Updates from the Chair

June 28, 2022
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……

Mike Cassell

cGMP Quality Assurance Manager
Eastman Chemical Company
GMP Committee Chair

Federation update

2022 Strategic Focus and Priority Objectives

CAPTION
Strategic Focus
Priority objectives

Visible particles

Raw materials used in recombinant / biological products

QbD, PAT, FRCs

Pediatrics

Microbiology

Supply chain security

Global expansion
- Collaboration in new regions

Excipient Composition
- Elemental Impurities

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
- FDA: novel excipients
- Role of excipients in medicines of the future

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

Stakeholder collaboration
- WHO projects
- Excipients usage / crossover areas (e.g. food)

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

LOW → MEDIUM → HIGH → PRIORITY

Federation (Priscilla)

- **IPEC EU**
  - Annual meeting held with EDQM & EMA in May to discuss current regulatory matters including CEPs, CPEs, PDG expansion
    - EDQM interested in CEP survey results & open to further discussion on CPEs!
  - Accepted as observer in EMA TiO2 discussion & will be permitted to comment on forthcoming EMA Q&A
  - IPEC Europe Forum held June 20, celebrated 30th anniversary
- **IPEC Japan**
  - After EI is implemented by JP in Dec. 2022, will review specific HM especially for excipients of natural origin. IJ seeking input for any implementation issues with removal of HM for monographs in EP or USP
  - GMP committee created a template derived from the IF EIP Guide to be used by excipient suppliers to provide info as a basis for virtual supplier audits in Japan
- **IPEC India**
  - Considering transition from Associate to Full member status in Fed.
- **IPEC China**
  - USP held a workshop on nitrosamines

Federation (Priscilla)

- **Federation Projects**
  - Presentation developed for IPEC's Nitrosamines Position Paper and given at a Lhasa webinar; available for member use
  - Regulatory database – arranging demos by Clarivate & Redica to determine feasibility
  - Nomination submitted for Observer status on ICH Q5C Stability WG
  - Participating in EDQM panel discussion on compendial harmonization in Sept
  - Established 3 year review of all IPEC guides & streamlined approval process
  - Initial meeting held on compendial convergence initiative
  - AGM meeting held in June, IA becomes President, IE Vice-President, IJ remains Treasurer

Committees

CRC
(Doug/Jennifer)

- **Monthly Compendial Review Meetings –** reviewed, in-process and completed activities by the sub team since the Q1'2022 CRC committee meeting. More details under Monthly Compendial Review Meeting slide.
- **USP discussions**

  IA leadership met with USP representatives at Exigent World. Currently working on a F2F meeting with USP in July **(Jen D, Catherine S., John G.)**
- **Compendial Joint Industry Team** – IPEC-Americas will host the 2022 compendial joint industry meeting. A small IPEC-Americas planning committee is currently forming and is soliciting agenda topics/potential invited speakers.
- **CPPQ Update** (Compendial Policy Process and Quality stakeholder discussion group) planning to meet with the British Pharmacopeia to discuss their pilot program.
- **Mutual Recognition of pharmacopeias –** Kick-off meetings scheduled for both US-Europe and US-Asia.
- **Other Compendial Topics**
  - IPEC China – "Green Environmental Protection"
  - Australia band on the use of Dichloromethane for safety reasons
  - Recent update to ChP monographs

Regulatory Affairs (Meera/Troy)

- **Presentation from European Pediatric Formulation Initiative (EuPFI) -** on risk assessment process for gathering safety and toxicity information, and an overview of the STEP (Safety and Toxicity of Excipients for Pediatrics) database
- **FDA IID –** continue to monitor and track FDA IID Quarterly updates, including replacement of max potency with MDE, revisions and deletions.
- **Reviewed IA comments to FDA Docket** No. FDA-2022-N0236 Prioritizing IID MDE and collapsing dosage forms
- **Reviewed IA comments to TGA -** regarding the proposed Poison Standard ban of methylene chloride (CH2Cl2)).
- **Current global trends/issues –** including efforts to establish a LATAM excipient working group to discuss regional regulator topics related to excipients.
- **Miscellaneous topics discussed**
  - FDA Guidance on Drug Products, Including Biological Products, that Contain Nanomaterials,
  - US Senate Bill on Supplements, Cosmetics and Ingredients,
  - FDA Draft Guidance on Risk Management Plans to Mitigate the Potential for Drug Shortages

GMP
(Mike/Beth)

- **Reviewed status of and progress towards IPEC Guides currently in-progress**
  - IPEC-PQG Excipient GMP How To Guide
  - IPEC-Americas GMP Audit Guide to the NSF/IPEC/ANSI 363 Standard.
  - IPEC Excipient Stability Guide revision
- **Update on 2022 EXCiPACT Board members**
- **Discussed** developing a position paper/guide covering potential risks associated with using food/cosmetic grade materials as excipients.

Excipient Qualification (Ann/Candy)


- **Certificate of Analysis Guide Revision** – Reviewed /addressed outstanding guide comments and discussed next steps for final review/approval and plans to publish.
- **Significant Change Guide Revision** – Discussed Federation activity to define best terminology for use in not only the Significant Change Guide, but other IPEC guides under development and/or revision. In addition, the updated guide Significant Change Guide will include individual decision tree diagrams in each relevant section of the guide (e.g., 6.1.1 Site Changes, 6.1.2 Scale Change, etc.)
- **Discussed potential topics -** to cover during future EQ meetings.

QbD
(Dave/Stacey)

- **ICH Q13 –** shared outcome from recent WG meeting and final review/comment to Step 2 guidelines.
- **PQRI workshop on Excipients and API Impact on Continuous Manufacturing –** reviewed workshop break-out session preliminary slides covering challenges experienced with material impact on CM processes and material characterization techniques.
- **Infographic** – discussed plans for next infographic in composition series – additives and process aids
- **PQRI Project** - discusses a proposed new project with PQRI on justifying a customized approach to all-in-one co-processed excipient development to meet the needs of Continuous Manufacturing.
- **Brainstormed** development of IPEC Guide/white-paper on excipient considerations in CM and how to Design for Purpose.
- **Pending article** – developed my members of QbD
  - Mitigating the risk from excipient variability, targeted for publication in Pharmaceutical Technology, fall 2022
  - Switching from Batch to Continuous: Don't Forget about Formulations" published in Tablets & Capsules, June 7, 2022

Scientific Affairs
(Lisa/Charlotte)


- **IQ-IPEC-Americas Novel Excipient working group** proposed preparing white-papers and backgrounder documents targeted at decoupling co-processed excipients from the definition of "novel excipient," at least from a "safety" perspective
- **Nitrosamine Cross-Functional Team** – webinar based on the position paper which was given by an IPEC-Americas member at a recent Lhasa nitrosamines workshop.
- **E171 TiO_2 ban in food products in Europe** – reviewed current concerns with the Europe ban for the use of TiO_2 in food products and proposed next steps for pharmaceutical companies.
- **IQ/IPEC E171 Working Group** – plans to publish papers, generate a survey and develop/hold joint workshops
- **Miscellaneous** - discussed topics for future SAC meetings, including the need to enhance engagement/ networking with academia

Users Network (Heather)

- Discussion of artificial flavor ingredients used in already approved ANDA products
- Overview of EW presentation *Technical Qualification of Alt Source Excipients* – annex to a guide/webinar/position paper?
- Potential topics/areas for future meetings:
  - Advanced manufacturing technologies for pharmaceutical products and the potential impact on excipient supply.
  - Re-occurring agenda item to encourage users to share general emerging regulatory issues/concerns, with excipients, potentially impacting the pharmaceutical industry.
  - More in-depth user discussion/needs/insights for topics reviewed during other committee meetings.
  - Potential new guides/position papers/white papers targeted for users
    - Best practices for users to evaluate/certify multi compendial excipients.
    - Best practices in identifying/qualifying excipient to use in biologics, pediatrics, parenteral as well as potential issues/concerns to consider.
    - Value of excipient supplier communication/partnership in supplying excipients for emerging technologies (e.g., continuous manufacturing, 3-D printing)

Committee Meeting Change

- Beginning September 2022
- Excipient Qualification Committee

  8:00 – 10:00 am
- Good Manufacturing Practices Committee

  10:30am – 12:30 pm

September meetings will take place at IPEC-Americas headquarters, Arlington, VA

September Meeting Dates 20th – 22nd

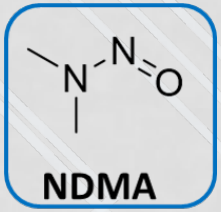
Monthly Compendial Review Meetings

- Update on the USP proposals in the Pharm Forum 48-3
- Reviewed changes to USP-NF 2022 Issue 3
- Alginates – continued discussion regarding ongoing issues/concerns
- Discussed request to USP for a session in a future Stakeholder Forum on the value and challenges of implementing advanced analytical techniques in compendial standards

Copies available to IPEC-Americas members in the IPEC-Americas Document Depot.

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.

Current Activities:

- IPEC-Federation presentation for nitrosamines was completed
- Webinar on IPEC activities during a Lhasa nitrosamines workshop
- Proposed feedback to FDA regarding a SBIA Generic Drug Forum (March 27, 2022) presentation on Nitrosamine impurities in Human Drug Products by Andre Raw, FDA.
- Shared FDA 2022 Generic Drug Science and Research Initiatives Workshop (May 9, 2022) nitrosamine presentations (nitrites in excipients, analytical methods, safety and risk assessment).

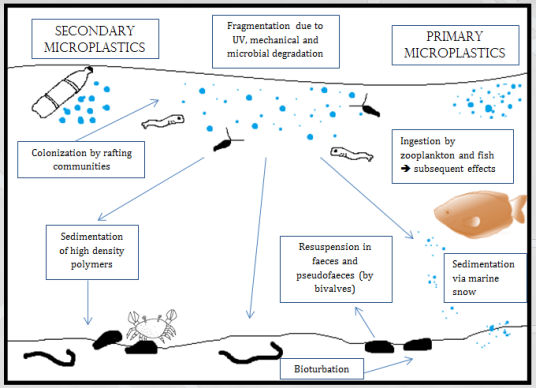
YouTube recordings:
https://www.youtube.com/playlist?list=PLUQMK8dt3D9d5MAJm_dGW8JznEm4Ur-R

Microplastics Cross Functional Team

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

Current Situation

It is anticipated that the final microplastics regulations will issued by the EU Commission in late 2022/ early 2023.



Current Team Activities

- "how to guide" has been published which provides guidance on complying with proposed regulation
- Currently working on a "*Microplastics discussion paper*" that discusses complexity with excipient data and finished dosage forms. This is intended to inform and bring excipient makers and drug manufacturers to a common understanding and a consensus opinion on strategy moving forward.

IPEC-Americas 2022 Q1 Dashboard

5 interactions with regulators/ pharmacopoeias

	CRC	RA	GMP	EQ	QbD	SAC	UN	LL	XC	IF	EW	TOTAL
FDA Docket comments		1										1
FDA Correspondence												0
FDA Public Mtg/training												0
USP correspondence	2											2
EDQM comments												0
ECHA (REACH Comments)												0
ICH Comments (ICH Q13 WG)												0
CDE Correspondence												0
NSF			1									1
TGA		1										1
Publications		1			1	1		1				4
Workshops			1									1
Webinars					1						2	3
Draft Guides (in-progress)			4	4								8
Published New/Revised Guides		1										1
Position Papers/White Papers			1			1						2
Industry collaboration/workshops/ presentations				1								1
Infographics					1				1			2

IPEC Foundation

IPEC Foundation Awards Applications Deadline Extended!

The IPEC Foundation is now accepting applications for the 2022 award season. **Deadline extended** to July 22, 2022.

www.ipecfoundation.org

The winners will be recognized during the IPEC Foundation's annual awards ceremony that will take place **on Sunday, October 16th, 2022 in Boston MA**.

Strategic Planning

Strategic Planning Team 1 Strategic Alliances and Partnerships

Strategic Alliances and Partnerships

- Assessing our partnerships, collaborations and alliances
- Identified potential partners
- Prioritized list
- Formation of a Latin American Working Group (in process)
- The PQRI Workshop on Managing API and Excipient Impact on Continuous Manufacturing - Virtual event – 105 attendees

Strategic Planning Team 2 Expanding Markets and Membership

Expanding Markets and Membership

1. The team has identified potential emerging areas which are important for excipients and adjacent markets (see below).
2. IPEC should take leadership position and reach out to both the industry and trade organizations to form alliances
3. Possible Collaboration between PDA and IPEC-Americas related to Biologic/Parenteral Excipients
4. Consider formation of focused teams on each area identified below:
   - Parenterals
   - Novel lipids (covid vaccine)
   - Emerging nano issues impacting excipients, food, cosmetics
   - Microplastics
   - OTC monographs
   - Dietary supplement and non-dietary ingredient issues
   - Sustainability

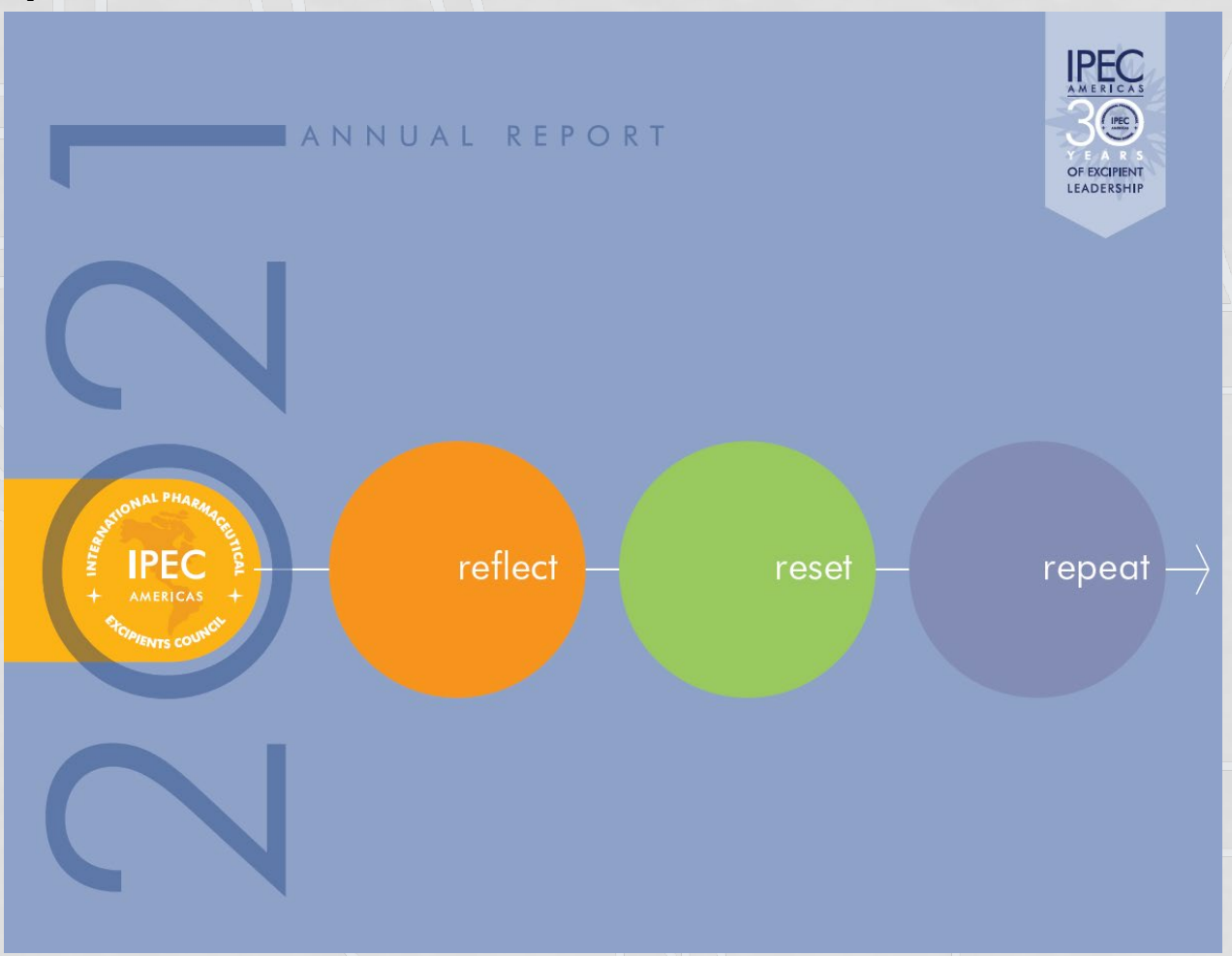
Membership

- New members in 2022 include:
- Greenfield Chemical Company – Joined 5/22
- Indorama Ventures – Joined 5/22
- SGS – Joined 6/22
- Dr. James Polli – University of Maryland School of Pharmacy
- Continued digital advertising using the Feathr platform
- Ongoing trade show presence to stimulate membership:
  - Excipient World – May 2-4
  - CPhI North America – May 17 – 19 - Booth and Technical Session
  - Controlled Release Society Annual Meeting – July 11-16 - Booth and Poster Session
  - AAPS – October 17 – 20 - Booth and Foundation Awards

Strategic Planning Team 3 Education

Completed and Published

Annual Report



Completed

2021 Year in Review Infographic

2021 YIR Updated Numbers and Copy

10/14/2021

Global Comments Submitted – 27

- 21 USP Official Correspondences
- 3 EDQM Comments
- 2 ICH Comments
- 1 PMDA Comment

FDA Engagements – 7

- 4 Docket Responses
- 2 GDUFA Meetings
- 1 QbD Training

Organizational Reach – 13

- 5 New Members (87 total)
- 1 New Partnership (GADA)
- Collaborations with 7 Associations

Position Papers – 4

- Qualifying excipient suppliers in lieu of an audit
- Recommendations for Responding to Requests from USP for Samples
- Microplastics
- Nitrosamines

Publications – 5

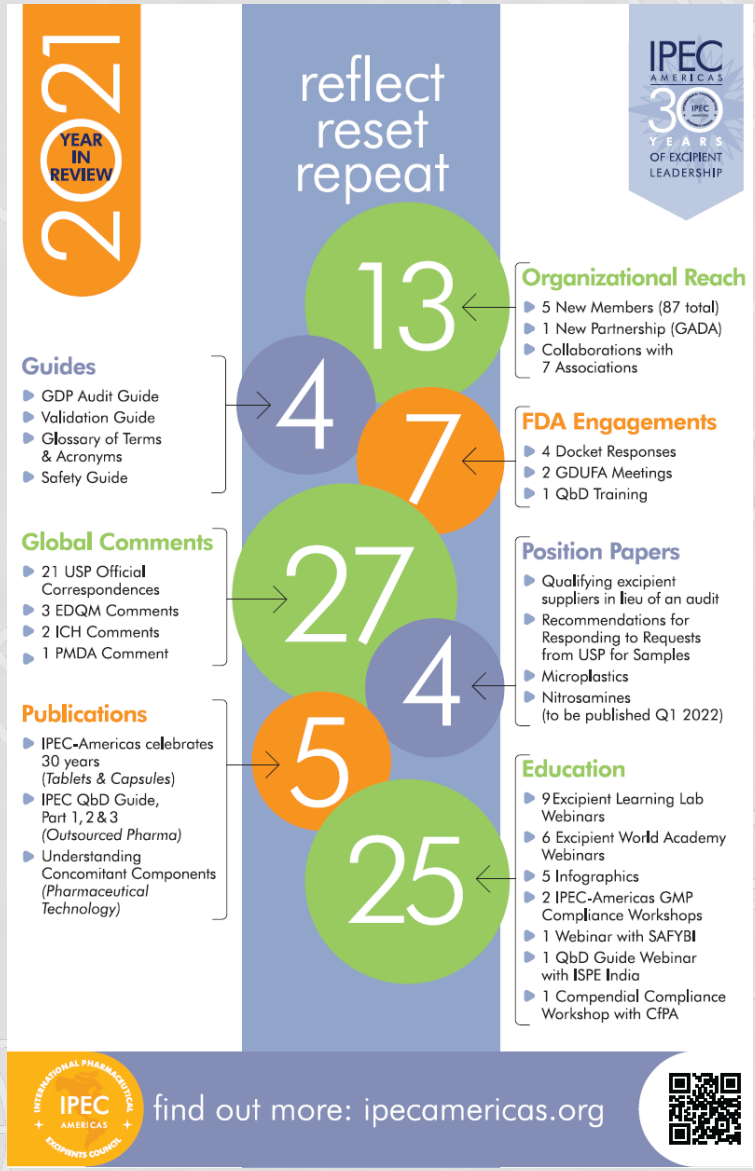
- IPEC-Americas celebrates 30 years (Tablets & Capsules)
- IPEC QbD Guide, Part I, 2 & 3 (Outsourced Pharma)
- Understanding Concomitant Components (Pharmaceutical Technology)

Education & Training – 25

- 9 Excipient Learning Lab Webinars
- 6 Excipient World Academy Webinars
- 5 Infographics
- 2 IPEC-Americas GMP Compliance Workshops
- 1 Webinar with SAFYBI
- 1 QbD Guide Webinar with ISPE India
- 1 Compendial Compliance Workshop with CfPA

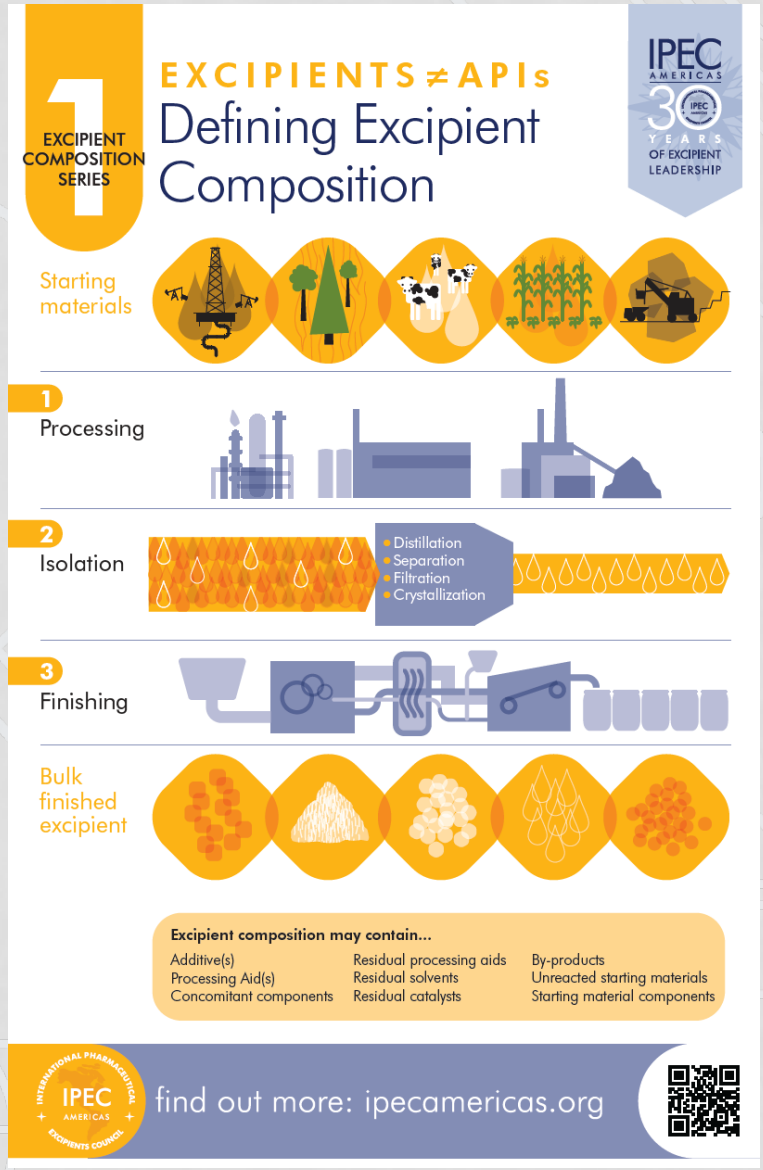
Guides Published & Revised – 4

- GDP Audit Guide
- Validation Guide
- Glossary of Terms & Acronyms
- Safety Guide



Completed

Defining Excipient Composition Infographic



Future

- **Video Collaboration with Clum Creative Based on Tablets & Capsules Education Article**
  - 45-60 second animation
- **Infographics** (estimated 1 per quarter)
  - Composition Series:
    - Importance of additives and process aids for FDA/Regulators
    - Impurities Decision Tree
  - Benefits of Membership (Dale's top 10)

2022 External Publications

- Trade Press publications
- Medicine Maker – upcoming series and interviews from Excipient World Event
- Tablets and Capsules – Excipient Issue (Microplastics, Educational Opportunities from IPEC, Continuous Manufacturing, Buying through Distribution
- Pharmaceutical Technology - Supplier Variability

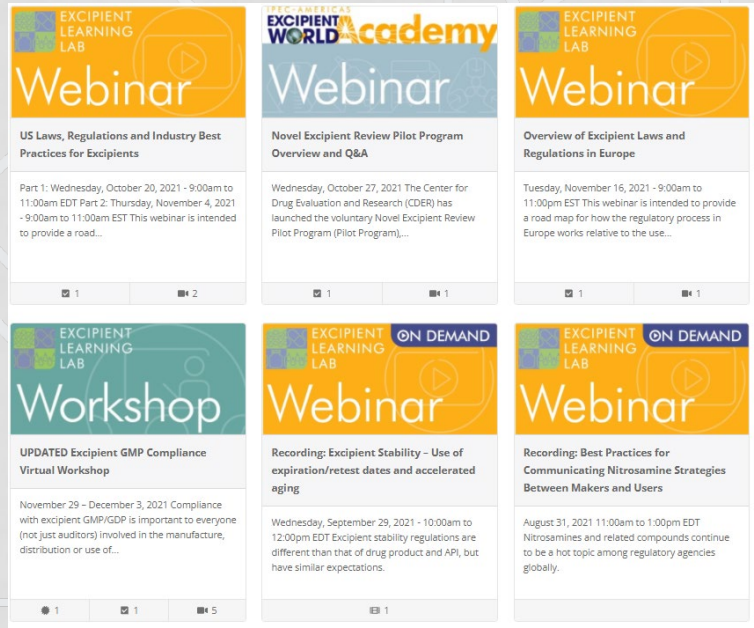
Excipient Learning Lab

Education.IPECAmericas.org

IPEC-Americas Excipient GMP Compliance Workshop

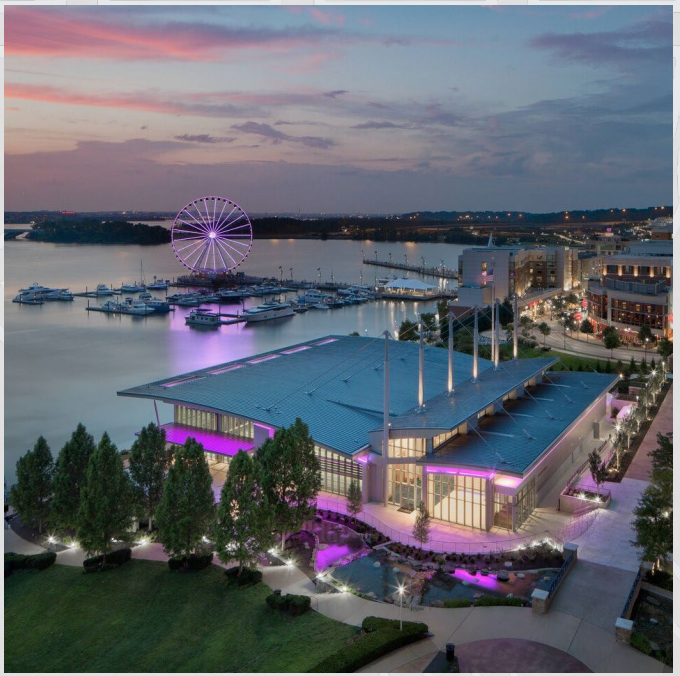
- May 23 – May 25 (virtual)
- 18 attendees

- Excipients: Compliance with Compendial and GMP Requirements (virtual)
- Joint workshop with CfPA
  June 13 – 15, 2022
  10 attendees



Excipient World Conference & Expo

Location & Dates



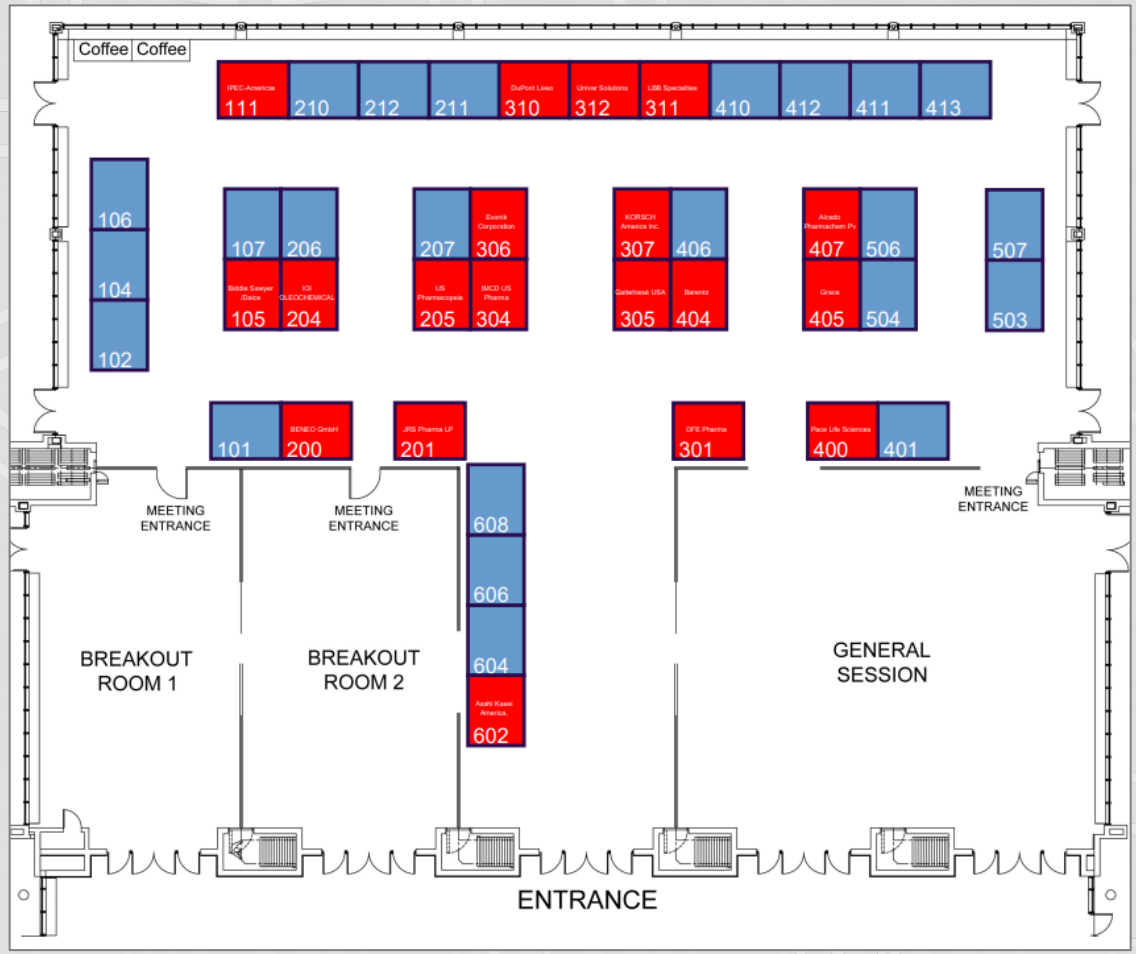
Workshops: May 1

Conference & Expo: May 2-3

Gaylord National Resort & Convention Center

(National Harbor, MD)

Floorplan (as of 06/06/22)



18 of 42 booths already sold! (42%)

Proposed Timeline

- Call for Papers: Sept. 6
- Abstract Deadline: Oct. 28
- Announce Initial Program: Dec. 2
- Open Registration: Jan. 9
- Early Bird / Hotel Deadline: April 10

Visit ExcipientWorld.org for more information.

Excipient World Academy

EW C&E 22 On-Demand

- A selection of Excipient World Conference & Expo presentations (12 total) is available
- Access to the recordings is **included in your Excipient World 2022 registration**
- Can be purchased in **a bundle** OR **a la carte**
- **Discounted pricing** available for IPEC-Americas members

Visit Education.IPECAmericas.org for more info.

Q3/Q4 Webinars

- 2022 Theme: Modernizing Excipient Technology - Need for excipients designed for purpose
- Planned topics:
  - Covid Vaccines & Beyond
  - 3D Printing
  - FDA Novel Excipient Review Pilot Program
- Revised Goal: Schedule 1-2 webinars per quarter in Q3 and Q4

Contact Courtney@ExcipientWorld.org if you are interested in presenting.

Questions?