Updates from the Chair

Multiple stakeholders; **one objective.**

March 22, 2022
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……

Ron Kelly, Ph.D.

Principal Product Quality Leader, Product Quality, Amgen, Inc.

Executive Committee Member

Nitrosamines Cross Functional Team Leader

Federation update

Federation (Priscilla)

IPEC Japan

- Annual symposium on January 28, with speakers from MHLW & PMDA
- JP 18 is now available in English - https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000066597.html
- Elemental Impurities is expected to be implemented in the JP in Dec. 2022

IPEC India

- IP is planning to publish chapters on nitrosamines & elemental impurities

IPEC China

- ChP seeking comments on proposal for incorporating ICH Q3C Residual Solvents – IPEC Federation sending comments to IPEC China for translation/submission to ChP this week

Federation (Priscilla)

- **IPEC EU**
  - Meeting scheduled with EMA May 3 to discuss current regulatory matters
  - Drafting communique for internal use on the current EU issues with ethylene oxide
  - IPEC Europe Forum week of June 20th Brussels
- **Federation Projects**
  - 2022 Strategic Plan approved
  - Nitrosamines position paper published; reviewing opportunities to present in Lhasa and USP-China webinars
  - Regulatory database – working with Clarivate & Redica to determine feasibility
  - Added atypical actives, issues with excipient CEPs and sustainability to 2022 objectives
  - New Zealand regulators sought input re: use of excipients in medicinal cannabis
  - Draft recommendation for future harmonization projects was submitted to PDG

Committees

CRC
(Doug/Jennifer)

- **Monthly Compendial Review Meetings –** reviewed in-process and completed activities by the sub team since the Q4'2021 CRC committee meeting. More details under Monthly Compendial Review Meeting slide.
- **USP Stakeholder events and training**
  - USP Open Forum: Modernization of USP Amino Acid Monographs (March 21, 2022.
  - The Future of Public Commenting (March 29, 2022)
  - Prescription/Non-prescription (PNP) Stakeholder Forum (April 11, 2022)
- **Compendial Joint Industry Team** – IPEC-Americas will host the 2022 compendial joint industry meeting. Planning currently in-process.
- **CPPQ Update** (Compendial Policy Process and Quality stakeholder discussion group) continued communication concerns between industry and USP and current strategy for how CPPQ members might better engage with stakeholders to resolve. Discussed preparing a publication for T&C.
- **Mutual Recognition of pharmacopeias -** IPEC Federation charter approved.

Regulatory Affairs (Meera/Kathy)

- **New RA VC and IID support person –**

Troy Barrix
Senior Regulatory Specialist – Celanese

Carmen Popescu
Global Pharma/Biopharma Technical Developer
Roquette America Inc.

- **FDA IID –** continue to monitor and track FDA IID Quarterly updates, including replacement of max potency with MDE, revisions and deletions. Reviewed status of MDE replacement for Phase 1-3 excipient lists and brainstormed Phase 4-6 excipient lists.
- **Microplastic –** provided update/overview (refer to CFT)
- **Strategic Team 3 expansion into excipients for parenteral** – provided overview and discussed strategy (refer to Strat 3).
- **Certificates of Suitability (CEPs) and Drug Master Files (DMFs)** discussion regarding position paper on the use of
- **Current global trends/issues**: implementation of ICH Q3D in Japan JP and Indian IP

GMP
(Mike/Beth)

- **Reviewed status of IPEC Guides in-progress**
  - IPEC-PQG Excipient GMP How To Guide
  - IPEC GMP Audit Guide
  - IPEC GDP How to Guide
  - IPEC-Americas GMP Audit Guide to the NSF/IPEC/ANSI 363 Standard.
- **Reviewed 2022 EXCiPACT Board plans**
- **Discussed recent International Coalition of Medicines Regulatory Authorities (ICMRA)** article entitled "Remote Inspections Can Complement, but Not Replace, Onsite Inspections."

Excipient Qualification (Ann/Heather)


- **New EQ VC**

Sarah Brittan
Lead Technical Service Engineer – Henkel

- **EIP/Sustainability and Responsible Sourcing guide** – consolidated information from the 5 regional PECs and will begin reviewing the draft during the next meeting.
- **Stability Guide Revision** – discussed description of very stable, stable and limited stability.
- **Certificate of Analysis Guide Revision** – Reviewed /addressed outstanding comments and formed small sub team to develop updated CoA template. Target finalizing/publishing in Q2'2022.
- **Significant Change Guide Revision** – Discussed proposed editorial changes and plans publish revised guide in Q2/3' 2022 ..

QbD
(Joe/Dave)


- **New QbD VC**

Stacey Bremer
Director, Product Stewardship Medical
Celanese

- **PQRI workshop on Excipients and API Impact on Continuous Manufacturing –** scheduled (virtual) for May 17-18, 2022. Reviewed updated agenda and list of invited speakers. https://pqri.org/cm_workshop/
- **Infographic** – published Part 1 of a new infographic series for excipient composition.
- **Discussed** next steps/meetings for ICH Q13 WG.
- **Brainstormed** other potential activities to include under the umbrella of the QbD/Composition committee.

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
- **IPEC Safety Guide for Pharmaceutical Excipients** – Two webinars, free to IPEC members, were held to provide an overview of the recently published IPEC Safety Guide for Pharmaceutical Excipients. .
- **E171 TiO_2 ban in food products in Europe** – review of current concerns with the recent ban in Europe for the use of TiO_2 in food products and proposed next steps for pharmaceutical companies.
- Medicine Maker recently posted a Novel Excipient IPEC-Americas panel video. Subsequent article currently in-process
- **Added a standing committee topic -** discuss emerging excipient "peer reviewed" articles considered to be "poor science." Intent would be to develop public comments, from IPEC-Americas, highlighting issues with these publications

Users Network (Heather)

- **Brainstormed** 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

- Thursdays – Beginning June 9,.2022
- Excipient Qualification Committee

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

  10:00am – 12:00 pm
- Quality by Design and Excipient Composition Committee

  1:00 – 4:00 pm.

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

June 7 - 9

Monthly Compendial Review Meetings

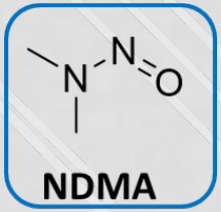
- New volunteer to help with meeting!

Candy Reynolds-Cummings
Quality Assurance and Regulatory Manager, Evonik Corporation

- Team meets monthly on second Monday of the month to discuss and review compendial postings. As appropriate, the team prepares comments/responses from IPEC-Americas to relevant pharmacopeias.
- Prepared and sent comments to:
  - 2022 01 21 – sent USP follow-up comments in response to November 22 Letter regarding PF 47(5) General Chapter <1083> Supplier Qualification follow-up questions.
  - 2022 02 02 - sent USP follow-up comments in response to November 22 Letter regarding PF 47(6) General Chapter <621> Chromatography.

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:

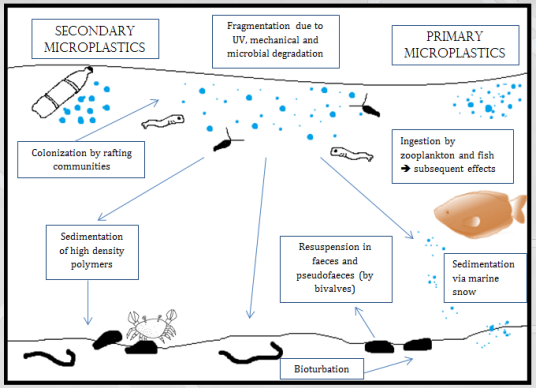
- Published position paper in collaboration with other IPEC regions focusing on excipients that provide consistent messaging on regulatory expectations and perspectives on excipient risk mitigations.

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 1Q 2022



Current Team Activities

Developing guides and documentation to assist both makers and users

- "how to guide" which essentially provides interpretive information for complying with the microplastics regulatory requirement – To be Published 3/22/22
- document to provide background on data requirements, complexity on generating and interpreting data

IPEC-Americas 2022 Q1 Dashboard

2 interactions with regulators/ pharmacopoeias

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

IPEC Foundation

IPEC Foundation Awards Applications Now Being Accepted!

The IPEC Foundation is now accepting applications for the 2022 award season.

www.ipecfoundation.org

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

Strategic Planning

Strategic Planning - 2022

Strategic Goals:

- Develop Strategic Alliances and Partnerships – IPEC-Americas will be more innovative and scale quicker by "pooling" expertise and resources for mutual benefit
- Market Expansion - Expand our reach to find new prospects with new uses of excipients
- Education - Establish a process for delivering exceptional and recognized excipient education

IPEC-Americas Mission: To advocate, educate, innovate and develop best practices for excipients, with a focus on patient safety.

.IPEC-Americas Vision: IPEC-Americas will be the preeminent authority and resource on pharmaceutical excipients

Strategic Planning 2022

	A	B	C	D	E	F	G
1			IPEC-Americas Strategic Plan 2022 - 2024				
2			Created on February 2, 2022				
3			VISION: IPEC-Americas will be the preeminent authority and resource on pharmaceutical excipients.				
4	**Goal 1:**	**Develop Strategic Alliances and Partnerships**		**EC LEAD: JANEEN**			
5	**Outcome:**	IPEC will be more innovative and scale quicker by "pooling" expertise and resources for both party's benefit					
6							
7		OBJECTIVE	TACTICS	STATUS	DUE DATE	MEASUREMENT	
8			Assemble a team: **		2022	Team assembled	
9			Define Criteria for Prioritization		2022	Document to guide the process	
10			Develop a partnership list	COMPLETE	2022	List finalized	
11			Gather information - understand the needs of each partner, what they bring to IPEC and what we can bring to them. Using the triage template	In process	2022	Competed templates	
12		Determine the most valuable alliances / partnerships OR those we need	Prioritze candidates for engagement		2022	Final datatbase for engagement	
13	1						
14			** Team to Include				
15			Big Picture Thinkers				
16			Broad Contacts				
17			Broad exposure beyond pharma				
18			Inactive and active members - and involved in potential partner organization				
19			Outside help for certain steps in the process				
20							
21	**Goal 2:**	**Market Expansion**		**EC LEAD: MEERA**			
22	**Outcome:**	**Expand our reach to find new prospects with new uses of excipients**					
23							
24		OBJECTIVE	Tactics	Status	Due date	Measurement	
25	1	Define resources to help educate potential market expansion	Identify member companys/individuals who already have a good undersstanding of market (parenterals) and products - ask them for time to discuss		2022	(1) More involvement from current members working on Parentals. (2) Identify key issues facing Parentals	
26	2	Plan to approach the new potential marke	Once progress on Objective 1 above, develop the next step plan		2022		
27	3	Consider Regulatory issues	Define regulatory challenges/implications/gaps from the findings above		2022		
28	4	Define Industry needs for Parenterals	Consider a roundtable with a group of Parenterals		2022		
29	2/21/2022	Set up a meeting with Glen at PDA, ACTION	What are issues, possibly work together on position paper, guide, workshops, etc. Include IQ, CBER, PQRI, as appropriate. Possibly have a keynote on parenerals for EW 2023, tie topic into EWA. Include tox people.				
30							
31							
32	**EC**	**Establish a process for delivering exceptional and recognized excipient education**		**EC Lead: Jessica**			
33	**Outcome:**	**Become known and recognized as much a source for E science as we are known for E quality and regulatory**					
34							

2022 Plan | TEAM 1 | TEAM 2 | TEAM 3 | XC | Chairs_VC | Consultants | Staff | Sheet2 | TEAM MEMBERS

Ready | Accessibility: Investigate

Type here to search

Strategic Planning Team 1 Strategic Alliances and Partnerships

Strategic Alliances and Partnerships

- Assessing our partnerships, collaborations and alliances
- Identified potential partners
- Next steps: Prioritize list
- Develop a "what's in it for us/them" strategy.

Strategic Planning Team 2 Expanding Markets and Membership

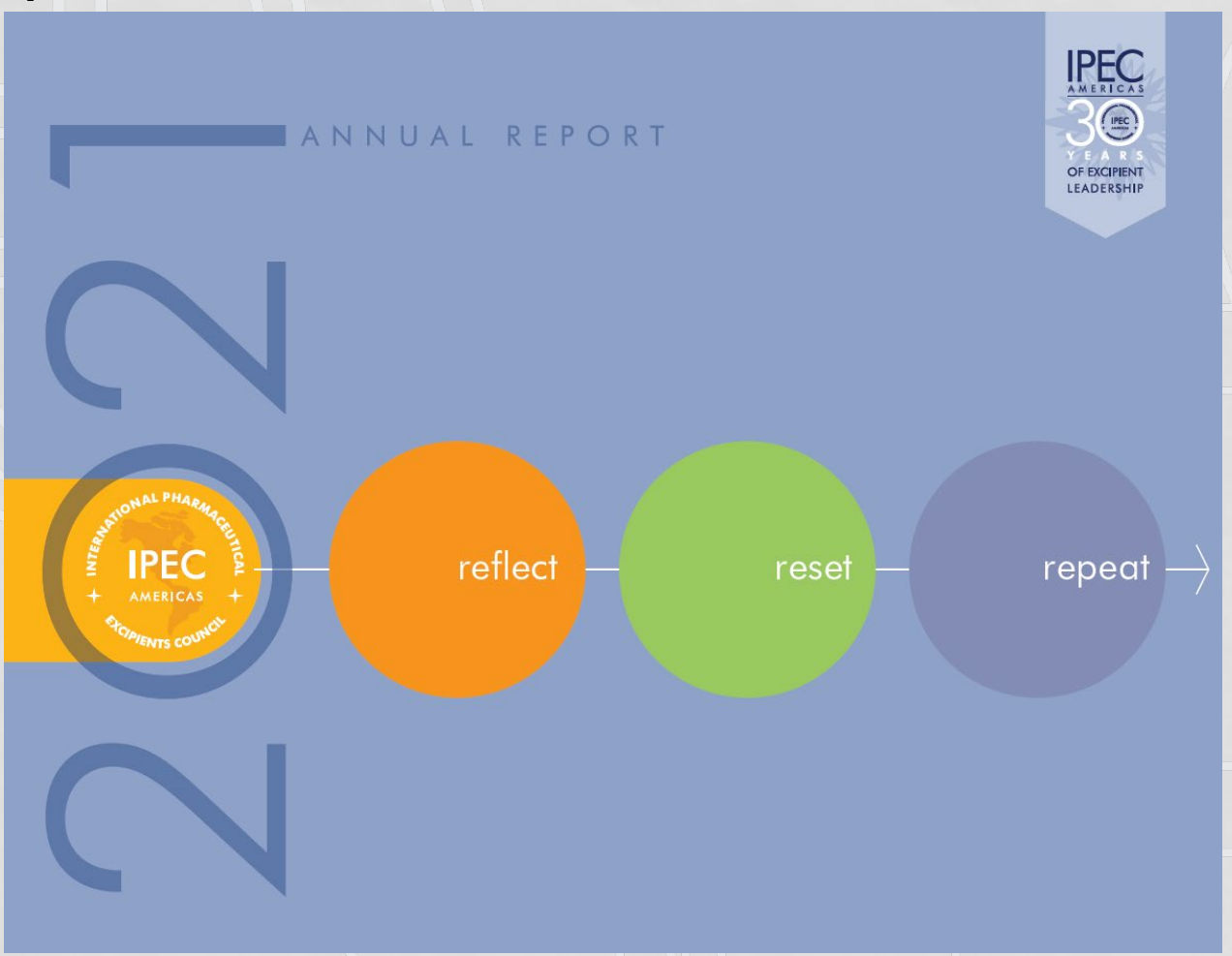
Expanding Markets and Membership

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. Collaboration with a trade organization may not always be effective. Identify potential companies and IPEC members for input on specific areas and expansion goals.
4. Define area(s) to take action: publish articles, host webinar and/or workshops.
5. 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

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

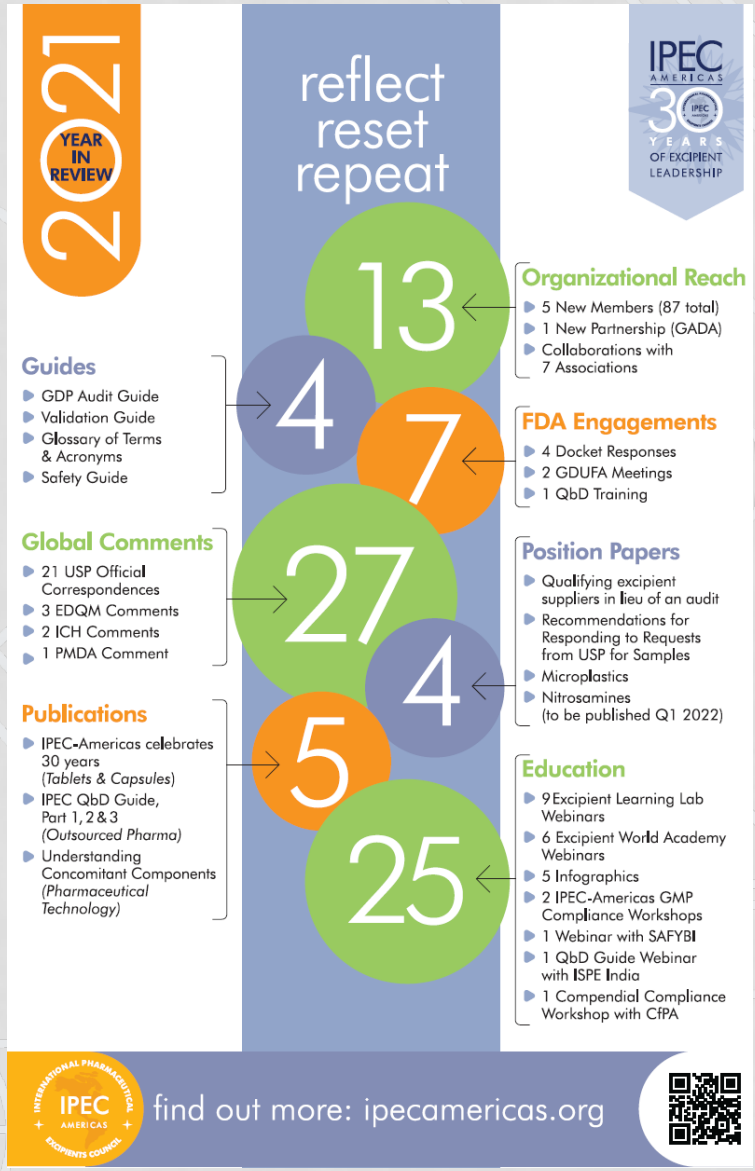
- IPEC-Americas celebrates 30 years (Tablets & Capsules)
- IPEC QbD Guide, Part I, 2 & 3 (Outsourced Pharma)
- Understanding Concomitant Components (Pharmaceutical Technology)

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

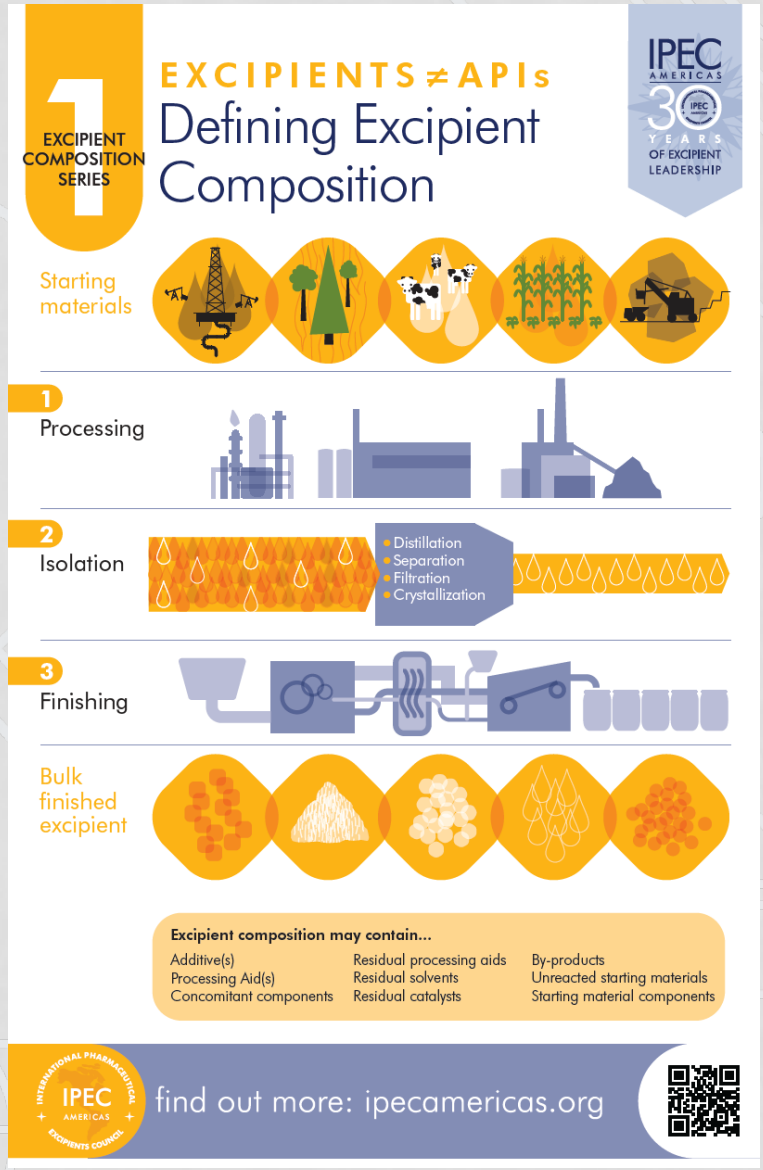
Guides Published & Revised – 4

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



Completed

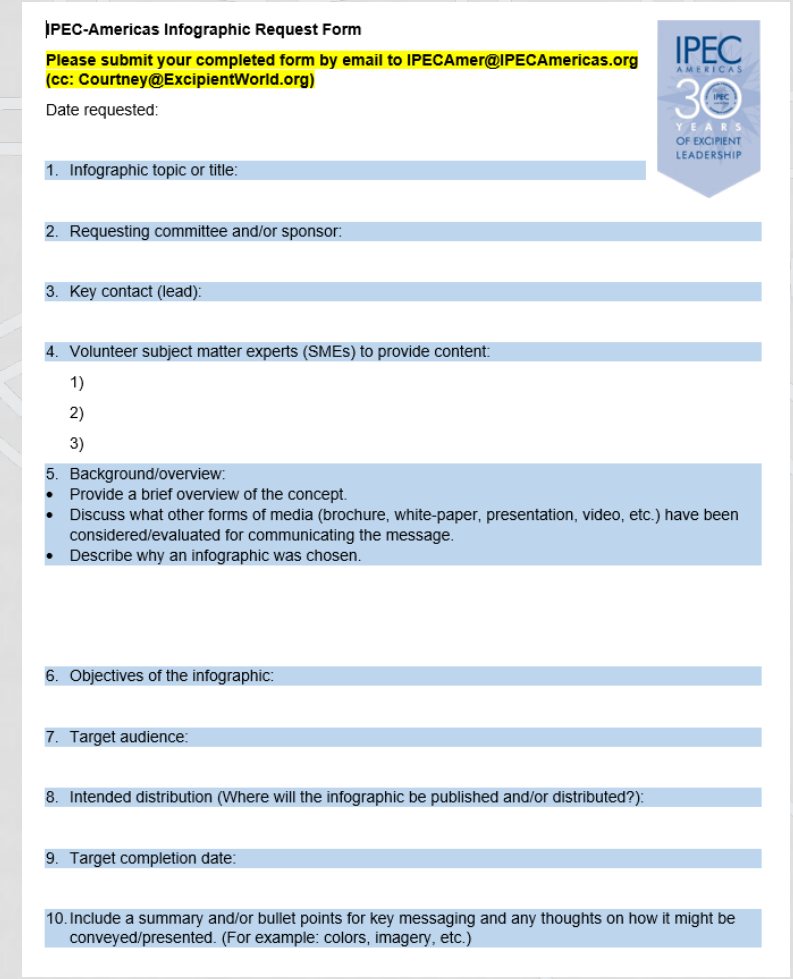
Defining Excipient Composition Infographic



Future

- **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)

Reminder



IPEC-Americas Infographic Request Form

Please submit your completed form by email to IPECAmer@IPECAmericas.org (cc: Courtney@ExcipientWorld.org)

Date requested:

1. Infographic topic or title:
2. Requesting committee and/or sponsor:
3. Key contact (lead):
4. Volunteer subject matter experts (SMEs) to provide content:
   1)
   2)
   3)
5. 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 an infographic was chosen.
6. Objectives of the infographic:
7. Target audience:
8. Intended distribution (Where will the infographic be published and/or distributed?):
9. Target completion date:
10. Include a summary and/or bullet points for key messaging and any thoughts on how it might be conveyed/presented. (For example: colors, imagery, etc.)

Infographic Request Form

- Infographics will be created in order that requests are received (with possible exceptions)
- Turnaround time is estimated to be 8 – 10 weeks
- The requesting committee is required to identify SMEs to assist throughout the process

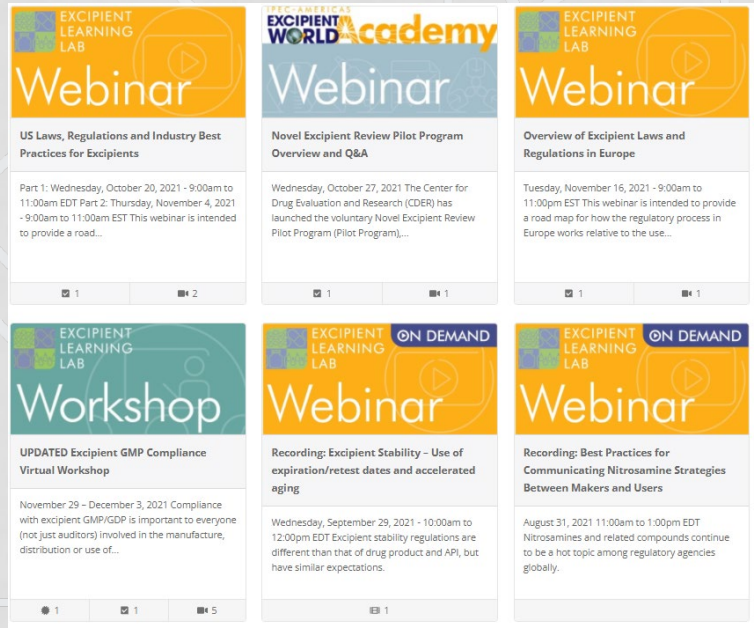
Excipient Learning Lab

Education.IPECAmericas.org

IPEC-Americas Excipient GMP Compliance Workshop

- May 23 – May 25 (virtual)
- Registration open!

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



Excipient World

Conference & Expo

Excipient World Conference & Expo

- May 2-4
- Location: Gaylord Palms
- Registration open 2022
- Exhibit & sponsorship sales ongoing

Top Reasons to Attend Excipient World 2022

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

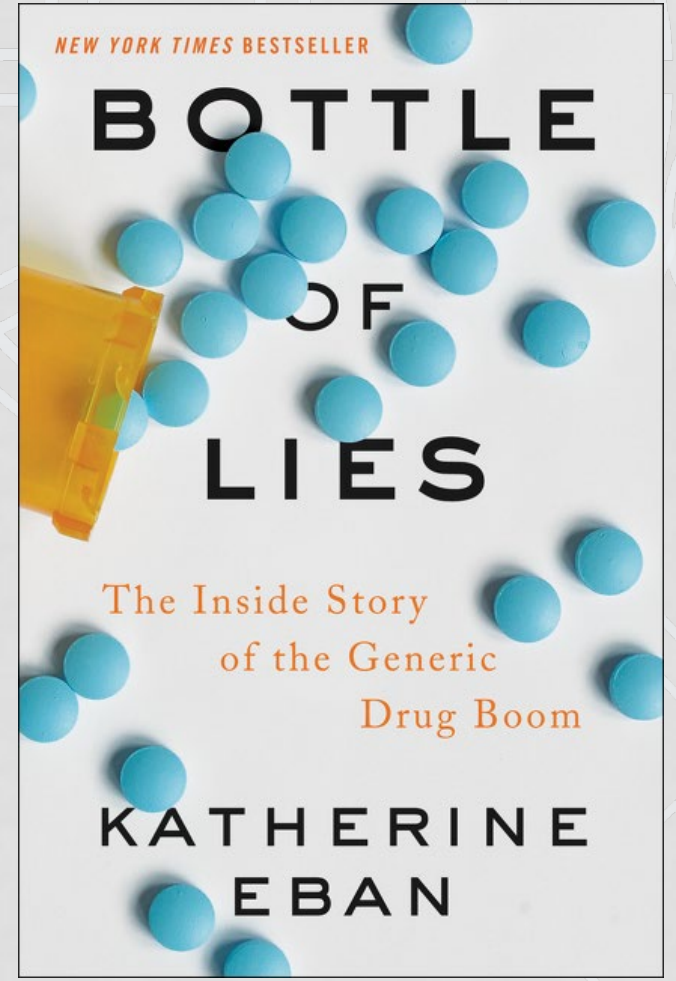
Opening Keynote

The Critical Impact of Excipients on the Physicochemical and Structural Characteristics of Topical Drug Products

Sam Raney, PhD
Associate Director for Science
FDA

Tuesday, May 3| 8 AM

Katherine Eban Events



May 3

Keynote: 3:30 - 4:30 PM

Book Signing: 4:30 - 5:30 PM

Closing Keynote

The Future of the Pharmaceutical Industry

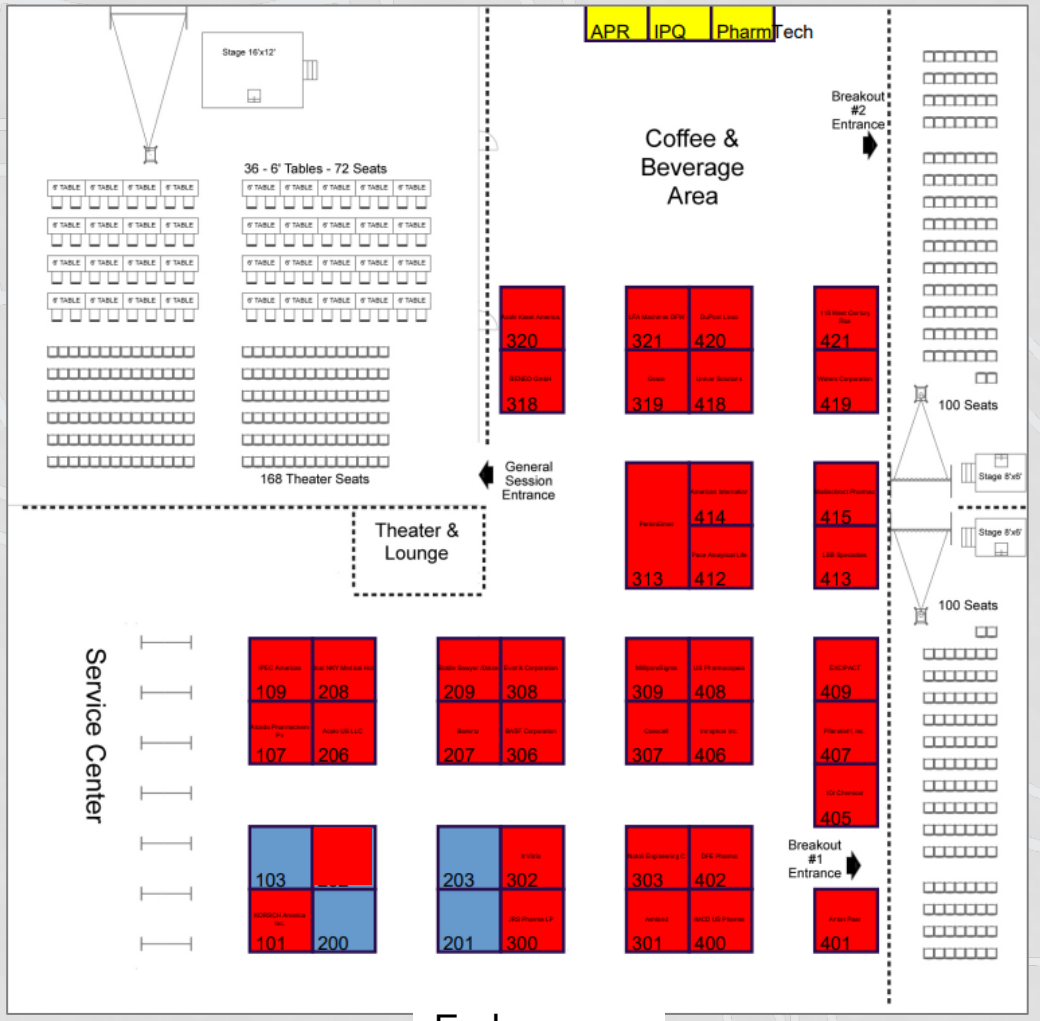
Lee Spach
Head Asset Lead
Sage Partnership
Biogen

Wednesday, May 4 | 3:30 PM

Poster Presentations

20+ posters will highlight
research and new discoveries

Event Floorplan



Red = Sold!

Blue = Available

as of 3/21/22

IPEC-Americas 30th Anniversary

Date: May 3, 2022

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!

Questions?