Updates from the Chair

March 27, 2024

Joe Zeleznik

Chair, IPEC-Americas

Multiple stakeholders; **one objective.**

Volunteer Appreciation

THANK YOU TO OUR MANY VOLUNTEERS!

SPOTLIGHT ON…….

1st Quarter Volunteer Spotlight

Bob Sulouff

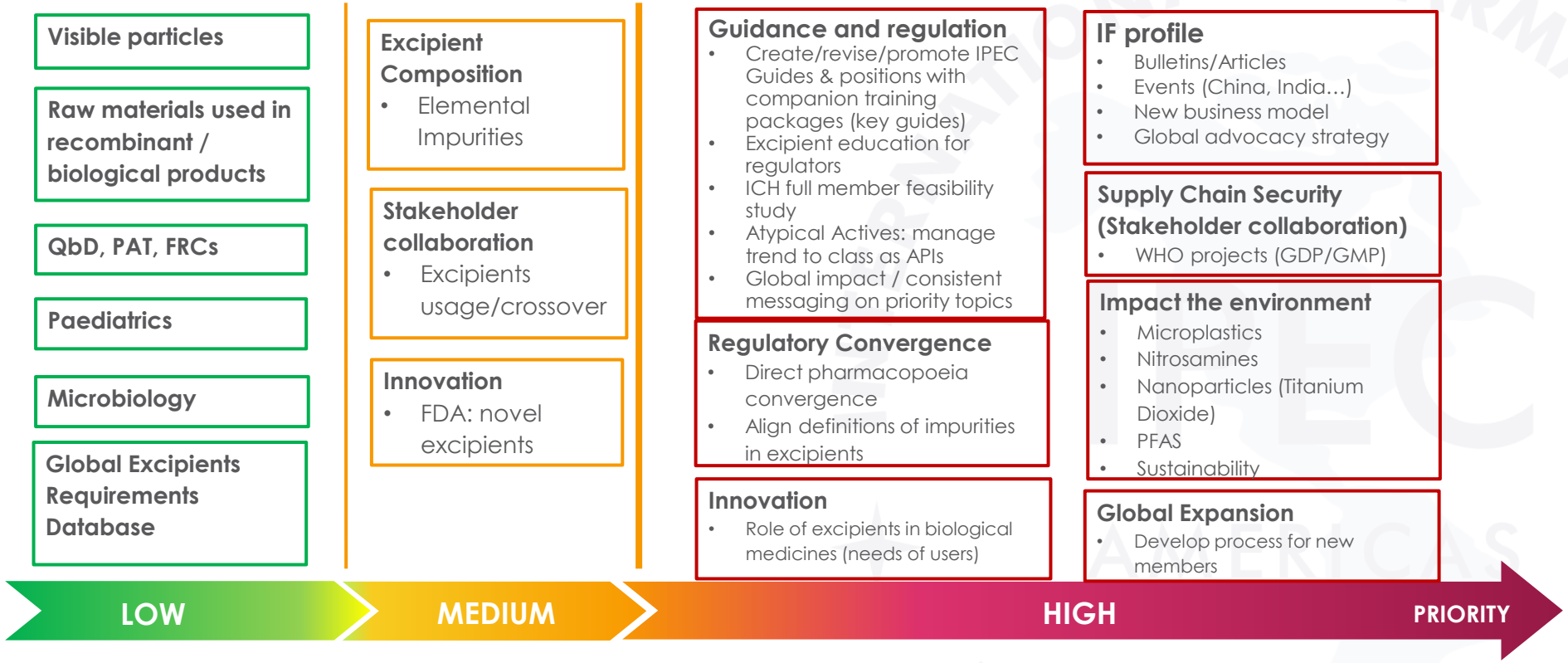
Regulatory Affairs Advocacy Manager

IFF

IPEC Federation (Priscilla)

- AGM held in February 2024. New officers elected:
  - President: IPEC Europe represented by Kevin Hughes
  - Vice-President: IPEC-Americas represented by Priscilla Zawislak
  - Treasurer: IPEC Japan represented by Hiroshi Watanabe
- Federation Board provided expectations to IPEC India regarding conditions to achieve full membership
- Published revised IPEC Federation Nitrosamines position paper
- Developing a model/process for expansion to other countries
- 2024 Strategic Focus & Priority Objectives approved

2024 Strategic Focus and Priority Objectives



Federation

- **IPEC EU**
  - IE met with EMA/EDQM to discuss excipient topics EMA is open to sharing their position with IPEC on co-processed excipients prior to public comment period
  - EDQM announced formation of WG to develop a CEP for excipients
- **IPEC Japan**
  - Discussing implementation of ICH Q3D for JPE and OTCs

Federation

- **IPEC India**
  - Supporting IPC's revision of Indian Pharmacopeia monographs
  - Annual conference being held Q2; Federation will have speaker on EG/DEG issues
  - Expects to meet with DCGI to emphasize importance of excipients and advocate for clarity in regulations with regard to excipients
- **IPEC China**
  - Microbial Control Project for Non-sterile Pharmaceutical Excipients
  - IPEC/PQG GMP Guide 2022 promotion In official excipient GMP projects
  - Transitioning to eCTD format for excipient dossiers

Committee Updates

Compendial Review and Harmonization Committee

Chair: Douglas Muse

Sr. Principal Associate, Compendial Affairs

Eli Lilly and Company

Vice Chair: Jennifer Putnam

Senior Supervisor AR&D

Perrigo

Compendial Review (CRC)

- **Monthly Compendial Review Meetings overview –**
  - reviewed/discussed proposals published in PF 50(1), PF 50(2) and PharmEuropa 36.1.
  - Reviewed new/updated official content (Eur. Ph. 11.5, USP/NF 2024 Issue 2)
  - Submitted comments to USP GC Prospectus <470> *Determination of Diethylene Glycol and Ethylene Glycol in Polyethylene Glycol*.
  - Next monthly Compendial Review Group will be April 15, 2024, from 1:00-2:30 pm EST.
- **Hosted invited guest speakers from USP**
  - Rich Panzer shared a presentation entitled USP Platform Status Update.
  - Dr. Hong Wang, Senior Scientific Liaison held an open discussion and Q&A covering various topics.
- **Update industry groups/meetings:**
  - CPPQ Update (Compendial Policy Process and Quality stakeholder discussion group). - discussion on USP Resolutions and proposal considerations for 2025 USP Resolutions
  - SEPC – Stakeholder Engagement Planning Committee - Continues focusing on how industry might better engage with the USP
  - C-JIG – Compendial Joint Industry Group Meeting – PDA will host this meeting in 2024.

Regulatory Affairs Committee

Chair: Bob Sulouff

Regulatory Affairs Advocacy Manager

IFF

Vice Chair: Troy Barrix

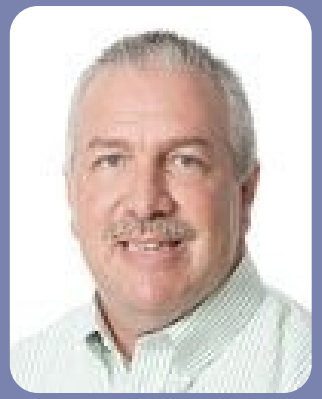
Principal Regulatory Compliance Specialist

Celanese

Regulatory Affairs

- **Reviewed US Regulatory Projects**
  - IPEC-Americas IID tracking spreadsheet was updated
  - Proposed forming a sub team to discuss how FDA might address inclusion of flavors in the IID.
  - Reviewed IPEC-Americas response/comments to FDA Docket No. FDA–2023-N-5653: Draft Report and Plan on Best Practices for Guidance
  - Discussed FDA DEG warning letter for failure to test ID of APIs and excipients (e.g. glycerin) at time received (incoming).
- **Regional Updates**
  - IPEC/ChemLeg microplastics cross functional team waiting for final EU Microplastic regulation and guidance prior to developing a position paper for suppliers and users in the medicinal sector.
  - Updated Europe and US PFAS regulations. EPA issued a Significant New Use Rule for PFAs (due to environmental concerns) and designating them as inactive on the TSCA inventory.
  - TiO_2 update –.PQRI TiO_2 position paper completed and published: https://pqri.org/wp-content/uploads/2024/01/PQRI-TiO2-Position-Paper-1-22-2024-final-for-website-posting.pdf.
  - EDQM has approval and is moving forward with creating a CEP for excipients.
- **Other topics**
  - IPEC Federation issued revised position paper, "The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products"
  - Discussed developing and maintaining a state regulatory tracking spreadsheet

Good Manufacturing Practices Committee



Chair: Mike Cassell

cGMP Quality Assurance Manager
Eastman Chemical Company

Vice Chair: Beth Febbo

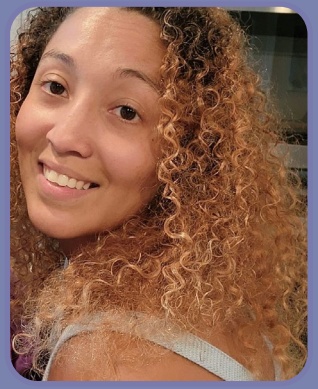
Global Laboratory & Project Manager
Henkel Corporation

Good Manufacturing Practices

- **Discussed working with NSF to submit NSF/IPEC/ANSI Excipient GMP Standard to FDA for recognition as a consensus standard.**
- **Reviewed status of and progress towards IPEC Guides currently in-progress**
  - IPEC Good Distribution Practices How to guide for Pharmaceutical Excipients targeted for publication Q2, 2024
  - IPEC Stability Guide revision charter approved. Initial draft targeted for Q2, 2024
- **Discussed potential guide revisions/ new position papers**
  - IPEC Risk Assessment guide – consider adding annexes for parenteral, pediatric and inhalation products
  - Position paper/guide to address cleaning of bulk shipping containers
- **Update on development of a new IPEC-Americas training/course**
  - To provide a fundamental overview of best practices for excipient GMPs. Content being adapted to classroom training (e.g., regulators, workshops, etc.) and webinar(s).
  - Discussed providing Excipient GMP 101 training to Thailand FDA

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

- **Status updates provided for current project tracking activities.**
  - IPEC Quality Agreement Guide and Template for Pharmaceutical Excipients published February 21, 2024. https://ipec-federation.org/ipec-qa-guide-templates/
  - IPEC Technically Unavoidable Particles Profile (TUPP) Guide published February 5, 2024. https://ipec-federation.org/ipec-tupp-guide/
  - Update on proposed corrections to 2022 IPEC CoA Guide were discussed and agreed to follow-up with both IPEC Federation and EXCiPACT®.
  - PharmTech video on *Making the Grade: The Importance of Using the Correct Excipient Grade in Drug Products* published:
- **Brainstorm/discussion on issues for introducing new excipients**
  - Identified potential gaps to consider (e.g., white paper or guide comparing requirements between food ingredient and excipient GMPs, white paper or guide on data integrity, etc.)
- **IPEC-Americas sustainability focused discussion group**
  - Group currently forming and soliciting volunteers from excipient manufacturers, distributors, and users to participate in a cross functional team to discuss trends, needs and next steps. Interested parties should send a request to participate to ipecamer@ipecamericas.org

Quality by Design

Chair: David Schoneker

Consultant

Black Diamond Regulatory Consulting

Vice Chair: Stacey Bremer

Director, Product Stewardship

Celanese

Quality by Design

- **Reviewed QbD webinars, articles and workshops**
  - Webinar: The Potential for a Ban on TiO2 (E171) use in Pharmaceuticals and the Impact on Patients and the Industry
  - Articles – Emerging Technology and Impact on Excipients & Excipient Considerations to ensure a robust continuous manufacturing process operation
  - PQRI workshops - GBHI 2024 (April 16-17, 2024) & Challenges and Opportunities for Modified Release (MR) Oral Drug Product Development Workshop (April 18, 2024).
- **Brainstormed ideas for future PQRI workshops.**
- **Discussed/proposed new/revised guides**
  - IPEC-Americas to develop a guide on Continuous Manufacturing
  - Proposal new guide on Excipient Interchangeability
  - Discussed integrating details from the QbD Sampling Guide into the 2020 International Pharmaceutical Excipient Council Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design (QbD) Guide

Scientific Affairs Committee

Co-Chair: Alexa Smith

Director, Global Quality & Regulatory Services
Colorcon

Co-Chair: Teresa Wegesser

Principal Scientist
Amgen

Scientific Affairs

- **Reviewed Scientific Affairs Survey results**
  - Aligned survey results with SAC key activities and began to identify targeted 2024 topics/speakers. The survey is still open and can be accessed here: https://www.surveymonkey.com/r/6ZQ8BQX
- **Discussed future webinar topic/outline**
  - In-process of developing a webinar on "*Read Across as an Alternative Approach for Assuring the Safety of Excipients.*" Webinar speakers to include George Daston (P&G), Jeff Pitt (IFF), Teresa Wegesser (Amgen) and Ron Filler (Drug Dev Consultants, Inc.)
- **Possible collaboration with the American College of Toxicologists (ACT).**
  - Determine if there is an opportunity for IPEC-Americas to partner with ACT on an excipient mini-symposia for the conference.

Users Network

- **Brainstorming session to better define scope and focus**
  - User group focus/mission
  - Key challenges for users
  - Need for more guidance from IPEC on how users might interpret and apply IPEC guides (e.g., TUPP, Stability, etc.)
- **Discussed and identified potential future projects**
  - Assessment of IPEC guides to determine if there are gaps in terms of how a user applies/interprets the guide.
  - Trade press article/webinar/ on the application of the stability guide (user perspective, extending dates, conveying the needs of the user with examples)
  - Development of guidance on how to evaluate surfactants (or other materials) that are not "new" in terms of overall use – but new to be used as a surfactant.

IPEC-Americas 2024 Q1 Dashboard

3 interactions with regulators/ pharmacopoeias

	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	1												1
EDQM comments													0
ECHA (REACH Comments)													0
ICH Comments (ICH Q13 WG)													0
OEHHA						1							1
Publications				1	1				4				6
Workshops													0
Webinars/Presentations		2									2		4
Draft Guides (in-progress)			3	2	1								6
Published New/Revised Guides				2									2
Position Papers/White Papers		1											1
Infographics									1				1

M = membership

IPEC Foundation

IPEC Foundation Awards

The IPEC Foundation is now accepting applications at www.ipecfoundation.org . **The Foundation Awards Ceremony will take place in Salt Lake City, Utah, October 22, 2024.**

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.

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.

IPEC Foundation Awards

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.

Nominate someone today: Deadline is June 15, 2024

Strategic Planning & Activities

Strategic Planning - 2024

Strategy Session

Bringing together key leaders, i.e., Executive Committee members, Committee Chairs and Vice Chairs, staff and key consultants to create a shared vision for the organization.

- Professionally Facilitated
- Review Mission & Vision & Core Values
- Review advance input of membership interviews and surveys

IPEC-Americas Mission: To advocate, educate, innovate and develop best practices for excipients, with a focus on patient safety.

IPEC-Americas Vision: IPEC-Americas will be the preeminent authority and resource on pharmaceutical excipients

Our Core Values As an Executive Committee We: Listen | Are Committed | Are Bold | Are Inclusive

Strategic Planning 2024 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.

Latin America Working Group

- Established 3 working subgroups:
  - Regulatory: Nitrosamines – 9 members
  - Quality: GMP – 16 members
  - Regulatory/ Quality: Atypical actives – 8 members

- **Nitrosamines**: in initial discussions to establish action plan to be deployed in 2024.
- **GMP/ Atypical actives**: mapped the need for educational programs in the region as a starting point towards the main goal: regional harmonization for quality and regulatory requirements.
- Ongoing meetings in local language
- If your company has business operations in Latin America who may want to participate in the working group please let IPEC-Americas Staff know.

LAWG

What's coming for 2024?

- Expand the WG's presence in LATAM: to establish a communication channel and a work plan with other key industry associations:
  - ASCIF/ ANDI- Colombia
  - SAFYBI – Argentina
  - Associacion farmaceutica Mexicana - Mexico
- To bring new IPEC members and non-members to the WG;
- To focus on educational initiatives in the region, with cross-collaboration of IPEC Americas: i.e.: **LATAM workshop:**
  - Format: hybrid event (F2F in Brazil and online) by Q4/24.
  - Duration and content: initially planned for a 1 or 2-day event, covering all hot topics for LATAM (nitrosamines, GMP, stability and atypical actives)
  - Audience: academia, industry, associations and local authorities.
  - First core meeting: March 13th, 2024

PQRI Activities

- PQRI TiO2 Workshop Summary Report was submitted to EMA in early February to provide scientific justification for why the Tio2 ban should NOT be extended to pharmaceuticals. The Report can be accessed here: PQRI-TiO2-Position-Paper-1-22-2024-final-for-website-posting.pdf
- PQRI held the following workshop on February 28-29, 2024: **MIDD Approaches in Pediatric Formulation Development Workshop**
- PQRI is co-sponsoring the PQRI/EUFEPS Global Bioequivalence Harmonization Initiative (GBHI): 6th International Workshop with EUFEPS on April 16-17, 2024. 6th International Workshop – GBHI 2024 – Product Quality Research Institute (pqri.org)
- This FDA/PQRI workshop will further explore discussions on MR products that will not be covered at GBHI 2024. **Challenges and Opportunities for Modified Release (MR) Oral Drug Product Development Workshop**

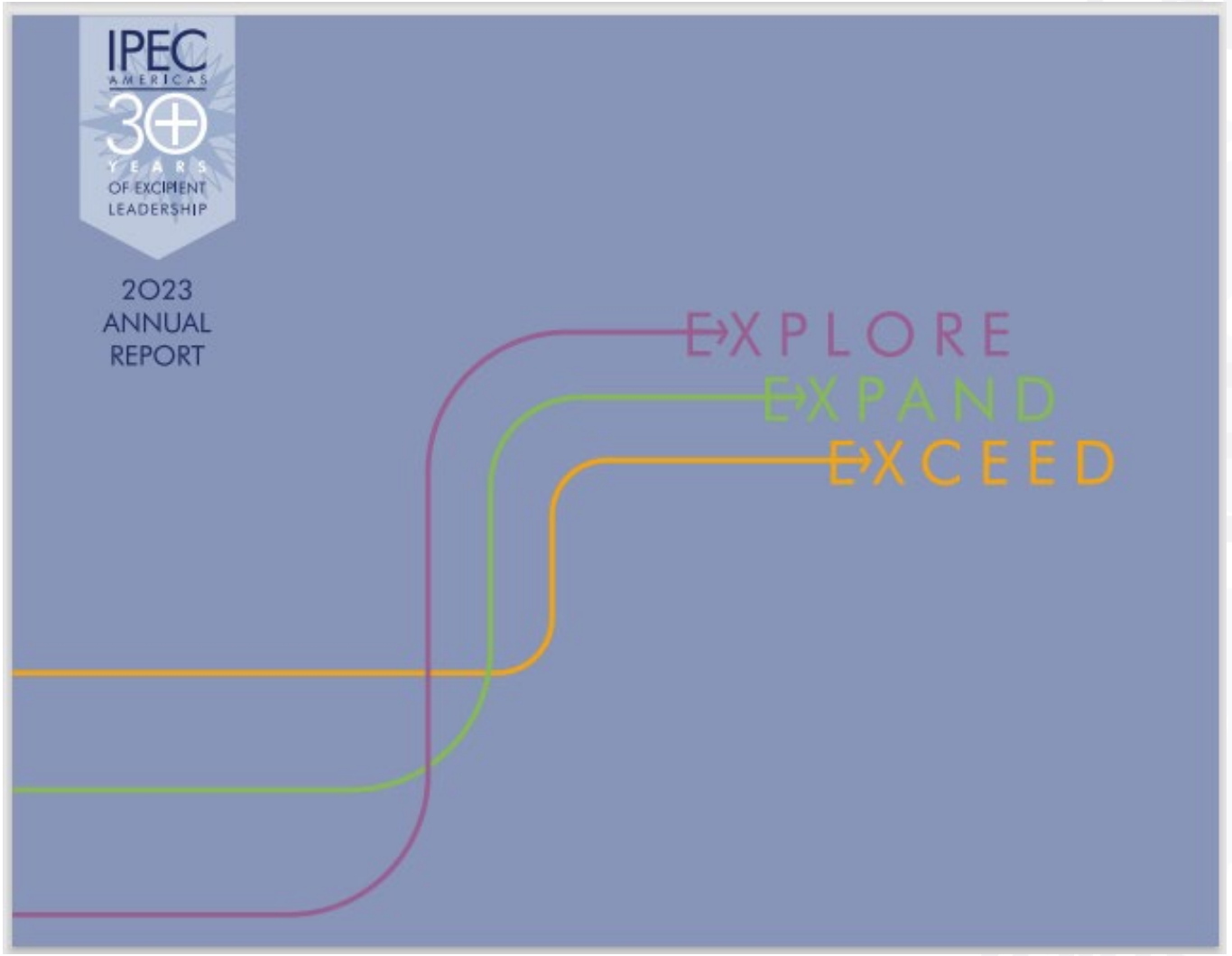
TiO2 Update

- New State Bill in CA – would ban FD&C Colors, TiO2 and some other additives from being used in any foods sold or provided in CA public schools

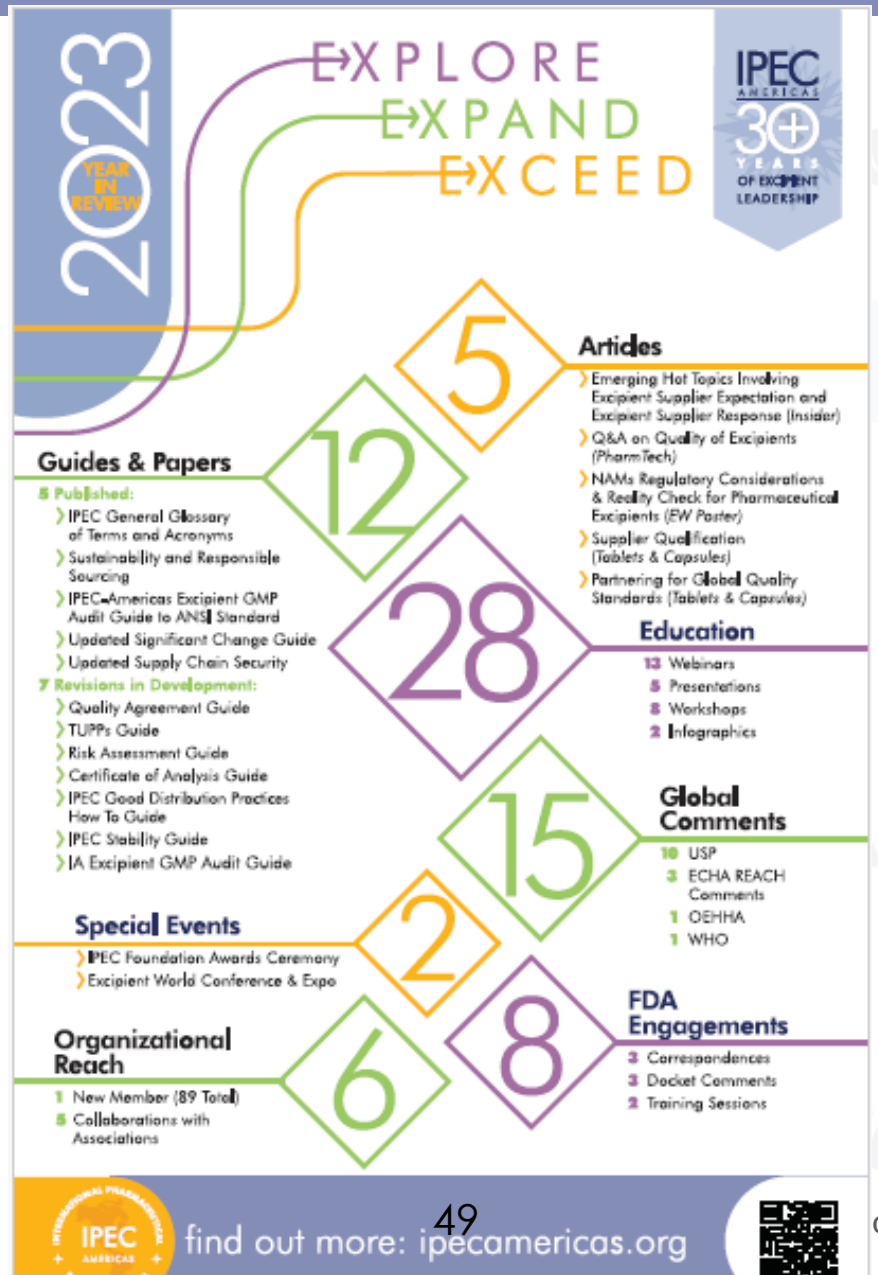
- New State Bills in NY – One bill would ban several food additives (including TiO2) from Foods by 1/1/2025; the other bill would require all companies who use any self-determined GRAS substance in a food product for sale in NY to notify the State of this use

- New State Bill in PA – would ban FD&C Colors for all foods – currently does NOT include TiO2

2023 Annual Report and YIR



2023 Year in Review



New Website Launch

- Higher Logic Platform
- Committee Communities
- Libraries – Public library, Member Library, Committee Library

www.ipecamericas.org

Excipient Learning Lab

EXCIPIENT LEARNING LAB

Date (2024)	Topic	Presenter(s)
January 17, 2024 11:00-1:00	The Potential Impact of the EU TiO2 Food Ban on Pharmaceuticals and Patients – Current Status	Dave Schoneker
March 12 & 13 10:00-12:00	Excipient Considerations in the Development and Approval of Animal Drug Products	GADA – CA, HS, SG IA – Priscilla, CVM – DL, KGR, AS, OS, SB
TBD	Read-Across as an Alternative Approach for Assuring the Safety of Excipients	George Daston (P&G), Jeff Pitt, Ron Filler, Teresa Wegesser
TBD	Excipient 101 - basics of excipient GMPs	Irwin Silverstein
TBD	Quality Management Maturity	Jason Kerr (Moderna)
	POTENTIAL – Microplastics update	Meera Raghuram
	POTENTIAL – Update for Regional excipient regulations (Europe, China, Latin America and the US)	Priscilla Zawislak
	POTENTIAL – TiO_2 update	Dave Schoneker

Excipient World Conference & Expo

Expo: May 13-14

Conference + Workshops: May 13-15

Gaylord Palms Resort & Convention Center

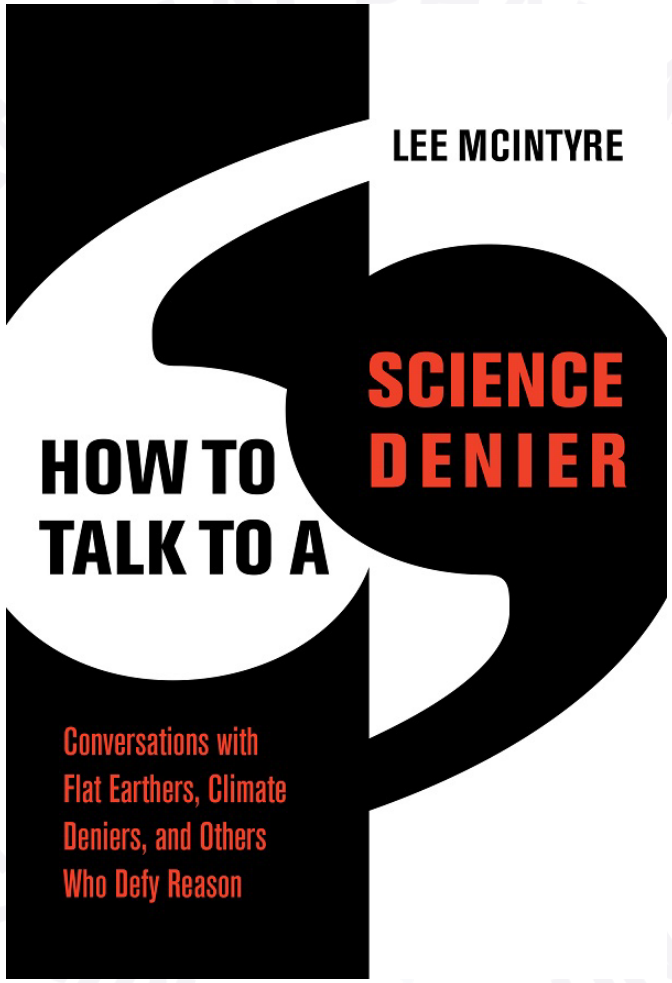
Kissimmee, FL (Orlando metro area)

Schedule: Sunday, May 12

- **7:30 am – 3:30 pm:** Golf Outing
- **5 pm – 7 pm:** Welcome Reception

Schedule: Monday, May 13

- **8 am - 5 pm:** Education
- **11 am - 7 pm:** Exhibits & Posters
- **5 pm - 7 pm:** Reception & Book Signing



Schedule: Tuesday, May 14

- **8 am - 5 pm:** Education
- **8 am - 2:30 pm:**

Exhibits & Posters

- **5:30 pm - 9 pm:**

Excipient World Celebration

Excipient World Celebration

- Tuesday, May 14
- 5:30 pm – 9:00 pm

Join us in the “backyard” for a casual evening of yard games, music and more!

Interactive Schedule

Participating Organizations

Aizon • Alcedo Pharmachem Pvt.Ltd. • Amgen • Asahi Kasei America, Inc. • Ashland Specialty Ingredients • Asymchem, Inc. • Azelis Americas, P&H • Barentz • BASF Corporation • BENEO GmbH • Biddle Sawyer • BioSpectra • Burdock Group • Captisol • Celanese • Clariant Corporation • Colorcon, Inc. • Cremer North America • dsm-firmenich • DuPont™ Liveo™ • Eastman Chemical Company • Evonik Corporation • EXCiPACT • Gattefossé USA • Gaylord Chemical Company, LLC • Hawkins Inc • IFF, Health & Biosciences • IMCD US Pharma • Ingredion Pharma Solutions • IOI Chemical • IPEC-Americas • JRS Pharma LP • Kisuma Americas Inc. • Kowa America Corporation • Lilly • Lubrizol • Mallinckrodt Pharmaceuticals • Merck & Co • Merck Animal Health • Moderna • Nisso America Inc. • Pace Analytical Life Sciences • Perrigo • Pet Flavors • Peter Cremer North America, LP • Pharmaceutical Technology • Procter & Gamble • Quadra Ingredients • Roche / Genentech • Roquette • RX-360 • SGS North America • Sigachi US, Inc. • TEK Products & Services, Inc • U.S. Food and Drug Administration • Univar Solutions • University of Maryland • University of Minnesota • US Pharmacopeia • Wuhan Healthgen Biotechnology Corp.

as of 2/10/24

International Journal of Pharmaceutical Excipients

- Formerly known as Journal of Excipients and Food Chemicals
- Keith Horspool, Ph.D., Chief Editor
- Undergoing rebrand
- **Vol. 15, Issue 1, 2024 Transitioning to the Future**

Published quarterly

2024 Committee Weeks

- **Dates for 2024 "IPEC Week"**
- Q 2 – June 11-13
- Q 3 - September 24-26
- Q 4 - December 3-5

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.**