Updates from the Chair

March 19, 2025

Joe Zeleznik

Chair, IPEC-Americas

Multiple stakeholders; **one objective.**

Volunteer Appreciation

THANK YOU TO OUR MANY VOLUNTEERS!

SPOTLIGHT ON…….

1st Quarter Volunteer Spotlight

Keith Horspool, Ph.D.
Editor in Chief
International Journal of
Pharmaceutical Excipients

IPEC Federation Updates

Federation (Priscilla)

- **IPEC Federation**
  - Annual General Meeting held in February. Current board terms in position through 2025
  - Each regional IPEC self-assessed adherence to the Federation Policy Manual
  - Pilot process for global expansion with a candidate from Korea
  - Federation fee structure changes proposed to bring parity to all regions

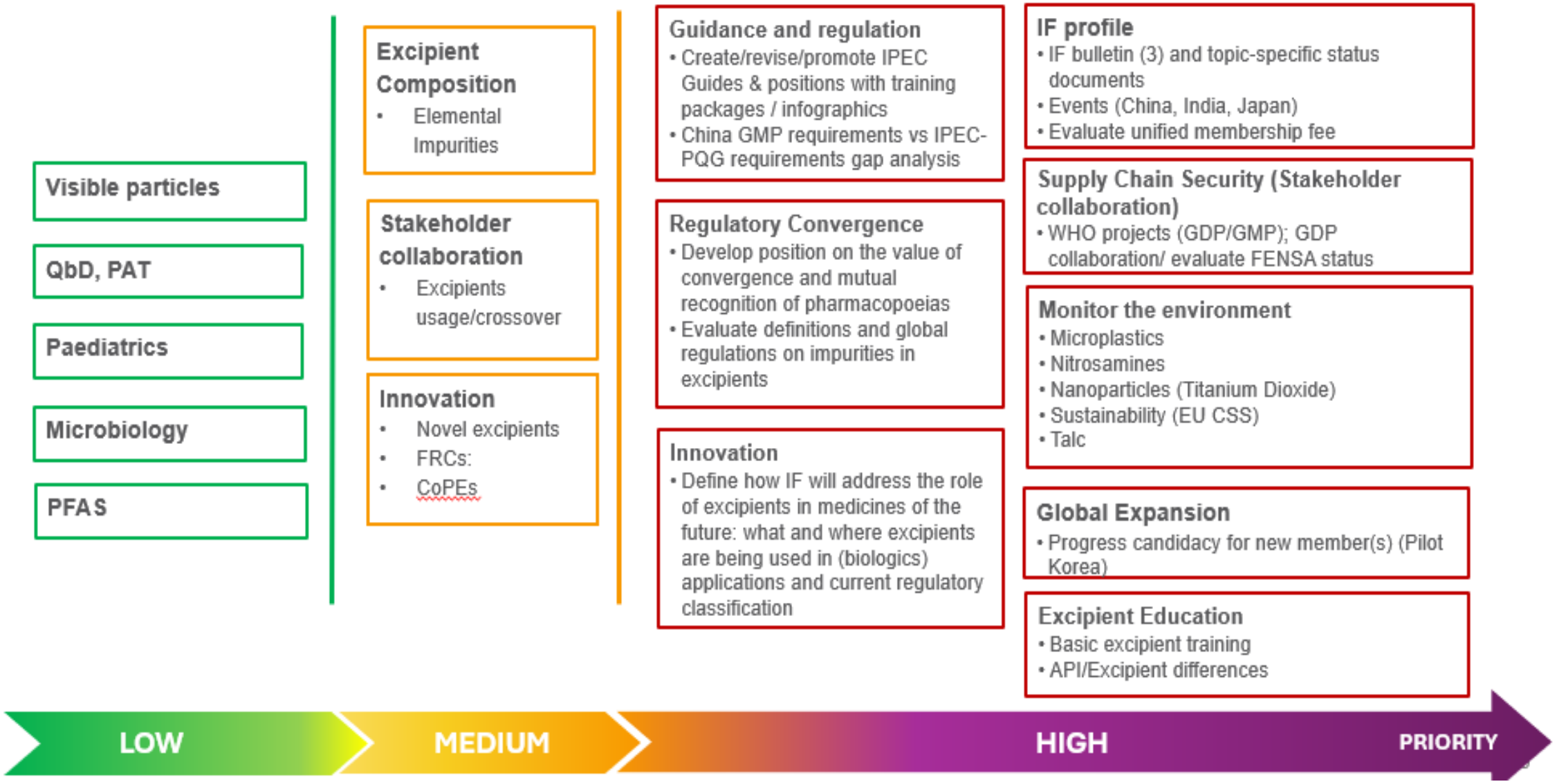
Federation

- GDP guide revision issued & training package under development
- QbD guide revision issued that incorporates QbD Sampling guide
- Stability guide revision in progress
- Risk Assessment guide under revision w/PDA
- Third Party Audit and Certification Programmes position paper issued
- Comments submitted for EMA Q&A on Co-processed Excipients
- Comments submitted to WHO on Continuous Manufacturing Guideline

Federation

- Issues management: microplastics, nano & TiO2 (position paper issued), PFAS, etc.
- IPEC China comparing requirements of NMPA's Excipient and Packaging Material GMP as Annexes of Drug GMP vs. IPEC PQG GMP; China implementation 1.1.2026
- Drafted 2025 Strategic Plan & Objectives
  - High priority: create a global package for basic excipient training:
    - Target audience: new industry professionals and regulatory authorities
    - Focus on fundamental excipient knowledge and differences between excipients and APIs

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 –
  - PF 50(6) and 50(1), PharmEuropa 37.1, EMA Q&A on DEG and EG testing and EXCiPACT® Certification for USP Verification Program
- **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.
- **Shared plans** for an EW25 poster for the QC Laboratory Instrument Survey
- **Reviewed Federation project activities** for IPEC Europe annex on dealing with multiple compendial methods and an update on polysorbate 20 harmonization.
- **Discussed other compendial topics** for ICH Q1A Stability, Indian Pharmacopeia, and Chinese Pharmacopeia National Pharmaceutical Excipient Standards 2025.
- **Richard Panzer, Senior Digital Product Manager and Marilyn Espinal, Senior Marketing Leader, both from USP,** shared a presentation focusing on ensuring innovation and customer centric solutions for USP.

Regulatory Affairs Committee

Chair: Bob Sulouff

Regulatory Affairs Advocacy Manager

IFF

Vice Chair: Troy Barrix

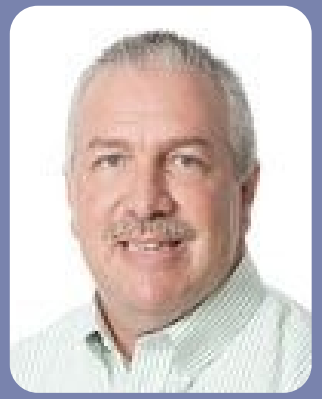
Principal Regulatory Compliance Specialist

Celanese

Regulatory Affairs

- **Update on Q1 2025 IID**
  - Reviewed IPEC-Americas IID workbook.
  - Currently working with Diana Solana-Sodeinde (FDA oversite for the IID database) on an IID presentation for Excipient World 2025 .
- **Discussed the following FDA topics**
  - FDA Docket No. FDA 2024-N-4821, Best Practices for FDA Communication with Interested Parties
  - FDA Docket No. FDA–2023-N-5653: Draft Report and Plan on Best Practices for Guidance
  - FDA external communications pause (Regulatory Freeze Memorandum)
  - FDA PRIME Program update request
  - FDA Draft Guidance – Considerations for Complying with 21 CFR 211.110 Sampling and testing of in-process materials and drug products
  - FDA Federal Notice to revoke color additive listing for use of FD&C Red No. 3 in food and ingested drugs
- **Regional Updates**
  - Status of ECHA Microplastics regulations and reporting requirements
  - Review of EMA GMP Q&A,
  - ANVISA reliance on EDQM CEPs for API,
  - PFAS Proposal 2023 for Entry Into Force and restrictions in India.

Good Manufacturing Practices Committee



Chair: Mike Cassell

cGMP Quality Assurance Manager
Eastman Chemical Company

Vice Chair: Beth Febbo

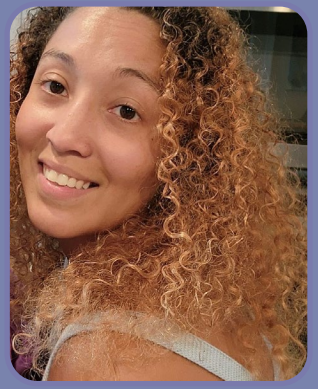
Global Laboratory & Project Manager
Henkel Corporation

Good Manufacturing Practices

- **Updates for:**
  - Submission of NSF/IPEC/ANSI Excipient GMP Standard to FDA for recognition as a consensus standard in Q2, still under review
  - Quarterly EXCiPACT Standard review/discussion.
    - Charlotte McIlvaine elected to represent IPEC-America,
    - USP now accepting EXCiPACT certification for USP Ingredient Verification Program.
  - China final GMP regulations for excipients.
  - Status of article comparing excipient GMPs (USP vs IPEC vs ANSI vs WHO vs EXCiPACT)
  - IPEC Federation Stability Guide revisions – 2025 status and plans.
  - IPEC-Americas Excipient GMP Audit Checklist to the revised IPEC GMP Guide.
  - Annex/Guidance for Parenteral Applications.
  - Potential 2025 webinar topics and volunteers.
- **Announced**
  - publication of the IPEC Federation position paper on Third Party Audit and Certification Programmes

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:**
  - When and where to use different customer agreements (e.g., NDAs, Quality agreements, etc.)
  - How IPEC might work with certification bodies (e.g., USP, EXCiPACT) to promote IPEC as the excipient trade association for excipient related information
  - Developing a guide or annex to an existing guide for setting specifications.
- **Updates for:**
  - Publication of IPEC Risk Assessment Guide revisions
  - 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
  - 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:**
  - IPEC-Americas/IPEC Europe comments to EMA regarding their 2024 Q4 EMA document entitled "Q&A regarding co-processed excipients used in solid oral dosage forms H and V (europa.eu)
  - IPEC position paper and/or infographic on Continuous Manufacturing
- **Updates for:**
  - Project to update the IPEC Co-processed Excipient Guide
  - Plans for Q3/Q4 2025 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.
- **Announcement for:**
  - Publication/posting of the 2025 QbD guide revision and free (to IPEC members) QbD Webinar.

Scientific Affairs Committee

Co-Chair: Alexa Smith

Director, Global Quality & Regulatory Services
Colorcon

Co-Chair: Teresa Wegesser

Principal Scientist
Amgen

Scientific Affairs

- **Presentation:**
  - *Excipient Selection for Pediatric Medicines;* Kevin Hughes Regional Regulatory Director EMEA) Coloron.
- **Discussion on:**
  - FDA Federal Notice *Color Additive Petition Request To Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs;* Jan. 16, 2025
  - Forming a NAMs deep dive sub-committee to distill FDA NAMs Reportion
    - Potential Approaches to Drive Future Integration of New Alternative Methods for Regulatory Decision-Making (fda.gov).
  - Applicability of SEND (standard for exchange of nonclinical studies) to excipients
- **Updates for:**
  - ECHA opinion and IARC classification of Talc timeline

Users Network

Chair: Jennifer Putnam

Senior Supervisor AR&D

Perrigo

Users Network

- **Discussion on:**
  - Plans to support revisions of IPEC Guides (from a User perspective):
    - GMP Certification Schemes & Body Qualification Guide for Pharmaceutical Excipients.
    - Stability Guide revision.
    - TUPPs Guide.
  - Development of an Annex/Guidance for Parenteral Applications
- **Shared:**
  - Draft Infographic on the ***IPEC Guides Road Map for Excipient Users***.

Monthly Compendial Postings Review

Reviewed New Proposals published in:

PF 51 (1) (comments due 30-Mar-2025)

PF 51(2) (updates included after 10-Mar-2025 will be reviewed at the next monthly meeting)

PharmEuropa 37.1 (deadline 31-Mar-2025)

PharmEuropa 37.2

Reviewed new/updated official content in:

USP/NF 2025 Issue 2

Pharmeuropa has updated their publication schedule and general information and will use an online format only in 2025

USP SEPC Webinar https://www.usp.org/events-training/usp-evolving-and-iterative-excipient-approaches

Discussion threads on the IPEC-Americas CRC Member Page regarding the Convention Cycle Nominating Committee and Council Reports

Next Compendial postings review:

14-Apr-2025 1-2:30 pm EDT (Remote)

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 will start 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 will be on data elements required for compliance including reporting requirements.
- The intent is to provide guidance to the market segment on best practices so there is common understanding and a harmonized approach.
- If interested in participating in development of this guide, please contact IPEC to join the microparticles team.

IPEC-Americas 2025 Q1 Dashboard

2 interactions with regulators/ pharmacopoeias

IPEC-Americas 2025 Q1 in Review

	CRC	RA	GMP	EQ	QbD	SAC	UN	LL	XC	IF	EW	M	
FDA Docket comments		1											1
FDA Correspondence													0
FDA Public Mtg/training													0
USP correspondence/meeting													0
EDQM comments													0
ECHA (REACH Comments)		1											1
ICH Comments (ICH Q13 WG)													0
OEHHA													0
Publications													0
Workshops													0
Webinars/Presentations	1		1		1	1							4
Draft Guides (in-progress)													0
Published New/Revised Guides			1										1
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 are now being accepted. Apply until June 15.

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
- Evaluating future seminar/workshop based on the success of the November seminar
- Following up with attendees to expand the group within the region
- If your company has business operations in Latin America who may want to participate in the working group please let IPEC-Americas Staff know.

PQRI Initiatives – Elemental Impurities

- PQRI's Interlaboratory Study Results have been published and is available free at:

[The Product Quality Research Institute elemental impurity interlaboratory study: Results and implications for industry – ScienceDirect]

- This paper will provide significant information to analysts involved in EI testing to help resolve analytical challenges

Journal of Trace Elements and Minerals 12 (2025) 100227

Contents lists available at ScienceDirect

Journal of Trace Elements and Minerals

journal homepage: www.elsevier.com/locate/jtemin

The Product Quality Research Institute elemental impurity interlaboratory study: Results and implications for industry☆

James M. Harrington[a,*], Donna S. Seibert[b], Glenn Williams[c,d], Thanh Nguyen[c,d], Denise McClenathan[e], Stephen W. Erickson[a]

[a] RTI International, Research Triangle Park, NC, United States of America
[b] Perrigo Company, Allegan, MI, United States of America
[c] Rigaku Corporation, The Woodlands, TX, United States of America
[d] VPrep Corp., Houston, TX, United States of America
[e] Procter and Gamble, Cincinnati, OH, United States of America

ARTICLE INFO

Keywords:
Elemental impurities
Method development
Interlaboratory study
USP 232/233
ICH Q3D

ABSTRACT

Introduction: Pharmaceutical laboratories experienced a paradigm shift in drug product elemental impurity (EI) expectations in International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline Q3D and United States Pharmacopeia (USP) General Chapters <232>/<233>. These guidelines describe a risk-based approach to EI analysis. Few systematic evaluations of interlaboratory performance on EI analysis in pharmaceutics have been conducted following these guidelines. Our goal is to address key technical challenges faced by laboratories during the implementation of these regulations.
Materials and Methods: We organized an interlaboratory study using standardized samples and methodology to assess sample preparation and analysis variability. Participants performed microwave-assisted acid preparation of simulated pharmaceutical products and analyzed Class 1 and 2A EI's by inductively-coupled plasma-mass spectrometry (ICP-MS). Several laboratories performed X-ray Fluorescence spectroscopy (XRF) for comparison.
Results: ICP-MS reproducibility was high both within and between laboratories, except for Hg and V. Exhaustive extraction and total digestion were generally comparable, between 87 and 111 % for As, Cd, Co, and Pb. Total digestion exhibited lower variability than exhaustive extraction. Two types of microwave systems produced comparable results for most elements except Hg and Pb. The summation approach was comparable to direct analysis of tablets except for Hg and Cd, but summation demonstrated greater variability. XRF showed good agreement with ICP-MS and low replicate variability within labs.
Discussion and Conclusions: While the results were generally favorable, they demonstrate that some technical challenges remain to be addressed related to standardizing laboratory practices including interference correction strategies and selection of preparation methods. We discuss implications for method transfer between laboratories.

Other PQRI Initiatives

- Co-processed Excipient (CPE) Workshop is being planned – possibly in Q3 or Q4 2025
  - Will cover the advantages of using CPEs, ongoing regulatory discussions regarding CPEs and the benefits to Continuous Manufacturing from using CPEs
  - Initial Planning Committee to meet shortly 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

Current Status – TiO2

- No News from the EU Commission yet on their decision about extending the TiO2 ban to pharmaceutical uses
  - This is overdue since a decision was expected in February 2025
  - Decision expected by the end of March 2025 but no guarantee that this will happen
  - No information is available yet regarding what the decision will be!

- No recent global developments regarding TiO2, except the State Bills in the U.S.; some include TiO2

- TDSC is working to get TiO2 removed from all State Bills which list it as an item to be banned, etc.

FDA Ban of FD&C Red #3

- FDA banned the use of FD&C Red #3 in foods (2027) and ingested drugs (2028) based on the Delaney Clause and a Color Additive Petition filed by several consumer groups

- FDA stated that they do not see any safety concerns related to humans based on a rat study from the 1980's which indicated a possible tumor concern. The mechanism which caused this concern in the rat does not exist in humans

- FDA had to ban FD&C Red #3 however due to some outdated wording in the Delaney Clause which states that a color additive must be banned if there is an indication of cancer in any human **OR ANIMAL** study, regardless if this is relevant to humans or not

- FD&C Red #3 cannot be easily replaced, especially in pharma applications

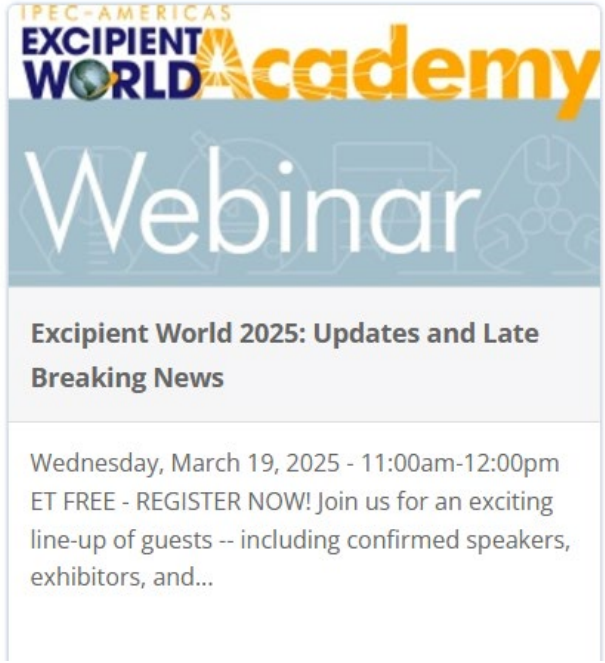
State Bills – Artificial (Synthetic) Colors & Certain Food Additives

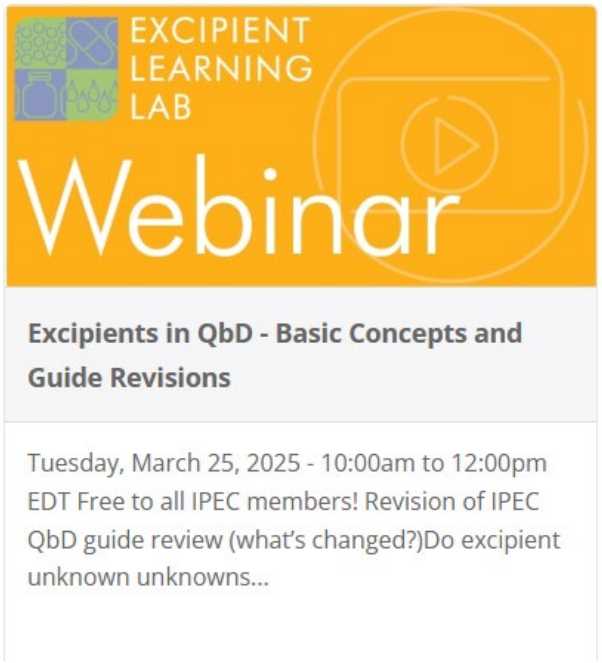
- RFK Jr. has stated that he wants all synthetic colors removed from foods during his term. This has triggered many State bills.
- Approx. 80 State bills have recently been introduced in a number of States to either ban or severely limit the use of synthetic colors in foods and some are moving through the legislative process
- Some State bills in states such as Oklahoma (Oklahoma-2025-SB4-Amended.pdf) would impact pharmaceuticals. It has already passed out of Committee
- IPEC-Americas is investigating how to possibly get involved in defending the use of synthetic colors with IACM and other groups

Education & Training

Excipient Learning Lab

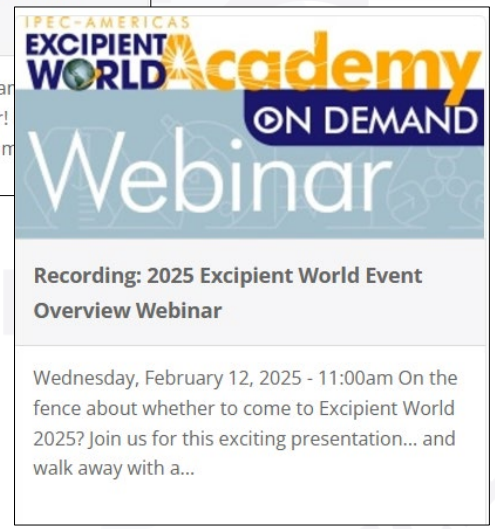
March 2025





January 2025

February 2025



NEW Infographic + Annual Report

- **Title:** 2024 Year in Review + Annual Report
- **Sponsor:** Education Strategy
- **Goal:** Q1
- **Status:** Complete

Excipient World 2025

Conference May 12-14
Expo May 13-14

Gaylord National Resort & Convention Center
(National Harbor, MD)

Education

Monday, May 12
9 am – 4 pm

Tuesday, May 13
8 am – 5 pm

Wednesday, May 14
9 am – 3 pm

Featured Presentations

FDA's IID Update & Vision

Diana Solana-Sodeinde,
CDER, OGD, FDA

Universal Ingredients: Can Excipients Bridge the Science Misinformation Gap?

Dr. Andrea Love, Biomedical Scientist,
Science Communicator

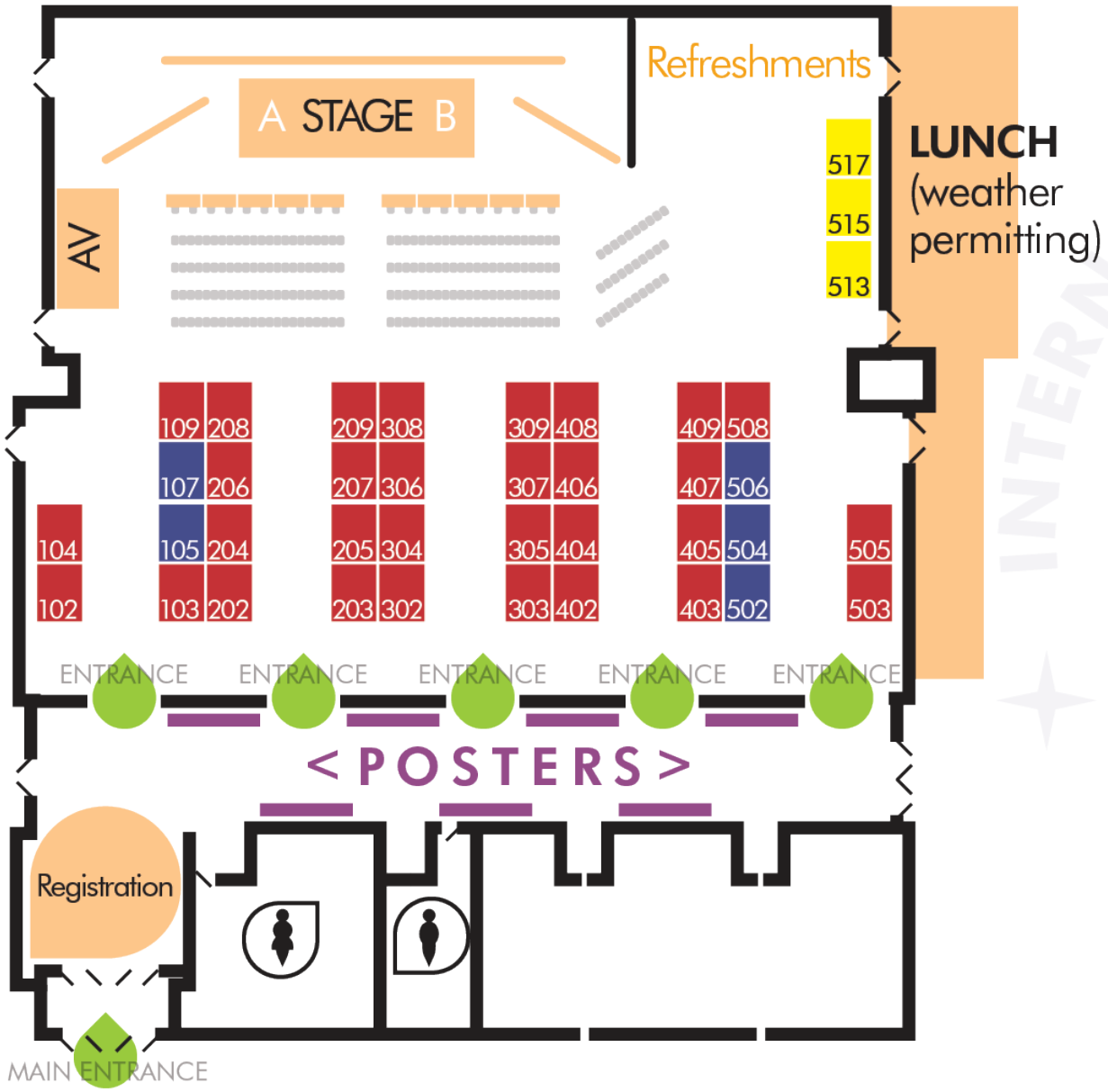
Exhibits and Posters

Monday, May 12
5 pm – 7 pm

Tuesday, May 13
8 am – 5 pm

Wednesday, May 14
9 am – 3 pm

Exhibits (as of 03.12.25)



Company	Booth
Asahi Kasei America, Inc.	409
Azelis Americas, P&H	104
BASF Corporation	303
BENEO GmbH	102
Biddle Sawyer	403
Clariant Corporation	206
Colorcon	209
Dow	407
dsm-firmenich	309
Evonik	405
EXCiPACT	302
Gattefossé USA	202
Gaylord Chemical	308
IFF Pharma Solutions	205
IMCD US Pharma	203
Indorama Ventures - Indovinya	304
Int'l Ingredients & Excipients	306
IOI Oleochemical	109
IPEC-Americas	505
KLK Oleo Emmerich	406
LBB Specialties	508
Lubrizol	404
Nagase & Co., Ltd.	305
Nisso America Inc.	409
osapiens Inc.	503
Pet Flavors	204
Pharmaceutical Technology	402
SGS North America Inc.	103
Shin-Etsu	307
Sprih Inc.	207
US Pharmacopeia	208

Networking/Evening Events

★**Sunday, May 11**

Welcome Reception

★**Monday, May 12**

Exhibit Hall Happy Hour

★**Tuesday, May 13**

Excipient World Celebration

PLUS ONE PASS

Hotel Deadline Approaching

- **Gaylord National Deadline = April 14**
- EW25 Group Rates
  - Standard Room $289 / night
  - Atrium Room $329 / night
  - Executive Suite $439 / night
- Link provided after event registration

EW25: Learn More & Register

Hotel Deadline = April 14

International Journal of Pharmaceutical Excipients

- Formerly known as Journal of Excipients and Food Chemicals
- Keith Horspool, Ph.D., Chief Editor
- Vol. 2 , Issue 1, Q1 2025, to be published March
- Ongoing acceptance of manuscripts, research articles, reviews, technical notes and opinion pieces

We have relocated!

- IPEC-Americas offices have moved!

New location:

We Work (co-working space)

901 N. Glebe Road, Arlington, VA

Ballston Metro Corridor

Closest Hotels, Hilton Arlington, Westin

2025 Committee Weeks

- **Dates for 2025 "IPEC Week"**
- Q 2 - June 3 - 5
- 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

Monday following "IPEC Week": Users Network: 2:00 – 3:00 pm

Questions

IPECAmericas.org
Education.IPECAmericas.org
ExcipientWorld.org

Multiple stakeholders; **one objective.**