Updates from the Chair

October 1, 2025

Joe Zeleznik

Chair, IPEC-Americas

Multiple stakeholders; **one objective.**

Volunteer Appreciation

THANK YOU TO OUR MANY VOLUNTEERS!

SPOTLIGHT ON…….

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3rd Quarter Volunteer Spotlight

Liz Tocce, Ph.D.
Associate Scientist
IFF
Vice Chair QbD Committee

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IPEC Federation Updates

Federation (Priscilla)

- Stability guide revision in progress
- Nitrosamines position paper & template revisions being circulated for approval
- Completed review of NMPA's excipient GMPs vs IPEC guidelines. Document being prepared for members outlining differences.
- ICH:
  - IPEC Fed. now represented on M7 Risk Assessment & Control of Nitrosamine Impurities; concept paper under development
  - ICH Q1 Step 2 Stability Guideline IPEC comments submitted via EMA

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Federation (Priscilla)

- Reviewing UNODC-WHO report on 'Contaminated Medicines and Integrity of the Pharmaceutical Excipients Supply Chain'
- Presented to Shanghai MPA and Indonesia BPOM (FDA) on excipient GMPs & EXCiPACT®
  - Indonesia plans to issue excipient GMP guidelines in Oct.
- Presenting at IPEC China conference in October
- IPEC-PDG meeting being held Oct 1 in Tokyo

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Federation – Regional IPEC Activities

- IPEC Europe
  - Decision not to ban TiO2 in pharmaceuticals
  - EC proposal on how to treat waste water to remove metabolites & active ingredients from pharmaceuticals; cost to be paid by chemical and pharma industries; pharma industry opposition
- IPEC Japan
  - Held an Introduction to Excipients course >100 attendees
  - Excipient workshop Oct 2 in Tokyo

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Federation – Regional IPEC Activities

- IPEC China
  - NMPA's Excipient and Packaging Material GMP as Annexes of Drug GMP sent for comments to IC membership
  - IPEC China conference in Nov.
- IPEC India
  - Committee being formed by DCGI to develop excipient GMP guidelines

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2025 Strategic Focus and Priority Objectives

Visible particles

QbD, PAT

Paediatrics

Microbiology

PFAS

Excipient Composition
- Elemental Impurities

Stakeholder collaboration
- Excipients usage/crossover

Innovation
- Novel excipients
- FRCs:
- CoPEs

Guidance and regulation
- Create/revise/promote IPEC Guides & positions with training packages / infographics
- China GMP requirements vs IPEC-PQG requirements gap analysis

Regulatory Convergence
- Develop position on the value of convergence and mutual recognition of pharmacopoeias
- Evaluate definitions and global regulations on impurities in excipients

Innovation
- Define how IF will address the role of excipients in medicines of the future: what and where excipients are being used in (biologics) applications and current regulatory classification

IF profile
- IF bulletin (3) and topic-specific status documents
- Events (China, India, Japan)
- Evaluate unified membership fee

Supply Chain Security (Stakeholder collaboration)
- WHO projects (GDP/GMP); GDP collaboration/ evaluate FENSA status

Monitor the environment
- Microplastics
- Nitrosamines
- Nanoparticles (Titanium Dioxide)
- Sustainability (EU CSS)
- Talc

Global Expansion
- Progress candidacy for new member(s) (Pilot Korea)

Excipient Education
- Basic excipient training
- API/Excipient differences

LOW → MEDIUM → HIGH → PRIORITY

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

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Compendial Review (CRC)

- **Monthly Compendial Review Meetings** overview –
  - Reviewed USP PF 51(4) and 51(5), PharmEuropa 12th Edition and JP
  - New Ph. Eur. Online-only Platform launched with the 12th Edition of the European Pharmacopoeia (Ph. Eur.). Publication Schedule
  - Next monthly Compendial Review meeting is October 13th, 2025, from 1:00-2:30 pm EST
- **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** Joint IPEC/PDG meeting will be held October 1, 2025, in Tokyo. The Federation is scheduled to provide a presentation on Excipient Nomenclature.
- **Shared information** for the upcoming virtual USP Excipient Forum entitled *Understanding Excipient Composition: Main and Minor Components and Organic Impurities* scheduled for December 9 & 11, 2025 from 8:30-12:30 each day.

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Regulatory Affairs Committee

Chair: Bob Sulouff

Regulatory Affairs Advocacy Manager

IFF

Vice Chair: Troy Barrix

Principal Regulatory Compliance Specialist

Celanese

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Regulatory Affairs

- **Update on 2025 IID**
  - Reviewed IPEC-Americas IID workbook for Q3, 2025, Results show that the number of updates/ MDE and deletions were down, and no corrections were made Q3.
- **Discussed the following Regulatory topics**
  - Shared comments prepared and submitted to
    - FDA for Docket No. FDA-2025-D-0507 Replacing color additives in approved or marketed drug products
    - FDA Commissioner Markay regarding FDAs National Priority Voucher Program (CNPVP) proposal.
    - US Department of Justice for Information on State Laws Having Significant Adverse Effects on the National Economy or Significant Adverse Effects on Interstate Commerce, Docket No. DOJ-OLP-2025-0169
- **Shared proposal for new IPEC-Americas guide** targeted at New Excipient Product.
- **Regional Updates**
  - IPEC Microparticles Task Force finalizing a How-To guide on microparticles and plans to develop/deliver a webinar in Q4, 2025.
  - Shared information on ECHAs new PFAS proposals and formation of an IPEC PFAS sub team to plan for potential excipient issues resulting from new PFAS restrictions/reporting and plan for 2026 ECHA commenting.
  - Provided an update on the European Court of Justice's (ECJ) decision to remove titanium dioxide (TiO2) from the carcinogenic classification and EU Commission staff confirmation that titanium dioxide should continue to be allowed in medicines.

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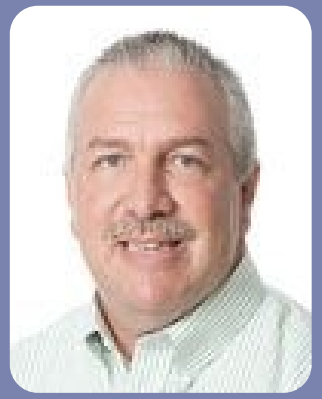
Good Manufacturing Practices Committee



Chair: Mike Cassell

cGMP Quality Assurance Manager
Eastman Chemical Company

Vice Chair: Beth Febbo

Global Laboratory & Project Manager
Henkel Corporation

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Good Manufacturing Practices

- **Discussion on:**
  - Shared that IPEC-Americas is still awaiting a response from NSF on issues identified with publication of the 2024 version of the NSF/IPEC/ANSI Standard for Pharmaceutical Excipients.
  - IPEC Federation sub-team reviewing final 2025 China GMP regulations, Annex 1, Pharmaceutical Excipients and preparing a document to assist excipient manufacturers in addressing customer or regulatory questions associated with those topics.
  - Updated status for revising/updating IPEC Stability Guide for Pharmaceutical Excipients, IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients, IPEC Good Distribution Audit guide and Good Manufacturing Audit guide for Pharmaceutical Excipients and new IPEC guide for Bulk Chemical handling.
  - IPEC-Americas sub team continues to develop comparison of excipient GMPs (USP vs IPEC vs ANSI vs WHO vs EXCiPACT).
  - Webinar on **Excipient GMP Differences, Risk Assessment, and Audit Findings** scheduled for Tuesday, November 11, 2025.

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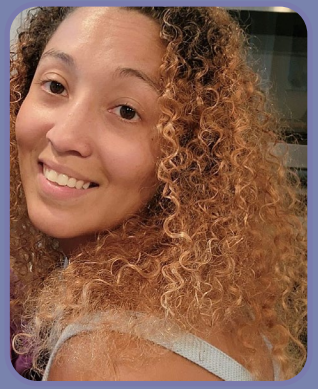
Excipient Qualification Committee

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



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

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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.
  - Developing a position paper or white paper for how an excipient manufacturer might exit/discontinue supply of excipients (e.g. USP certified) that have traditionally been supplied to the pharmaceutical market
- **Updates for:**
  - Planned revisions to Federation guides for Qualification of Excipient and Excipient Information Package and templates.
  - 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
  - Webinar on **Risk Assessment How To - Practical Application of Guides and Tools** scheduled for Thursday, October 23, 2025

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Quality by Design

Chair: David Schoneker

Consultant

Black Diamond Regulatory Consulting

Vice Chair: Liz Tocce, Ph.D.

Associate Scientist

IFF

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Quality by Design

- **Discussion on:**
  - Issues and planned updates/revision to IPEC Composition Guide
  - New Excipient Composition Infographic 4 on Impurities and 5 on Composition Profile
  - New position paper and infographic on how to use excipient in continuous manufacturing.
- **Updates for:**
  - 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)
  - Comments submitted to USP for General Chapter ⟨1037⟩ Process Analytical Technology—Theory.
  - Plans for 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.
  - Looking for a new volunteer to lead a project in developing an IPEC-Americas guide on Excipient Interchangeability

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Scientific Affairs Committee

Co-Chair: Alexa Smith

Director, Global Quality & Regulatory Services
Colorcon

Co-Chair: Teresa Wegesser

Principal Scientist
Amgen

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Scientific Affairs

- **Discussion on:**
  - Comments to FDA Docket No. FDA-2025-D-0507, Replacing Color Additives in Approved or Marketed Drug Products.
- **Updates for:**
  - IPEC-Americas Talc sub-committee activities:
    - Developed a survey to better understand what it would take to replace talc in both OTC and Rx products.
    - Developing strategy for how to respond to the FDA Expert Panel conclusion that talc should be banned due to the precautionary principle
  - Alternative Methodologies sub-committee activities:
    - Continue developing a NAMS toolbox/workflows, a review article for the International Journal of Pharmaceutical Excipients, and potential partnering/collaboration with other industry groups
    - Based on new/emerging information/initiatives discussed updating the IPEC Safety Guide to expand on excipient information on alternative methodologies and use of AI.
  - Soliciting topics/posters for Excipient World 2026 Conference and Exposition.

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IPEC-Americas 2025 Q3 Dashboard

10 interactions with regulators/ pharmacopoeias

IPEC-Americas 2025 Q1 through Q3 in Review

	CRC	RA	GMP	EQ	QbD	SAC	UN	LL	XC	IF	EW	M	
FDA Docket comments		4											4
FDA Correspondence		1											1
FDA Public Mtg/training													0
USP correspondence/meeting	2				1								3
EDQM comments													0
ECHA (REACH Comments)		1											1
EMA comments													0
ICH			1										1
Publications			1		1				3				5
Workshops													0
Webinars/Presentations	3	4	2		5	2			8				24
Draft Guides (in-progress)													0
Published New/Revised Guides				1	1								2
Position Papers/White Papers				1									1
Infographics							1		1				2

M = membership

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Education & Training

Excipient Learning Lab

EXCIPIENT LEARNING LAB

Date	Title/Topic	Presenter(s)
October 23	Risk Assessment How To – Practical Application of Guides and Tools	> Dale Carter (Maker) > Jen Putnam (User) > Charlotte Mcilvaine (Distributor)
November 5	Update on TiO2	> David Schoneker
November 11	Excipient GMP Differences, Risk Assessment, and Audit Findings	> Irwin Silverstein > Jim Morris > Dale Carter
Q4 2025	Best Practices for European Microparticles Restrictions	> Meera Raghuram

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Excipient World 2026

Build Your Case:

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EW26 Program

Overall EW26 Theme

Harmonize in Music City

Program Theme

Excipients: The Heartbeat of Pharm Country – Powering Science, Drug Formulation, and Patient Safety

Program Description

The education program will **highlight the fundamental role excipients play in pharmaceutical drug delivery**—from the earliest design stages through patient acceptance—while **delving into evolving needs and innovative solutions** across formulation, regulation, and supply chain.

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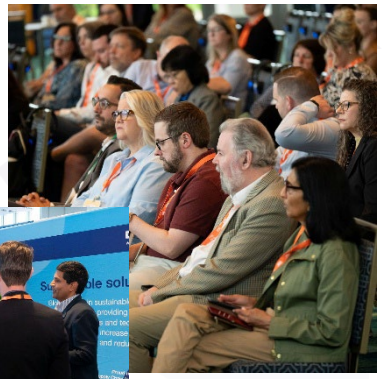
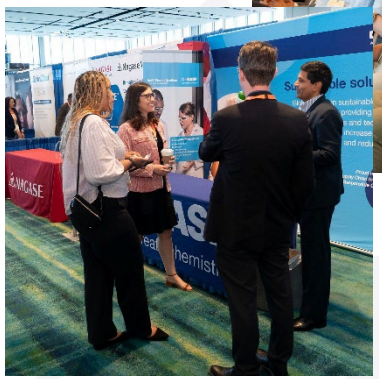
EW26 Program: Sneak Peek





Build Your Case:

Keynote

- Otilia Koo, Novo Nordisk
  (Chair-Elect, AAPS)

Biologics Summit

- Format: Full-day workshop
- Topic: Raw Materials for Biologics and Advanced Therapies
- Moderators: Basak Clements (biomatria), Nigel Langley (gChem), Lili Belcastro (BMS)

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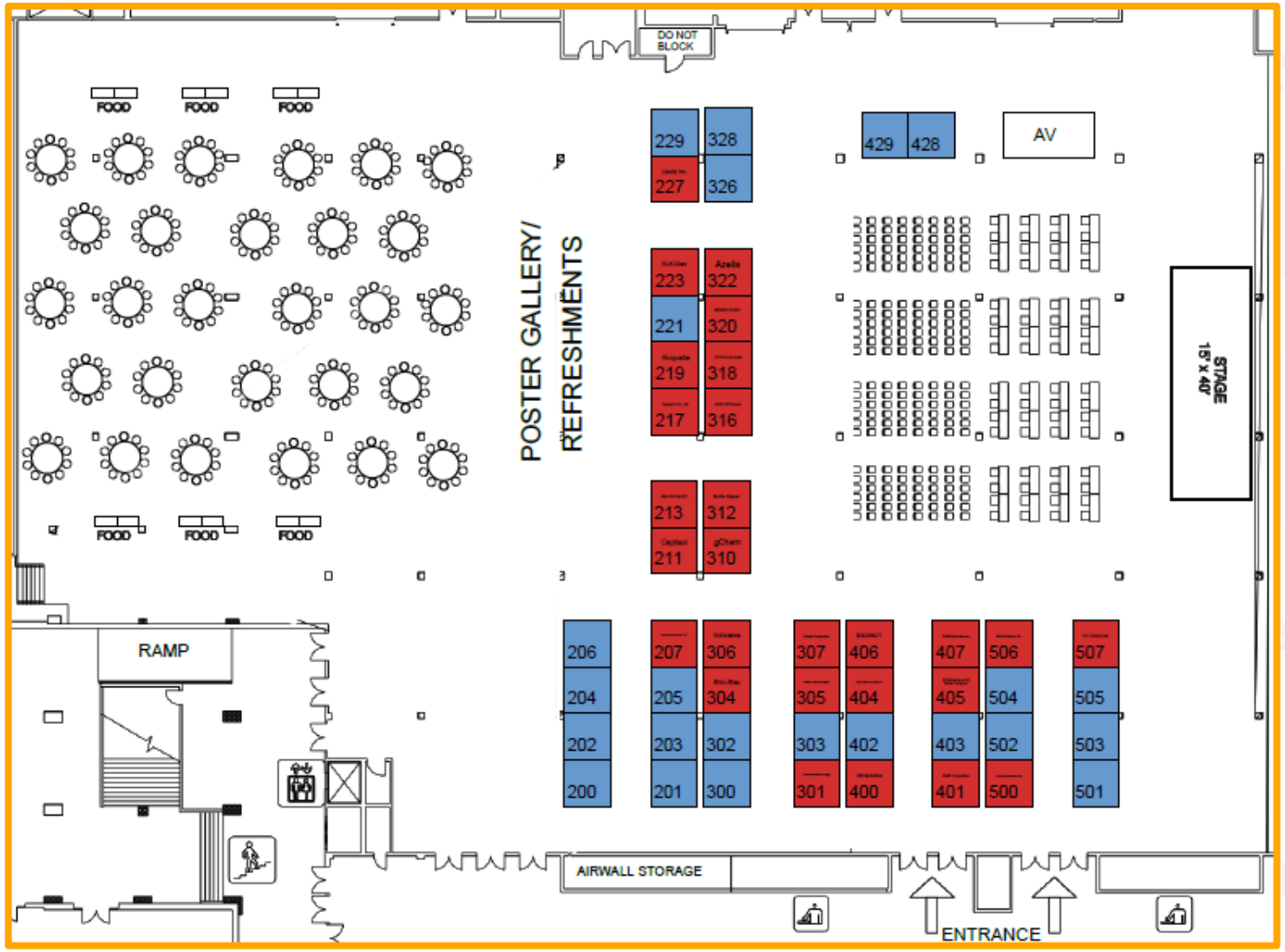
EW26 Expo Map



Company	Booth
Asahi Kasei America, Inc.	404
Azelis	322
BASF Corporation	401
BENEO GmbH	320
Biddle Sawyer	312
Captisol	211
Clariant Corporation	307
dsm-firmenich	213
EP Minerals a US Silica Company	405
ERWEKA, a VERDER company	305
EXCiPACT	406
gChem	310
IMCD US Pharma	316
Indorama	306
IOI Chemical	507
KLK Oleo	223
LBB Specialties	400
Lipoid	227
Lonza	207
Nagase & Co., Ltd.	217
Nisso America Inc.	506
Pharmaceutical Technology	301
Prachin Chemical Inc.	500
Roquette	219
SGS North America	407
Shin-Etsu	304
US Pharmacopeia	318

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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 (RSVP required)

IPEC AMERICAS 35 YEARS STRONG

IPEC-AMERICAS EXCIPIENT WORLD

Build Your Case

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IPEC Foundation

Foundation Award Videos

Foundation Awards Videos

- **Purpose:** Provide background on each award – reason for naming, etc.
- **Lead:** Staff
- **Goal:** November 2025

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IPEC Foundation Award Ceremony

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

The Ralph Shangraw Memorial Award
Dr. Paul Heng, National University of Singapore

The Patrick DeLuca Emerging Researcher Award
Dr. Khanh Tran, MIT

Henk de Jong Industrial Research Award
Dr. Örn Almarsson, AXELYF

- Five (5) annual graduate student travel scholarships recognize excellence in research conducted at the graduate level in the field of excipients.

  Ms. Yijing Huang, Purdue University
  Mr. Nileshkumar Malavia, UCONN
  Mr. Chanakya Patil, Purdue University
  Mr. Vishvesh Raje, St. John's University
- Mr. Tianyi Xiang, University of Minnesota

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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.

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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.
- Successful 3 day webinar September 9 – 11
- Over 70 attendees
- Ongoing meetings (every 2 months)
- If your company has business operations in Latin America who may want to participate in the working group please let IPEC-Americas staff know.

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International Journal of Pharmaceutical Excipients

- Formerly known as Journal of Excipients and Food Chemicals
- Keith Horspool, Ph.D., Chief Editor
- Vol. 2 , Issue 3, Q3 2025, now published
- Ongoing acceptance of manuscripts, research articles, reviews, technical notes and opinion pieces
- Submit a manuscript – no fees!

INTERNATIONAL JOURNAL OF PHARMACEUTICAL EXCIPIENTS

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2025 Committee Weeks

- **Dates for 2025 "IPEC Week"**
- Q 4 – December 2-4
- **Dates for 2026 "IPEC Week"**
- • March 3 – 5
- • 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)

QbD/EC 1:00 – 4:00 pm

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Call for Candidates - Elections

Five offices are open for election:

- Chair-Elect – 2-year term (6 year commitment)
- Vice Chair for Administrative Affairs – 3-year term
- Vice Chair for Harmonization and Compendial Monograph – 3-year term
- Two Executive Committee Officers – 2-year term

Job descriptions available in the members library

Contact staff if you are interested in a leadership position

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Questions

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Education.IPECAmericas.org
ExcipientWorld.org

Multiple stakeholders; **one objective.**