

Committee Accomplishments

	A	B	C	D	E	F
1	Project name	Committees	Possible Federation Activity	Description	Final deliverable	DATE COMPLETED
2	SME Engagement/Knowledge Sharing with SAC Members	Scientific Affairs	N/A	Identify and invite industry SMEs to share knowledge on excipients used in/needed for pediatrics and/or injectables to IPEC members. Knowledge to feed into future guidance development.	Presentations at Q2 SAC 2025 meetings	3-Jun-25
3	EW25 Experts Panel: Addressing Misinformation Insights and Strategies	Executive Committee	N/A	panel of experts to discuss the impact of misinformation on public health	EW 2025 Panel discussion	14-May-25
4	Excipients in Quality Risk Management of Pharmaceutical Products	Quality by Design	N/A	Complex systems are characterized by unpredictable emergent behaviours which can confound risk analyses and control strategies, leading to sudden product failures. Quality Risk Management per ICH Q9(R1) is a necessary but insufficient requirement.	EW 2025 Presentation	14-May-25
5	QC lab capability survey	Compendial Review/Harmonization	N/A	Share results from QC Lab Capability Survey	EW 25 Poster	13-May-25
6	QC lab capability survey	Compendial Review/Harmonization	N/A	Survey to collect data from global PEC members regarding testing capabilities of excipient QC release labs, including instrumentation available and analyst expertise	share analytical capability with USP, ideally during a stakeholder forum	13-May-25
7	Excipient Innovation Roundtable: Strategies in Development of New Excipient Products	Regulatory Affairs	N/A	Featured key stakeholders to provide their insight on strategies for introduction of new excipient products.	EW 2025 Round Table	13-May-25

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8	State of the Industry – QC Laboratories Instrument Survey	Compendial Review/ Harmonization	N/A	The purpose was to determine the current “State of the Industry” for QC laboratory Instrumentation and Equipment, specifically barriers that may be encountered preventing stakeholders from evaluating new or revised procedures published in the Pharmacopeia Forum.	EW 2025 Poster	13-May-25
9	European Decisions Impacting Excipients	Regulatory Affairs	N/A	roundtable session to discuss the regulatory environment in Europe and its implications for excipient manufacturers and users. Includes current issues and regulatory challenges with the implementation of new regulations for: <ul style="list-style-type: none"> • Titanium Dioxide (TiO2) • Co-processed Excipients • Atypical Actives • Nitrosamines • Innovation 	EW 2025 Round Table	13-May-25
10	Excipients 101 Workshop	Strategic Team 3	N/A	Covered the essential regulatory, quality and formulation aspects of common excipients used in oral solid dosage forms.	EW 2025 Conference Workshop	12-May-25
11	Biologics Summit: Advances in Cell and Gene Therapy	Executive Committee	N/A	workshop focusing on the latest advancements in cell and gene therapy. Feature insightful presentations and a dynamic panel discussion, providing a comprehensive overview of current trends, challenges, and future directions in the field.	EW 2025 Conference Workshop	12-May-25

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12	IPEC Good Distribution Practices Guide for Pharmaceutical Excipients Update	Good Manufacturing Practices	N/A	overview of the significant updates and overview and enhancements made to the recently published IPEC GDP How-To guide.	EW 2025 Conference Workshop	12-May-25
13	The Increased Relevance of Excipients in the Pharmaceutical Industry	Regulatory Affairs	N/A	Presentaton for CPhI NA - scheduled for delivery on May 21, 2025	CPhI presentaton during NA Conference	7-May-25
14	Department of Commerce Docket No. 25041-0065 RE Pharmaceutical & Pharmaceutical Ingredients	Regulatory Affairs	N/A	IPEC-Americas comments to Bureau of Industry and Security, U.S. Department of Commerce Docket No. 25041-0065 (XRIN 0694-XC120): Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. Regulations.gov ID BIS-2025-0022. In reference to broad tariffs on pharmaceutical excipients.	Submitted docket comments	6-May-25
15	Update of Risk Assessment Guide	Excipient Qualification	Yes	Review the 2017 Risk Assessment Guide for possible update	Published revised Federation Risk Assessment guide	6-May-25
16	Presentation at IFPAC	Quality by Design	N/A	IPEC-Americas presentation on excipients used for continuous manufacturing for 2025 IFPAC Conference	Presentation at IFPAC	5-Mar-25
17	Third Party Audit and Certification Programmed	Good Manufacturing Practices	Yes	Update the 2015 IPEC Federation position paper on Third Party Audit and Certification Programmes	Publish updated Position paper on Third Party Audit and Certification Programmes	27-Feb-25

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18	USP innovation and customer centric solutions	Compendial Review/ Harmonization	N/A	Richard Panzer, Senior Digital Product Manager and Marilyn Espinal, Senior Marketing Leader, Product & Growth Strategy spoke on ensuring innovation and customer centric solutions for USP	USP Presentation to CRC	26-Feb-25
19	QbD Sampling Guide	Quality by Design	Yes	Integrate the details of the QbD Sampling Guide into the 2020 International Pharmaceutical Excipient Council Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design (QbD) Guide	Combined Guide for Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design and QbD Sampling	25-Feb-25
20	SME Engagement/Knowledge Sharing with SAC Members	Scientific Affairs	N/A	Identify and invite industry SMEs to share knowledge on excipients used in/needed for pediatrics and/or injectables to IPEC members. Knowledge to feed into future guidance development.	Presentations at Q1 SAC 2025 meetings	25-Feb-25
21	IPEC-Americas 2024 Year in Review	Executive Committee	N/A	This infographic gives a high-level snapshot of our accomplishments in 2024.	Infographic on IA 2024 accomplishment	20-Feb-25
22	IPEC-Americas 2024 Annual Report	Executive Committee	N/A	Detailed information about IPEC-Americas accomplishments in 2024	2024 Annual Report	20-Feb-25
23	IPEC GDP Guide for Pharmaceutical Excipients	Good Manufacturing Practice	N/A	the IPEC GDP) Guide was revised and republished (Version 3) as a “how to” Guide in October 2024. The webinar will provide a high-level overview of the guide while highlighting significant changes between version 2 and version 3.	ELL webinar on revised IPEC GDP Guide	30-Jan-25

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24	FDA Docket Number: FDA-2024-N-4821	Regulatory Affairs	N/A	Docket Number: FDA-2024-N-4821 relative to Best Practices for FDA Communication with Interested Parties	Docket Comments Submitted	27-Jan-25
25	ECHA - Consultation on the implementation of the reporting requirements of the REACH restriction on microplastics	Regulatory Affairs	N/A	ECHA has launched a consultation to seek comments on a proposal for reporting of estimated emissions of SPM (synthetic polymer microparticles) for certain derogated uses from REACH restriction on microplastics (Entry 78 of Annex XVII).	Comments to ECHA	3-Jan-25
26	SME Engagement/Knowledge Sharing with SAC Members	Scientific Affairs	N/A	Identify and invite industry SMEs to share knowledge on excipients used in/needed for pediatrics and/or injectables to IPEC members. Knowledge to feed into future guidance development.	Presentations at SAC 2024 meetings	3-Dec-24
27	New USP Flavor Monograph for Distilled Lime Oil	Compendial Review/Harmonization	N/A	talk with Flavor RX to determine any comments or concerns that they might have regarding USP proposing a new monograph for distilled lime oil or any other potential monograph for flavors.	USP letter	30-Nov-24
28	EMA Q&A regarding co-processed excipients used in solid oral dosage forms H and V	Quality by Design	Yes	IPEC-Americas intent to develop both high-level and detailed comments, to first share/discuss with IPEC Europe then submit to EMA, regarding their concerns which include, but not limited to, the Q&A potential misunderstanding of co-processed excipient fundamentals.	comments to EMA on their Co-processed excipient Q&A	26-Nov-24

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29	QC Laboratory Instrument Survey presentation	Compendial Review/ Harmonization	N/A	Provide summary of QC lab survey results at 2024 Compendial Joint Industry Group meeting hosted by PDA on November 20-21st	Presentations at JIG meeting	20-Nov-24
30	IPEC-Americas LATAM Working Group Seminar 2024	Regulatory Affairs	N/A	2024 IPEC-Americas LATAM Working Group Seminar, which will present a "Panorama and Update on Nitrosamines, Atypical Actives, and GMP for Excipients" and feature presenters from the United States, Brazil, and Mexico	LATAM Seminar	19-Nov-24
31	Quality Management Maturity	Excipient Qualification	N/A	Based on 2023 ELL webinar survey, intited Jason Kerr from Moderna to give an ELL webeinar on the FDA QMM program	ELL webinar on FDA QMM	6-Nov-24
32	Alternative Methodologies sub team activities	Scientific Affairs	N/A	Following publication of the IPEC Safety Guide for Pharmaceutical Excipients, a global sub team of Safety Guide contributors continue to monitor current and emerging trends in use/acceptance of alternative methodologies by healthcare regulatory authorities.	Develop webinar and/or article on alternative methodologies	30-Oct-24

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33	IPEC Good Distribution Practices How To Guide	Good Manufacturing Practices	Yes	The GDP Guide was revised in 2017. For next revision, this guide would be updated to include information on how to implement the requirements. Need to prioritize this project based on resources. On hold for now. GDP Guide members: Lisa Frame, Erica V., Luc S. with Charlotte M. - lead	Published GDP How To Guide	17-Oct-24
34	USP GC <1078> Excipient GMP re-write	Good Manufacturing Practices	N/A	USP GC <1078> Excipient GMP revisions have now been completed and the final version is scheduled to be published in December 2024. Sub team to review previous version vs revised version (and USP response to comments received on first revision) for any concerns/issues.	IA review of revised USP <1078> Excipient GMPs	16-Oct-24
35	Excipient Excellence: The Power of Excipient Grade Selection	Excipient Qualification	N/A	CPHI Europe(Milan) panel discussion on Excipient Excellence: The Power of Excipient Grade Selection"	Panel discussion at CPHI Europe	9-Oct-24
36	Excipient GMP 101 Webinar/Training	Good Manufacturing Practice	N/A	Regulators outside US requested short webinar on excipient GMP, but IPEC does not currently have such a webinar. Suggested to develop an Excipient GMP 101 course to provide basic excipient GMP training/overview for regulators and people new to excipients (both manufacturers and users).	Excipient GMP 101 webinar/course for management	9-Oct-24

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37	Excipient GMP 101 Webinar/Training	Good Manufacturing Practices	N/A	Regulators outside US requested short webinar on excipient GMP, but IPEC does not currently have such a webinar. Suggested to develop an Excipient GMP 101 course to provide basic excipient GMP training/overview for regulators and people new to excipients (both manufacturers and users).	Excipient GMP 101 webinar/course for management	1-Oct-24
38	Excipient GMP Compliance Workshop	Good Manufacturing Practices	N/A	Compliance with excipient GMP/GDP is important to everyone involved in the manufacture, distribution or use of excipients. This workshop includes analyzing essential elements and expectations related to excipient GMP/GDP for materials intended for use in pharmaceuticals or dietary supplements and reviews the EXCiPACT Excipient GMP Certification scheme/updated NSF/IPEC/ANSI 363-2019.	Workshop held	20-Sep-24
39	PharmTech cover story on "Excipient Quaity"	Excipient Qualification	N/A	Publication based on PharmTech video interview (with Felicity Thomas) on the importance of excipient grade.	Pharmaceutical Technology article - published	10-Sep-24
40	Insider Articles on our Library of IPEC Guides and Postion Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 15 - Hot Topics involving excipients (e.g., nitrosamines, TiO2, microplastics, etc.)	9-Aug-24

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41	CLH proposal on silicon dioxide	Regulatory Affairs	N/A	Prepare comments from IA to European Chemicals Agency (ECHA) in response to the Dutch Competent Authority's request (RIVM) for the harmonized classification of silicon dioxide, specifically Synthetic Amorphous Silica (SAS), as Specific Target Organ Toxicity-Repeated Exposure Category 1 (STOT RE 1) by inhalation.	On-line comment submission to ECHA	8-Aug-24
42	Insider Articles on our Library of IPEC Guides and Position Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 14 - Regional excipient laws, regulations, and guidelines.	23-Jul-24
43	Update definition for excipient impurities/ concomitant components	Quality by Design	Yes	Diverse project team (e.g., QbD, GMP, etc.), to better define excipient impurities and concomitant components and develop a strategy moving forward, including revisions to IPEC Glossary and guides, as appropriate	Updated definition for excipient impurities and concomitant components. Defined strategy to communicate (e.g., infographic), and where necessary, update IPEC documents.	15-Jul-24
44	2022 IPEC Certificate of Analysis Guide	Excipient Qualification	Yes	Two concerns raised with 2022 CoA guide: o text requiring CoA date of approval to be shown on COA and o 2nd COA example for a COA that is not hand-signed, yet showing ID of the person approving the COA along with date of approval.	updated CoA guide	12-Jul-24

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45	USP proposed Resolution Concepts	Compendial Review/ Harmonization	N/A	Prepare IPEC-Americas comments/support for proposed resolutions for the USP 2025-2030 Convention cycle	Submit IPEC-Americas comments on proposed resolutions for the USP 2025-2030 Convention cycle	29-Jun-24
46	USP Draft Proposed Bylaw Amendments	Compendial Review/ Harmonization	N/A	Prepare IPEC-Americas comments/support for changes to bylaws for the USP 2025-2030 Convention cycle	Submit IPEC-Americas comment for changes to bylaws for the USP 2025-2030 Convention cycle	29-Jun-24
47	ChP GC <0251>	Compendial Review/ Harmonization	Y	Review the revised ChP <0251> chapter on Pharmaceutical Excipients and provide feedback from IA to the Federation by June 30, 2024	IA comments sent to Federation	28-Jun-24
48	Excipients: Compliance with Compendial and GMP Requirements	Good Manufacturing Practices	N/A	The International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) and Cobblestone have developed a comprehensive accredited course. The training includes an introduction to pharmacopeias, with an emphasis on the USP-NF and Ph. Eur., and a global perspective that touches on other pharmacopeias.	Joint Course delivered	18-Jun-24
49	Article on excipient considerations to ensure a robust CM process operation	Quality by Design	N/A	Develop article to examine the key information needed for excipients and their potential impact on CM processes. Focus on information from presentations during PQRI Workshop entitled "Managing Excipient and API Impact on Continuous Manufacturing" held virtually on May 17th and 18th, 2022	Article published in PharmTech	13-Jun-24

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50	Insider Articles on our Library of IPEC Guides and Postion Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 13- Excipient Master Files	12-Jun-24
51	Insider Articles on our Library of IPEC Guides and Postion Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 12- supply chain considerations for pharmaceutical excipients	29-May-24
52	Alternative Analytical Procedures for Excipient Quality Control Testing	Quality by Design	N/A	covers the use of alternative procedures to demonstrate equivalency to compendial procedures	EW 2024 Conference Presentation	15-May-24
53	Insider Articles on our Library of IPEC Guides and Postion Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 11- Excipient User Quality by Design and Continuous Manufacturing activities	15-May-24
54	Titanium Dioxide Industry Updates	Regulatory Affairs	N/A	A collaborative team of experts from IQ, IPEC-Americas and IPEC Europe have combined their efforts to provide an overview of ongoing activities retated to TiO2. The presentation included a brief background and summary, a look at the use of TiO2 in pharmaceutical applications, and current US state legislative activity.	EW 2024 Conference Presentation	14-May-24

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55	Commercial Drug Product Formulation Development Road Map Using IPEC Excipient Guides		N/A	This workshop demonstrated how the IPEC Papers and Guides can accelerate the use of excipients during the development and commercialization of new drugs. IPEC guides can help drug development teams avoid pitfalls that could delay development and submission of drug applications	EW 2024 Conference Workshop	14-May-24
56	3D Printing: Emerging Technologies and Functionality of Polymeric Excipients in Drug Product Development	Quality by Design	N/A	Covered key functionality of polymeric excipients and their utility in 3D Printing in drug development. Particular focus was given to hot melt extrusion and extruded filaments suitable for optimizing 3D Printing.	EW 2024 Conference Workshop	14-May-24
57	Expectations for Developing and Sharing Excipient Composition Information	Quality by Design	N/A	Provides an understanding of the fundamental sources and types of components that might be present in an excipient, offer best practices for characterizing an excipient composition profile and discuss potential analytical variabilities and limitations. In addition, presenters suggested best practices for excipient manufacturers to communicate composition information with users and regulators while avoiding potential pitfalls	EW 2024 Conference Presentation	14-May-24

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58	Exploring Today's Excipient Landscape: Trends, Risks and Regulations	Executive Committee	N/A	Panel discussion on perspectives from USP, IA and IE regarding trends in political and consumer pressure challenging science based regulatory agency decisions.	EW 2024 Conference Panel Discussion	14-May-24
59	Biologics Summit: Breakthroughs in Drug Delivery and Medical Devices	Executive Committee	N/A	Set of industry presentations on 1) The role of excipients in drug delivery CQAs of Drug Coated Balloons 2) Microneedles for drug and vaccine delivery 3) Liquid Embolic System for the treatment of stroke 4) Impact of PLGA Characteristics on the performance of long acting injectables	EW 2024 Conference Workshop	13-May-24
60	Excipients 101 Workshop	Strategic Team 3	N/A	Covered the essential regulatory, quality and formulation aspects of common excipients used in oral solid dosage forms.	EW 2024 Conference Workshop	13-May-24
61	Global Impact of PFAS Regulatory Restriction on Excipients	Regulatory Affairs	N/A	Review of PFAS regulations and restrictions based on EU proposed restrictions on their use and undesirable toxicological and ecotoxicological properties	EW 2024 Conference Presentation	13-May-24
62	CDER Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	Good Manufacturing Practices	N/A	Submit the ANSI 363 Standard to FDA for consideration as an FDA Reference Standard for excipient GMPs	ANSI 363 Excipient GMP Standard recognized by FDA as a voluntary consensus standard	7-May-24

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63	PF 50(2) Proposed Revisions to USP GN	Compendial Review/ Harmonization	N/A	<p>A team of CRC members has been formed to prepare comments regarding the proposed revisions to USP General Notices posted in PF 50(2).</p> <ul style="list-style-type: none"> •Minor clarifications in 3.10 Applicability of Standards •Addition of new 5.15 Definition •Revision of 5.60 Impurities and Foreign Substances •Clarification in 5.80 Reference Standard allowing the use of digital reference standards 	IA comments to USP GN proposal	29-Apr-24
64	Insider Articles on our Library of IPEC Guides and Postion Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 10 - Excipient Qualification	17-Apr-24
65	Insider Articles on our Library of IPEC Guides and Postion Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 9 - Excipient Qualification	3-Apr-24
66	Insider Articles on our Library of IPEC Guides and Postion Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 8 - Excipient Qualification	20-Mar-24
67	Insider Membership Article #1	Strat team 3	N/A	Article on "How has IPEC benefited your company, industry.",	Quarterly articles published in the IPEC Insider	20-Mar-24

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68	2024 Excipient World Conference & Expo Webinar	Excipient World	N/A	Late Breaking News: 2024 Excipient World Conference & Expo. Join us for special announcements! We have an exciting line-up of guest speakers who will share new details about what to expect this May.	EW webinar to promote conference and expo	20-Mar-24
69	Excipient Considerations in the Development and Approval of Animal Drug Products	Regulatory Affairs	N/A	IPEC-Americas/GADA co-sponsored webinar on excipients considerations in the development and approval of animal drug products	Webinar	12-Mar-24
70	Insider Articles on our Library of IPEC Guides and Position Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 7 - Excipient GDP and GDP Audit Guides	7-Mar-24
71	FDA Docket No. FDA–2023-N-5653	Regulatory Affairs	N/A	IPEC-Americas comments uploaded to FDA Docket No. FDA–2023-N-5653: Draft Report and Plan on Best Practices for Guidance	IA comments to FDA Docket No. FDA-20230N-5653	4-Mar-24
72	USP for <470> Determination of Diethylene Glycol and Ethylene Glycol in Polyethylene	Compendial Review/ Harmonization	N/A	IPEC-Americas comments to USP for <470> Determination of Diethylene Glycol and Ethylene Glycol in Polyethylene	IA comments for USP <470>	29-Feb-24
73	The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products	Regulatory Affairs	Yes	Revised IPEC Federation position paper entitled "The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products"	Revised IPEC position paper published	27-Feb-24
74	Update of Quality Agreement Guide	Excipient Qualification	Yes	Review the 2017 Federation Quality Agreement guide and re-issue updated version	Published revised Federation Quality Agreement guide	21-Feb-24

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75	2024 Excipient 4World Conference & Expo Webinar	Excipient World	N/A	Late Breaking News: 2024 Excipient World Conference & Expo. Join us for special announcements! We have an exciting line-up of guest speakers who will share new details about what to expect this May.	EW webinar to promote conference and expo	21-Feb-24
76	Update of TUPPs Guide	Excipient Qualification	Yes	Review the 2015 Federation TUPPs guide and re-issue updated version	Published revised Federation TUPPs guide	5-Feb-24
77	IPEC-Americas 2023 Year in Review	Executive Committee	N/A	This infographic gives a high-level snapshot of our accomplishments in 2023.	Infographic on IA 2023 accomplishment	24-Jan-24
78	PQRI Workshop TiO2 Position Paper	Quality by Design	N/A	PQRI TiO2 Workshop Organizing Committee/speakers position paper providing an overview of the information presented and ideas discussed during breakout sessions related to TiO2 safety and the challenges of using TiO2 alternatives in many drug applications	TiO2 position paper completed and published	22-Jan-24
79	OEHHA reassessment of Ethylene Oxide	Scientific Affairs	N/A	Prepare seconds set of written comments from IPEC-Americas makers and/or users of EtO for TITLE 27, CALIFORNIA CODE OF REGULATIONS, AMENDMENT TO SECTION 25705	IPEC-Americas comments to OEHHA	19-Jan-24

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80	Potential Impact of the EU TiO2 Food Ban	Regulatory Affairs	N/A	. This webinar will focus on the actual safety situation with TiO2, the potential use of TiO2-free coatings and the associated challenges being faced by the industry, regulators and patients, if TiO2 were to be banned in pharmaceutical applications.	IA LL Webinar on TiO2	17-Jan-24
81	PharmTech video on Excipient Grade	Excipient Qualification	N/A	PharmTech video interview (with Felicity Thomas, European/Senior Editor – Pharmaceutical Technology Group) on the importance of excipient grade. To be used as part of the PharmTech Drug Digest video series	Pharmaceutical Technology Video interview (with 5 IPEC-Americas members) - published	8-Jan-24
82	Insider Articles on our Library of IPEC Guides and Position Papers	Strat Team 3	N/A	Series of DID YOU KNOW articles targeted to make our public audience aware of our extensive library of resources	Part 6 - Risk Assessment for Excipients	1-Jan-24