Updates from the Chair

June 26, 2025

Joe Zeleznik

Chair, IPEC-Americas

Multiple stakeholders; **one objective.**

Volunteer Appreciation

THANK YOU TO OUR MANY VOLUNTEERS!

SPOTLIGHT ON…….

2nd Quarter Volunteer Spotlight

Ellen Grippi
G-ENP/MR – Regulatory Affairs and Quality, SA
BASF

IPEC Federation Updates

Federation (Priscilla)

- **IPEC Federation Activities**
  - Continuing to collaborate with WHO on nitrosamines, GDPs and contamination issues
    - Creating GDP training package
  - Making contacts in Africa as part of excipient awareness/training objectives
  - ICH:
    - IPEC Fed. now represented on M7 Risk Assessment & Control of Nitrosamine Impurities; concept paper under development
    - ICH Q1 Step 2 Stability Guideline open for public comments (IPEC comments due early July)
  - Attended USP Convention
  - Invited member of USP planning committee for excipient topics

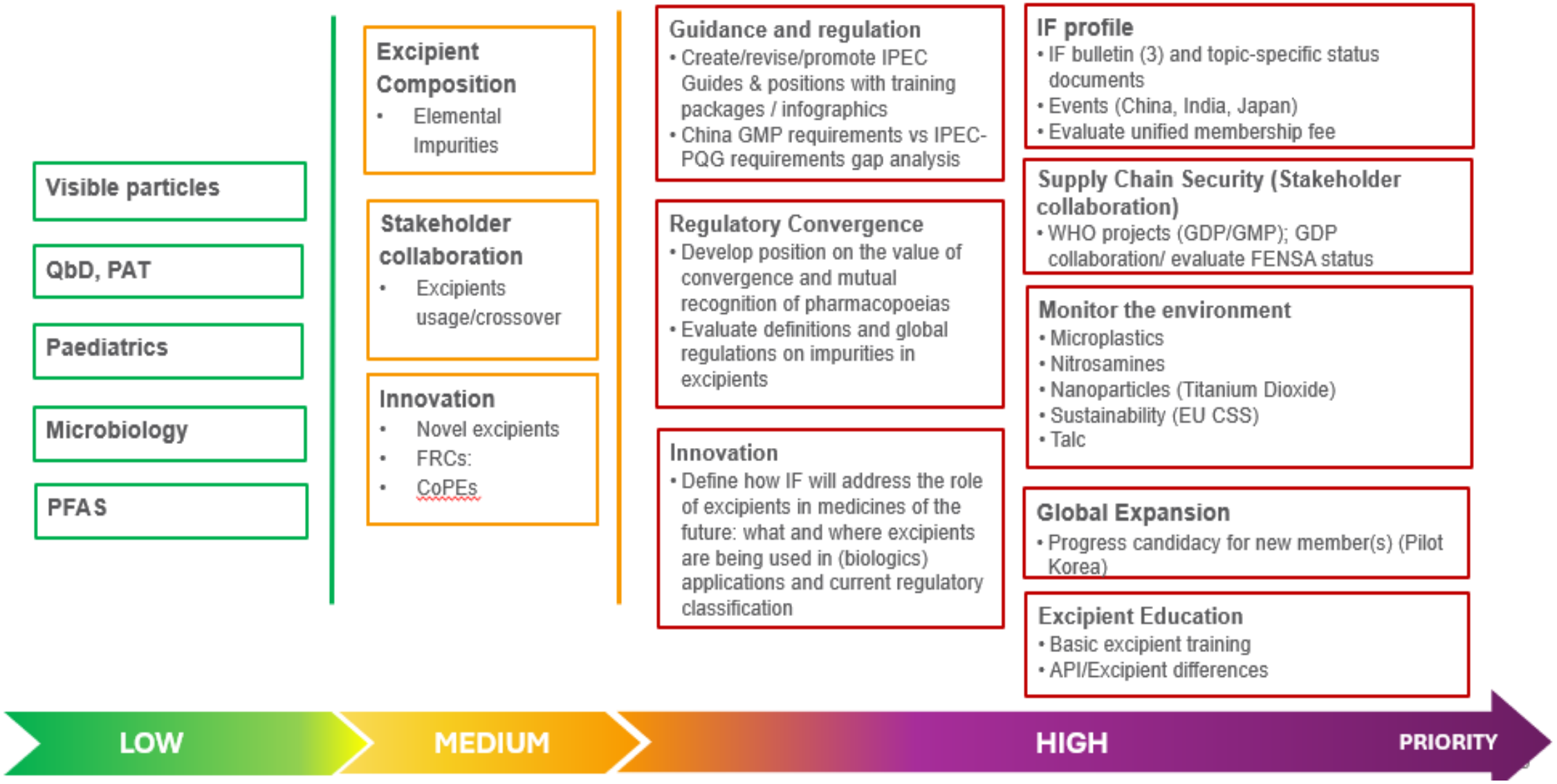
Federation

- Stability guide revision in progress
- Risk Assessment guide under revision w/PDA
- Comments to EMA Q&A on Co-processed Excipients documented for IPEC members (internal use only)
- Nitrosamines position paper & template under revision – addressing recent guidances & questions received from pharma
- Excipient Composition, Qualification & EIP guides under review for revision
- Position papers under development for: atypical actives, data integrity & AI, pharmacopeia convergence & mutual recognition

Federation – Regional IPEC Activities

- IPEC Europe:
  - New chair Corrine Roth, new vice chair Kevin Hughes
  - Presenting to EDQM in June re: CEPs for excipients
- IPEC Japan
  - Issuing Federation nitrosamines template in Japanese
  - Seminar planned in conjunction with IPEC-PDG Oct. meeting
- IPEC China
  - Comparison of NMPA's Excipient and Packaging Material GMP as Annexes of Drug GMP vs. IPEC PQG GMP completed; to be discussed in future meeting
  - IPEC China conference in Nov.
- IPEC India conference July 25

2025 Federation Strategic Focus and Priority Objectives



Committee Updates

Compendial Review and Harmonization Committee

Chair: Douglas Muse

Senior Principal Associate,

External Engagement and Advocacy (EEA)

Lilly

Vice Chair: Kathryn McCullough

Regulatory Affairs Health Care | ESHQ-Regulatory Affairs | Health Care

Evonik

Compendial Review (CRC)

- **Monthly Compendial Review Meetings** overview –
  - USP 2025, Issue 2, postings since May, PF 51(3), discussed revised publication schedule for PharmEuropa
  - USP announcements: newly elected Council of Experts for the 2025-2030 cycles & Board of Trustees for the 2025-2030 cycle
  - Next monthly Compendial Review meeting is July 14th, 2025, from 1:00-2:30 pm EST
- **Shared feedback** from the 2025 EW poster on *QC Laboratory instrument survey*
- **Provided updates** for IPEC-Americas activities with SEPC – Stakeholder Engagement Planning Committee, CPPQ – Compendial Policy, Process, and Quality stakeholder organization, JIG – Joint Industry Group Meeting.
- **Reviewed Federation project activities** for next scheduled PDG meeting and an update on sharing the harmonized polysorbate monograph with USP.
- **Discussed other compendial topics:** ICH Q1A (stability), Q4 (pharmacopoeias), M4Q and Q6 (specifications); Indian Pharmacopeia pyrogen testing changes vs USP 5.1.13 Pyrogenicity, and Chinese Pharmacopeia National Pharmaceutical Excipient Standards 2025.
- **Shared information** for USP Excipient Forum targeted for Q4, 2025. Tentative title: *Understanding excipient composition, main and minor components and organic impurities*.

Regulatory Affairs Committee

Chair: Bob Sulouff

Regulatory Affairs Advocacy Manager

IFF

Vice Chair: Troy Barrix

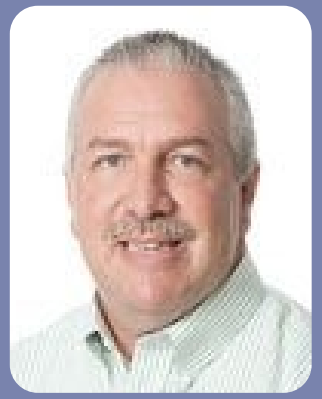
Principal Regulatory Compliance Specialist

Celanese

Regulatory Affairs

- **Update on Q1 2025 IID**
  - Reviewed IPEC-Americas IID workbook for Q2, 2025, including need to update/reissue
  - Currently working with Giuseppe Randazzo (Association for Accessible Medicines) for IID issues/topics for AAM to include in their 2027 GDUFA negotiations.
- **Discussed the following Regulatory topics**
  - FDA Docket No. FDA-2025-D-0507 Replacing color additives in approved or marketed drug products and identified a sub team to develop and submit comments by July 29, 2025
  - FDA PRIME Program update (from member participating in the program)
  - Reviewed and discussed various recent FDA announcements.
- **Regional Updates**
  - IPEC Microparticles Task Force developing a How-To guide on microparticles and plans to develop/deliver a webinar in Q4, 2025
  - Requested talking points for Federation to discuss with WHO regarding TRS 1060 - Annex 2: WHO good practice considerations for the prevention and control of nitrosamines in pharmaceutical products
  - Atypical Actives Guide sub-team formed and will help update Federation position paper on Good Manufacturing Practices for Atypical Actives.

Good Manufacturing Practices Committee



Chair: Mike Cassell

cGMP Quality Assurance Manager
Eastman Chemical Company

Vice Chair: Beth Febbo

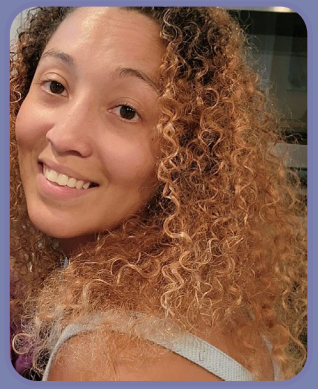
Global Laboratory & Project Manager
Henkel Corporation

Good Manufacturing Practices

- **Discussion on:**
  - Changes to recently published 2024 version of the NSF/IPEC/ANSI Standard for Pharmaceutical Excipients. Provided feedback to NSF and currently awaiting their response.
  - Quarterly EXCiPACT Standard review/discussion. EXCiPACT® currently looking to partner with IPEC-Americas to help support EXCiPACT® auditor training.
  - IPEC China reviewed, translated and compared the 2022 versions vs the 2025 version of 2025 China GMP regulations, Annex 1, Pharmaceutical Excipients in Chinese. GMP committee to review changes and communicate any MAJOR findings back to IPEC China.
  - Provided overview of upcoming changes to the ICH Q1: Stability Testing for Drug Substances and Drug Products. The Federation collecting comments through July 7 from regional PECs and submitting collective comments to ICH, (July 30 deadline to ICH).
  - Comparing excipient GMPs (USP vs IPEC vs ANSI vs WHO vs EXCiPACT) Article/Creating a matrix. Sub team is currently scheduling additional meetings and targeting Q4 for completion.
  - Currently supporting development and/or revision of Federation GDP Audit guide and Bulk Chemical handling.

Excipient Qualification Committee

Chair: Candy Reynolds-Cummings
Quality Assurance and Regulatory Manager
Evonik



Vice Chair: Kayla Thompson Allen
Regulatory Professional, Food, Nutrition & Pharmaceuticals
Ashland

Excipient Qualification

- **Discussion on:**
  - How IPEC might work with certification bodies (e.g., USP, EXCiPACT) to promote IPEC as the excipient trade association for excipient related information.
  - Planned revisions to Federation guides for Qualification of Excipient and Excipient Information Package and templates.
  - USP <1115> Bioburden Control of Nonsterile Drug Substances and Products how its application might relate to excipients
- **Updates for:**
  - Status/update on revision to IPEC Stability Guide
  - Review and revision of PDA IPEC TR 54-6 Risk Assessment for Excipient Report
  - Position paper on difference between excipient GMP's and food GMP's
  - ICH Q1 (stability) call for Step 2 document public comments
  - Sustainability and Responsible Sourcing

Quality by Design

Chair: David Schoneker

Consultant

Black Diamond Regulatory Consulting

Vice Chair: Liz Tocce, Ph.D.

Associate Scientist

IFF

Quality by Design

- **Discussion on:**
  - New excipients and co-processed excipients covered during the 2025 IFPAC Annual Conference held March 2-5 in Bethesda Maryland
  - IPEC-Americas/IPEC Europe position paper based on comments for 2024 Q4 EMA document entitled "Q&A regarding co-processed excipients used in solid oral dosage forms H and V (europa.eu)
  - Federation plans to update IPEC Composition Guide
  - New USP stimuli articles and general chapter on Process Analytical Theory. Considering whether or not to prepare and submit comments from IPEC-Americas
- **Updates for:**
  - Project to update the IPEC Co-processed Excipient Guide
  - Plans for Q4 2025/Q1 2026 PQRI workshop on Co-processed Excipients to Enhance Medicinal Product Development and Continuous Manufacturing
  - Plans for PQRI workshop and/or position paper to address DEG/EG Container Testing.
  - Excipient Composition Infographic on Concomitant Components

Scientific Affairs Committee

Co-Chair: Alexa Smith

Director, Global Quality & Regulatory Services
Colorcon

Co-Chair: Teresa Wegesser

Principal Scientist
Amgen

Scientific Affairs

- **Presentation:**
  - *Oral Pediatric Drug Product Development;* Bhanu Bejgum, PhD (presenter) and co-authored w/Behnoush Khorsand, PhD – Amgen Inc.
- **Discussion on:**
  - FDA PRIME program update from a program participant. Committee working to determine next steps.
  - FDA Expert Panel discussion on talc (Expert Panel with the FDA on Talc). Formed a sub-committee to provide feedback to the FDA.
  - NAMs sub-committee distilling FDA NAMs Report on Potential Approaches to Drive Future Integration of New Alternative Methods for Regulatory Decision-Making (fda.gov). And developing a NAMS toolbox/workflows, a review article for the International Journal of Pharmaceutical Excipients, and potential partnering/collaboration with other industry groups
  - Developing a Journal article reviewing misinformation trends and realities. Potentially partner with industry SME(s)

Users Network

Chair: Jennifer Putnam

Senior Supervisor AR&D

Perrigo

- Sunsetting the group due to limited attendance
- integrating UN topics into the quarterly committee meetings
- The UN will continue to be active during other committee meetings and monitor discussions for UN related topics.
- UN members are encouraged to lead projects or participate on teams to share user expertise and perspective.
- Can regroup as needed for specific projects

Monthly Compendial Postings Review

Reviewed USPNF Issue 2
<233> Elemental Impurities – Procedures: harmonized with European Pharmacopeia, Japanese Pharmacopeia, and/or the Indian Pharmacopeia

-

PF 51(3)

- Development of subcommittee to draft comments comparing currents methods used in monographs to new chapter <320> regarding NMR Spectroscopy
- Comments due by July 31, 2025
- Pharmeuropa 37.2:
- 5.1.13 Pyrogenicity: Comments due by June 30, 2025
- IPEC-Americas CRC QC Lab Instrument Survey presented at Excipient World and shared with USP personnel that were present
- PRIME program: a member shared at EW that they received communication from FDA indicating that the program was being discontinued, another member shared during the Q2 meeting that they had received the same communication
- Mark your calendars for December 9 &11, 2025
- USP Excipients Stakeholder Forum 8:30 am to 12:30 pm

Microplastics Cross Functional Team

Team Description

A cross functional team including members of the Pharma Chemleg team, IPEC-Americas and IPEC- Europe

Current Activities

- Microparticles cross functional team has started working on best practices guide for the medicinal products market segment which will be helpful to both excipient makers and users.

- The focus of this guide is on data elements required for compliance, including reporting requirements. Relevant illustrative examples for medicinal products will be included to provide clarity.

- The intent is to provide guidance to the medicinal product market segment on best practices so there is common understanding and a harmonized approach.

- It is anticipated that work on the guide will be completed by end of 3Q 2025. Communications on webinars/training will be provided to members as we get closer to publishing the final guide.

IPEC-Americas 2025 Q2 Dashboard

4 interactions with regulators/ pharmacopoeias

IPEC-Americas 2025 Q1 through Q2 in Review

	CRC	RA	GMP	EQ	QbD	SAC	UN	LL	ST3	IF	EW	XC	
FDA Docket comments		2											2
FDA Correspondence													0
FDA Public Mtg/training													0
USP correspondence/meeting	1												1
EDQM comments													0
ECHA (REACH Comments)		1											1
ICH Comments (ICH Q13 WG)													0
OEHHA													0
Publications													0
Workshops			1						1			1	3
Webinars/Presentations	3	3			2	2						1	11
Draft Guides (in-progress)		2	3	2	2								9
Published New/Revised Guides				1	1								2
Position Papers/White Papers													0
Infographics									2				2

M = membership

IPEC Foundation

IPEC Foundation Awards

The Foundation Awards Ceremony will take place in San Antonio Texas, November 11, 2025.

Applications can still be accepted - although the deadline has passed.

The Ralph Shangraw Memorial Award for individuals with outstanding research contributions in the study of excipients or excipient-related technology.

The Patrick DeLuca Emerging Researcher Award recognizes a beginning career scientist (post Ph.D.) who has demonstrated interest and dedication to the area of excipients.

Henk de Jong Industrial Research Award – Submit an application to recognize YOUR colleagues

The Five (5) annual graduate student travel recognizes excellence in research conducted at the graduate level in the field of excipients.

Strategic Objectives

Strategic Planning Goals

- **Goal A:** Critical stakeholders understand and advocate for the essential role excipients play delivering active pharmaceutical ingredients.

- **Goal B:** IPEC-Americas is the primary resource for excipient guidelines, standards and education for excipients.

Strategic Alliances and Partnerships

Latin America Working Group

- Objective – Sharing knowledge about trending topics in the LATAM region, strengthening the presence and promoting the LATAM WG within excipients and pharmaceuticals stakeholders.
- Hot topics for LATAM (nitrosamines, GMP, stability and atypical actives)
- Audience: academia, industry, associations and local authorities.
- Ongoing meetings in local language
- Prioritizing guides for translation
- Webinars planned for August and September
- If your company has business operations in Latin America who may want to participate in the working group please let IPEC-Americas Staff know.

EXCIPIENT LEARNING LAB

Webinar

IPEC-Americas LATAM Working Group
Excipients 101

August 6, 2025 - **3:00pm – 4:00pm BRT**
12:00pm – 1:00pm CT

Topics: Definitions and Regulatory Considerations

Note: Presented in Spanish

Multiple stakeholders; **one objective.**

EXCIPIENT LEARNING LAB

Webinar

IPEC-Americas LATAM Working Group Webinar Series 2025

Save the date: September 9, 10, 11

Topics: GMP and GDP guides, audits, certificate of analysis, significant change, supplier qualification, quality agreements, and excipient information package.

Note: Presented in Spanish

Multiple stakeholders; **one objective.**

INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL IPEC AMERICAS

Current Status – TiO_2

- No News from the EU Commission yet on their decision about extending the TiO_2 ban to pharmaceutical uses
  - This is overdue since a decision was expected in February 2025
  - No information is available yet regarding what the decision will be!
  - A provision in the new pharmaceutical legislation being developed may allow for a mechanism for continued use of TiO_2, but we do not know if they will use this
- No recent global developments regarding TiO_2, except the State Bills in the U.S. that continue to sometimes include TiO_2
- TDSC is working to get TiO_2 removed from all State Bills which list it as an item to be banned, etc.
- Still waiting for FDA decision on the CSPI Color Additive Petition requesting FDA to ban TiO_2 – Not sure how this will be impacted by MAHA movement initiatives

State Bills – Artificial (Synthetic) Colors & Certain Food Additives

- **RFK Jr.** has stated that he **wants all synthetic colors removed from foods** during his term. This has triggered many State bills
- **Approx. 80 State bills** have recently been introduced in a number of States to either ban or severely limit the use of synthetic colors in foods and some are moving through the legislative process
- Some **State bills** in states such as **Oklahoma** would have impacted pharmaceuticals. However, this bill died when the session ended – could be reintroduced in the next session
  - Oklahoma-2025-SB4-Amended.pdf

State Bills – Artificial (Synthetic) Colors & Certain Food Additives

- **TEXAS** - This bill (now a law) will require warning labels on food products which contain any of 44 Food Additives including TiO_2 and the Synthetic Colors and appears to be effective on **9/1/2025**.
  - **Drugs and dietary supplements** are **specifically exempted** from this labeling requirement at this time
- **LOUISIANA** – A similar bill to the Texas bill is under development
- **NEW YORK** – A bill was proposed to require all self-affirmed GRAS substances used in food to submit a detailed GRAS Notice to NY regulators - However, this bill also died when the session ended – could be reintroduced in the next session

FDA "Expert" Panel on Talc

- **Many industry groups are deeply alarmed** by the process utilized by the U.S. Food and Drug Administration (FDA) for its recent panel on talc.
- **The panel's one-sided composition** and failure to include the most recent extensively peer reviewed scientific studies is particularly troubling.
- The strongest available evidence across multiple fields of study clearly demonstrates **that talc does not cause cancer.**
- However, **this panel unanimously stated that Talc should be banned** using a precautionary approach which is not justified by the science, especially for oral drugs.

PQRI Initiatives

- Co-processed Excipient (CPE) Workshop is being planned – possibly in Q4 2025 or Q1 2026
  - Will cover the advantages of using CPEs, ongoing regulatory discussions regarding CPEs and the benefits to Continuous Manufacturing from using CPEs
  - Initial Planning Committee is currently meeting to plan the program
- DEG/EG Position Paper to justify reduced container testing for qualified suppliers
  - Volunteers will be meeting soon to discuss developing a PQRI proposal
- A webinar series is being developed by the PQTC on "Addressing root cause of Complete Response Letters (CRLs) issued in response to BLA Licensing Approvals"

Education & Training

Excipient Learning Lab

EXCIPIENT LEARNING LAB

Date	Title/Topic	Presenter(s)
August 6	Excipients 101 Intro > Overview of Sources/Applications > Regulatory Considerations **NOTE: Presented in Spanish**	Ellen Grippi
September 9-11 3 days 2 hours/day	Overview of the IPEC Guides > Day 1: GMP and GDP > Day 2: Audit, Certificate of Analysis and Significant Change > Day 3: Supplier Qualification, Quality Agreement, EIP **NOTE: Presented in Spanish**	> Thiago Souto > Norma Amilpa > TBD
September 10	Navigating Excipient Filings: Where are they required, and where do they apply?	Priscilla Zawislak
October 23	Risk Assessment How To: Practical Application of Guides and Tools	> Dale Carter (Maker) > Jen Putnam (User) > Charlotte Mcilvaine (Distributor)
November 11	Excipient GMP Differences, Risk Assessment, and Audit Findings	> Irwin Silverstein > Jim Morris > Dale Carter

Infographics

- **Updated Title:** Navigating IPEC Guides and Position Papers: A Map for Excipient Users
- **Sponsor:** Users Network
- **Goal:** Summer 2025
- **Next Steps:**
  - Finalize
  - Submit for approval

Videos

Foundation Awards Videos

- **Purpose:** Provide background on each award – reason for naming, etc.
- **Lead:** Foundation Board
- **Goal:** November 2025
- **FIRST Meeting:** June 11, 1pm

Excipient World 2025

May 2-6, 2026

Gaylord Opryland Resort & Convention Center

Nashville, TN

Planning Kickoff: July 2025

Survey-Driven Focus Areas:

- Audience Building
- Exhibitor Experience

Education

Monday, May 4
9 am – 4 pm

Tuesday, May 5
8 am – 5 pm

Wednesday, May 6
9 am – 3 pm

Networking/Evening Events

★**Sunday, May 3**

Welcome Reception

★**Monday, May 4**

Exhibit Hall Happy Hour

★**Tuesday, May 5**

IPEC-Americas 35th Anniversary Celebration – @Grand Ole Opry

Exhibits and Posters

Monday, May 4
5 pm – 7 pm

Tuesday, May 5
8 am – 5 pm

Wednesday, May 6
9 am – 3 pm

Expo Map

Company	Booth
Asahi Kasei America, Inc.	404
Azelis	322
BASF Corporation	401
BENEO GmbH	320
Biddle Sawyer	312
Clariant Corporation	307
dsm-firmenich	213
EP Minerals a US Silica Company	405
EXCiPACT	406
gChem	310
IMCD US Pharma	316
Indorama	306
IOI Chemical	507
KLK Oleo	223
LBB Specialties	400
Nagase & Co., Ltd.	217
Nisso America Inc.	506
Pharmaceutical Technology	301
SGS North America	407
Shin-Etsu	304
US Pharmacopeia	318

Hotel Deadline

- **Gaylord Opryland Deadline = April 2, 2026**
- EW25 Group Rates
  - Standard Room $304 / night
  - Atrium Room $364 / night
- Link provided after event registration

EW26: Learn More & Register

IPEC-AMERICAS EXCIPIENT WORLD 2026

NASHVILLE

International Journal of Pharmaceutical Excipients

- Formerly known as Journal of Excipients and Food Chemicals
- Keith Horspool, Ph.D., Chief Editor
- Vol. 2 , Issue 2, Q2 2025, now published
- Ongoing acceptance of manuscripts, research articles, reviews, technical notes and opinion pieces

2025 Committee Weeks

- **Dates for 2025 "IPEC Week"**
- Q 3 - September 16 - 18
- Q 4 – December 2-4

Tuesday: Scientific Affairs Committee
2:00 – 5:00 pm

Wednesday: CRC and RA 8:00 am – 5:00 pm

Thursday: EQ and GMP Extended time
8:00 am – 12:00 pm (flexible start time)

QbD/EC 1:00 – 4:00 pm

General Update Session - TBD

Questions

IPECAmericas.org
Education.IPECAmericas.org
ExcipientWorld.org

Multiple stakeholders; **one objective.**