Updates from the Chair

Multiple stakeholders; **one objective.**

March 27, 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……

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Troy Barrix
Senior Regulatory Compliance Specialist Product Stewardship

Celanese

Vice Chair – Regulatory Affairs Committee

Celanese
The chemistry inside innovation™

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Federation Update

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Federation (Priscilla)

- **IPEC EU**
  - IPEC Europe – Forum held in Lisbon, March 2023
  - Contacted EDQM/EMA re: CPEs, CEPs, composition
- **IPEC Japan**
  - EI's official/Heavy metals removed from JP
  - IJ submitted comments re: application of EIs to OTCs
- **IPEC India**
  - Presented at Indian Pharmaceuticals Congress, Jan 2023
  - Requesting full membership in IPEC Federation
- **IPEC China**
  - Submitted comments to NMPA re: revision of 2006 GMPs for excipients

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Federation (Priscilla)

- **Federation Projects**
  - Regulatory database – follow-up with Clarivate in Feb with search terms
  - ICH Q5C Stability WG – sub-groups working on sections
  - IPEC-PDG meeting held in Feb 2023 – IPEC India and Indian Ph. now members
  - Collaboration project initiated with WHO re: recent incidents of cough syrup contamination with DEG in Southeast Asia, Africa and Uzbekistan
  - Revision of Nitrosamines position paper and template
  - Draft 2023 Strategic Plan

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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

LOW → MEDIUM → HIGH → PRIORITY

DRAFT

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Committees

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CRC
(Doug/Jennifer)

- **Monthly Compendial Review Meetings overview –** reviewed and discussed postings in PF 48(6), PF 49(2) and PharmEuropa 34.4. Next monthly compendial review WebEx scheduled for Monday, April 10 from 1:00-2:00. Plans for a more thorough review of PF 49(2) during April WebEx.
- **USP discussions/training -** Four invited guest from USP attended Q1 committee meeting and provided training and/or overview on:
  - **Richard Panzer -** organization of USP website and tips for use
  - **Dr. Catherine Sheehan/Dr. Hong Wang -** USP Stakeholder Engagement Model
  - **Yognandan Pandya -** available for Q&A
- **Update for the following industry groups/meetings:**
  - **CPPQ Update** (Compendial Policy Process and Quality stakeholder discussion group)
  - **SEPC** – Stakeholder Engagement Planning Committee – USP planning committee
  - **JIG** – Joint Industry Group Meeting
- **Review of Federation Project activities**
  - **Mutual Recognition of pharmacopeias** – project charter approved February 2023
  - **EDQM issue** - EU agency interpretation of requirement for additives & process aids.
  - **Annual IPEC/PDG meeting** - held February 28, 2023
- **T&C article**
  published February 1, 2023 entitled '[Planning for Global Quality Standards](#).

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Regulatory Affairs
(Meera/Troy)

- **IPEC tracking spreadsheet of FDA IID quarterly postings –** Reviewed Q1 2023 IID posting information and IID sub team letter to IID mailbox with cc to Susan Zuk sharing information on inconsistencies found in database reporting from Q1 2022 through Q1 2023.
- **2023 Federation Nitrosamine questionnaire -** being revised to add clarification to certain sections/excipient requirements. Revised questionnaire to be re-published soon. Efforts underway to prepare and publish a journal article/position paper on nitrosamines in the Journal of Organic Process and Research Development.
- **Overview of the Modernization of Cosmetic Regulation Act (MoCRA)** - signed into law at the end of 2022.
- **Updated status of international regulatory issues regarding –**
  - **EU microplastic restrictions/regulations** and their potential to impact medicinal products
  - **TiO_2 ban** in food uses and potential future impact to pharm.
  - **EU Medicinal Product Regulation** – EU Directives are being updated.
  - **IPEC-Americas LATAM excipient working group** to discuss regional regulator topics related to excipients

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GMP
(Mike/Beth)

- **Reviewed status of and progress towards IPEC Guides currently in-progress**
  - Published the IPEC-Americas GMP "How to" Audit guide to the NSF/IPEC/ANSI 363 Good Manufacturing Practices (GMP) for Pharmaceutical Excipients Standard and held a webinar to introduce the new guide on January 25, 2023.
  - Update provided on current Federation project to revise/update the International Pharmaceutical Excipients Council Good Distribution Practices How to guide. Phase 1 by IPEC-Americas targeted for completion in Q2.
- **Shared EU Medicinal Product Regulation** – EU Directives are being updated. A review of pending EU legislation, specific for excipient related topics, was created and is available for IPEC-Americas members.
- **Reported that USP has reviewed** and is addressing IPEC-Americas comments <USP 1078> Excipient GMP.
- **Introduced Federation project to collaborate with WHO** as a result on their investigation into recent drug product contamination issues which have resulted in patient fatalities. Several issues were linked back to supply chain issues

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Excipient Qualification
(Ann/Candy)

- **Significant Change Guide Revision** – Updated: IPEC Significant Change Guide for Pharmaceutical Excipients – IPEC Federation (ipec-federation.org) published on February 27 and is exclusively available to members until end of May.
- **Sustainability and Responsible Sourcing section of the EIP Guide** – Excipient Information Package User Guide and Template, Part IV: Sustainability published March 8, 2023 and is exclusively available to members until June 8, 2023.
- **Discussed** potential articles to develop/publish in 2023.
- **Reviewed and discussed** comments received and next steps for revision of 2015 IPEC Technically Unavoidable Particle Profile (TUPP) Guide.

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QbD
(Dave/Stacey)

- **ICH Q13 –** update on ICH Q13 Implementation Working Group (IWG) activities to develop training materials to promote adoption of the published ICH Q13 .
- **PQRI workshop on Co-processed Excipients to Enhance Continuous Manufacturing** – discussed/reviewed workshop proposal.
- **Infographic** – Discussed the efforts to develop a third infographics on major and minor impurities (previously known as concomitant components).
- **Discussed developing:**
  - position paper to provide guidance on excipient considerations in CM and how to design for purpose.
  - two part article on emerging technology and impact on excipient (need for novel excipients and functionalities) with excipient fundamentals (review of excipient characterization).

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Scientific Affairs
(Lisa/Charlotte)

- **IQ-IPEC-Americas Novel Excipient working group** finalizing backgrounder to support decoupling co-processed excipients from the definition of "novel excipient," at least from a "safety" perspective. Targeting submission to FDA by end of March and quick talk presentation at Excipient World in May 2023.
- **Update and discussion on Academic Sub Team** project to develop an Excipient 101 course/workshop, both for academia and industry. Currently developing outline/content. .
- **Updated on joint IPEC-Americas/CRS "Biologics Summit**." Part 1 scheduled for May 1as part of the Excipient World Conference. Part 2 to be scheduled as part of the CRS conference in July 2023. https://s6.goeshow.com/ipec/annual/2023/biologics_summit.cfm
- **Reviewed NAMS survey results** and discussed plans for a webinar later in 2023 to review results. Poster presentation targeted for Excipient World in May 2023.

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Monthly Compendial Postings Review

- Reviewed proposals published in PF 49(1) and PharmEuropa 35.1 as well as new/updated official content of USP/NF 2023 Issue 2
  - PF 49(2) to be published on 1-Mar-2023, will review at CRC if available
- Comments were submitted to new proposed USP GC <312> Molecular Weight Determination for Alginates
  - Comments had previously been submitted when GC prospectus was published – USP responded at the time referencing an article written by USP
  - Further response from USP has not been received
- EDQM has requested data from IA members to support comments submitted regarding maintaining specific EI tests in monographs for natural materials for which there is a known risk for the EI to be present
- USP responded to comments submitted to the proposal to remove the Aspartame Acesulfame NF monograph, clarifying their rationale

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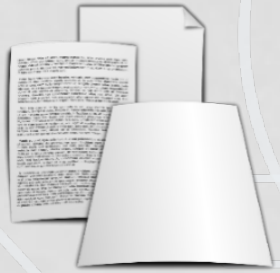
Nitrosamines Cross Functional Team

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 Q1 2023 Accomplishments:

- IPEC Federation issued Nitrosamine Questionnaire
  - Rebranded IPEC-Europe Questionnaire
  - Rebranding was deemed appropriate as the IPEC Europe Questionnaire has been adopted and used globally and a decision was taken to make the same format available through all IPEC associations
- Position paper currently being updated for publication in special issue of Organic Process & Research Development
  - 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.

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Microplastics Cross Functional Team

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

Current Situation

- EU proposal modified to include stringent testing requirements (solubility, biodegradation etc.)
- Industry has commented opposing above requirements. It does not appear that industry input will result in changes to proposal.
- Committee vote to final regulations anticipated in late April 2023

Current Team Activities

The team is awaiting publication of final regulations prior to taking any actions on issuing a position paper and updating the "how to guide".

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IPEC-Americas 2023 Q1 Dashboard

3 interactions with regulators/ pharmacopoeias

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

M = membership

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IPEC Foundation

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IPEC Foundation Award Applications Now Being Accepted

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).

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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: June 15, 2023

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Strategic Team Updates

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Strategic Planning Team 1 Strategic Alliances and Partnerships

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Strategic Alliances and Partnerships

- Assessing our partnerships, collaborations and alliances
- Identified potential partners; Prioritized list
- Background information about each organization has been populated. The team is now capturing additional details into each template.
- Formation of a Latin American Working Group - in process.

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Latin America Working Group

- Kick off call took place on Mar 07th 2023
  - Reviewed background information, purpose, goals, hot topics, group structure discussion
- Follow up call – 3/22 – Identified and prioritized hot topics
- Currently – 14 companies interested
- 2 Safybi webinars scheduled - scheduled for April and May 2023
- 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.

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Strategic Planning Team 2 Expanding Markets and Membership

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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
  - CRS & EW workshop is planned for 2023

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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)

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Strategic Planning Team 3 Education

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YIR Infographic

2022 Year in Review

Guides: (9)

- 3 Published:
  - Stability Guide
  - CoA Guide
  - IPEC-PQG Excipient GMP Guide
- 6 In-Development:
  - Sustainability
  - Significant Change
  - Quality Agreement
  - TUPPs
  - GMP Audit Gui ANSI Standa
  - Good Di ces

Position Papers (2)

Microplasti

Globa ments (14

- Official espondences
- 2
- 1 E omment
- 1 NSF Comment
- 1 TGA Comment

Publications (14)

- 4 Tablets & Capsules
- 4 The Medicine Maker
- 4 Journal of FEC
- 1 PharmTech
- 1 BioPharm International

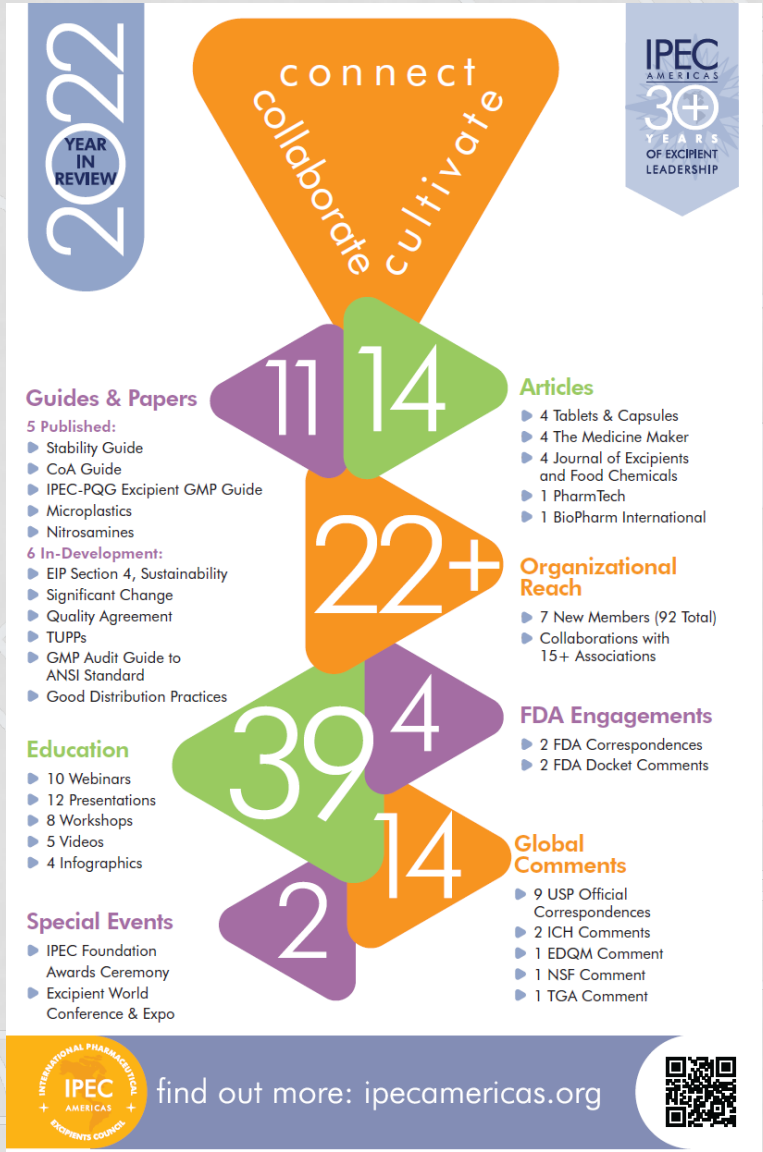
Organizational Reach (?)

- 7 New Members (92 Total)
- 1 New Partnership (CRS)
- Collaborations with X Associations

FDA Engagements (4)

- FDA cover letter and Safety guide submitted to FDA
- FDA letter to OPQ Mailbox, Andre Raw, Ashley Boam
- IPEC-Americas comments to docket FDA-2022-N-1633 "Abbreviated New Drug Application Submissions--Amendments to Abbreviated New Drug Applications Under Generic Drug User Fee Amendments."

DRAFT



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Infographics (estimated 1 per quarter)

- **Intro to committee meetings (What to expect in your first committee meeting): Q1/Q2 2023**
- Composition Series:
  - Concomitant components / Minor components
- Benefits of Membership Series:
  - Biologics

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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
- **NEW:** Keywords have been added to help with searchability of completed items

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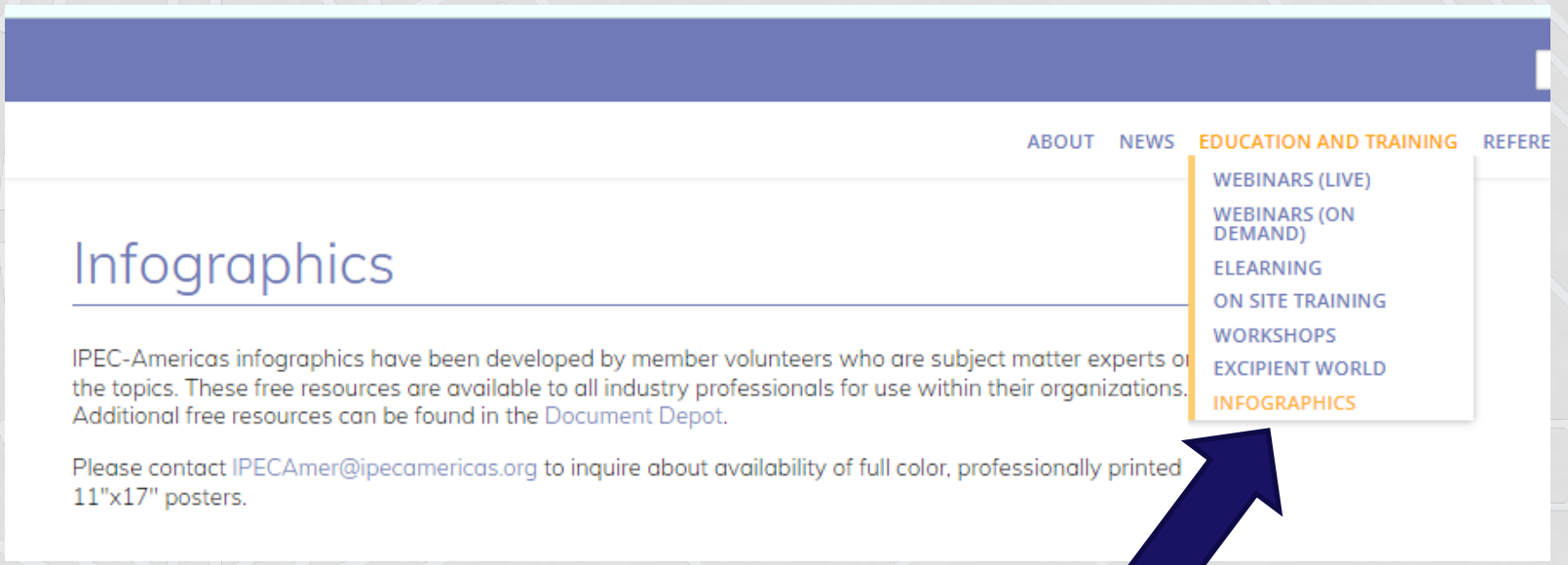
Infographic Location



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

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YIR & Annual Report

- Theme: Connect, Collaborate, Cultivate

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Excipient Learning Lab

- Next up:
  - Webinar: April 4 - Late Breaking News: 2023 Excipient World Conference & Expo
  - Webinar: April 5 - Best Practices for Communicating Excipient Sustainability Information to Excipient Users
  - Workshop: June 12 – 14 - IPEC-Americas and CfPA Co-Sponsor Virtual Course – Excipients: Compliance with Compendial and GMP Requirements

EXCIPIENT LEARNING LAB

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Excipient World Conference & Expo

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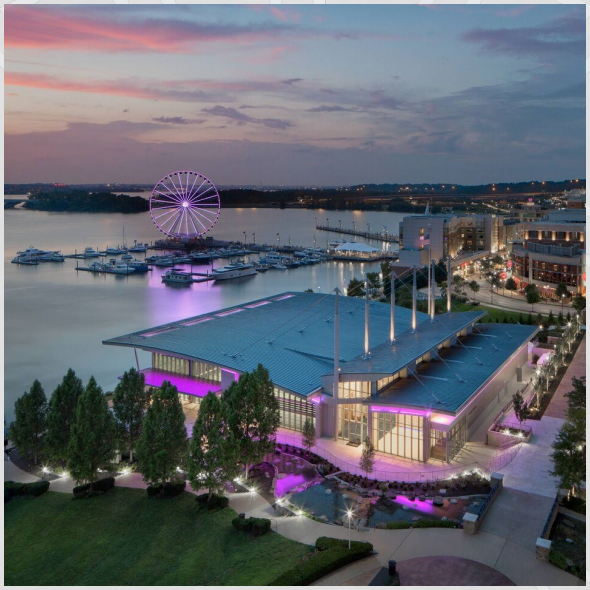
Location & Dates

IPEC-AMERICAS EXCIPIENT WORLD 2023 NATIONAL HARBOR



Workshops: May 1

Conference & Expo: May 2-3

Gaylord National Resort & Convention Center

(National Harbor, MD)

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Top 3 Reasons to Attend Excipient World

1. **Further your education** by attending in-depth workshops, engaging educational sessions, and dynamic general sessions presented by renowned industry experts and FDA
2. **Increase your access to the latest innovations** from the industry's leading suppliers
3. **Expand your network** of formulator, R&D, regulatory & compliance, quality assurance/control, supply chain, and other manufacturing professionals

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Education Highlights
May 1: Workshops

Morning Workshop
9:00 AM – 12:00 PM

A Deep Dive into Supplier Qualification and COA

Afternoon Workshop
1:00 PM – 4:00 PM

Key new IPEC Papers and Guides: What you need to know!

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Education Highlights
May 1: Biologics Summit

NEW FOR 2023!

biologics summit

CRS IPEC

advancing science as one industry

a Controlled Release Society and IPEC-Americas joint program

THEME:

Subcutaneous Delivery of High Dose mAbs

PART 1 May 1

(Co-located with Excipient World Conference & Expo)

PART 2 July 24

(Co-located with CRS Annual Meeting & Expo, Las Vegas)

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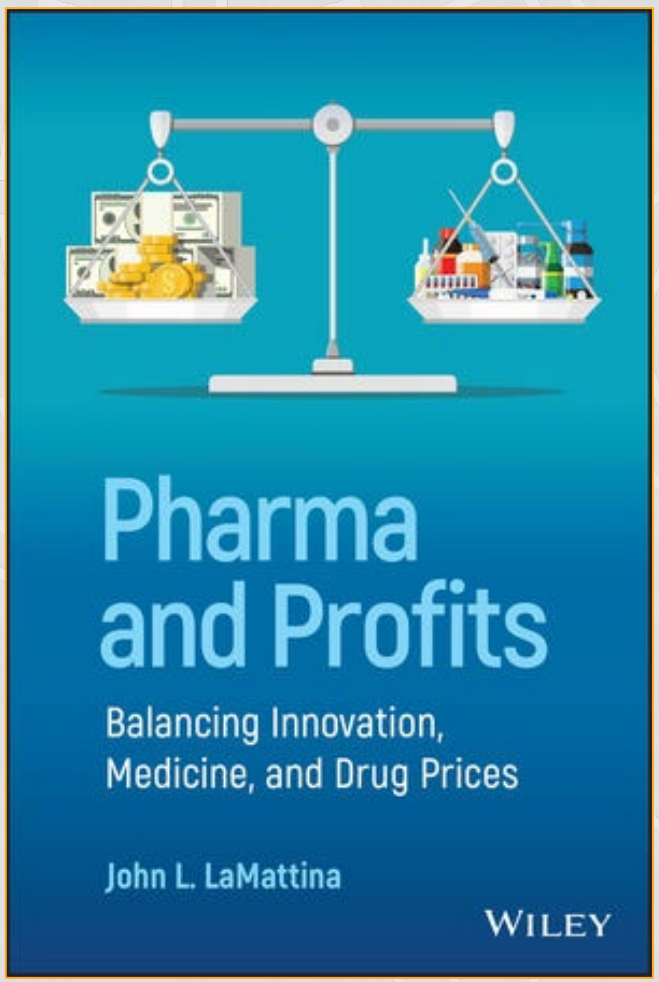
Special Events



Tuesday, May 2

Keynote: 3:30 PM

Book Signing: 4:30 PM

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FOUR FDA Speakers

JOIN US FOR THESE KEY SESSIONS

FDA's Recent Quality Concerns with Excipients

Francis Godwin, MBA
Office Director
OMQ, OC, CDER, FDA

Update on FDA's Inactive Ingredient Database

Susan Zuk,
OPQ, CDER, FDA

A Critical Overview of the Biological Effects of Excipients

Eleftheria Tsakalozou and **Fang Wu**,
OGD, ORS, DQMM, CDER, FDA

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Networking Events

Join us for THREE evening networking events!

MAY 1

MAY 2

MAY 3

Over **5 hours** of networking breaks & exclusive exhibit floor time

PLUS ONE PASS

Over **10 hours** of meals & evening networking events

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Excipient World Celebration

Date: May 2, 2023

Time: 5:30-9:30 (Eastern)

Cost: Access is included with your registration.

PRIME TIME: Playing music from today's hottest hits to yesterday's finest jazz medleys and selections from Motown 60's, Funky 70's, 80's and 90's!

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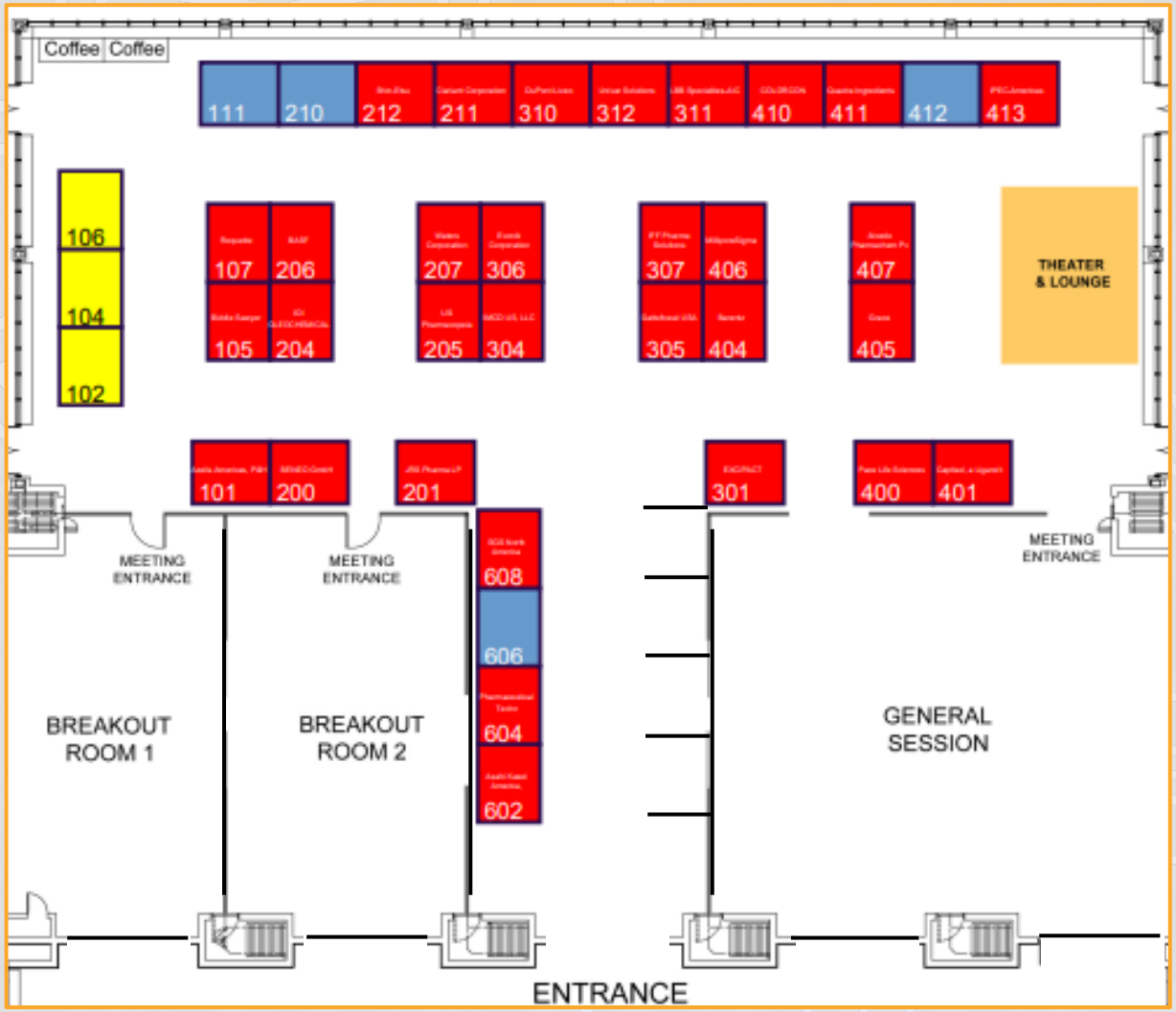
Exhibits



as of 03/23/23

Red = Sold!

Yellow = Hold

Blue = Available

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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 2 - May 16 – 18

Q 3 - September 19 – 21

Q 4 - December 5 – 7

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PQRI Activities

Hybrid Event

PQRI
Product Quality Research Institute

SAVE THE DATES!

REGISTRATION TO OPEN IN APRIL 2023.

PQRI WORKSHOP:

TiO2 Use in Pharmaceuticals - *Global Regulatory and Technical Challenges*

TUES. - WED.
JUNE 13-14, 2023

ROCKVILLE, MD
Location to be confirmed

8 AM - 5 PM
each day

WORKSHOP OBJECTIVES

The objective of this workshop is to bring together material suppliers, the pharmaceutical industry, and regulatory experts to discuss the impact removing titanium dioxide would have along with the benefits and challenges of the alternatives to titanium dioxide for use in solid oral dosage forms. This workshop will address the following key areas:

- Build awareness for the industry by giving an overview of the issue, an interpretation of the data related to TiO2 safety, and the potential impact a ban out titanium dioxide would have on patients.
- Overview of what is happening globally because of the EU regulation.
- Present the technical challenges that pharmaceutical companies are likely facing when trying to formulate new and reformulate existing drug products with the currently available alternatives. Discuss alternatives for oral solids and oral suspensions.
- Identify areas that need further research to support technical initiatives related to possible additional safety study requirements to support continued safe use of TiO2 or technologies related to the use of TiO2 alternatives where desired.
- Possible classification of titanium dioxide as something other than a colorant.

+1 (202) 230-5607

PQRISecretariat@pqri.org

Stay up to date by visiting the Workshop Website at:
https://pqri.org/tio2-workshop-2023/

www.pqri.org

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Questions?

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