Updates from the Chair

June 20, 2023
Nigel Langley, Ph.D.
Chair, IPEC-Americas

Multiple stakeholders; **one objective.**

International Pharmaceutical Excipients Council

Collaborative solutions for excipient industry stakeholders

Volunteer Appreciation

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

Elizabeth Febbo
Global Laboratory & Project Manager
Drug Delivery Polymers
Henkel Corporation
Vice Chair – GMP Committee

Federation Update

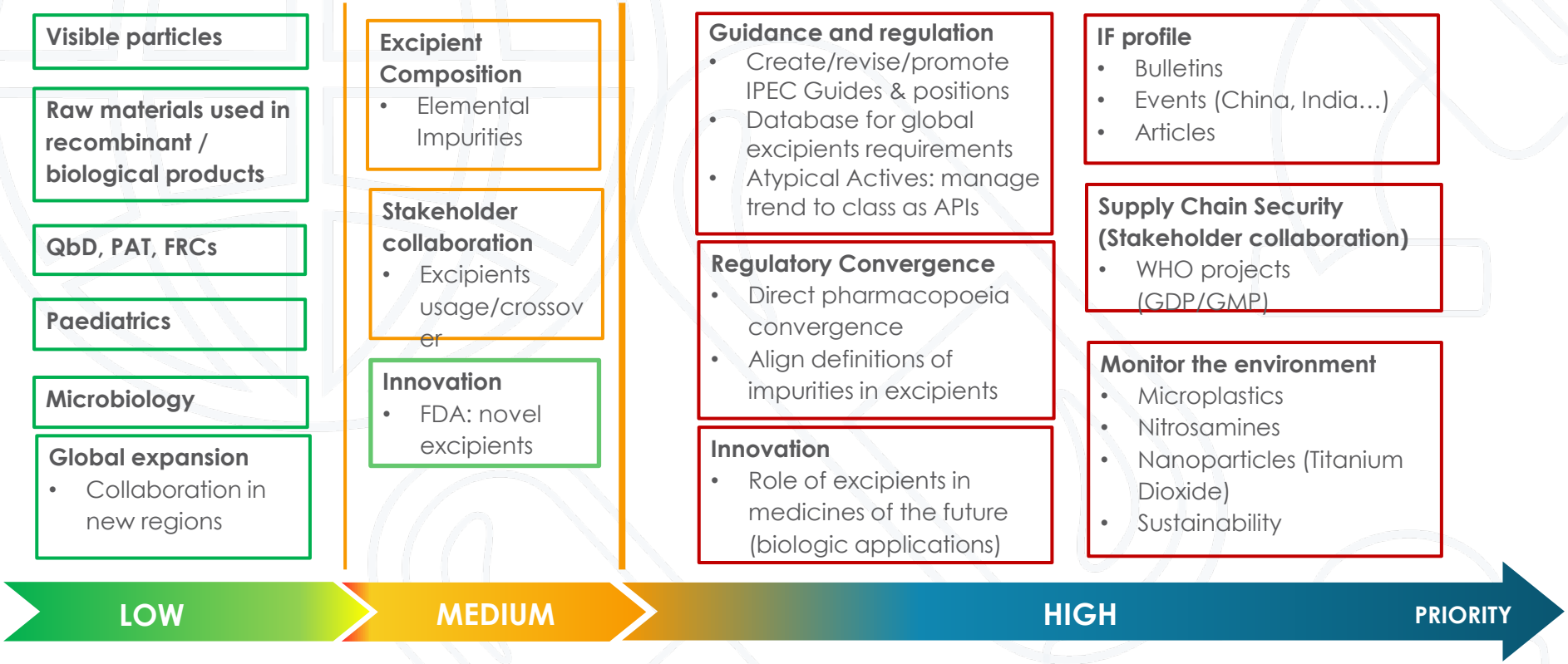
Federation (Priscilla)

- **IPEC Federation**
  - Annual General Meeting held in May
  - 2023 Budget & strategic plan were approved
  - Clarivate proposal for a database was reviewed and feedback was provided for modifications
    - May also be getting a proposal from Redica
  - Comments were provided to WHO re: draft revision of their excipient GMP guidelines
  - ICH Q1 WG met in June and shared early draft guide
- **IPEC EU**
  - Task groups have been established on hot topics such as PFAS, EU Pharma Legislation package
  - Teams working on position papers re: CPEs and microplastics – drafts will be shared for comment
- **IPEC India**
  - Annual conference held May 26
  - EXCiPACT® webinar in June to promote the certification scheme

Federation (Priscilla)

- **IPEC Japan**
  - GAB did not accept IJ input to GMP Guidelines, therefore IJ remains neutral on whether companies should take GMP certification under that guideline
    - GAB recently indicated they may consider the input in the next revision
- **IPEC China**
  - Possible conference in Oct.
  - Collaborating with Shanghai Excipient Lab on biopharmaceuticals and microbial controls for excipients
  - Received 2 recognition awards from ChP for collaboration
  - Gave seminar on guidelines for microbial controls for excipients and other hot topics
  - ChP Draft Elemental Impurities chapter comments due 7/24. Waiting for IC comments.
  - CDE may publish a change guide for excipients (IC provided the IPEC Significant Change guide)

2023 Strategic Focus and Priority Objectives



Committees

CRC
(Doug/Jennifer)

- **Monthly Compendial Review Meetings overview –** reviewed and discussed postings in PF 49(3) and new JP General Information Chapter on weighing and use of a balance. Next monthly compendial review WebEx scheduled for Monday, July 10 from 1:00-2:00 EDT.
- **Shared USP interaction at Excipient World 2023**
  - USP-NF meetings and interactions
  - USP presentation on the *iterative approach and how it could be applied to Novel excipients*
  - Invitation/brainstormed topics for USP to participate in September quarterly CRC meeting
  - Discussion regarding FDA Guidance on testing high-risk drug products for DEG and EG.
- **Update for the following industry groups/meetings:**
  - **CPPQ Update** (Compendial Policy Process and Quality stakeholder discussion group). - (reviewed draft CPPQ Tips document for using USP-NF/PF integrated platform, beta testing of USP-NF/PF Customer Advisory Board CAB and British Pharmacopeia pilot program)
  - **SEPC** – Stakeholder Engagement Planning Committee - Currently focusing on how industry might better engage with the USP
  - **JIG** – Joint Industry Group Meeting – planning for meeting Q4'2023.
- **Review of Federation Project activities**
  - **Mutual Recognition of pharmacopeias** – charter approved, reviewed the project justification and purpose.
  - **EDQM issue** - EU agency interpretation of requirement for additives & process aids.

Regulatory Affairs (Meera/Troy)

- **Frank Switzer, FDA –** provided an overview of Unique Ingredient Identifiers (UNII) and their impact (resulting from FDA cosmetic reforms) on application of UNIIs to cosmetic ingredients.
- **Susan Zuk, FDA –** shared an overview of her EW 2023 entitled "Inactive Ingredient Database (IID) Update 2023.
- **Discussion regarding:**
  - 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
  - ECHA PFAs Restriction Proposal
  - REACH April 2023 approval to post draft amendment on restriction of synthetic microparticles
- **Shared information on:**

  PQRI TiO2 workshop took placeJune 13 & 14 in Rockville Maryland. Workshop outcome to be shared with EMA in an attempt to influence their decision on how to address the future use of TiO2 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.
  - Revision of IPEC Stability Guide for Pharmaceutical Excipients.
- **Reviewed and discussed Francis Godwin's 2023 EW FDA presentation entitled "FDA's Recent Quality Concerns with Excipients.".**
- **Reported that USP continues to review** and address IPEC-Americas comments <USP 1078> Excipient GMP.
- **Shared IPEC-Americas comments to Federation for feedback to WHO** draft Excipient GMP Guideline
- **Reported that Jessica Cansler has joined the EXCiPACT® board** and that EXCiPACT® recently published a new guide on Pharmaceutical Auxiliary Materials (PAMs).

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**
  - T&C article entitled "Qualifying Excipient Vendors Can Strengthen Supply Chain" was finalized and published in June.
  - new article/publication targeted at excipient supplier expectations and limitations for addressing and managing for emerging regulatory and User issues (e.g., risk assessments for nitrosamines, EtO, DEG/EG, and sustainability practices/questionnaires).
- **NEW Standing EQ committee monitoring/discussion** for emerging activities related to sustainability and responsible sourcing.
- **Webinar**
  - Managing Excipient Significant Change: Best Practices, scheduled for November 8 from 10-12

QbD
(Dave/Stacey)

- **Continuous Manufacturing**
  - Confirmed that ICH Q13 Implementation Working Group continues to develop training materials to promote adoption of the published ICH Q13 .
  - Reviewed a new Centers of Excellence Initiative- The National Institute for Pharmaceutical Technology and Education (Nipte.org) targeted at "advances in continuous manufacturing."
- **PQRI workshop on Co-processed Excipients to Enhance Continuous Manufacturing** - continued to discussed/reviewed workshop proposal.
- **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**
  - Excipient Composition Fundamentals, Profile Characterization, Communication to Users

Scientific Affairs (Lisa/Charlotte)


- **IQ-IPEC-Americas Novel Excipient working group**
  - Sent and received FDA feedback on backgrounder to support decoupling co-processed excipients from the definition of "novel excipient".
  - Presented a "quick talk" at the 2023 EW Conference and Expo entitled *De-coupling certain co-processed excipients from regulatory definition of "novel"*.
- **Update and further discussion on Academic Sub Team** project to develop an Excipient 101 course/workshop, targeted for both academia and industry. Charter approved, currently developing 10-12 lectures focusing on oral excipients. Course targeted for completion March 2024.
- **Shared outcome of joint IPEC-Americas/CRS "Biologics Summit**." Part 1, which took place during the 2023 EW Conference and Expo, included ~35 attendees. Main excipient issues identified included: viscosity modification and stability (agglomeration prevention of proteins). Part 2 scheduled for CRS Annual Meeting July 24-27 in Las Vegas.
- **Reviewed EW poster entitled *NAMs Regulatory Considerations & Reality Check for Pharmaceutical Excipients*.**

Users Network (Heather)

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

- FDA Final guidance "*Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol*"
- California OEHHA proposal to lower the "safe harbor" level for ethylene oxide from 2 µg/day to 0.058 µg/day "*Notice of Proposed Rulemaking Title 27, California Code of Regulations Amendment to Section 25705 Specific Regulatory Levels Posing No Significant Risk*".
- FDA Docket FDA-2023-N-1585 to solicit public comments on the *Identification, Assessment, and Control of Nitrosamine Drug Substance-Related Impurities in Human Drug Products*.
- FDA response to IQ/IPEC-Americas regarding their request for the Agency to decouple co-processed excipients from the definition of "novel excipient."
- EU initiative to overhaul European Medicines Agency (EMA) new version of the "*3-year work plan for the Quality domain*" for the period January 2021 - December 2023.

Monthly Compendial Postings Review

- Reviewed proposals published in:
  - PF 49(2) and PF 49(3)
    - Comments being drafted regarding revisions to Acetyltributyl Citrate and Histidine monographs published in PF49(3) (due Jul-31-2023)
  - PharmEuropa 35.2
  - JP Drafts – December 2022 and March 2023 (No. 1 and No. 2)
- Reviewed new/updated official content of USP/NF 2023 Issue 3 (effective Dec-01-2023)
  - Implementation of the revised Talc USP monograph referencing new USP <901> Detection of Asbestos in Pharmaceutical Talc is delayed for 24 months (Dec-01-2025) to allow stakeholders adequate time to implement the new X-Ray Diffraction and Polarized Light Microscopy techniques
- Next compendial postings reviews:
  - July 10th 1 – 2:30 pm EDT
  - August 14th 1 – 2:30 pm EDT

Nitrosamines Cross Functional Team

Objective:

Address nitrosamine related concerns with a focus on excipients. Lead, learn from, and leverage expertise in support of driving nitrosamine understanding /risk/ mitigations.

Overview of Q2 2023 Accomplishments:

- IPEC-Federation position paper on nitrosamines currently being updated
  - Focus on excipients that provide consistent messaging on regulatory expectations and perspectives on excipient risk mitigations.
- Continuing to monitor global regulatory developments with a focus on excipients.

Microplastics Cross Functional Team

A cross functional team including members of the Pharma Chemleg team, IPEC-Americas and IPEC- Europe

Current Situation

- Proposed text approved – voted on in the REACH Committee meeting 26th April.
- Proposal enters 3-month period of scrutiny by European Parliament & Council.
- Next: Publication in the Official Journal & Entry into Force (EIF) 20 days later.
- Further updates to the restriction, minor changes to the existing text:

https://ec.europa.eu/transparency/comitology-register/screen/documents/083921/6/consult?lang=en

Current Team Activities

- The previously issued “how to guide” will be updated.
- A brief position paper focusing on data needs to ensure there is consistency in excipient enquiries and responses between excipient makers and users is being considered.

IPEC-Americas 2023 Q2 Dashboard

6 interactions with regulators/ pharmacopoeias

	CRC	RA	GMP	EQ	QbD	SAC	UN	LL	XC	IF	EW	M	TOTAL
FDA Docket comments		0											0
FDA Correspondence		1				1							2
FDA Public Mtg/training		1											1
USP correspondence/meeting	2												2
EDQM comments													0
ECHA (REACH Comments)													0
ICH Comments (ICH Q13 WG)													0
CDE Correspondence													0
NSF													0
WHO		1											1
Publications	1			1		1							3
Workshops				1		1					1		3
Webinars/Presentations			3			1			1		4		9
Draft Guides (in-progress)			2	3									5
Published New/Revised Guides			1	2									3
Position Papers/White Papers													0
Infographics									1				1

M = membership

IPEC Foundation

IPEC Foundation Award Applications Now Being Accepted

Deadline is June 15, however, applications will still be considered. The winners will be recognized during the IPEC Foundation's annual awards ceremony that will take place **on Tuesday, October 24, 2023 in Orlando Florida.**

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. (postdoctoral fellows, research assistant professors and early stage assistant professors).

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: www.ipecfoundation.org
  Deadline: NOW!

Strategic Team Updates

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

Strategic Alliances and Partnerships

- Assessing our partnerships, collaborations and alliances
- Identified potential partners; Prioritized list

- PDA representatives attended the XC meeting to discuss possible areas of collaboration.
- GADA is now re-engaging with IPEC-Americas. Other priority groups are AAM, PQRI.
- Latin American Working Group - in process with ongoing meetings.

Latin America Working Group

- Meeting regularly in local language
- Increased awareness and interest from attendees during Excipient World.
- An in-person workshop is being considered
- Currently – 14 companies interested
- 2 Safybi webinars took place - April and May 2023
- 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.**

Expanding Markets and Membership

- The team has identified potential emerging areas which are important for excipients and adjacent markets.
- IPEC is connecting with industry and trade organizations to form alliances
- Parenterals are a key strategic goal for this group. PDA is open to collaborating with IPEC-Americas, as they have worked with us in the past.
- Ideas under discussion include:
  - Training in 2023 related to parenterals, lipids
  - A journal article related to excipients & adjuvants
  - Consider a joint technical document with PDA on parenterals including excipients

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

2023 Schedule

EXCIPIENT LEARNING LAB

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
July/Aug?	Pharmaceutical excipients in veterinary products	**Potential speakers:** GADA (Courtney A, Shane G), CVM and IPEC
September ?	NAMs Regulatory Considerations & Reality Check for Pharmaceutical Excipients	TBD from SAC NAMS subteam
October 10 from 10-12	Expectations for Sharing Excipient Composition Information	Joe Z, Dave S, Paul S, Beth Febbo
October	Nitrosamines update and status	TBD
November 8 10:00-12:00	Best Practices for handling Significant Change for Excipients	Ann Gulau, Jen Putnam, Priscilla Zawislak
November?	TiO2 update and status of new information	Dave Schoneker

Webinars and Workshops

- **June 22:** Compliance with EU REACH Synthetic Polymer Microparticles Regulations - What you need to know!

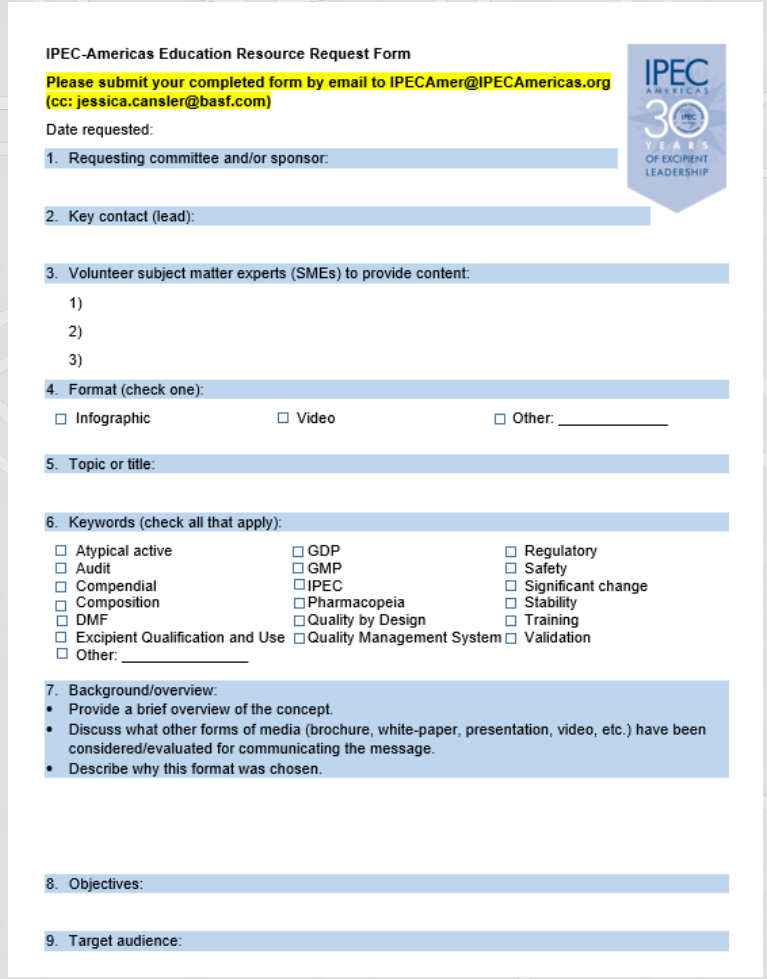
- **Oct. 3-5:** Excipient GMP Compliance Workshop

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

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: _____		

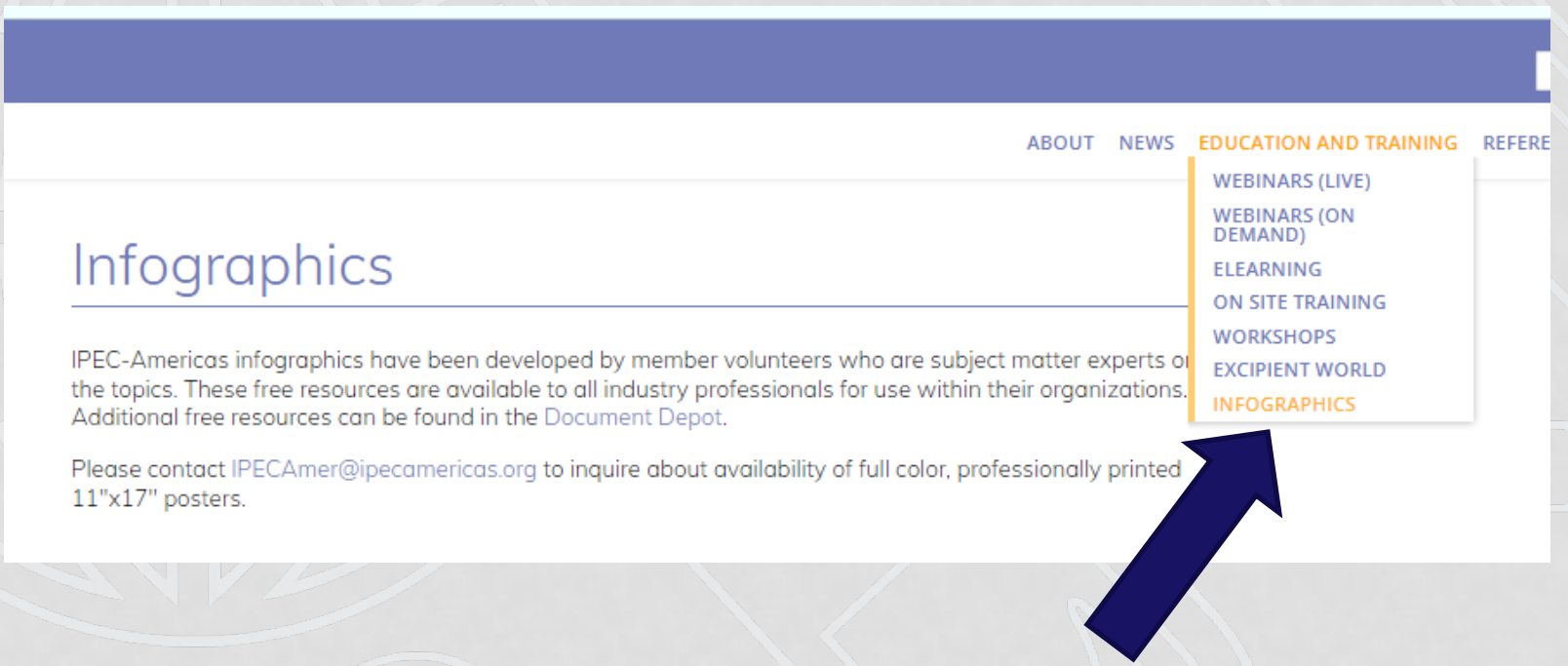
7. Background/overview:
- Provide a brief overview of the concept.
- Discuss what other forms of media (brochure, white-paper, presentation, video, etc.) have been considered/evaluated for communicating the message.
- Describe why this format was chosen.

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

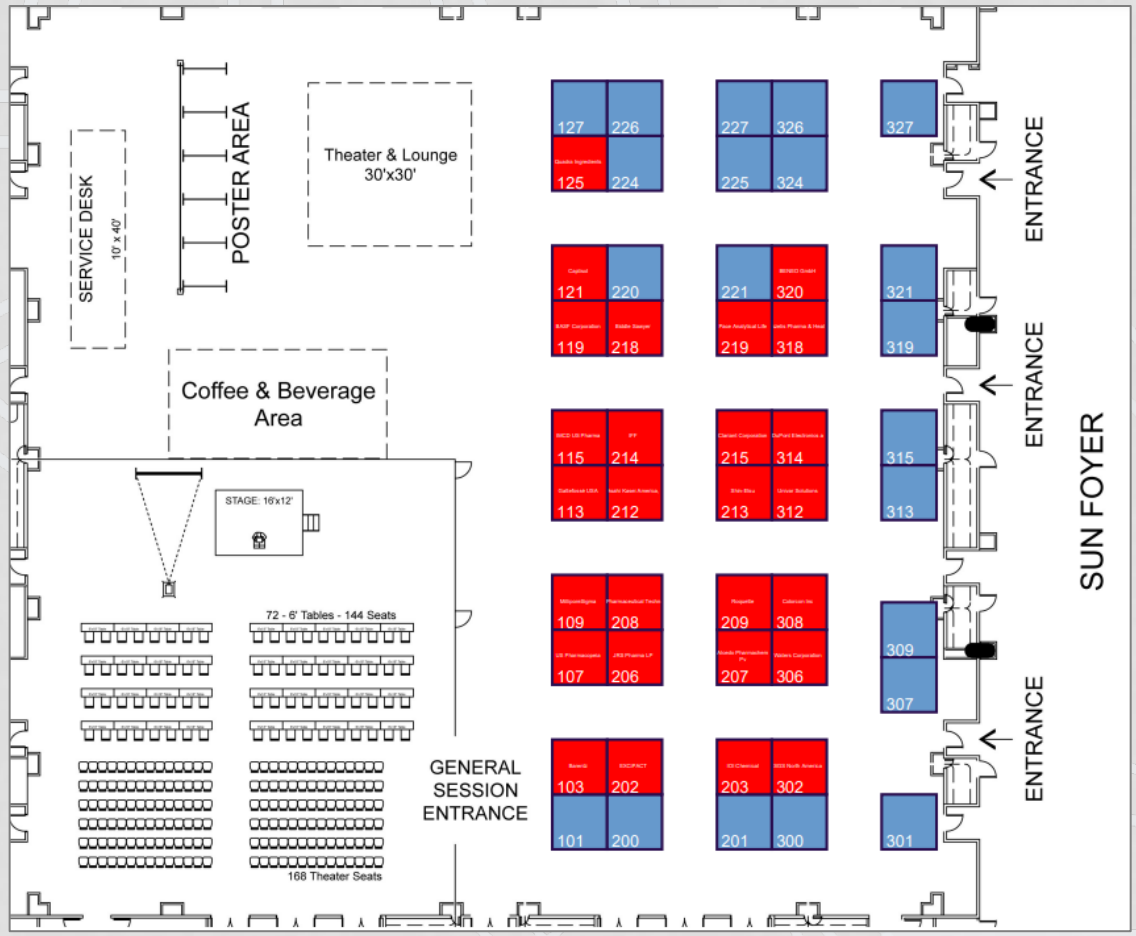
Conference & Expo: May 13-14

Workshops: May 15

Gaylord Palms Resort & Convention Center

(Kissimmee, FL)

Floorplan (as of 05/15/23)



IPEC-AMERICAS EXCIPIENT WORLD 2024 ORLANDO

Conference&Expo May 13–14 | Workshops May 15

27 of 48 booths already sold! (56%)

Preliminary Development Timeline

- **Call for Papers:** June 19
- **Abstract Deadline:** September 8
- **Announce Initial Program:** October 13
- **Open Registration:** November 1
- **Early Bird Deadline:** January 31
- **Hotel Deadline:** April 12

2023 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 "IPEC Week"

Q 3 - September 12-14

Q 4 - December 5 – 7

Questions?