

IPEC-Americas Board of Trustees/ General Update December 7, 2022

Nigel Langley
Chair, IPEC-Americas

Multiple
stakeholders;
one objective.



► International Pharmaceutical Excipients Council ◀
Collaborative solutions for excipient industry stakeholders



But First.... Volunteer Recognition!

Special Thanks To....

4th Quarter Volunteer Spotlight

Brian AC Carlin
Consultant



Corporate Spotlight Award - 2022

Organization(s) – Founding Member

Dow Chemical Co. –

Nicole Martin

DuPont – Thomas “Tim” White

IFF – Priscilla Zawislak

Kathy Ulman Volunteer Award

Purpose of the Award:

To recognize individuals whose long term commitment and efforts substantially contribute to IPEC-Americas mission.

Priscilla Zawislak - 2022



Recognition from the Federation





Staff Recognition



15 Year
Anniversary!

Tammy Kramer



2022 – Reconnecting

2022 – Reconvening in Person

- ▶ Continued to find new ways of meeting and collaborating
- ▶ Increased frequency of meetings
- ▶ Increased engagement from members
- ▶ Completion of projects, articles, position papers
- ▶ Federation publications
- ▶ Comments to FDA, EDQM and USP
- ▶ Increased educational opportunities



Shout out to.....

Our committee Chairs and Vice Chairs!

Compendial Review and Harmonization Committee



Chair: Douglas Muse

- Associate Consultant – Compendial Affairs
- Eli Lilly and Company



Vice Chair: Jennifer Putnam

- R&D Supervisor II
- Perrigo

Regulatory Affairs Committee



Chair: Meera Raghuram

- Manager, Global Regulatory Strategy and Policy, Personal, Home and Health Care
- Lubrizol Advanced Materials, Inc.



Vice Chair: Troy Barrix

- Senior Regulatory Compliance Specialist
- Celanese

Good Manufacturing Practices Committee



Mike Cassel

- cGMP Quality Assurance Manager
- Eastman Chemical Company



Vice Chair: Elizabeth Febbo

- Global Laboratory & Project Manager
- Henkel Corporation

Excipient Qualification Committee



Chair: Ann Gulau

- Quality Manager for Nutrition & Biosciences-Pharma Solutions
- IFF



Vice Chair: Candy Reynolds-Cummings

- Quality Assurance and Regulatory Manager, Smart Materials & Speciality Additives
- Evonik

Quality by Design



Chair: David Schoneker

- Director
- Black Diamond Regulatory Consultant



Vice Chair: Stacey Bremer

- Director, Product Stewardship
- Celanese

Scientific Affairs Committee



Chair: Lisa Webber

- Director – SQM/Procurement Process Deployment
- Johnson & Johnson



Vice Chair: Charlotte McIlvaine

- Manager - North America Pharma Quality
- Univar Solutions USA Inc.

Users Network



Chair: Heather Sturtevant

- Manager, Technical Operations
- McNeil Consumer Health (J&J)



Shout out to.....

Our Executive Committee

IPEC-Americas Executive Committee



CHAIR:
Nigel Langley , BASF Corp



CHAIR ELECT
Joe Zeleznik,



Vice Chair for Compendial Harmonization and Monographs
Douglas Muse, Lilly Corporate Center



Officer
Dale Carter, Evonik



Vice-Chair for Science and Regulatory Policy
Priscilla Zawislak, IFF



Vice Chair for Administrative Affairs
Meera Raghuram, Lubrizol Advanced Materials



Vice Chair for User Relations
Heather Sturtevant, Johnson & Johnson



Vice-Chair for Membership
George Collins, Vanderbilt Mineral Co



Officer
Paul Smutz, Global Compliance Manager, Henkel



Officer
Ron Kelly, Amgen



Officer
Gina Marsee, Merck & Company



Immediate Past Chair
Janeen Skutnik-Wilkinson



Membership

Members/Membership update

- ▶ As of 11/30/2022 total membership: **92**
- ▶ 42 Makers, 14 Users, 9 Distributors
- ▶ 13 Consultants, 2 Associations, 1 Publication, 2 Academic Institution, 3 Academic, 5 Graduate Students, and 1 Specialized Services
- ▶ 2 of the distributors are now full members IMCD and Univar

Membership Update

Members lost: 4

- ▶ Chandra Sekhar retired
- ▶ Mingtai because of the time difference
- ▶ PerkinElmer because of internal changes
- ▶ St. John's University did not specify

New Members 3

- ▶ Dr. James Polli – New academic member
- ▶ Dr. Kendal Pitt – New academic member
- ▶ SGS North America – New specialized services member
- ▶ Greenfield Global
- ▶ Indorama Ventures (Oxiten)
- ▶ Clariant
- ▶ Moderna Inc.



2022 IPEC-Americas Achievements

IPEC-Americas 2022 Dashboard

~17 interactions
with regulators/
pharmacopoeias

	CRC	RA	GMP	EQ	QbD	SAC	UN	LL	XC	EW	TOTAL
FDA docket comments		2									2
FDA correspondence						2					2
USP correspondence	7			2							9
EDQM comments	1										1
TGA comments		1									1
NSF comments			1								1
ICH comments					1						1
Publications	1	1		1	2				9		14
IPEC Workshops	1	2	2		1			1		1	8
IPEC LL Webinars		3		1	1			1		4	10
Excipient World Webinars						7					7
Published NEW Guides											0
Published Revised Guides			1	2							3
In-process DRAFT Guides			4	2							6
Position & White Papers		1				1					2
Industry collaboration/presentations	2	3	1	2		4					12
Infographic & videos					2				5	1	8



Committee Highlights

Compendial Review and Harmonization Committee:

Chair: Douglas G. Muse

- ▶ Associate Consultant - Compendial Affairs
- ▶ Eli Lilly and Company

Vice Chair: Jennifer Putnam

- ▶ R&D Supervisor II
- ▶ Perrigo

2022 Compendial Review & Harmonization

**Face-to-face
meeting between
USP and IPEC-
Americas**

Comments to USP Stimuli Article
“USP’s Iterative Approach to
Standards Development and
the ‘Emerging Standards’ ”

Feb

Mar

Apr

May

Jun

Jul

Aug

USP Comments

- GC <621>
Chromatography

Workshop with CfPA

Excipients:
Compliance with
Compendial and
GMP Requirements

**Face-to-face
meeting between
USP and IPEC-
Americas**

2022 Compendial Review & Harmonization

T&C article *"Perspective:
The Value of Participation
in Setting Global Quality
Standards"*

**Host Joint
Compendial
Industry Meeting**

Sep

Oct

Nov

Dec

USP Comments

- removal of the Aspartame Acesulfame NF Monograph
- GC <5.15> Definition

EDQM Comments

- deletion of As and Pb

ONGOING

Monitoring and update for/from:

- USP Cross functional Team
- USP General Notices Project Team
- USP Compendial Process Improvement (CPI) Team
- PDG harmonization efforts

Regulatory Affairs Committee

Chair: Meera Raghuram

- ▶ Manager, Global Regulatory Strategy and Policy, Personal, Home and Health Care
- ▶ Lubrizol Advanced Materials, Inc.

Vice Chair: Troy Barrix

- ▶ Senior Regulatory Compliance Specialist
- ▶ Celanese

2022 Regulatory Affairs

IPEC Position Paper

How to document to the ECHA's Proposal for an EU-wide Restriction on Intentionally Added Microplastics

TGA Comments

proposed change to poison control regulation

Docket No. FDA-2022-N-0236

Prioritizing IID MDE and collapsing dosage forms

Mar

Apr

May

Jun

Excipient World Conf & Expo

- **Workshop:** An Overview of Excipient Reg/req in key Regions and Country
- **Presentation:**
 - Atypical Actives
 - Impact of the EU E171 Ban on Pharmaceuticals
 - Impact of EU Microplastic Regulations

T&C article

Eye on Excipients

Proposed EU Rules on Small Molecules Could Lead to Big Implications

2022 Regulatory Affairs

IPEC Webinar
Excipient Laws,
Regulations and
Best Practices in
China

IPEC Webinar
Excipient Laws,
Regulations and
Best Practices in
Japan

IPEC Webinar
Excipient Laws,
Regulations and
Best Practices in
LATAM

Aug

Sep

Oct

Nov

Dec

APV/IE/IA/IQ
TiO₂ Workshop

Docket No.
FDA-2022-N-1633
ANDA Amendment

AAM Meeting
- IID Q3/Q4 issues

ONGOING

Monitoring and update for/from:

- Microplastics Cross functional Team
- Monitoring TiO₂ situation (e.g., ban in EU)
- IID publishing issues
- Engagement/Advocacy with FDA and global regulatory bodies

Good Manufacturing Practices Committee

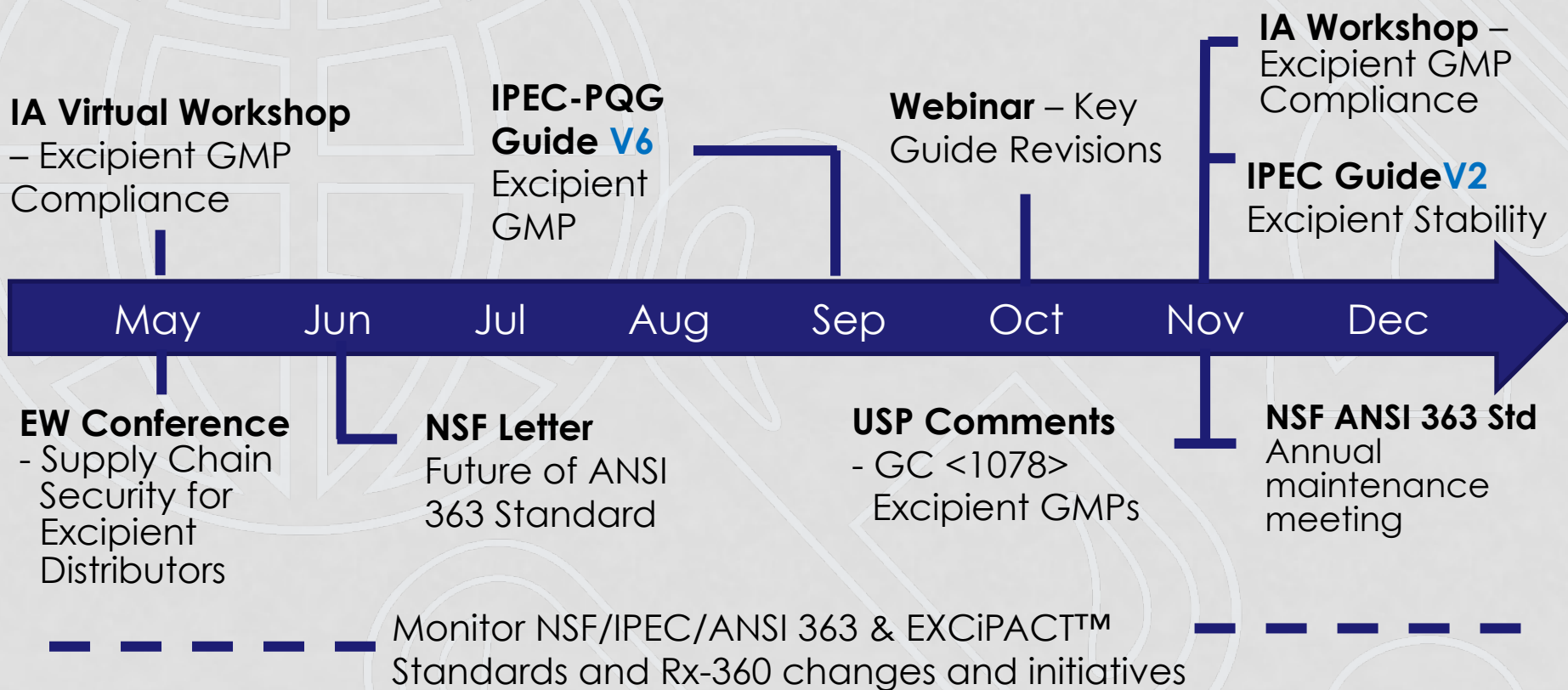
Chair: Mike Cassell

- ▶ cGMP Quality Assurance Manager
- ▶ Eastman Chemical Company

Vice Chair: Elizabeth Febbo

- ▶ Global Laboratory & Project Manage
- ▶ Henkel Corporation

2022 Good Manufacturing Practices



In-Progress	Target
New IPEC-Americas Excipient GMP Audit Guide to ANSI Standard	Q1' 2023
New IPEC GDP How To Guide for Pharmaceutical Excipients	TBD

Excipient Qualification Committee

Chair: Ann Gulau

- ▶ Quality Manager for Nutrition & Biosciences-Pharma Solutions
- ▶ IFF

Vice Chair: Candy Reynolds-Cummings

- ▶ Quality Assurance and Regulatory Manager, Smart Materials & Speciality Additives
- ▶ Evonik

2022 Excipient Qualification

EW Conf Presentations

- Qualification of Alternate Excipient Sources
- Sustainability for excipients

USP Comments

- GC <1083> Good Distribution

BioPharm Int article

The Role of CoAs in Supplier Oversight

Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec

USP Comments

- GC <1083> Good Distribution

IPEC Guide V2

Excipient CoA

In-Progress	Target
Sustainability, Social Compliance and Responsible Sourcing EIP	Q1 ' 2023
Significant Change Guide for Pharmaceutical Excipients – Revision	Q1 ' 2023
Quality Agreement Guide - Revision	TBD
Technically Unavoidable Particles – Revision	TBD

Quality by Design/Excipient Composition

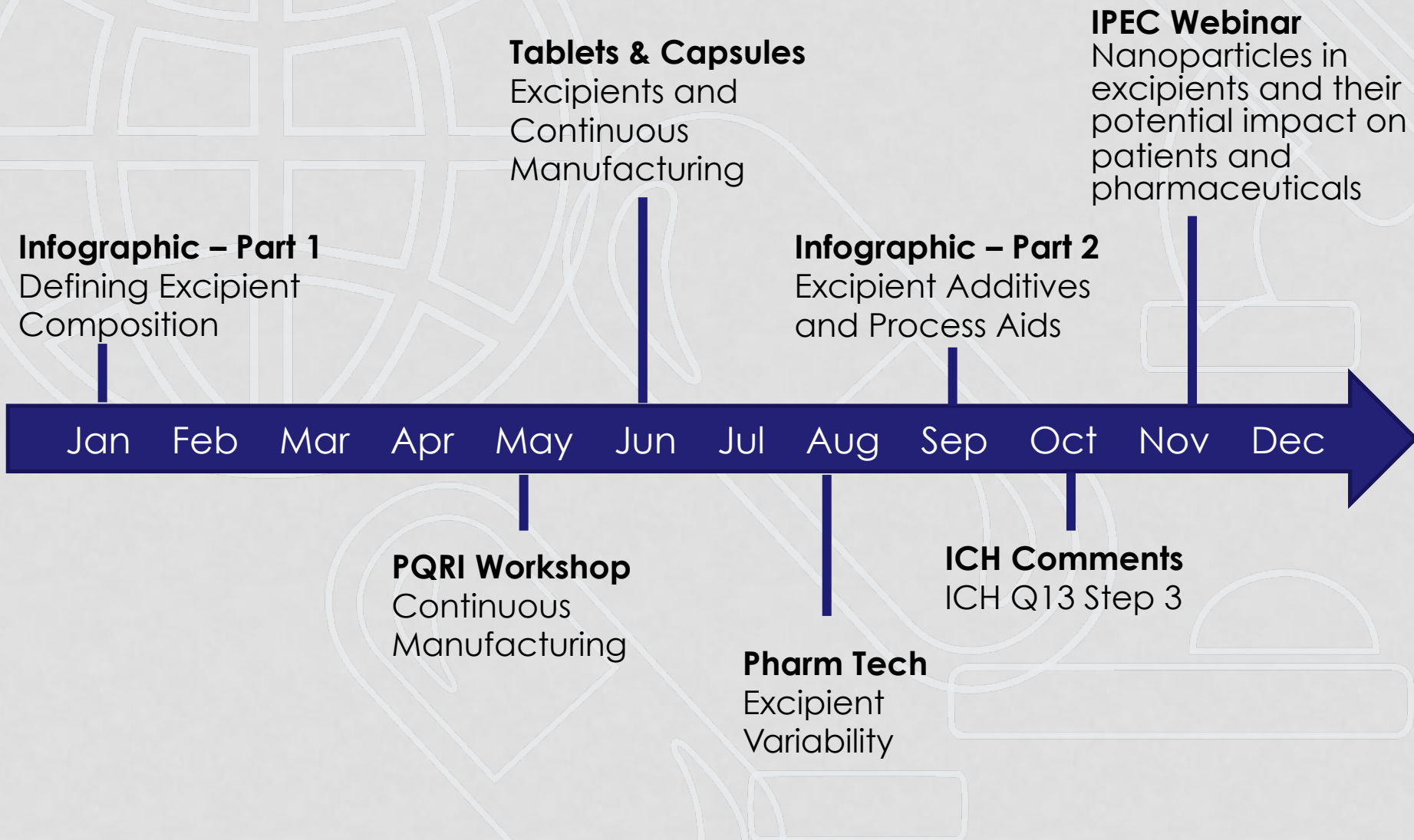
Chair: David R. Schoneker, MS

- ▶ Consultant
- ▶ Black Diamond Regulatory Consultant

Vice Chair: Stacey Bremer

- ▶ Director, Product Stewardship
- ▶ Celanese

2022 Quality by Design Committee



Scientific Affairs Committee

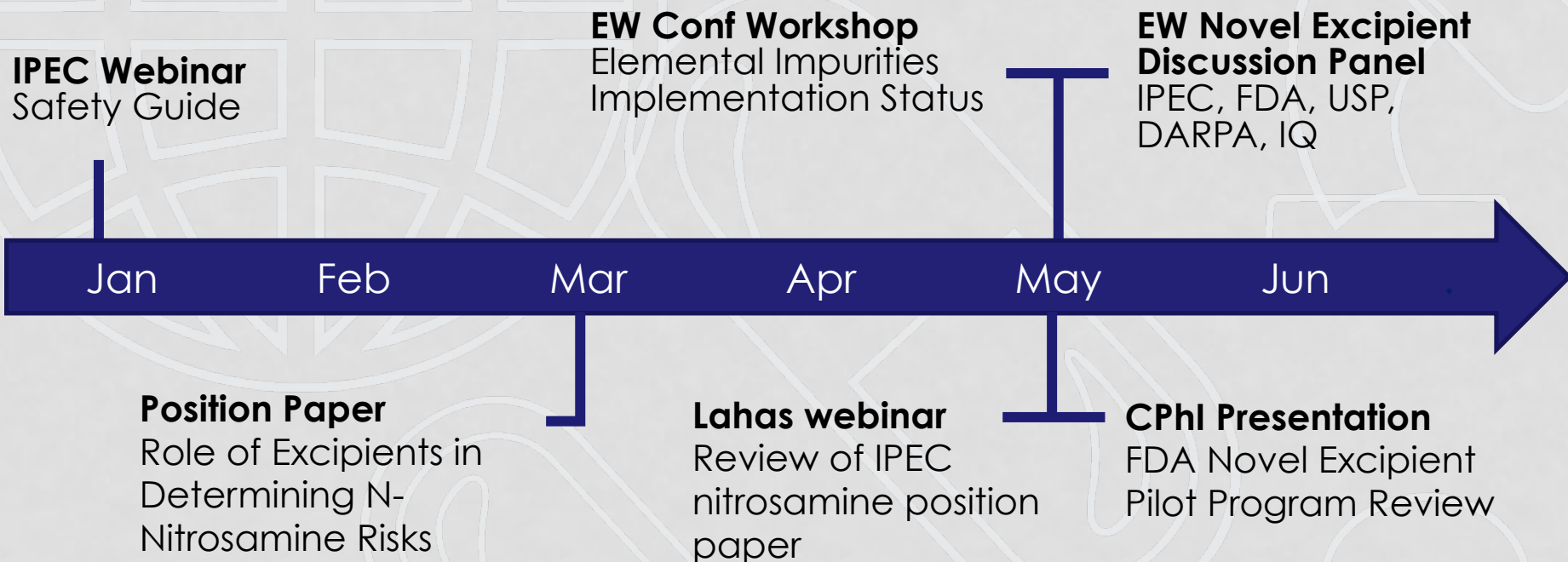
Chair: Lisa W. Webber

- ▶ Director – SQM/Procurement Process Deployment
- ▶ Johnson & Johnson

Vice Chair: Charlotte McIlvaine

- ▶ Manager - North America Pharma Quality
- ▶ Univar Solutions USA Inc.

2022 Scientific Affairs



2022 Scientific Affairs

Gastroenterology
letter to editor

FDA Letter
regarding overview control
of nitrosamine Imp

**FDA Voluntary
Consensus Std**
Submitted IPEC Safety
Guide

CPhI Podcast
Importance of novel
excipients for innovative
drug development

Jul

Aug

----- ONGOING -----

In-Progress

Target

Monitoring FDA Review of Novel Excipient Pilot

N/A

Nitrosamine Cross-Functional Team

N/A

Users Network

Network Leader: Heather Sturtevant

- ▶ Manager, Technical Operations
- ▶ McNeil Consumer Healthcare (J&J)
- ▶ Vice Chair for User Relations, IPEC-Americas

2022 Users Network

User Discussion on:

- 1) FDA final guidance “Good ANDA Submission Practices”
- 2) Brainstorm future discussion topics

User Discussion on:

- 1) Approval in Europe of EU GMP Annex 1 – Manufacturing of sterile medicinal products
- 2) Review of USP stimuli article on Mutagenic Impurities and Potential Mutagenic Impurities in the USP-NF

Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec

User Discussion on:

- 1) Discussed and polled users regarding FDA requests for reducing the level of artificial flavor ingredients used in previously approved ANDA products
- 2) Shared and discussed an EW presentation on Technical Qualification of alternate sourced excipients

Latin America Working Group

- ▶ Working group established 2022
- ▶ Open to existing members with operations in LA
- ▶ Survey deployed to member company reps to identify companies with operations in LA
- ▶ Follow up request for contact information for LA reps
- ▶ 2 Safaybi webinars scheduled - postponed (World cup conflicts) re-scheduled for April 2023
- ▶ Currently – 16 companies interested – confirmed contacts (waiting for additional 4 more)
- ▶ Kick off call will be scheduled for Q1 2023
- ▶ Contact IPEC-Americas Staff for more information



Excipient World

Excipient World Academy



- ▶ 2022 Theme: Modernizing Excipient Technology - Need for excipients designed for purpose
 - **Covid Vaccines & Beyond** - mRNA vaccine future uses and connection to biologics
 - **3D Printing** – Excipients designed specifically for 3D printing
- ▶ Recorded Webinars Available:

www.Education.IPECAmericas.org

Questions?

Courtney@ExcipientWorld.org

Excipient World Conference & Expo



May 1: Workshops

May 2-3: Conference & Expo

Gaylord National

Resort & Convention Center
(National Harbor, Maryland)

Keynote speaker

Dr. John L. LaMattina

Author and former President of Pfizer R&D

Learn more...

www.ExcipientWorld.org

Courtney@ExcipientWorld.org

Excipient World Conference & Expo

Exhibit Update:

- ▶ 50% of exhibit floor sold
- ▶ 21 booths available



Booth	Company Name
407	Alcedo Pharmachem Pvt.Ltd.
602	Asahi Kasei America, Inc.
404	Barentz
200	BENEO GmbH
105	Biddle Sawyer /Daicel
211	Clariant Corporation
310	DuPont Liveo
306	Evonik Corporation
301	EXCiPACT
305	Gattefossé USA
405	Grace
304	IMCD US, LLC
204	IOI OLEOCHEMICAL
111	IPEC-Americas
201	JRS Pharma LP
311	LBB Specialties
406	MilliporeSigma
400	Pace Life Sciences
312	Univar Solutions
205	US Pharmacopeia
207	Waters Corporation

Interested in exhibiting?
Patty@ExcipientWorld.org

Excipient World Conference & Expo



2023 Development Timeline

- ✓ Call for Papers: Sept. 6
- ✓ Strategic Planning: Sept. 29
- ✓ Abstract Deadline: Oct. 28
- ✓ Announce Initial Program: Dec. 2
- ▶ Open Registration: Jan. 9
- ▶ Early Bird / Hotel Deadline: April 10
- ▶ Excipient World: May 1-3

Excipient World Future Dates



Save the dates... through 2025!

- ▶ May 13 – 15, 2024: Gaylord Palms
- ▶ May 12 – 14, 2025: Gaylord National

Learn more...

www.ExcipientWorld.org

Courtney@ExcipientWorld.org



Outreach

2022 IPEC Federation Activities



▶ IPEC EU

- Annual meeting held with EDQM & EMA in May to discuss current regulatory matters including CEPs, CPEs, PDG expansion
- Accepted as observer in EMA TiO₂ discussion

▶ IPEC Japan

- 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

- Regulators issued draft revision of the Drug & Cosmetic Act for public comment; no mention of excipients
 - Il request to separate excipients from finished drugs and requested to be included on the Technical Advisory Board

▶ IPEC China

- CPC is in the process of incorporating ICH Q3C Residual Solvents in the ChP

Federation 2022 (Priscilla)

► Federation Projects

- Presentation developed for IPEC's Nitrosamines Position Paper; available for member use
- Regulatory database – working with 2 companies to determine feasibility
- Achieved Observer status on ICH Q1/Q5C Stability WG – concept paper and business plan approved
- Participated in EDQM panel discussion on compendial harmonization in Sept
- Established 3 yr review of all IPEC guides & streamlined approval process
- Compendial convergence initiative
- Revised guides published by Federation: GMP, Stability, COA
- Guides in progress: EIP-Sustainability, Significant Change

2022 Strategic Focus and Priority Objectives

CAPTION
Strategic Focus
Priority objectives

Visible particles

Raw materials used in
recombinant /
biological products

QbD, PAT, FRCs

Paediatrics

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



Cross Functional Teams

Monthly Compendial Posting Review

- ▶ Reviewed proposals published in PF 48(5), PF 48(6) and PharmEuropa 34.4 as well as new/updated official content of Eur. Ph. 11.1 and USP/NF 2023
- ▶ Comments submitted include:
 - Comprehensive response letter submitted regarding complete rewrite of USP <1078> GMP for Bulk Pharmaceutical Excipients (GMP committee project)
 - Comments drafted for USP Stimuli Article: *Mutagenic Impurities and Potentially Mutagenic Impurities in the USP-NF* encouraging USP to maintain alignment with ICH and to continue excluding excipients from PMI guidance
- ▶ Possible divergence between EDQM and USP policies for maintaining vs. removing specific EI tests in monographs for natural materials
 - USP: Revised alginates monographs effective in USP/NF 2023 (May-1-2023) will maintain Pb and As tests
 - EDQM: Proposed revision published in PharmEuropa 34.4 to remove Pb and As tests from several magnesium and aluminum material monographs

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 be issued by the EU Commission in 1Q 2023

Current Team Activities

Developing guides and documentation to assist both makers and users proactively prepare for implementation of regulatory requirements

- ▶ A “**how to guide**” draft interpreting compliance requirements was completed and the final version published in early 2022
- ▶ A document addressing data required on excipient polymers critical for evaluating applicable derogations and compliance with labeling/reporting requirements is expected to be completed in early 2023

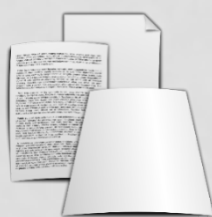
Nitrosamines Cross Functional Team

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 2022 Accomplishments:

- 
- ▶ Published position paper in March 2022
 - Link to position paper (https://ipec-federation.org/wp-content/uploads/2022/02/202203_IF_Nitrosamines-Position-Paper_FINAL.pdf)
 - Focus on excipients that provide consistent messaging on regulatory expectations and perspectives on excipient risk mitigations.
 - ▶ Presented at the Lhasa webinar “An Introduction to Nitrite in Excipient Testing to Accelerate Route Cause Investigation of Nitrosamines”
 - Elizabeth Tocce presented on behalf of IPEC-Federation
 - ▶ Participated in AAPS “Ask Me Anything” expert session on nitrosamines
 - Ron C. Kelly represented IPEC-Americas
 - ▶ Submitted comments to FDA requesting clarity on nitrosamine presentation “FDA Overview Control of Nitrosamine Impurities in Human Drugs” in relation to requirements for excipients
 - ▶ Continuing to monitor global regulatory developments with a focus on excipients.



Strategic Planning

International Pharmaceutical Excipients Council of the Americas Strategic Plan 2022 - 2025



IPEC-Americas Vision

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

IPEC-Americas Mission

To advocate, educate, innovate and develop best practices for excipients, with a focus on patient safety.

Develop Strategic Partnerships and Alliances

Market Expansion

Establish a process for delivering exceptional and recognized excipient education

- IPEC will be more innovative and scale quicker by "pooling" expertise and resources for mutual benefit
- Determine the most valuable and essential alliances / partnerships
- Expand our reach to find new prospects with new uses of excipients
- Define resources to help educate potential market expansion
- Become known and recognized as much a source for excipient science as we are known for excipient quality and regulatory
- Establish/Validate and then broaden audience

Our Core Values - As an Executive Committee We: Listen | Are Committed | Are Bold | Are Inclusive

Strategic Planning

Partnerships and Collaborations

Lead - Janeen and Priscilla

- Identify stakeholders/other organizations with common objectives - COMPLETE
- Define potential areas of engagement – IN PROCESS
 - ✓ CHP Collaboration – benzene contamination in aerosols
 - ✓ Joint Industry Meeting (CPPQ)
 - ✓ IQ collaboration – TiO_2
 - ✓ LAWG Formation
- Develop strategy for collaborations – IN PROCESS

Strategic Planning – Team 2

Markets and Membership (Lead – Meera Raghuram)

Expansion to adjacent markets and emerging technologies

1. Identifying potential emerging areas which are important for excipients and adjacent markets
2. Taking leadership in reaching out to industry & trade organizations to form alliances
3. Continue identification/seeking input from potential companies active in emerging areas
4. Focused sub-teams on in-depth analysis, ranking new opportunities and defining next steps.
5. Potential actions include:
 - taking a lead on round table discussions with key stakeholders,
 - webinars,
 - peer reviewed articles
 - targeting specific companies/associations.

Strategic Planning Team 3

Education (Leads – Jessica Cansler

Define Education and establish process and tools by which to deliver

1. Infographics – 4 infographics completed in 2022; Request form updated with keywords for better searchability
2. Videos – 4 videos completed in 2022
3. ELL/EWA webinars, workshops, & eLearning courses – 10 webinars & 2 virtual workshops in 2022
4. IA education/tools for membership - Value Proposition Video/Annual Report/YIR completed (collaborated with/supports membership team initiatives)
5. IA website updates – added Document Depot Explainer videos to website for ease of access



Excipient Learning Lab

Educational Programming



- ▶ 6 Learning Lab Team Webinars
 - Safety Guide
 - Excipient laws, regulations, best practices in China
 - Excipient laws, regulations, best practices in Japan
 - Excipient laws, regulations, best practices in LATAM
 - Key IPEC Guides
 - Nanoparticles in excipients and their potential impact on patients and pharmaceuticals
- ▶ 2 Excipient GMP Compliance Virtual Workshop
- ▶ 2 EW Conference Workshops (Key Guides & Elemental Impurities)
- ▶ CfPA Virtual Workshop Collaboration – *Excipients: Compliance with Compendial and GMP Requirements*
- ▶ Training webinar per request from Lhasa
 - Lhasa webinar on IPEC Nitrosamine position paper



IPEC Foundation

IPEC Foundation 2022

IPEC Foundation Award Winners:

■ Ralph Shangraw Memorial Award

- Dr. Mansoor Khan, Texas A&M University Rangel College



■ Henk de Jong Industrial Research Award

- Dr. James Wesley, Eli Lilly

■ Patrick DeLuca Emerging Researcher Award

- 2021 winner and 2nd year progress report:
Dr. Na Li, University of Connecticut



Graduate Student Winners:

- Mr. Mustafa Bookwala, Duquesne University
- Mr. Suraj Fanse, UCONN
- Mr. Jinghan Li, University of Minnesota
- Mr. Sichen Song, University of Minnesota
- Ms. Ruochen Yang, Purdue University



2023 Committee Meetings

- ▶ Tuesday: Safety 2:00 – 5:00 pm
- ▶ Wednesday: CRC and RA 8:00 am – 5:00 pm
- ▶ Thursday: EQ and GMP Extended time 8:00 am – 2:00 pm (flexible start time)
QbD/EC 2:00 – 5:00 pm
- ▶ Monday following “IPEC Week”: Users Network: 2:00 – 3:00 pm

Dates for 2023 “IPEC Week”

February 27 – March 2

May 16 – 18

September 19 – 21

December 5 – 7

PQRI Activities

- ▶ Artificial Intelligence Application in Continuous Validation of the Process – **Running**
- ▶ Topical Drug Classification System Project – **On Hold**
- ▶ Restricted Delivery Systems in Children's OTC Liquid Medications - **Running**
- ▶ Excipient and API Impact on Continuous Manufacturing Workshop – May 17-18, 2022
- ▶ Patient Centric Specification Development Focus Group – what is the best way to handle impurity specifications in APIs and Excipients? Actual Patient Risk vs. Process Capability? **Focus Group routinely meeting**
- ▶ Drug-Device Combination Products Focus Group – Inconsistencies from Regulator Expectations related to materials used and other areas. **Focus Group routinely meeting**



Board of Trustees



Elections Results



Treasurer's Report

Current Bank Balances

- ▶ \$ Principal account: **\$148,047 (11/29/22)**
- ▶ \$ Money market account: **\$596,193 (11/29/22)**
- ▶ \$ TD Ameritrade Investment: **\$1,070,726 (11/29/22)**
- ▶ **Account opened July 2016**
- ▶ **2022 IPEC-A Contributions - \$800,000**
- ▶ \$ TOTAL Cash Assets:
- ▶ **\$1,775,533(as of 11/29/22)**
- ▶ **Organization is financially solvent with significant resources in reserves.**

Complete Balloting/Tally

Election of Officers - Results

Vice Chair for Administrative Affairs

Meera Raghuram

Director, Regulatory Strategy and Policy, Lubrizol

Vice Chair for Harmonization and Compendial Monograph

Doug Muse

Sr. Principal Associate, Compendial Affairs

Global Quality Laboratories

Eli Lilly

Executive Committee Officers:

Jennifer Putnam Senior Supervisor R&D

Perrigo

William Dale Carter

Head of Quality, Business Line Silica, NA

Evonik

Questions?

Thank you for your continued support in council activities.

YOU are the heartbeat of our organization.



Stay safe and healthy. We hope to see you in 2023!

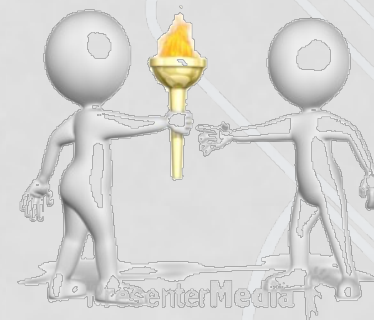
2022 Dues Increase

IPEC-Americas Bylaws Article III, Section 2 **Council Member Dues**

(b) Notice of Dues Change. Council Members shall be notified of any change in the annual dues rates at least twelve (12) months in advance.

The Executive Committee has approved a 1.7% CPI increase beginning 2021 - However, they agreed to postpone implementation due to COVID-19. To be implemented in 2022.

	Current	Increase	New
A.	\$9,500.00	\$162.00	\$9,662.00
B.	\$15,748.00	\$268.00	\$16,016.00
C.	\$21,336.00	\$363.00	\$21,699.00
D.	\$27,432.00	\$466.00	\$27,898.00
E.	\$33,528.00	\$570.00	\$34,098.00



Passing of the “torch”

Thank you Janeen – Welcome Nigel!





Shout out to.....

Our Wonderful Staff!

IPEC- Americas Staff!



Kim Beals



Tammy Kramer



Courtney
Nazareno



Dorothy Ferro



Year in Review

Excipient World Academy



Sponsorships Available!

Benefits:

- ▶ **Visibility:** Recognition on promotional materials
- ▶ **Qualified leads:** Registration list with emails
- ▶ **Thought leadership:** Provide moderator for Q&A
- ▶ **Access:** 5 complimentary registrations

Interested in sponsoring?
Patty@ExcipientWorld.org

Thank you Courtney!

Excipient World pivoting, Excipient World Academy, Strategic Team 3 support, 30th anniversary video!



Courtney
Nazareno

Board of Trustees

IPEC-Americas

Annual Board of Trustees Meeting

Wednesday, December 8, 2021

5:15 PM

IPEC-Americas WebEx

IPEC- Americas Staff!



Kim Beals



Tammy Kramer



Courtney
Nazareno



Dorothy Ferro