Updates from the Chair

March 26, 2026

Gina Marsee

Chair, IPEC-Americas

Multiple stakeholders; **one objective.**

Volunteer Appreciation

THANK YOU TO OUR MANY VOLUNTEERS!

SPOTLIGHT ON…….

1st Quarter Volunteer Spotlight

Mike Polito

Regulatory Expert

Actives and Formulation – Americas

MilliporeSigma

Shout out To

USP Additives Issue Team
Jenn, George and Dave and all involved ….Thank YOU for YOUR persistence on the additives and processing aids issue.

Welcome New Members!

- University of Alabama
- MLC Consulting
- DSM Nutritional Products
- Ali Pharma Solutions

IPEC Federation Updates

Federation (Priscilla)

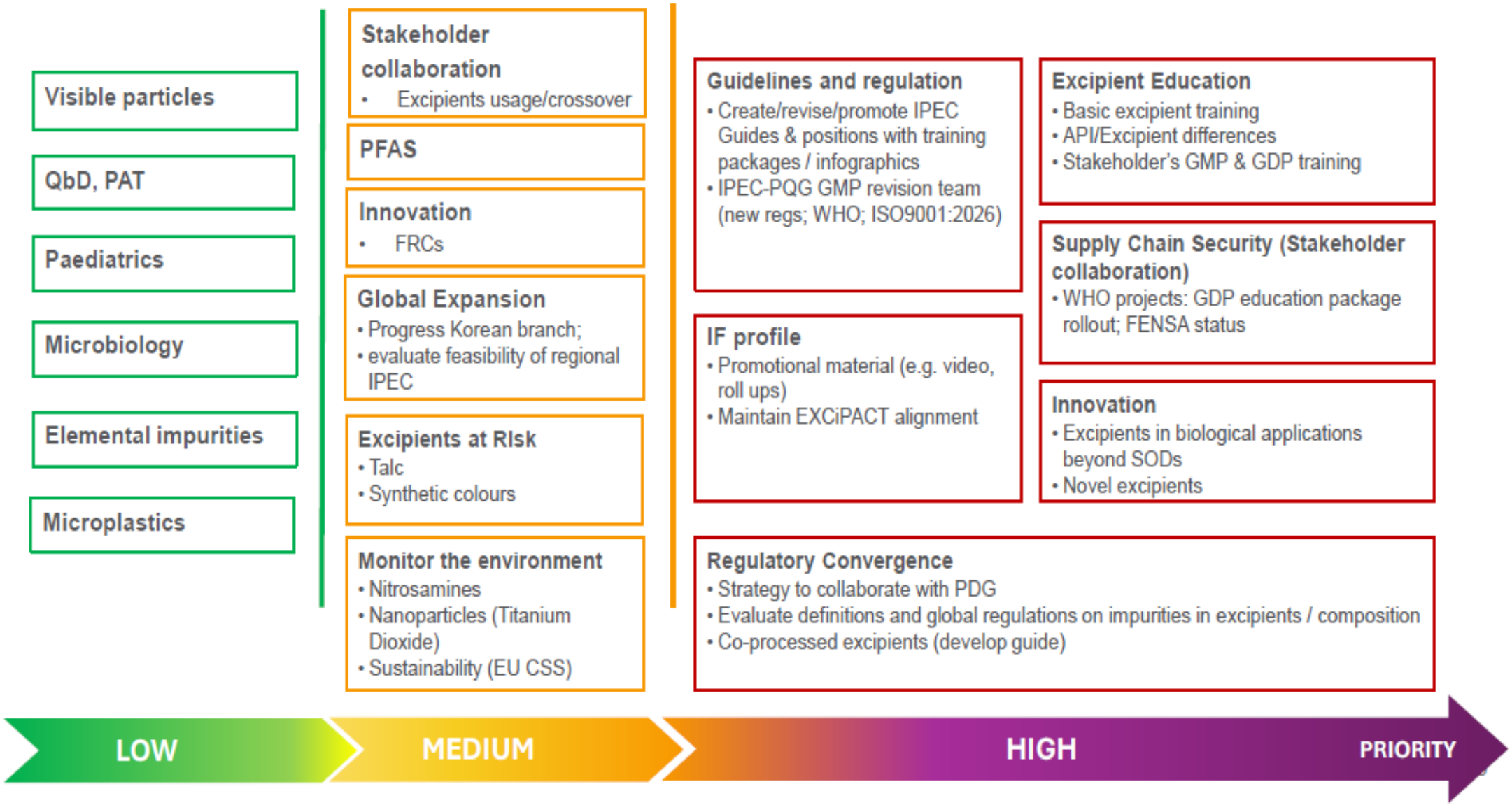
IPEC Federation Activities

- Annual General Meeting held in February
  - Strategic objectives for 2026 developed
- Stability guide revision to be published by April
- Excipient GMP Certification Scheme and CB Qualification, Excipient Qualification and Excipient Composition Guides under final revision
- IPEC/PDA Risk Assessment Guide revision starting
- Q&A developed for members re: China Excipient GMPs
  - Comments provided to EXCiPACT® regarding plans to develop GMP annexes by country
- Comments provided to BPOM on Indonesia's draft GMPs for excipients
- Developing a streamlined process to facilitate guide revisions

Federation (Priscilla)

- **IPEC Europe**
  - Developed 5 yr plan: 4 pillars – innovation, impact, added value, knowledge
  - Partnering with EFCG on advocacy topics for excipients
- **IPEC Japan**
  - JPED (excipients directory) and JPE (excipient pharmacopoeia) being revised in 2026
- **IPEC China**
  - Jiangsu FDA planning to write a book about excipient manufacture and GMP requirements and asked for IC input
  - NMPA & provincial FDAs interested in excipient GMP training
- **IPEC India**
  - DCGI is developing an excipient GMP guideline

2026 Strategic Focus and Priority Objectives



Committee Updates

Compendial Review and Harmonization Committee

Chair: Janeen Skutnik-Wilkinson

Sr. Director, GPO Reg, Intelligence & Advocacy

Lilly

Vice Chair: Kathryn McCullough

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

Evonik

Compendial Review (CRC)

- **Monthly Compendial Review Meetings** overview –
  - Reviewed/discussed new postings in USP PF52(2), USPNF 2026 Issue 4 and Pharmeuropa Issue 38.2.
  - Shared outcome of discussion with USP regarding additives and process aids
  - Gave an update on USP Digital Documentary Standards (dDS)
  - Next monthly Compendial Review meeting is April 6, 2026, from 1:00-2:30 pm EDT
- **Shared information** on the Talc General Announcement and USPs stakeholder request for input on available reference materials and XRD/PLM testing services
- **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.
- **Discussed** IPEC Japan's current strategy to publish the first digital issue of the Japanese pharmaceutical excipients directory (JPED) 2026 and efforts to complete major revisions to the Japanese Pharmaceutical Excipient (JPE) 2026.
- **Reviewed Federation project activities**.

Regulatory Affairs Committee

Chair: Bob Sulouff

Senior Manager Regulatory Affairs

Roquette Americas

Vice Chair: Troy Barrix

Principal Regulatory Compliance Specialist

Celanese

Regulatory Affairs

- **Update on Q1 2026 IID**
  - Reviewed IPEC-Americas IID workbook. Noted that for Q1'2026 the FDA did not report any changes or deletions to the IID listings.
- **Discussed the following current and emerging regulatory topics**
  - IPEC-Americas New Excipient Product Development Guide *Advancing Excipient Innovation Through Risk-Based Frameworks FDA Docket No. FDA–2023-N-5653: Draft Report and Plan on Best Practices*
  - Proposed updates/revisions to the US DMF Guide
  - FDA Docket No. FDA-2025-D-2275 for ICH M4Q(R2) The CTD – reviewed comments from IPEC-Americas
  - FDA assessment of BHA FDA Launches Assessment of BHA, a Common Food Chemical Preservative | FDA. Although currently specific to foods, members agreed to monitor
- **Regional Updates**
  - FDA call for comments to SUPAC Guidance's (Docket No. FDA-2026-N-0809).
  - Artificial colors: FDA Takes New Approach to "No Artificial Colors" Claims | FDA
  - February 25, 2026 IPEC-Americas Learning Lab webinar recording on - *Best Practices for European Microparticles Restrictions* is **available for free to IPEC-Americas members**.

Good Manufacturing Practices Committee

Chair: Mike Cassell

President
MLC GMP Quality Consulting

Vice Chair: Michael Hicks

Project Specialist,
Drug Delivery
Henkel Corporation

Good Manufacturing Practices

- **Provided updates for:**
  - Formation of a sub team to monitor issues/topics with NSF/IPEC/ANSI Excipient GMP Standard and search for a new Standards Writing Body sponsor.
  - Announcement of Excipient GMP Compliance in-person Workshop June 23-25, 2026
  - Plans to assess new ISO 9001 GMP Standard for potential impact on current IPEC guide and position papers.
  - FDA Docket No. FDA-2026-N-0746. Agreed to re-submit NSF/IPEC/ANSI 363 Excipient GMP Standard to FDA through the CDER Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality
  - Status and next steps for IPEC Stability Guide, V3 and IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients, V2.
  - Sub-team progress in comparing excipient GMPs (USP vs IPEC vs ANSI vs EXCiPACT)
  - Plans to review and revise 2021 GDP Audit Guide to align with 2024 GDP How To Guide.
  - Excipient World 2026 presentation entitled: *Is IPEC-PQG GMP up to the task of being the foundational GMP for excipients worldwide?* scheduled for May 6, 2026

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

- **Provided updates for:**
  - Article, position or white paper defining critical points for excipient users to consider when an excipient manufacture discontinues supply of an excipient
  - Article, position or white paper on interpretations of regulations and techniques to help Over the Counter (OTC) manufacturers as they prepare to conduct audits of their suppliers
  - Article, position or white paper on Using a 3rd Party GMP Distributor Audit/report to demonstrate that a distributor complies with appropriate excipient GMP requirements.
  - Application of USP GC <1115> Bioburden Control For Non-Sterile Drug Substance to excipients
  - Revision to IPEC Qualification of Excipients (QoE) Guide (2020) – routing for Federation review/approval.
  - Revision to IPEC Excipient Information Package Part I - III Guide (2020) – updating to include EIP Part IV Guide.
  - NEW IPEC-Americas Guide on Setting Product Specifications – currently under development

Quality by Design

Chair: David Schoneker

Consultant

Black Diamond Regulatory Consulting

Vice Chair: Liz Tocce, Ph.D.

Associate Scientist

IFF

Quality by Design

- **Reviewed and discussed:**
  - Forming a sub-team to review and develop IPEC-Americas comments to FDA Docket No. FDA-2026-N-0809 – Recommendations on Industry Scale-up and Post Approval Change Guidance.
  - EMA final Q&A regarding co-processed excipients used for solid oral dosage forms, published January 28, 2026. Agreed to review further and determine next steps.
  - 2026 fall PQRI workshop on Co-processed Excipients to Enhance Medicinal Product Development and Continuous Manufacturing.
  - Status and next steps for revising and publishing 2026 IPEC Composition Guide for Pharmaceutical Excipients, V3. Among other revisions, updates to include/consider better harmonization of terms/definitions, reference to how/when to update composition profiles, and addition of a composition profile protocol/template.
  - Final draft/edits to Part 4 composition infographic entitled "Excipient Impurities, Contaminants and Adulterants. Part 5 to focus on the Composition Profile.
  - New position paper on how best to use excipients in continuous manufacturing. Currently in-process of developing an outline based on historical work.
  - Updated project, project leads and volunteers to develop an IPEC-Americas position paper or guide on Excipient Interchangeability based on a recent article on Supplier Qualification.

Scientific Affairs Committee

Co-Chair: Alexa Smith

Director, Global Quality & Regulatory Services
Colorcon

Co-Chair: Teresa Wegesser

Principal Scientist
Amgen

Scientific Affairs

- **Invited presentations from:**
  - Basak Clements, PhD - ***Advanced therapy materials: their unique challenges, control requirements and how IPEC can help***.
  - Keith Horspool, PhD – ***International Journal of Pharmaceutical Excipients*** https://jefc.scholasticahq.com/.
- **Updates and discussion on:**
  - NAMs sub-team activities including:
    - Scientific and Regulatory posters for EW 2026
    - IPEC-Americas Learning Lab plans for webinar on Safety Evaluation of Novel Excipients
    - Plans to update the IPEC Safety Guide to expand on excipient NAMS information
  - Shared and briefly discussed a recent judge ruling on a talc trade libel case ***119123634273.pdf***. Ruling provides evidence that *Dr. Moline's 2020 Article entitled "Mesothelioma Associated with the Use of Cosmetic Talc"* was based on false information.

IPEC-Americas 2026 Q1 Dashboard

4 interactions with regulators/ pharmacopoeias

IPEC-Americas 2026 Q1 in Review

	CRC	RA	GMP	EQ	QbD	SAC	UN	LL	XC	IF	EW	M	
FDA Docket comments													0
FDA Correspondence		1											1
FDA Public Mtg/training													0
USP correspondence/meeting	3												3
EDQM comments													0
ECHA (REACH Comments)													0
ICH Comments (ICH Q13 WG)													0
Pharma trade associations						1							1
Publications													0
Workshops													0
Webinars/Presentations		1											1
Draft Guides (in-progress)		3	5	5	2								15
Published New/Revised Guides													0
Position Papers/White Papers		1											1
Infographics									2				2

M = membership

Education & Training

Excipient Learning Lab

Date (2026)	Topic	Presenter(s)
February 18	Excipient World 2026: Updates and Late Breaking News	Courtney Nazareno
February 25	IPEC Guide on Best Practices for European REACH Restriction on Synthetic Polymer Microparticles	Meera Raghuram
March 18	Excipient World 2026: Updates and Late Breaking News	Courtney Nazareno
May 20	Key Revisions to IPEC Excipient Stability Guide, Version 3	T Desravines, B Suloff, P Zawislak, M Weedon
Q2' 2026	Key Revisions to IPEC Excipient Composition Guide, Version 3	TBD
Q3' 2026	Future use of NAMs in the Safety Evaluation of Novel Excipients	T Wegesser, R Filler, D Schoneker, T Gorski, J Pitt
Q3/Q4' 2026	New Product Development Guide	M Raghuram, D Schoneker
September 30	US Laws, Regulations and Industry Best Practices for Excipients	P Zawislak
TBD	Excipient QMS design, CAPA, NCR, Deviations, and Batch Record Review	I Silverstein, D Carter, M Cassell

Excipient GMP Compliance *In-Person* Workshop

June 23 - 25, 2026

IPEC-Americas Headquarters
901 N Glebe Road, Suite 500
Arlington, Virginia

Presenters:

- **Irwin B. Silverstein, Ph.D.**
  Lead Trainer, IPEC-Americas Excipient Learning Lab
- **Mike Cassell**
  Trainer, IPEC-Americas Excipient Learning Lab

Excipient World

Pre-Conference May 3
Conference & Expo May 4–6

IPEC-AMERICAS
EXCIPIENT WORLD
2026
NASHVILLE

Gaylord Opryland Resort & Convention Center
(Nashville, TN)

FDA Speaker: May 6, 8AM

FDA's Perspective on Excipient Component Nomenclature and Compendial Requirements for Excipient Composition

Adchara Pongpeerapat
OPQ | CDER | FDA

IPEC-AMERICAS EXCIPIENT WORLD 2026 NASHVILLE

FDA Speaker: May 6, 2PM

Safeguarding Against Diethylene Glycol Contamination: Lessons from Recent Outbreaks

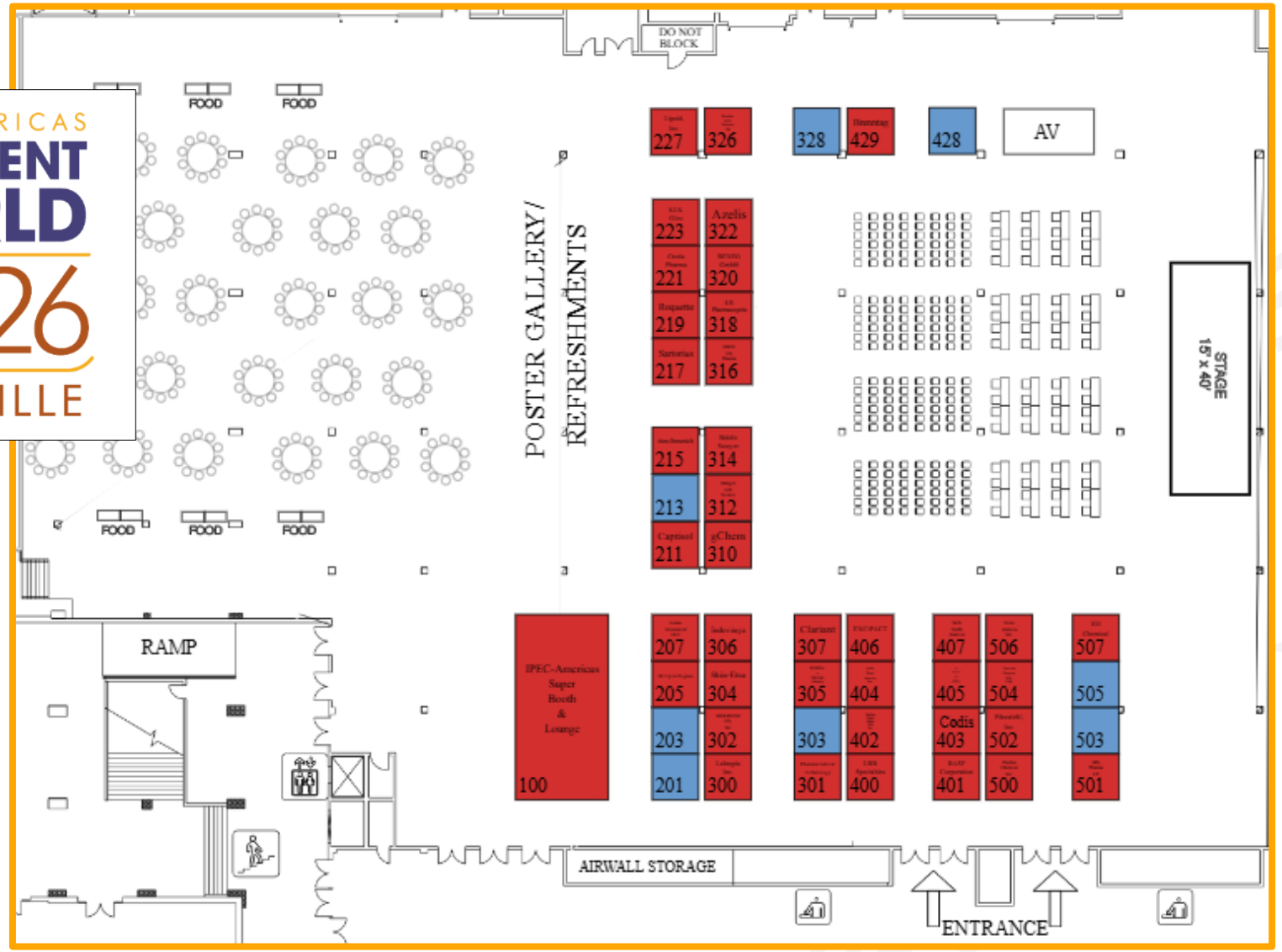
Matt Dionne, PharmD, MBA
Compliance Officer
OMQ | CDER | FDA

IPEC-AMERICAS EXCIPIENT WORLD 2026 NASHVILLE

Expo Map

Red = Sold
Blue = Available

IPEC-AMERICAS
EXCIPIENT WORLD
2026
NASHVILLE



IPEC-Americas 35th Anniversary Celebration

- **Date:** May 5, 2026
- **Time:** 5:00 pm Reception; 7:00 pm ***Live Opry Show***
- **Location:** Grand Ole Opry
- **Cost:** Access is included with your EW26 registration

Build Your Case

Hotel Deadline

- **Gaylord Opryland Deadline = April 2**
- EW26 Group Rates
  - Standard Room $304 / night
  - Atrium Room $364 / night
- Link provided after event registration

JOIN US FOR

IPEC-AMERICAS EXCIPIENT WORLD 2026 NASHVILLE

MAY 4-6

CELEBRATING IPEC AMERICAS 35 YEARS STRONG

HARMONIZE in MUSIC CITY

Gaylord Opryland Resort & Convention Center
Nashville, TN

IPEC Foundation

Foundation Award Applications

- **Deadline:** June 15, 2026
- **The Ralph Shangraw Memorial Award** is to be given to any person that has provided outstanding research in the study of excipients or excipient-related technology. **($10,000)**
- **The Henk de Jong Industrial Research Award** recognizes individuals in industry for their outstanding achievements and contributions in excipient research and innovation.
- **The Patrick DeLuca Emerging Researcher's Award** – 2 year award -The IPEC Emerging Researcher Award will be presented to a beginning career scientist post Ph.D. (postdoctoral fellows, research assistant professors and early-stage assistant professors). **($15,000 per year)**
- **Five (5) annual graduate student travel scholarships** will be awarded and acknowledged for their excellence in research conducted at the graduate level in the field of Excipients. Students with recent significant contributions to formulation science and technology through innovative research with excipients are eligible for this award. **($2,000 each)**

IPEC Foundation Award Ceremony

The Foundation Awards Ceremony:

In Conjunction with AAPS PharmSci 360
New Orleans, Louisiana
October 25-29, 2026.

The Foundation awards ceremony is scheduled to take place Tuesday evening, October 27, in New Orleans.

www.ipecfoundation.org

Award winners contribute research papers into the International Journal of Pharmaceutical Excipients for further exposure and recognition.

Strategic Objectives

Strategic Planning Session 2026

- Hilton Head, SC, February, 2026
- 25 individuals including Executive Committee members, Committee Chairs,Vice-Chairs, staff
- Development and refinement of three strategic objectives including actions:

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.

- **Goal C:** IPEC-Americas is a modern, effective and growing organization.

2026 Strategic Planning

Media/Communications Training

- Media training workshop held; designed to help facilitate discussions with the media and the general public to explain the importance and critical role that excipients play in finished drug products.

Strategic Alliances and Partnerships

USP IPEC-Americas Meet & Greet

- Monday, March 2, 2026
- Meeting with Fouad Atouf, Ph.D.,
- Chief Science Officer and Catherine Sheehan, DRSc. MS. MS., Senior Director, Foods and Excipients Documentary Standards & Compendial Policy Global Science and Standards
- Gina, Priscilla, Jennifer, Kim

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.
- Hybrid Workshop Planned Q4, 2026, Brasil
- Place TBD: Sindusfarma auditorium in Sao Paulo?
- Topics TBD: GMP/GDP (maybe a GDP focus); RETEST of raw materials + others
- Ongoing meetings (every 2 months)
- Next meeting: May 18th (with 1/3 reserved for EXCiPACT and certification topics with Iain and Yanet from MX)
- If your company has business operations in Latin America who may want to participate in the working group please let IPEC-Americas staff know.

LATAM WG 2026 Ongoing tasks

- **Ongoing tasks:**
- Translation of 08 guides: Completed under review within the LATAM WG colleagues, deadline March/2026.
- 2026 event planning
- Next meeting: May 18th (with 1/3 reserved for EXCiPACT and certification topics with Iain and Yanet from MX)
- Mexican Forum follow up meetings with the event's committee: Idea to have an excipients' free course in partnership with the university (UDLAP).

Joint Association Industry Collaboration Group (JAICG)

- **Latest JAICG meeting was held on March 17, 2026**
- **Key topics discussed:**
  - **Self-affirmed GRAS Issues**
    - Many state bills being proposed - NY has been passed in the Senate and has advanced to the Assembly - would require GRAS notifications with significant amounts of data to be submitted to the state and when accepted the substance would be listed in a public database along with key use information
    - FDA Mandatory GRAS Regulation is expected in the next few months
    - Several federal bills have been proposed in Congress - Marshall Bill most likely to proceed
  - **Synthetic (FD&C) Colors**
    - No further information concerning removal by FDA recently
    - Enforcement Discretion Policy established by FDA to allow for companies who do not use FD&C colors but do use natural colors to label products with the following: "Contains No Artificial Color" - goes against the law and could present legal challenges in the future for companies who do this and create significant consumer confusion
    - Several additional state bills include possible bans or limitations on the use of certain synthetic colors
    - West Virginia IACM Lawsuit - Judge has temporarily blocked the synthetic color ban for foods while case is decided saying there is no substantiation for a ban

Talc

- **Talc**
  - EUROTALC held a webinar on March 24, 2026 concerning the REACH Classification as a 1B Carcinogen
    - Science does not substantiate this classification
    - EUROTALC is working to try to change this position by ECHA and is looking from industry support
    - EUROTALC has been invited to participate in JAICG for future discussions
- **Next Meeting - April 16, 2026**

PQRI Initiatives

- **Co-processed Excipient Workshop**
  - Planning Committee met on March 12, 2026
  - PQRI Workshop being planned for Q3 or Q4, 2026 probably at USP Headquarters in MD - possibly coordinate with a USP Excipients Stakeholders meeting
  - Will be an in-person/hybrid meeting to provide easy access globally but maintain in-person benefits
  - Will address issues regarding the EMA Q&A document on CPEs
  - Agenda will include discussions on the following points:
    - The need and benefits of co-processed excipients and descriptions of co-processing methods and manufacturing realities.
    - Regulatory status and safety assessment
    - Customer concerns and equivalency between manufacturers
    - Product comparisons and continuous manufacturing relevance
    - Process controls, GMP, and perceived risks
    - Need for Monograph Development
    - Potential case studies and historical examples

- **PQRI Project on DEG/EG Container Testing**
  - Initial project discussion has support from the PQTC
  - Objective - A Position Paper defining what type of data and supplier qualification controls might justify moving away for individual container testing
  - Volunteers have been identified
  - Initial meeting will be planned in Q2 to initiate actions

PQRI Elections and Open Positions

- Dave Schoneker will begin as Chair of the PQRI Steering Committee starting in Q2
- Several candidates have come forward for Board Chair and Board Member Positions - Ratification of these positions will be completed on March 30th
- Still looking for a Steering Committee Vice Chair who would then become Chair in 2028 - Any Volunteers? Let Dave Schoneker know ASAP

International Journal of Pharmaceutical Excipients

- Formerly known as Journal of Excipients and Food Chemicals
- Keith Horspool, Ph.D., Chief Editor
- Vol. 3 , Issue 1, Q1 2026, To Be Published – 3/31/2026
- Ongoing acceptance of manuscripts, research articles, reviews, technical notes and opinion pieces
- Submit a manuscript – no fees!

INTERNATIONAL JOURNAL OF PHARMACEUTICAL EXCIPIENTS

2026 Committee Weeks

- **Committee meeting schedules and structure are under review based on feedback received from the strategic planning survey and interviews.**

- **June meetings to be virtual.**
- **Dates for 2026 "IPEC Week"**
- June 9 – 11
- Sep. 22 – 24
- Dec. 8-10

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)

Thursday: QbD/EC 1:00 – 4:00 pm

Questions

IPECAmericas.org
Education.IPECAmericas.org
ExcipientWorld.org

Multiple stakeholders; **one objective.**