Updates from the Chair

Multiple stakeholders; **one objective.**

October 18, 2023
Nigel Langley, Ph.D.
Chair, IPEC-Americas

International Pharmaceutical Excipients Council

Collaborative solutions for excipient industry stakeholders

Volunteer Appreciation

- THANK YOU TO OUR MANY VOLUNTEERS!
- SPOTLIGHT ON……

Congratulations!

Phil Travis

Associate Director, Compendial Compliance & Advocacy

Organon

Federation Update

Federation (Priscilla)

- **IPEC Federation**
  - IPEC Federation Supply Chain Security position paper was published and shared with WHO to further engage on recent adulteration events
  - The latest draft of the IPEC Federation Nitrosamines position paper is being revised & will go to the regional IPECs for approval in a couple weeks
- **IPEC EU**
  - IPEC Europe attended a joint association meeting including CEFIC and EFPIA on the proposed PFAS ban
  - Surveying members via questionnaire to evaluate impact of PFAS ban on excipients and APIs
- **IPEC India**
  - IPEC Federation Board in discussion with IPEC India regarding conditions to achieve full membership

Federation (Priscilla)

- **IPEC Japan**
  - IPEC Japan held its AGM in June; a new Chair and Vice-Chair were appointed.
- **IPEC China**
  - Hosting excipient conference this week in Beijing
  - IC is evaluating a 'how-to' document on dossier preparation including excipients for consultation issued by the CDE
  - Submitted to ChP its position that it is not mandatory for excipient manufacturers to conduct elemental impurities (EI) risk assessments and EIs may be monitored not subject to routine control
  - IC is working to establish a collaboration with the Shanghai NMPA for excipients audits
  - The establishment of a new IC structure in mainland China has been finalised

2023 Strategic Focus and Priority Objectives

Visible particles

Raw materials used in recombinant / biological products

QbD, PAT, FRCs

Paediatrics

Microbiology

Global expansion
- Collaboration in new regions

Excipient Composition
- Elemental Impurities

Stakeholder collaboration
- Excipients usage/crossover

Innovation
- FDA: novel excipients

Guidance and regulation
- Create/revise/promote IPEC Guides & positions
- Database for global excipients requirements
- Atypical Actives: manage trend to class as APIs

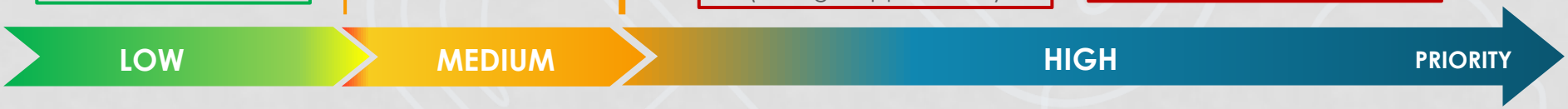
Regulatory Convergence
- Direct pharmacopoeia convergence
- Align definitions of impurities in excipients

Innovation
- Role of excipients in medicines of the future (biologic applications)

IF profile
- Bulletins
- Events (China, India…)
- Articles

Supply Chain Security (Stakeholder collaboration)
- WHO projects (GDP/GMP)

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



Committees

CRC (Doug/Jennifer)

- **Monthly Compendial Review Meetings overview –** reviewed and discussed postings in PF 49(5) as well as current and next steps for USP Chapter <86> Bacterial Endotoxins Test Using Recombinant DNA. Next monthly compendial review WebEx scheduled for Monday, October 16 from 1:00-2:00 EDT.
- **Hosted invited guest speakers from USP**
  - Dr. Galina Holloway, Senior Scientific Liaison who provided a presentation entitled "*Brief Overview of USP's Ongoing Work Relating to Excipient Composition and Impurities*."
  - Dr. Tong (Jenny) Lui, Senior Scientific Liaison who provided a presentation entitled "*USP Progress on Diethylene Glycol and Ethylene Glycol (DEG/EG) Identification (ID) Tests in Excipient Monographs and Polysorbates Monograph Updates*."
  - Richard Panzer, Senior Digital Product Manager – provided information on the USP Consumer Advisory Group (CAB) and invited any interested party to join/participate.
- **Update industry groups/meetings:**
  - **CPPQ Update** (Compendial Policy Process and Quality stakeholder discussion group). - discussion on recap of 2020 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 – discussed October 11 workshop in Chicago.
- **Review of Federation Project activities**
  - **Mutual Recognition of pharmacopeias** – update on team activities.
  - **Polysorbate 20 harmonization** - team collecting comments to prepare a proposal.

Regulatory Affairs (Meera/Troy)

- **Reviewed activates completed since Q2 committee meeting:**
  - OEHHA Proposal to update NSRL for ethylene oxide to 0.058 micrograms per day.
  - FDA Docket FDA-2023-D-1573 for testing high-risk drug products for DEG and EG
  - FDA Docket FDA-2023-N-1585 on Identification, Assessment, and Control of Nitrosamine Drug Substance-Related Impurities in Human Drug Products
  - FDA Docket FDA-2023-C-1487 on revoking color additive listings for use of TiO_2 in foods.
  - Microplastic webinar.
- **Reviewed IPEC and PQRI comments to ECHA PFAs Restriction Proposal**
- **Shared information on:**
  - FDA CDRH *Best practices for regulatory commenting.*
  - Recently published proposed bill (H.R. 4263) potentially impacting the label/labeling of drug ingredients derived from food allergens and gluten containing grains.
  - EU Microparticles regulatory proposal update provided. IPEC-Americas/IPEC Europe Q&A being developed as a "How to" document for reporting purposes.
  - California legislation passed Assembly Bill 418 banning the manufacturing and sale of food products that contain four common food additives; however, at the last minute TiO_2 was removed from the bill.
  - Results from PQRI workshop held June 13 & 14, currently being used to develop a position paper to be shared with EMA in an attempt to influence their decision on how to address the future use of TiO_2 in drug products going forward.

GMP
(Mike/Beth)

- **Reviewed status of and progress towards IPEC Guides currently in-progress**
  - IPEC Good Distribution Practices How to guide for Pharmaceutical Excipients.
- **Discussed partnering with PDA to develop an Annex/Guide focused on excipient use and requirements for parenteral drug applications.**
- **Discussed development of a new IPEC-Americas webinar** targeted at providing a fundamental overview of best practices for excipient GMPs (e.g., excipient GMP 101).
- **Shared recent FDA white paper** "*CDER's Quality Management Maturity (QMM) Program: Practice Areas and Protype Assessment Protocol Development*".
- **Reviewed and discussed the recently published IPEC Federation Position Paper on Supply Chain Security** entitled "*Latest fatal incidents with contaminated medicinal syrup during 2022/2023*."

Excipient Qualification (Ann/Candy)

- **Reviewed and discussed comments received and next steps for revision of IPEC Guides**
  - IPEC TUPPS Guide.
  - IPEC Quality Agreement Guide.
- **Publication/articles**
  - IPEC-Americas provided responses/views to PharmTech questions summarized in an article entitled "*In Equal Measures: The Importance of Excipient Quality*" which published in September 2023
- **IPEC CoA Guide**
  - discussed need to revisit clauses in the IPEC CoA guide requiring the date of approval for a CoA not hand signed, identification of person approving the CoA and date of approval.
- **Webinar**
  - Managing Excipient Significant Change: Best Practices, scheduled for November 8 from 10-12

QbD
(Dave/Stacey)

- **PQRI workshop on Co-processed Excipients to Enhance Continuous Manufacturing** - continued to discussed/reviewed 2024 workshop proposal.
- **Discussed**
  - Recent USP-NF stimuli entitled "*Proposed Definitions of Excipient Components - Revisions to 2018 Definitions*." Joint sub-committee (CRC and QbD) formed to review article and develop comments from IPEC-Americas.
- **Publication/articles**
  - Emerging technology and impact on excipient – The need for novel excipients and functionalities. Article to include excipient fundamentals and a review of excipient characterization activities (2-part article).
  - Excipient considerations for use in continuous manufacturing and how to design for purpose.
- **Webinar**
  - Expectations for Sharing Excipient Composition Information, October 10 2023.
- **Miscellaneous**
  - Examined various current and proposed terms/definitions for inclusion in the 2023 IPEC General Glossary of Terms and Definitions.

Scientific Affairs
(Lisa/Charlotte)


- **IQ-IPEC-Americas Novel Excipient working group**
  - Received FDA feedback on backgrounder to support decoupling co-processed excipients from the definition of "novel excipient".
  - Prepared and sent follow-up response to FDA requesting a meeting.
- **Update and further discussion on Academic Sub Team** project to develop an Excipient 101 course/workshop, targeted for both academia and industry. Workshop planned for EW 2024.
- **Shared outcome of joint IPEC-Americas/CRS "Biologics Summit**." Part 2, held July 24, 2023 as part of the CRS Annual Conference. The July 24 Summit targeted Subcutaneous delivery of highly concentrated, highly viscous mAbs (monoclonal antibodies) and hosted ~200 attendees.
- **Update from NAMS (New Approach Methodologies) sub-team**, including proposal for adding term/definition for NAMS in revised IPEC glossary, plans to include a presentation on NAMS as part of EW 2024 and potential to host IPEC-Americas webinar on NAMS in 2024**.**

Users Network
(Heather)

User Network committee members discussed various regulatory topics previously covered in other committee meetings.

> *In PF49(5), USP published another set of proposed monographs for hard gelatin, HPMC and pullalan capsules. USP has previously published multiple iterations of proposals for these monographs but did not move forward with implementing them due to significant stakeholder feedback. Users of these capsules should review the proposals and submit comments to USP if there are any concerns about the feasibility of the procedures and/or acceptance criteria. These proposals will be further discussed at the next monthly compendial postings discussion on 16-Oct 1-2:30pm*

Committee also discussed purpose for team and potential topics to cover during future committee meetings.

Monthly Compendial Postings Review

- Reviewed proposals published in:
  - PF 49(4) and 49(5)
  - USP Notice for <86> Bacterial Endotoxins Test Using Recombinant Reagents
  - PharmEuropa 35.2, 35.3
  - PF 49(6) and Pharmeuropa 35.4 will be reviewed on 16-Oct
- Comments submitted:
  - Letter to USP requesting rationale for impurity limits proposed for Acetyltributyl citrate (revised) and Histidine (new) NF monographs
  - Letter to USP commenting positively on the transparency of sharing stakeholder comments and USP responses to Stimuli Article "Understanding the Composition and Quality of Polysorbates to Strengthen USP–NF Compendial Standards"
- Reviewed new/updated official content:
  - Eur. Ph 11.3 (effective 1-Jan-24)
- Next compendial postings reviews:
  - 16-Oct-23 1 – 2:30 pm EDT
  - 13-Nov-23 1 – 2:30 pm EST

Microplastics Cross Functional Team

- The final microparticle regulation is published as a Commission Regulation (EU) 2023/2055 (Official Journal).
- It will enter into force on 17 October 2023, when all microparticles without transition times or derogations will be banned (above the cut-off limit.
- Medicinal products are derogated from the ban and certain labelling and reporting requirements will apply to makers/users.
- Team will be communicating on timeline for IPEC guidance in the near future.

IPEC-Americas 2023 Q3 Dashboard

18 interactions with regulators/ pharmacopoeias

	CRC	RA	GMP	EQ	QbD	SAC	UN	LL	XC	IF	EW	M	TOTAL
FDA Docket comments		3											3
FDA Correspondence		1				2							3
FDA Public Mtg/training		1	1										2
USP correspondence/meeting	4	1			1								6
EDQM comments													0
ECHA (REACH Comments)		2											2
ICH Comments (ICH Q13 WG)													0
OEHHA Correspondence						1							1
NSF													0
WHO		1											1
Publications	1			2		1							4
Workshops			1	1	1	1					1		5
Webinars/Presentations		3	3			2			1		4		13
Draft Guides (in-progress)			3	4						1			8
Published New/Revised Guides			1	2									3
Position Papers/White Papers			1										1
Infographics									1				1

M = membership

IPEC Foundation

IPEC Foundation Award Ceremony

The 2023 Foundation awards ceremony will be held on October 24, in Orlando Florida during AAPS PharmSci 360.

The IPEC Foundation Award winners are:

Ralph Shangraw Memorial Award – for individuals who have provided outstanding research contributions in the study of excipients or excipient-related technology:

Dr. Michael Repka, University of Mississippi

Henk de Jong Industrial Research Award - recognizes individuals working in an industrial setting who have made significant contributions in the field of excipient technology:

Dr. Haichen Nie, Teva Pharmaceuticals

IPEC Foundation Award Ceremony

- **Patrick DeLuca Emerging Researcher Award –** Recognizes a beginning career scientist (post Ph.D.) who has demonstrated interest and dedication to the area of excipients:

  Dr. Sabrina Banella, University of Ferrara

- **Graduate Student Award Winners**:

  Ling Zhu, University of Connecticut
  Jiawei Wang, University of Texas at Austin
  Ruifeng Wang, University of Connecticut
  Zijian Wang, University of Minnesota
  Weizhou Yue, University of Rhode Island

Strategic Team Updates

Team 1 & 2 combined: Strategic Alliances and Partnerships and Expanding Markets and Membership

Strategic Alliances and Partnerships Expanding Markets/Membership

- Combined goals
- Assessing our partnerships, collaborations and alliances
- Ongoing collaborations with:
  - Parenteral Drug Association
  - Generic Animal Drug Alliance
    - Upcoming joint webinar – March 12 – 13, 2024
  - Pharmaceutical Quality Research Institute
  - Controlled Release Society - CRS

Latin America Working Group

- Meeting regularly in local language
- Aspirus – New Regional Member
- Currently – 15 companies involved
- 2 Safybi webinars took place - April and May 2023
- An in-person workshop with Safybi is being considered
- Ongoing meetings
- **If your company has business operations in Latin America who may want to participate in the working group please let IPEC-Americas Staff know.**

Membership

- New members in 2023 include:
  - Gaylord Chemical Company
- Continued digital advertising using the Feathr platform (example ad below)

- Ongoing trade show presence to stimulate membership:
  - CPhI North America: April 25 – 27 (Booth #1147 - Technical Session)
  - Excipient World Conference & Expo: May 1-3, Washington DC area
  - Controlled Release Society Annual Meeting: July 24 – 27, Las Vegas NE (Booth #113)
  - PDA/FDA Joint Regulatory Conference, Washington, DC Sept. 18 – 21

    Booth #23
  - AAPS: October 17-20 Orlando, Florida (Booth #3001 and Foundation Awards Ceremony)

Strategic Planning Team 3 Education

Excipient Learning Lab

EXCIPIENT LEARNING LAB

2023 Schedule

Date (2023)	Topic	Presenter(s)
Jan 25	GMP Audit Guide to ANSI standard	Irwin Silverstein
March 23 9:00-10:30	Significant Change Guide	Ann Gulau, Jen Putnam,
April 5 9:00-11:00	IPEC NEW EIP Sustainability Guide + review of other EIP guides	Meera Raghuram, Priscilla Zawislak, Iain Moore
June 22 11:00-1:00	Compliance with EU REACH Synthetic Polymer Microparticles Regulations - What you need to know!	Meera Raghuram
October 3 – 5 8:00-4:00	Excipient GMP Compliance in-person Workshop	Irwin Silverstein, Jeffery Brambora
October 10 from 10-12	Expectations for Sharing Excipient Composition Information	Joe Z, Dave S, Paul S, Beth Febbo
November 8 10:00-12:00	Best Practices for handling Significant Change for Excipients	Ann Gulau, Jen Putnam, Priscilla Zawislak
November 15 11:00-1:00	Why an effective CAPA system is important to excipient companies	Irwin/Jim Morris
November 28 11:00-1:00	The Potential Impact of the EU TiO2 Food Ban on Pharmaceuticals and Patients – Current Status	Dave Schoneker
TBD	Nitrosamines update and status	TBD

2024 Schedule

Date (2024)	Topic	Presenter(s)
March 12 & 13 10:00-12:00	Excipient Considerations in the Development and Approval of Animal Drug Products	GADA - TBD IPEC-Americas - Priscilla CVM - TBD
TBD	NAMs Regulatory Considerations & Reality Check for Pharmaceutical Excipients	TBD from SAC NAMS sub team

Webinars and Workshops

- **November 8:** Best Practices for handling Significant Change for Excipients!
- **November 15**: Why an effective CAPA system is important to excipient companies

- **On-Demand:**
  - FDA's Recent Quality Concerns with Excipients
  - Update on FDA's Inactive Ingredient Database

Certificate of Attendance

NEW

"Did you know this webinar may count toward continuing education credits?

Check with your credentialing organization to confirm.

A certificate of participation will be available for download upon completion of the webinar."

In Process:
Website Relaunch - Higher Logic Platform

- **Purpose:**
  1. Single source of truth for membership and marketing contact data
  2. Simplify workflow for the team
  3. Establish website analytics
- **Sponsor:** XC/Staff
- **Goal:** Q4 2023

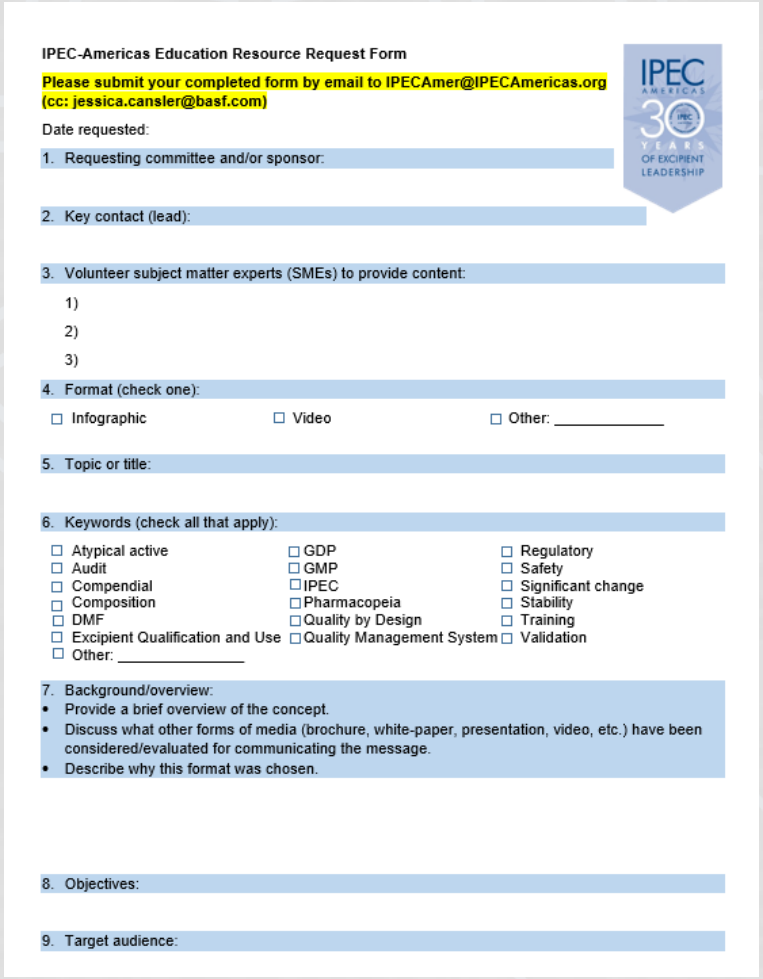
Completed Infographic

- **Title:** Your IPEC-Americas Meetings: What to Expect
- **Purpose:** Demonstrate what to expect and the value of attending IPEC-Americas Meetings.
- **Sponsor:** Membership

Infographics

- Next Up:
  - Intro to committee meetings (What to expect in your first committee meeting)
  - Composition Series: Concomitant components / Minor components
- Coming Soon:
  - Benefits of Membership Series: Biologics

Request a Resource



IPEC-Americas Education Resource Request Form

Please submit your completed form by email to IPECAmer@IPECAmericas.org (cc: jessica.cansler@basf.com)

Date requested:

1. Requesting committee and/or sponsor:

2. Key contact (lead):

3. Volunteer subject matter experts (SMEs) to provide content:

   1)

   2)

   3)

4. Format (check one):

☐ Infographic ☐ Video ☐ Other: _____

5. Topic or title:

6. Keywords (check all that apply):

☐ Atypical active	☐ GDP	☐ Regulatory
☐ Audit	☐ GMP	☐ Safety
☐ Compendial	☐ IPEC	☐ Significant change
☐ Composition	☐ Pharmacopeia	☐ Stability
☐ DMF	☐ Quality by Design	☐ Training
☐ Excipient Qualification and Use	☐ Quality Management System	☐ Validation
☐ Other: _____		

7. Background/overview:

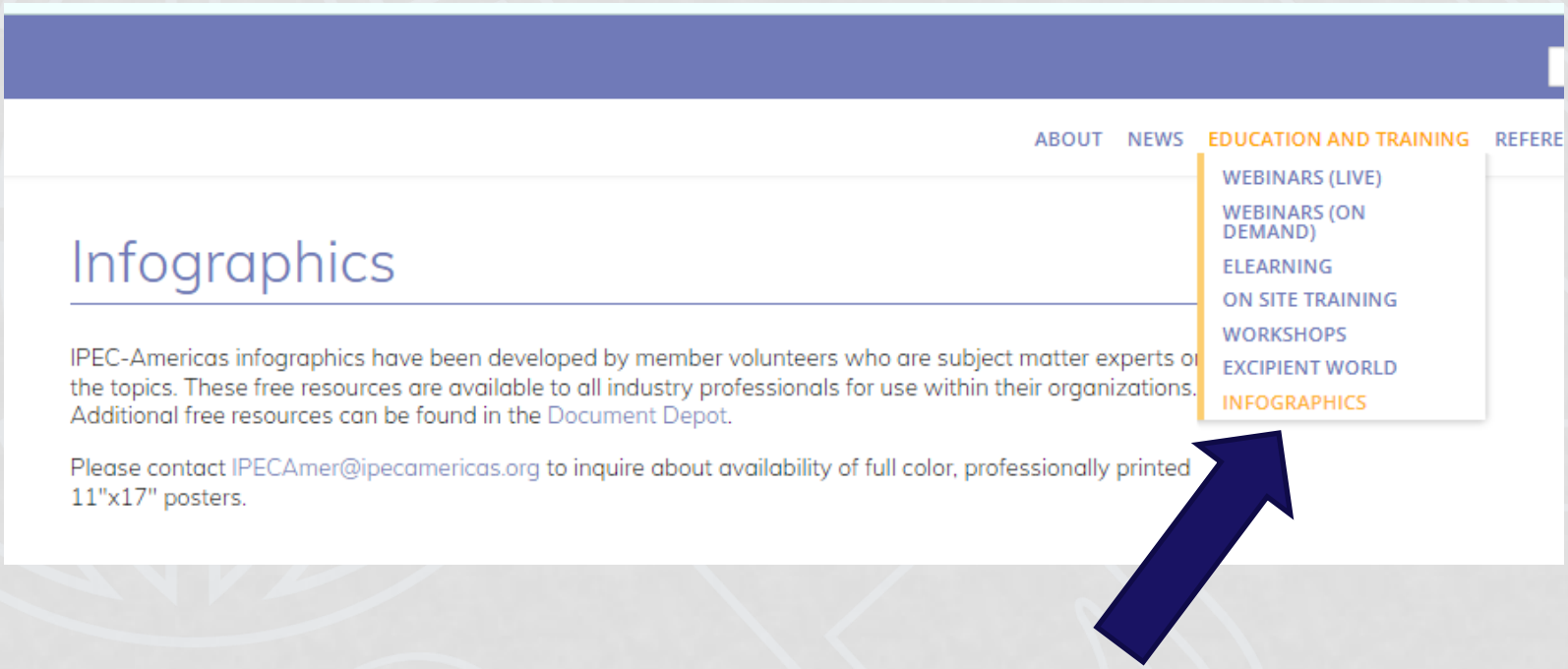
- Provide a brief overview of the concept.
- Discuss what other forms of media (brochure, white-paper, presentation, video, etc.) have been considered/evaluated for communicating the message.
- Describe why this format was chosen.

8. Objectives:

9. Target audience:

- Request Form is in the Document Depot
- Resources will be created in order that requests are received (with possible exceptions)
- Turnaround time is estimated to be 8 – 10 weeks

Infographic Location



Completed infographics available on IPEC-Americas website under Education & Training

Excipient World Conference & Expo

Location & Dates

IPEC-AMERICAS EXCIPIENT WORLD 2024 ORLANDO

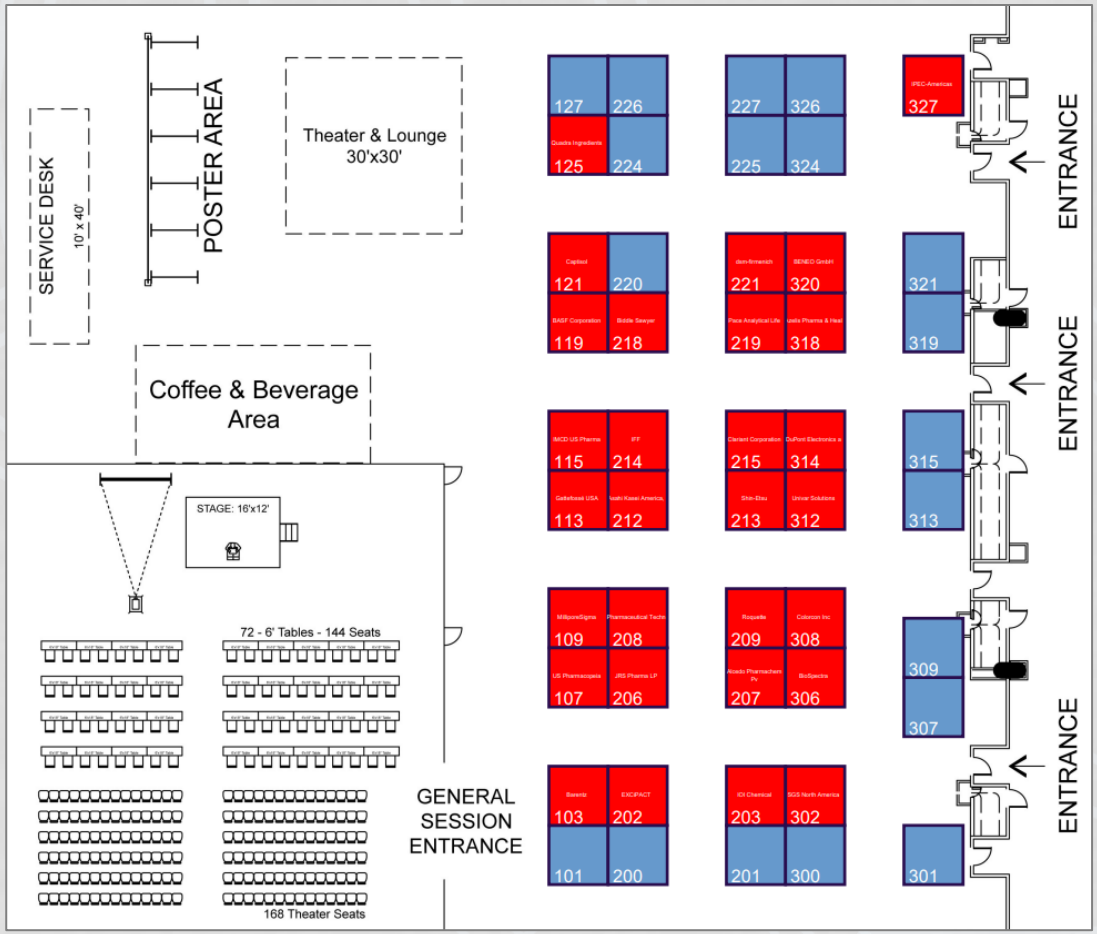
Conference&Expo May 13–14 | Workshops May 15

May 13 – 15, 2024

Gaylord Palms Resort & Convention Center

(Kissimmee, FL)

Floorplan (as of 10/12/23)



IPEC-AMERICAS EXCIPIENT WORLD 2024 ORLANDO

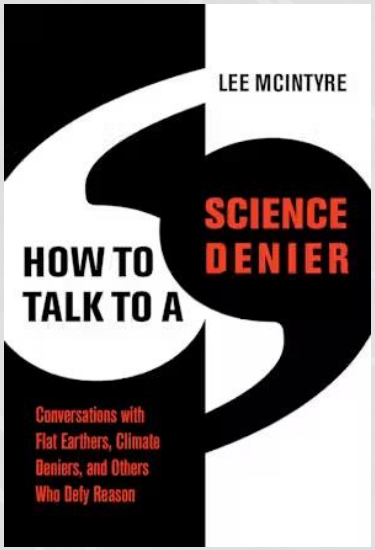
Conference&Expo May 13–14 | Workshops May 15

Company	Booth
Alcedo Pharmachem Pvt.Ltd.	207
Asahi Kasei America, Inc.	212
Azelis Americas, P&H	318
BASF Corporation	119
BENEO GmbH	320
Barentz	103
Biddle Sawyer	218
BioSpectra	306
Captisol	121
Clariant Corporation	215
Colorcon Inc	308
DSM Nutritional Products AG	221
DuPont Electronics and Industrial	314
EXCIPACT	202
Gattefossé USA	113
IFF	214
IMCD US Pharma	115
IOI Chemical	203
IPEC-Americas	327
JRS Pharma LP	206
MilliporeSigma	109
Pace Analytical Life Sciences	219
Pharmaceutical Technology	208
Quadra Ingredients	125
Roquette	209
SGS North America	302
Shin-Etsu	213
US Pharmacopeia	107
Univar Solutions	312

Program Update

FDA Speaker Invites (Sent)

- Amanda Jones (IID)
- June Page (Data Integrity)
- Francis Godwin (Quality)



Author Invite (Pending final negotiations)

- Lee McIntyre

Lee McIntyre is a Research Fellow at the Center for Philosophy and History of Science at Boston University. He is the author of *Dark Ages: The Case for a Science of Human Behavior*, *Post-Truth*, and *The Scientific Attitude: Defending Science from Denial, Fraud, and Pseudoscience*, all published by the MIT Press.

Development Timeline

- **Call for Papers:** June 19
- **Abstract Deadline:** September 22
- **Announce Initial Program:** October 27
- **Open Registration:** November 1
- **Early Bird Deadline:** January 31
- **Hotel Deadline:** April 12

2024 Committee Meetings

- 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

Dates for 2023-2024 "IPEC Week"

Q 4 - December 5 – 7

Q 1 – March 5 – 7

Q 2 – June 11 – 13

Q 3 – September 24 – 26

Q 4 – December 3 - 5

Questions?