs	Regulatory Affairs	N/A	IPEC-Americas webinar to highlight excipient regulatory requirements in China	Webinar - IPEC-Americas	5/20/2020
50	USP comments related to Maltol monograph	Compendial Review/Harmonizatio n	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
51	The Importance of Excipients in Continuous	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
52	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
53	Comparison of Requirements for	Excipient Qualification	N/A	Develop a white-paper comparing the regulatory requirements for food additives vs excipients vs dietary	IPEC-Americas White-Paper comparing regulatory	4/2/2020
54	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
55	Excipients: Compliance with Compendial and GMP	Good Manufacturing Practice	N/A	IPEC-Americas and the Center for Professional Development (March 19/20, 2020)	IPEC-Americas/CfPA Workshop	3/19/2020
56	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	IPEC-Americas/PDA Workshop	3/4/2020

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57	Untangling the confusion about what excipient	Regulatory Affairs	N/A	IPEC-Americas webinar to define supplier comments for the IPEC-Americas nitrosamine template and user	Webinar - IPEC-Americas	3/3/2020
58	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
59	Supplier-dependent excipient performance:	Quality by Design	N/A	IPEC-Americas webinar to address the impact of multi-sourcing of excipients on the manufacture, quality,	Webinar - IPEC-Americas	2/20/2020
60	IPEC-Americas comments to FDA on open docket for TDDS 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	2/12/2020
61	IPEC-Americas comments to FDA on open docket for	Regulatory Affairs	N/A	Prepare and submit comments to open docket FDA-2019-N-5464 Novel Excipient Review Program Proposal;	IA comments submitted to Docket No. FDA-2019-N-5464 Novel	2/12/2020
62	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	2/12/2020
63	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)	2/12/2020
64	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

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65	Qualifying an Excipient Supplier; Alternatives to	Good Manufacturing Practice	N/A	IPEC-Americas webinar to address what a pharmaceutical company should do when their excipient	Webinar - IPEC-Americas	1/22/2020
66	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
67	IPEC-Americas comments to FDA on open docket for	Regulatory Affairs	N/A	Prepare and submit comments to open docket FDA-2012-D-0880: Assessing User Fees Under the Generic Drug	IA comments submitted to Docket No. FDA-2012-D-0880: Assessing	12/18/2019
68	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
69	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
70	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
71	IPEC-Americas follow-up with FDA on meeting	Regulatory Affairs		Prepare and Submit letter highlighting list of current issues that require collaboration/input from FDA to	Letter to Lyndsay Hennessey Janet Woodcock and potential follow-up	12/10/2019
72	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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73	USP draft Resolutions 2020-2025	Compendial Review/Harmonizatio	N/A	Develop and submit excipient resolution proposals to USP for 2020-2015 cycle. Represent IPEC-Americas as	Two IPEC-Americas 2020-2025 excipient resolutions presented at	10/8/2019
74	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
75	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,	Presentations by PZ and DS at EXPOFYBI 2019	9/24/2019
76	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
77	IA presentation at Xavier Combination Products	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
78	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
79	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
80	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

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81	Excipient elemental Impurity requests from FDA	Compendial Review/Harmonizatio	N/A	Many Companies are receiving customers letters indicating errors from FDA and requesting 3 batches of	IPEC letter to FDA (Tim McGovern & Danae Christodoulou) requesting	5/29/2019
82	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
83	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-	5/29/2019
84	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
85	Microplastics Implications for Medicinal	Regulatory Affairs		1) IPEC-Americas to develop a "Microplastics" industry statement/position paper	Position Paper on Microplastics and IPEC comments to REACH	5/29/2019
86	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
87	Request meeting with FDA to discuss urgent Elemental	Regulatory Affairs		Some FDA reviewers are sending out INCORRECT responses to drug sponsors directing them to acquire	Send Letter (request) to FDA and schedule meeting with FDA	3/25/2019
88	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

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89	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
90	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
91	Complexity of Setting Specifications for Excipient	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	12/14/2018
92	USP Stimuli article The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities	Compendial Review/Harmonizatio n	N/A	Prepare a response to USP Stimuli article	USP response to USP	12/14/2018
93	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
94	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
95	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
96	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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97	China proposed guideline for Production of Control	Regulatory Affairs	N/A	Provide IA comments to Federation pertaining to DRAF China Guideline. Federation to consolidate/translate	IA comments sent to Federation	11/4/2018
98	Training for the new USP on-line platform	Compendial Review/Harmonizatio n	N/A	Provide training to IPEC-Americas member on the "new on-line USP plaform"	WebEx trainig provided	10/30/2018
99	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	IA comments uploaded into Docket FDA-2018-D-1067-0002. FDA	10/18/2018
100	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
101	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.	Internal Flow Chart of Best Practices	10/3/2018
102	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
103	FDA guidance on Elemental Impurities	Compendial Review/Harmonizatio	N/A	Waiting on Final FDA guidance	completed	8/7/2018
104	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

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
105	USP appeal request to postpone USP 41-NF 36	Regulatory Affairs	No	Submit appeal letter to USP to postpone USP 41-NF 36 Supplement 2, GC <467> Residual Solvents from	Appeal letter sent to USP from 1) IPEC-Americas	8/1/2018
106	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
107	USP Veterinary Workshop	Regulatory Affairs	No	Provide Animal Health (veterinary) community with an overview of the importance of excipients used in animal	Presentation from IPEC-Americas entitled "Quality and Safety of	7/19/2018
108	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
109	Prepare and submit comments to USP on PF	Quality by Design Product Development	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	7/17/2018
110	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
111	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
112	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

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
113	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	IPEC DMF Guide: Phase I - US DMF	5/21/2018
114	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
115	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
116	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
117	Docket No. FDA-2017-D-6352-0001: Gluten in Drug	Regulatory Affairs	No	Provide comments to docket pertaining to Gluten in Drug Products and Associated	IPEC-Americas comments uploaded to FDA Docket folder	3/19/2018
118	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-	3/6/2018
119	Docket No. FDA-2017-D-6854: Good ANDA	Regulatory Affairs	No	Provide comments to docket pertaining to Good ANDA Submission Practices related to expectations for atypical	IPEC-Americas comments uploaded to FDA Docket folder	3/5/2018
120	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	2/21/2018

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121	Quality Agreement Guide	Excipient Qualification	Yes	Revise 2009 Quality Agreement and develop new version	Revised and updated version of Quality Agreement Guide as	2/21/2018
122	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	IPEC-Americas comments uploaded to FDA Docket folder	1/12/2018
123	Docket No. FDA-2017-N-5101 for Review of Existing	Regulatory Affairs	No	Provide comments to docket (FDA-2017-N-5092) established by FDA seeking comments from interested	IPEC-Americas comments uploaded to FDA Docket folder	12/6/2017
124	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
125	Docket No. FDA-2017-N-5094 for “Review of	Regulatory Affairs	No	Provide comments to docket (FDA-2017-N-5094) established by FDA seeking comments from interested	IPEC-Americas comments uploaded to FDA Docket folder	12/6/2017
126	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
127	Docket No. FDA-2017-N-2697 Continuous	Quality by Design Product Development	No	IPEC-Americas has reviewed the public docket titled, “Developing Continuous Manufacturing of Solid Dosage	IPEC-Americas comments uploaded to FDA Docket folder	9/20/2017
128	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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129	IPEC Global Risk Assessment Strategy (RAT -	Excipient Qualification	Yes	1. The initial intent was to develop a comprehensive risk assessment guide with sections covering risk assessment	IPEC Americas will provide to IPEC Federation- the following content	6/7/2017
130	ANSI cGMP for Pharmaceutical Excipient Standard	Good Manufacturing Practices	Yes	Develop ANSI Pharmaceutical Excipient Standard	Approved ANSI Pharmaceutical Excipient Standard	6/7/2017
131	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	Sell sheet to promote IPEC certification	6/7/2017
132	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
133	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
134	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
135	Article or position paper to clarify this misuse of the	Good Manufacturing Practices		There are companies misusing the TUPPS guidance for poor GMPs. Credibility of guide is questioned because of	TUPPS Position paper to clarify potential misuse of Guide	6/7/2017
136	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

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
137	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
138	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.)	6/7/2017
139	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	3/22/2017
140	EMA guidance on Elemental Impurities	Compendial Review/Harmonization		EMA Issued Final Guidance. Discussion at the June CRC meeting	Complete	3/20/2017
141	Excipient eCTD DMF strategy for discounted	Regulatory Affairs		Ongoing discussions with various suppliers and vendors on available "discounted" eCTD support available for	Discounted eCTD excipient DMF support and training awareness	3/13/2017
142	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
143	Preparation of US excipient Regulatory process flow	Regulatory Affairs		Description of how the regulatory produces works in the US for IPEC China	April/May 2017	3/13/2017
144	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

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
145	Response to FDA regarding family approach and IID	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
146	QbD Sample Guide	Quality by Design Product Development		QbD Sampling Guideline - User and supplier sections to be merged	Published IPEC QbD Sampling Guide	12/6/2016
147	WHO - Good Pharmacopoeial Practices	Compendial Review/Harmonizatio			Complete	12/1/2016
148	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
149	Final Controlled Correspondence guidance	Regulatory Affairs		Requires review and team discussion on next steps and possibly approaching the agency to suggest alternate	FDA Comments/follow-up	6/6/2016
150	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
151	Docket No. FDA-2015-21149: Request for Quality			need to prepare and submit comments to FDA with regards to their DRAFT Quality Metrics Guidance as it	IPEC-Americas Comments to open FDA Docket on Quality Metrics	11/2/2015
152	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

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
153	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
154	IPEC Americas Position Paper	Regulatory Affairs		Position paper on IID status, critical issues and next steps	Position Paper	10/15/2015
155	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
156	IPEC testimony at FDA public meeting seeking input on the reauthorization of the Generic Drug User Fee Act	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	10/15/2015
157	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
158	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
159	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

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
160	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
161	July 30 meeting with FDA	Regulatory Affairs		Discussion and presentation to agency on Toxicology/safety utilizing a family approach	FDA meeting	10/15/2015
162	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	10/15/2015
163	Review of IID issues related to the August 12, 2015	Regulatory Affairs		Compilation and submission of urgent issues to the agency related to August 2015 IID update.	Urgent IID Issues Documentation	10/15/2015
164	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
165	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	IPEC Comments to Docket No. FDA-2015-20556: Technical Document for Using the Inactive Ingredient Database; Establishment of a Public Docket	10/12/2015
166	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	PQRI/USP Workshop on Elemental Impurity Requirements in a Global Environment – Next Steps?	4/1/2015
167	IPEC-Americas comments for Final FDA Guidance on ANDA Refuse to Receive	Regulatory Affairs				2/6/2015

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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
168	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
169	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	10/23/2014
170	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
171	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	IPEC position paper clarifying FDA's requirement and applicability to excipient documents	6/1/2014
172	DMF Workshop at ExcipientFest	Regulatory Affairs		IPEC-Americas to host DMF workshop at 2014 ExcipientFest Americas	DMF workshop - complete	5/28/2014
173	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	Representative from IPEC-Americas to speak at FDA public meeting on OTC drugs Complete	5/28/2014
174	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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1	**Project name**	**Committees**	**Possible Federation Activity**	**Description**	**Final deliverable**	**DATE COMPLETED**
175	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	Published article on phthalates and comments to EMA	2/28/2014
176	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
177	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	The regulatory team will consider developing and posting an FAQ based on questions/comments	12/18/2013
178	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
179	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
180	FDA QbD Workshop	Quality by Design Product Development		Joint FDA OGD and IPEC-Americas QbD Workshop	Workshop scheduled and delivered October 16 and 21, 2013	10/16/2013
181	Technically Unavoidable Particles Profile (TUPP) Guide	Good Manufacturing Practices		Develop IPEC TUPP GUIDE	Published IPEC TUPP GUIDE	9/18/2013
182	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 -	Response to USP from member companies	9/13/2013
183	USP Excipient Stakeholder Forum	Compendial Review/Harmonization		IPEC-Americas asked to chair USP Stakeholder Forum	USP Stakeholder Forum participation	9/13/2013
184	FDA OGD training materials and session	Quality by Design Product Development		Finalize training materials for FDA OGD and deliver training to new reviewers	FDA QbD training sessions scheduled	9/13/2013
185	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"	FDASIA, Title 3 Letter to FDA	9/13/2013
186	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	FDASIA, Title 11, Section 1126 Letter to FDA	9/13/2013

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187	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	FDASIA, Title 7 Letter to FDA	9/13/2013
188	Brazil/Argentina GMP Workshops	Good Manufacturing Practices		To provided excipient training to ANVISA (Brazilian regulators) and Sindusfarma (industry organization in Brazil)	Excipient workshops scheduled and delivered August 19 and 21, 2013	8/26/2013
189	Coalition letter to USP	Compendial Review/Harmonizatio n		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]	Letter sent to USP on March 27, 2013	5/13/2013
190	DOE/Design/Space/Control Strategy Checklist	Quality by Design Product Development		Create checklist of DOE/Design Space/Control Strategy	Final checklist of DOE/Design Space/Control Strategy	5/1/2013
191	Gutter Oil PharmTech article	Excipient Qualification		Article in PharmTech entitled “Supply Chain Security Requires Standardized Excipient Information“	Published in PharmTech on March 1, 2013	1/29/2013