Updates from the Chair

June 20, 2024

Joe Zeleznik

Chair, IPEC-Americas

Multiple stakeholders; **one objective.**

Volunteer Appreciation

THANK YOU TO OUR MANY VOLUNTEERS!

SPOTLIGHT ON…….

2nd Quarter Volunteer Spotlight

Kayla Thompson Allen

LIFE SCIENCES REGULATORY PROFESSIONAL - AMERICAS

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Ashland™ always solving

Federation Update

IPEC Federation (Priscilla)

IPEC Federation

- Comments were provided on:
  - ICH Q1 Stability draft (constituency review); IPEC comments were successfully incorporated at the ICH June meeting
  - WHO GMPs for Excipients used in Pharmaceutical Products
  - WHO GMPs for Excipients used in Pharmaceutical Products – Appendix 1 Risk Management in the Production & Control of Excipients
  - WHO GMPs for Excipients used in Pharmaceutical Products – Appendix 2 Examples of High Risk Excipients
    - Concerns raised within the Federation about WHO's perspectives on excipients
  - Participated in meeting with EFPIA & IFPMA re: WHO nitrosamines guideline and signed on to joint comment letter
  - ChP General Chapter 251 General Requirements for Excipients

IPEC Federation

- Developing a model/process for expansion to other countries
  - One member company has proposed forming an IPEC organization in Korea
- Webinar on nitrosamines has been updated for the latest version of the position paper
- Plans to develop excipient education for regulators – build on IPEC-Americas Excipients 101 course
- Atypical Actives – proposal to elevate to Fed. Level project

- **IPEC EU**
  - Still waiting for EMA Q&A on co-processed excipients - focused on quality, not inspections
  - EMA inspectors WG reported inspection deficiencies of pharma companies with their formal risk assessments for excipients; this may contribute to the CPE issue; consider this in revision of PDA/IPEC Risk Assessment guide
  - Monitoring proposed EU Pharma Regulations
  - Published summary of March Lhasa workshop on nitrosamines

- **IPEC India**
  - Annual conference held May 31; IPEC Federation speaker for EG/DEG

- **IPEC Japan**
  - Holding conference in July for those new to excipients
- **IPEC China**
  - Conference in October; no longer affiliated with CCFDIE
  - New website
  - PEG monographs under revision – aligning EG/DEG limits with other pharmacopeia
  - Submitting comments for ChP Gen. Chapter 251
  - Will hold excipient GMP training session in Oct. in collaboration with EXCiPACT®

Committee Updates

Compendial Review and Harmonization Committee

Chair: Douglas Muse

Sr. Principal Associate, Compendial Affairs

Eli Lilly and Company

Vice Chair:

Volunteer Needed

Compendial Review (CRC)

- **Monthly Compendial Review Meetings** overview –
  - PF 50(3) and PharmEuropa 36.2 and new effective content USP/NF 2024 Issue 3.
  - Comments submitted to proposed revisions to USP General Notices published in PF 50(2)
- **Provided training** on use of new IPEC-Americas website capability for monitoring CRC postings and communication
- **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 and a QC Laboratory Instrument survey.
- **Reviewed Federation project activities** for Mutual recognition project and PDG Polysorbate 20 harmonization project team.
- **Discussed ChP GC <0251> Pharmaceutical Excipients**. Comments due by June 30 to Federation. Highlights will be reviewed/captured during User Network meeting
- **Deep dive discussion into the USP Convention 2025-2030 documents**. Reviewed and developed comments and/or endorsements for:
  - draft proposed USP convention bylaw amendments.
  - USP proposed resolution concepts

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**
  - Discussed developing a guide or white paper on strategy and issues with Novel Excipients that are not NCEs
  - Provided update on Q2 IID postings and discussed inviting Amanda Jones (FDA OGD IID owner) to future meeting
  - Provided update on Atypical Actives sub-team activities, including plans for escalation to Federation project.
  - Reviewed Section 2.1.2 (Excipients) of a CVM draft guidance developed by the VICH working group entitled: Pharmaceutical Development VICH GL61.
- **Regional Updates**
  - Provided update on final microplastics regulation an efforts by Cefic and EFfCI to develop and publish their own "how to" guidance documents.
  - Discussed ECHA SEAC (Socio-Economic Analysis) and RAC (committee for risk assessment) committees review and discussion on PFAS regulations as well as PFAS restrictions underway in Minnesota, Illinois and Kentucky
- **Other topics**
  - Shared State Regulatory Tracking document – developed a spreadsheet (similar to TDMA TiO2) for listing substances that states are proposing to ban. Spreadsheet to identify states, ingredients, and status of any proposal (e.g. PFAS, TiO2).

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

- **Submitted 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 GDP How to Guide targeted for publication in September
  - IPEC Stability Guide and ICH Q1 Drug Substance and Product Stability guidance
- **Discussed potential guide revisions/ new position papers**
  - Comparison of excipient GMPs for IPEC vs ANSI vs USP vs EXCiPACT vs WHO
  - Update of IPEC-PQG Excipient GMP guide to include how to conduct risk assessments for parenteral, pediatric and inhalation products as well as requirements for contract manufacturers
- **Update on development of a new IPEC-Americas training/course**
  - Excipient GMP training including an introductory webinar targeted for October 2024.
- **Review of revised USP GC <1078> Excipient GMPs**
  - Review revision targeted for publication in December 2024 vs current version.

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.**
  - Volunteers have been identified (by Federation) and lined copies of the following Risk Assessment Guides were sent out (by Federation) for review and comment by June 19.
    - IPEC Risk Assessment Guide 2017
    - Joint PDA/IPEC TR No. 54-6 Formalized Risk Assessment for Excipients, 2019
  - Proposed corrections to 2022 IPEC CoA Guide were discussed and agreed to follow-up with both IPEC Federation and EXCiPACT®.:
- **Sub team to discuss issues for introducing new excipients**
  - Initial sub-team meeting held in April. Minutes to be added to EQ Library.
- **IPEC-Americas sustainability focused discussion group**
  - Current group strongly soliciting and encouraging 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**
  - PharmTech to publish an article on "Excipient considerations to ensure a robust CM process operation" on-line in June/July and in print in September
- **Hosted Sharon Nowak from K-Tron** (equipment manufacturer) to speak on Excipient Considerations for Continuous Manufacturing
- **Brainstormed ideas for future PQRI workshops.**
  - Re-initiated planning for a PQRI Workshop on Co-processed excipients that focuses on their use, functionality and performance, not regulatory aspects.
- **Discussed/proposed new/revised guides and projects**
  - Discussed project to better define excipient impurities and concomitant components and develop a strategy moving forward, including revisions to IPEC Glossary and guides
  - Reviewed and discussed Concomitant Component infographic.
  - Proposed new guide on Excipient Interchangeability based on recent article on Supplier Qualification. Sub committee to review and update charter
  - Incorporating 2016 IPEC-Americas QbD Sampling Guide into 2020 IPEC Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design (QbD) Guide.
  - Discussed re-engaging with FDA on additives and processing aids in pharmaceutical excipients

Scientific Affairs Committee

Co-Chair: Alexa Smith

Director, Global Quality & Regulatory Services
Colorcon

Co-Chair: Teresa Wegesser

Principal Scientist
Amgen

Scientific Affairs

- Discussed developing a guide or white paper on Novel Excipients that are not NCEs.
- Proposed a potential position paper, guide and/or guide supplement differentiating the concept between "Risk Assessment" and "Hazard Identification," including the need for risk-based decisions to balance risk vs benefit.
- Suggested creating/communicating positive excipient messaging – how to develop a positive, simplistic message regarding the need for and benefits of excipients (benchmarking others, such as IFAC) and get the message out through social media.
- Shared recent draft WHO nitrosamine and ICH Q3E guidelines with IPEC-Americas members for comment.
- Shared USP Novel Excipient Hub and discussed how IPEC-Americas members might participate/contribute.
  - USP Global Policy Position_NovelExcipients_Paper_2024.pdf
  - LINK to Excipients Hub: https://www.usp.org/excipients/novel-excipients
- Promoted IPEC-Americas webinar entitled "Read-Across as an Alternative Approach for Assuring the Safety of Excipients" scheduled for October 30.
- Identified and briefly discussed a couple recent poorly reviewed scientific articles. Anyone identifying articles of concern should send copy to ipecamer@ipecamericas.org with request to forward to SAC sub team members.

Users Network

Chair: Jennifer Putnam

Senior Supervisor AR&D

Perrigo

Users Network

- Brainstormed Atypical Actives including how users are managing their use as an API and what challenges other challenges they might have.
- Briefly discussed need to review ChP - <0251> Pharmaceutical excipients draft revision and provide any comment by June 30.
- Continued discussion (from Q1) for potential UN committee activities: Agreed to:
  - consider adding information on administration of biologics and parenterals as IPEC guides are updated.
  - Survey members to determine which guide updates would be most impactful to biologics and parenteral (could become a UN project)
- In addition, reminded committee of current documents out for comment

Monthly Compendial Postings Review

- Reviewed new proposals published in PF 50(3) and PharmEuropa 36.2
- New/updated official content in USP/NF 2024 Issue 3 (effective 1-Dec-2024) reviewed during Q2 CRC
- Comments submitted to proposed changes to USP General Notices as published in PF 50(3)
- USP 2025-2030 Convention Cycle proposed resolution concepts and bylaw amendments under review for endorsement and/or comments
- Draft comment letters are now being posted to the CRC community library on the IPEC-Americas website to enable all members to provide input – set your communication preferences to receive notifications!!
- Next compendial postings review:
- 8-July-2024 1 – 2:30 pm EDT (Remote)

IPEC-Americas 2024 Q2 Dashboard

5 interactions with regulators/ pharmacopoeias

	CRC	RA	GMP	EQ	QbD	SAC	UN	LL	XC	IF	EW	M	
FDA Docket comments		1											1
FDA Correspondence			1										1
FDA Public Mtg/training													0
USP correspondence/meeting	2												2
EDQM comments													0
ECHA (REACH Comments)													0
ICH Comments (ICH Q13 WG)													0
OEHHA						1							1
Publications				1	1				4				6
Workshops		1	1	1	1						2		6
Webinars/Presentations		3			2				1		2		8
Draft Guides (in-progress)			3	2	1								6
Published New/Revised Guides				2									2
Position Papers/White Papers		1											1
Infographics									1				1
Position Papers/White Papers		1											1
Infographics									1				1

M = membership

IPEC Foundation

IPEC Foundation Awards

The IPEC Foundation will still accept an any additional awards applications. Submit before the end of June.
www.ipecfoundation.org.

The Foundation Awards Ceremony will take place in Salt Lake City, Utah, October 22, 2024.

Please submit candidates for the Industrial Research Award –

The Henk de Jong Industrial Research Award recognizes individuals in industry for their outstanding achievements and contributions in excipient research and innovation.

ICH Update

- Met in Fukuoka, Japan June 4-5, 2024
- **Membership** -ANMAT Argentina and JFDA Jordan have been approved as new members of ICH
- **New Topics** - New topic proposal on Nitrosamines - adopted
- **Implementation of ICH Guidelines: NMPA**
  - Q13 will be implemented 13 June 2024
  - Special thanks to Brian Carlin

- ICH Official web site : ICH – Press release
- Topic updates and presentations located on IPEC-Americas website

Other Strategic Activities

Latin America Working Group

What's coming for 2024?

- A hybrid webinar initiative: November 19th, 2024
- Location: Merck Auditorium – Barueri – Sao Paulo - Brazil
  - 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
- 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 Activities

- IPEC-Americas plans to restart efforts for a workshop on Co-processed Excipients to Enhance Medicinal Product Development and Continuous Manufacturing. This workshop will primarily address the need for co-processed excipients and the performance benefits that they can bring to CM and drug development.
- PQRI's Product Quality Technical Committee (PQTC) is developing a project to address sustainability in the pharmaceutical industry including the pharmaceutical supply chain.
- PQRI Survey – post approval changes to Nasal Suspensions/Solutions https://s.alchemer.com/s3/Regulatory-Challenges-for-Post-approval-Changes-of-Nasal-Spray-Products (deadline extended to 7/31)
- https://s.alchemer.com/s3/Regulatory-Challenges-for-Post-approval-Changes-of-Nasal-Spray-Products

PQRI Nominations

- Election of PQRI Steering Committee Vice Chair
- Congratulations to Dave Schoneker, representing IPEC-Americas!

TiO2 Update

- California has introduced a new bill to ban TiO2 as well as all the synthetic FD&C colors for any foods sold in public schools. The bill has already passed the Assembly and is currently being debated in the Senate.
- Still waiting for FDA to publish their opinion on the Food additive petition submitted by the NGOs to ban TiO2 in all foods in the U.S. FDA is expected to reject this petition based on their earlier outcomes and what they recently published on their website at: Titanium Dioxide as a Color Additive in Foods | FDA
- Titanium Dioxide as a Color Additive in Foods | FDA

New Website Launch

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

Website Adoption

- **Goals:**
  - Short Term: Chairs as champions for member adoption
  - Long Term: Website becomes effective communication/collaboration tool

- **Initiatives:**
  - Awareness Efforts (Insider, Emails, Social Media)
  - Training Resources (Live Webinars, Videos, Articles, etc.)
  - Practice "Communities"

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
June 17 – 18, 2024	IPEC-Americas and Cobblestone Joint Course – Excipient: Compliance with Compendial and GMP Requirements	Irwin Silverstein Joe Abanese
September 18-20, 2024	Excipient GMP Compliance in-Person Workshop	Irwin Silverstein Katherine Ulman
October ??, 2024	Excipient GMP 101 - basics of excipient GMPs	Irwin Silverstein
October 30, 2024 – 9:00am-11:am	Read-Across as an Alternative Approach for Assuring the Safety of Excipients	George Daston (P&G), Jeff Pitt, Ron Filler, Teresa Wegesser
November 6, 2024 - 12:00am to 2:00pm	Quality Management Maturity	Jason Kerr (Moderna)
	POTENTIAL – Microplastics update – as new information becomes available	Meera Raghuram
	POTENTIAL – Update for Regional excipient regulations (Europe, China, Latin America and the US)	Priscilla Zawislak
	POTENTIAL – TiO_2 update – as new information becomes available	Dave Schoneker

Excipient World Conference & Expo

Successful event!

Gaylord Palms Resort & Convention Center Kissimmee, FL (Orlando metro area)

40 Booths

266 participants

39 speakers

IPEC-AMERICAS EXCIPIENT WORLD MAY 13–15 2024 ORLANDO

Location & Dates

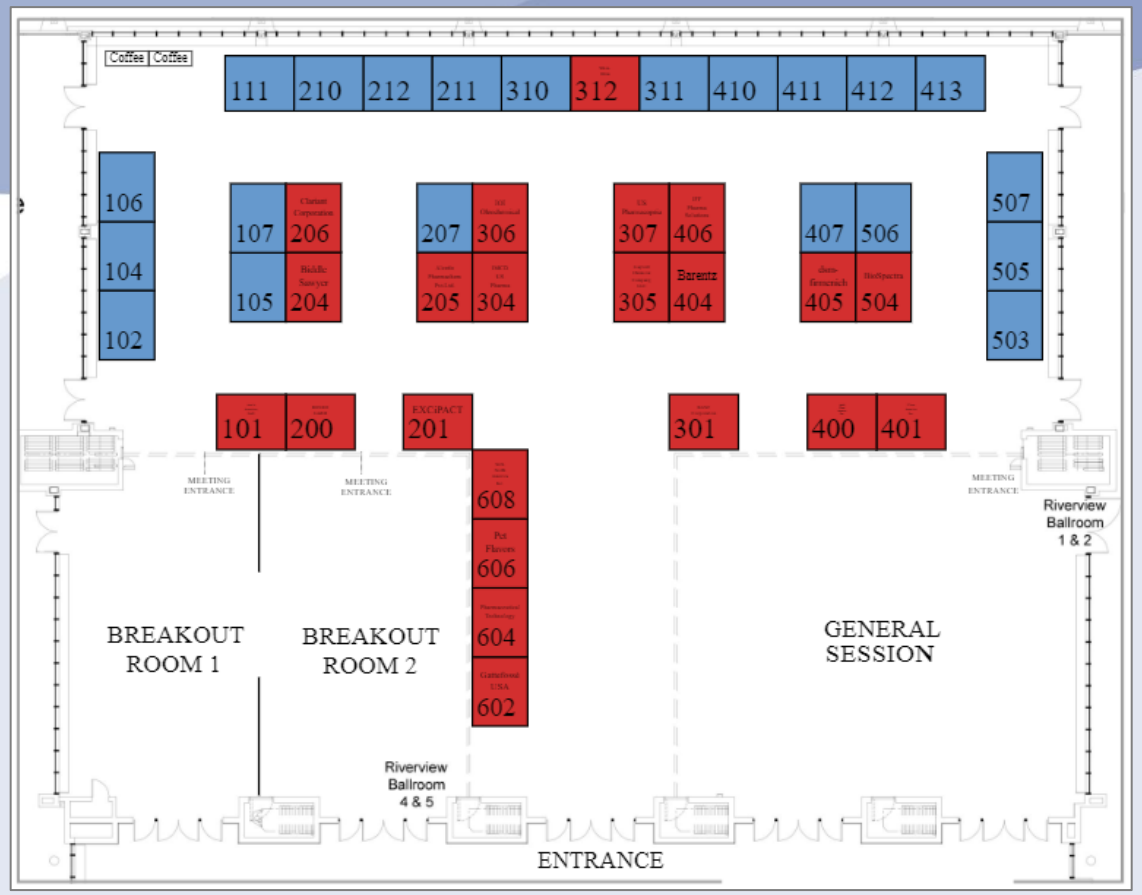
IPEC-AMERICAS EXCIPIENT WORLD 2025 NATIONAL HARBOR

Conference: May 12-14

Expo: May 13-14

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

Floorplan (as of 06.10.24)



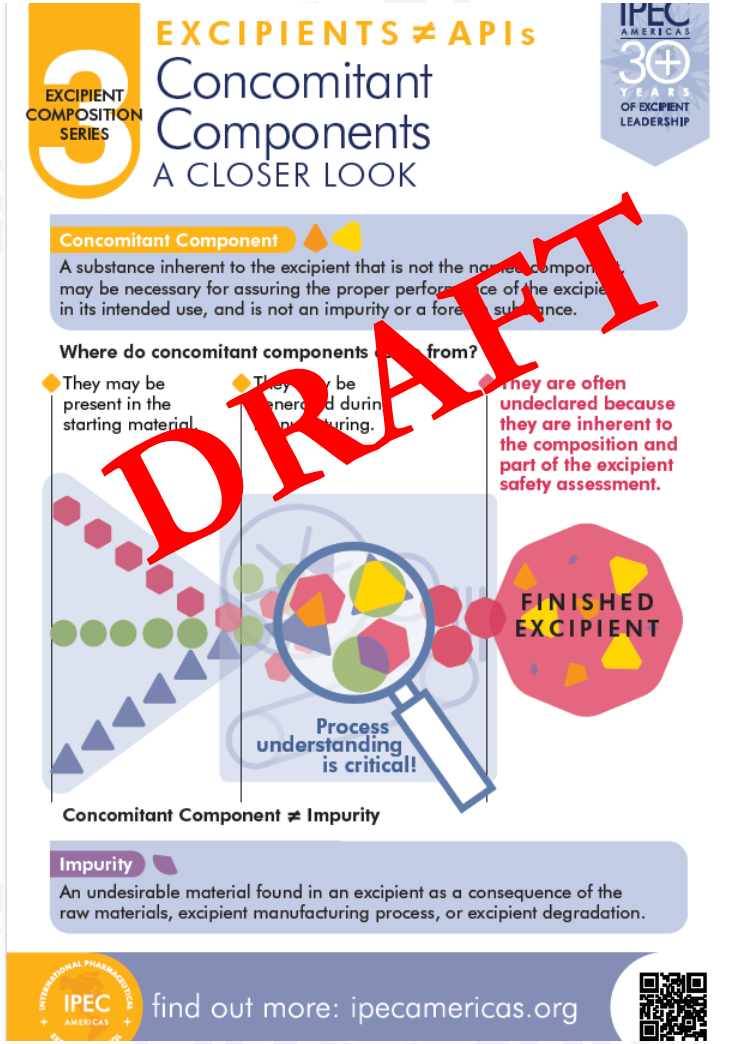
22 booths already sold!

EXCIPIENT WORLD 2024 ORLANDO

CONVERGENCE CONNECTION CONVERSATION COLLABORATION

ConComCom(ponents)

- **Purpose:**
  - Define where concomitant components get are in the manufacturing process.
  - What should users ask suppliers during the supplier/excipient qualification process to obtain the information they need?
- **Sponsor:** QbD Committee
- **Status:** One comment to go!



NEW Infographic

- **Working Title:** Novel Excipients – Snapshot of Regulatory Process
- **Sponsor:** SAC
- **Goal:** Q3/Q4
- **Next Steps:**
  - Call for Volunteers
  - Draft Request Form

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 – Q2 Issue soon to be published

2024 Committee Weeks

- **Dates for 2024 "IPEC Week"**
- 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.**