

ANNUAL REPORT

2020



resiliency





# Multiple Stakeholders, One Objective

IPEC-Americas brings together diverse stakeholders that share a common objective: Safe and effective production and use of excipients.

## MISSION

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

To promote patient safety, IPEC-Americas will support its stakeholders by using collaboration, science and risk-based methodologies to:

- Provide interpretation, education, training and guidance for current and future pharmaceutical excipient regulations and science.
- Develop and implement appropriate quality practices throughout the supply chain for continued availability of pharmaceutical excipients for use in the development and manufacture of medicines.
- Encourage the development and use of new and novel excipients.

## VISION

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



# 2020

A challenging year for us all

**P**ivot. Shift. Adapt. Adjust.

These are just a few of the words that define 2020.

Resiliency. Leadership. Action.

These are just a few of the words that define IPEC-Americas.



In spite of the rapidly changing global events of 2020, I am proud to report that our organization was able to continue its mission ...” to advocate, educate, innovate

and develop best practices for excipients, with a focus on patient safety”. In fact, IPEC-Americas was extraordinarily productive during one of the most challenging years of its 30-year existence.

Even in the midst of global chaos our volunteers continued to participate and engage in various activities related to the safe and productive manufacture, distribution and use of excipients. We have an engaged, growing, and energetic membership. Our financial reserves are strong and our leadership team is dedicated to our vision, “to be the pre-eminent authority on excipients”.

We are well positioned for growth and sustainability as we embark on our 30th anniversary. We continue to raise awareness of the critical role of excipients in pharmaceutical drug products and to gain credibility as the experts in this arena.

Thank you for taking the time to review our annual report. We look forward to celebrating our 30th anniversary together in 2021!

A handwritten signature in blue ink that reads "Janeen Skutnik-Wilkinson".



**Janeen Skutnik-Wilkinson**

Chair - IPEC-Americas  
Director,  
Global Regulatory  
CMC Policy &  
Intelligence Head  
Biogen

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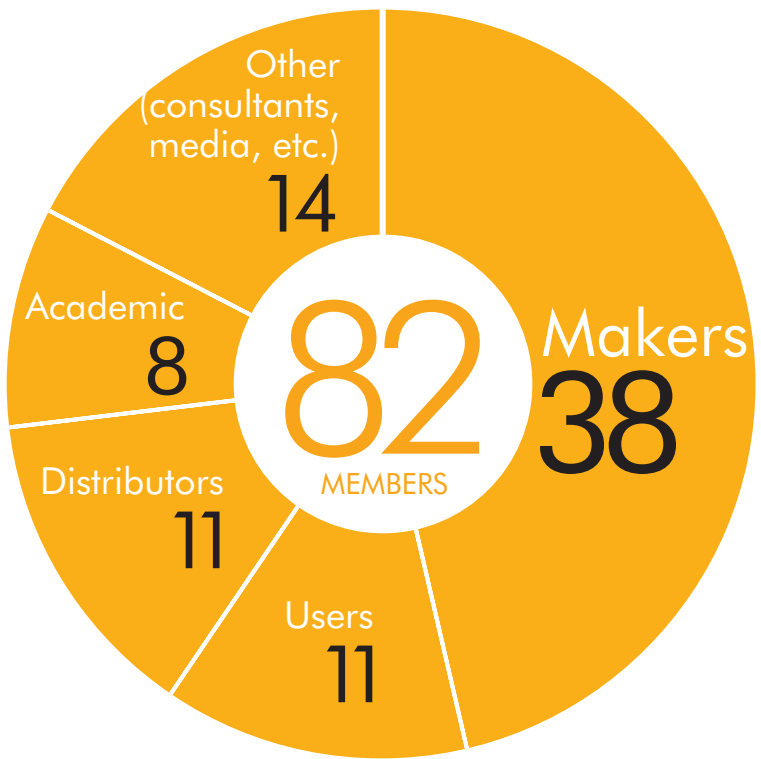
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# Membership

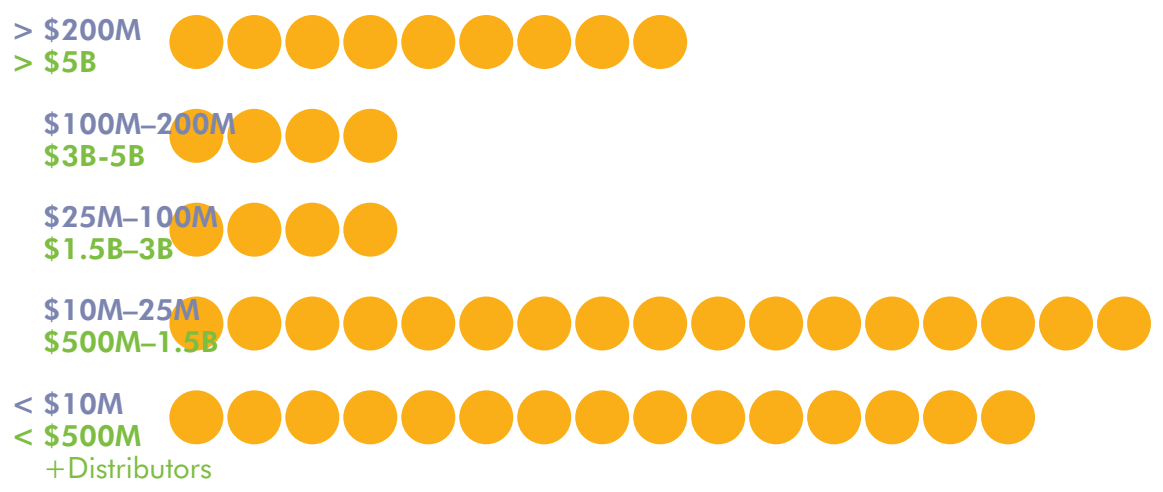
Excipient movers and shakers

**Our diverse mix** of members provides different perspectives—ensuring our vitality.



## Members by size (annual revenue)

MANUFACTURER/SUPPLIER OF EXCIPIENTS  
MANUFACTURER OF FINISHED PRODUCTS



We welcomed these new members in 2020...



# Influencing

## Strategic Advocacy+ Communications

**D**uring 2020, IPEC-Americas member company volunteers spent countless hours writing and reviewing IPEC-Americas publications, developing and/or revising guidelines and position papers, while our team worked tirelessly to communicate our messages.

### Cooperation makes things happen

Key to our effectiveness in advancing excipient industry aims is purposeful collaboration with various entities including:

- AAM – Association for Accessible Medicine
- AAPS – American Association of Pharmaceutical Scientists
- CHPA – Consumer Healthcare Products Association
- CRS – Controlled Release Society
- GADA – Generic Animal Drug Association
- IFPAC – International Foundation Process Analytical Chemistry
- IPQ – International Pharmaceutical Quality
- PDA – Parental Drug Association
- PQRI – Pharmaceutical Quality Research Institute
- Rx-360
- SAFYBI – The Argentine Association of Pharmacy and Biochemistry
- Sindusfarma – The Brazilian Pharmaceutical Industry Association Industry
- USP – United States Pharmacopeia

### Constructive commenting

Our team of staff and industry experts diligently commented to both local (Food & Drug Administration [FDA] and United States Pharmacopeia [USP]) as well as these global regulatory/pharmacopeial bodies.

- ANVISA – Brazilian Health Regulatory Agency
- ChP – Chinese Pharmacopoeia
- ECHA – European Chemicals Agency
- EDQM – European Directorate for the Quality of Medicines
- NMPA – National Medical Products Administration

### The IPEC-Americas Insider ▶

Designed to increase external communications with members and to broaden our outreach into member company personnel, reached almost 4000 readers bi-weekly, with a delivery rate over 70% and an average open rate of 45%.



# Influencing continued

## Sharing Knowledge

IPEC-Americas  
Proposals for  
Consideration during  
GDUFA III  
Negotiations

Priscilla Zawislak  
Immediate past chair,  
IPEC-Americas

Multiple  
stakeholders;  
**one objective.**



International Pharmaceutical Excipients Council  
Collaborative solutions for excipient industry stakeholders


IPEC-Americas provided public comments during an FDA open meeting on key excipient issues to consider during FDA GDUFA III negotiations.

Speaking out about current Inactive Ingredient Database (IID) issues, IPEC-Americas reached out to advocate for change at the FDA.




**IPEC Position Paper**  
**Data Integrity for Pharmaceutical Grade Excipients**  
30 April 2020

**Purpose of Position Paper:**  
This paper describes IPEC's position on the relevance of data integrity guidance documents to the manufacture and supply of excipients.  
NOTE: Within this paper, supplier will refer to both the excipient manufacturer and distributor.



**IPEC Position Paper**  
**Pharmaceutical Excipients GMP Documents supported by the IPEC Federation**  
22 June 2020

**Purpose of Position Paper:**  
Several different excipient Good Manufacturing Practice (GMP) documents are in use. This position paper explains the purpose of these documents. Information, the excipient manufacturer can have a better informed decision regarding which they will use.



Janeen Skatnik-Wilkinson  
Chair, International Pharmaceutical Excipients Council of the Americas  
1138 N. 10<sup>th</sup> Street, Suite 500  
Arlington, VA 22201

## Enhancing Communication Tools

We continue to analyze and improve the user experience on the IPEC-Americas web site, as well as build a more strategic, cohesive and robust online outreach through social media, industry partnerships and other targeted digital marketing.










Our website is a vital portal for members and a go-to source for makers, buyers, academia, the media and the general public.

60k+

Unique page views



A key knowledge base for members and industry accessed via the website.

405

Unique sign-ins



# influencing continued

## IPEC Federation

We are one of the founders of and active contributors to the IPEC Federation—the global organization that promotes quality and safety in pharmaceutical excipients.

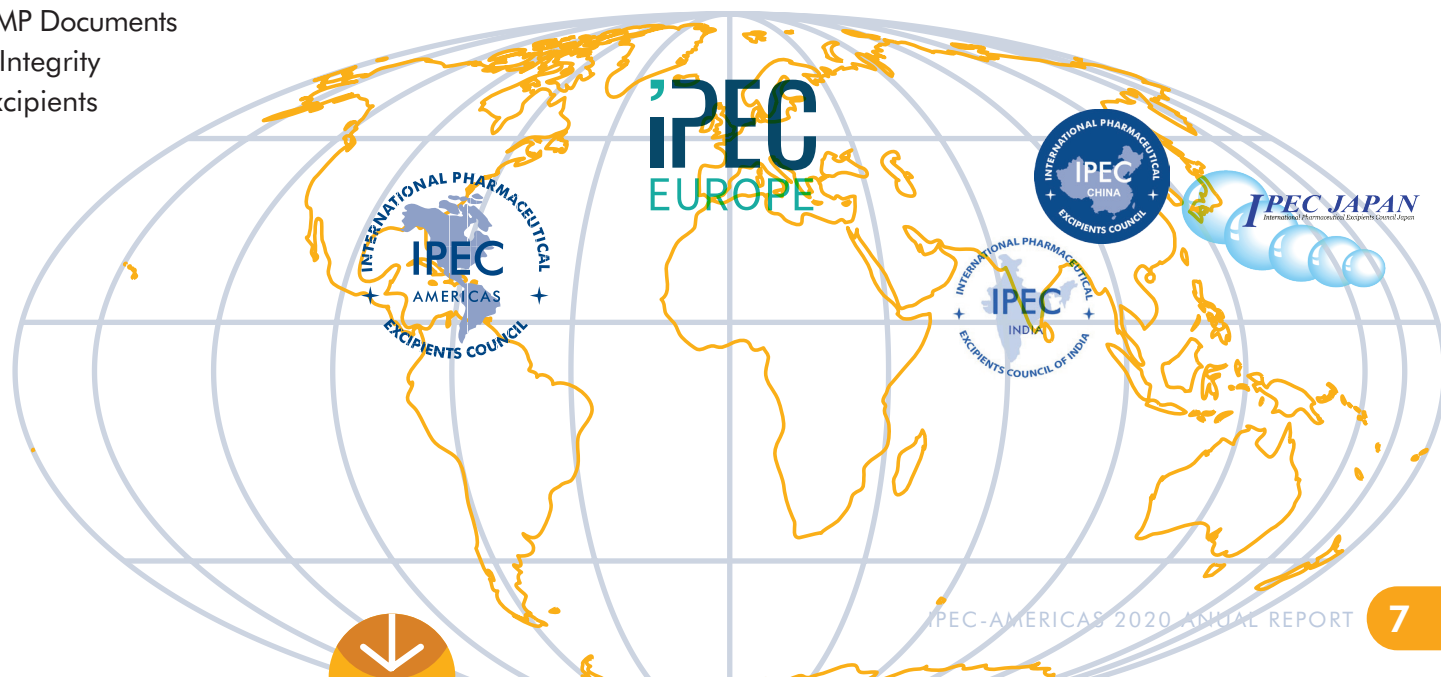
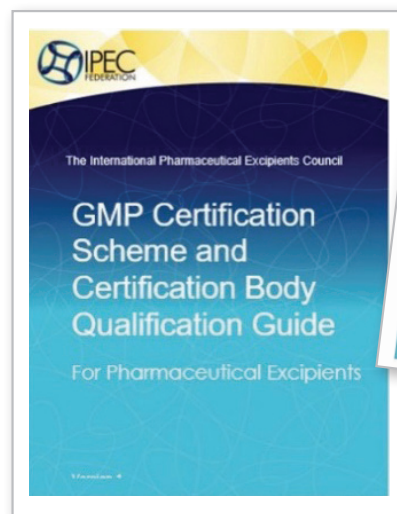
The Federation consists of the five existing regional IPECs—advocating for the industry with one unified voice.



In 2020, IPEC-Americas worked with the IPEC Federation members to

revise and republish the IPEC Composition Guide for Pharmaceutical Excipients and the IPEC Qualification of Excipients for Use in Pharmaceuticals Guide and Checklist. In addition, two new IPEC Guides and two new position papers describing Pharmaceutical Excipient GMP Documents supported by the IPEC Federation and Data Integrity Considerations for Pharmaceutical Grade Excipients were published.

- The IPEC Federation brings together our global Pharmaceutical Excipients Council partners.



# Education

Virtually vital

**C**ollaborations within our community looked a little different in 2020. Although we were unable to meet in person at Excipient World Conference & Expo, we had an exceptional year of virtual interactions through our educational programs.

## Bring it on(line)

Our nimble team adapted quickly and produced a record number of online educational resources—keeping our community informed and connected!



EXCIPIENT  
LEARNING  
LAB

Our primary learning program has become *the* authority and resource for education and training in pharmaceutical excipients.

3

Workshops

13

Webinars



Leveraging the equity of our annual Excipient World Conference, EWA promotes the scientific discussion of excipient topics through virtual (for now) learning.

4

Webinars



Journal of  
Excipients and  
Food Chemicals  
(JEFC)

Our peer-reviewed publication stands as the industry source for research/review articles, technical notes and opinion pieces related to excipients and food chemicals.

10

Scientific  
articles  
published

WEBINARS+  
WEBCASTS

832

total  
interactions

550

unique  
participants

96

largest number  
of attendees  
in a single  
webinar



## Advancing excipient relevance

**E**ndeavors which promote understanding of excipients not only advance our objectives, but also builds trust in our members' companies, products, and services. Plus, support for up and coming industry leaders fosters interest and talent for the future!

### Supporting research & innovation

#### IPEC Foundation

The IPEC Foundation is the charitable arm of the International Pharmaceutical Excipients Council of the Americas and is a 501(c)3 organization. The IPEC Foundation awards grants-in-aid, travel, and meeting grants to qualified individuals and organizations and is supported through IPEC-Americas resources (financial and staffing) and public contributions. The pharmaceutical ingredients, delivery systems and policies of tomorrow will be better for the world by supporting promising students and forward-thinking entities today.



#### Awards

The Foundation held its annual awards ceremony virtually on Sunday, October 25, 2020. Several winners were recognized for their efforts and contributions to the field of excipients. The awards and recipients are listed at right and on the following page.



#### Ralph Shangraw Memorial Award

for individuals who have provided outstanding research contributions over a number of years.  
**Dr. Eric Munson,**  
Purdue University

#### Henk de Jong Industrial Research Award

recognizes individuals in industry who have made significant contributions to excipient technology.  
**Dr. Ali Shaukat,**  
BASF

#### Patrick DeLuca Emerging Researcher Award

Presented to a beginning career scientist (post Ph.D.) who has demonstrated interest and dedication to the area of excipients  
**Dr. Tze Ning Hiew,**  
Purdue University

*more awards on next page>*



# Philanthropy

## continued



### Leadership Development

The IPEC Foundation acknowledges excellence in research conducted at the graduate level in the field of excipients.

► Scenes from our 2020 Graduate Student Scholarship Awards which was held virtually.



### SPOTLIGHT ON

### GRADUATE STUDENT AWARD WINNER

## Tingting Li

Ms Li's research focuses on development and optimization of mucoadhesive formulation and improvement.

Tingting has published 10 papers, has filed one patent application, and has made 8 poster presentations!

She is keen on applying her knowledge and experiences to development and formulation of various drug products after graduation.



### Graduate Student Award Winners

Scholarship winners receive a \$1,500 stipend and membership in IPEC-Americas for one year.

**Mr. Andre Beringhs**  
University of Connecticut

**Ms. Guluza Buyukgoz**  
New Jersey Institute of Technology

**Ms. Eylul Cetindag**  
New Jersey Institute of Technology

**Ms. Navpreet Kaur**  
University of Minnesota

**Ms. Tingting Li**  
University of Connecticut





## FINANCIALS

### INCOME

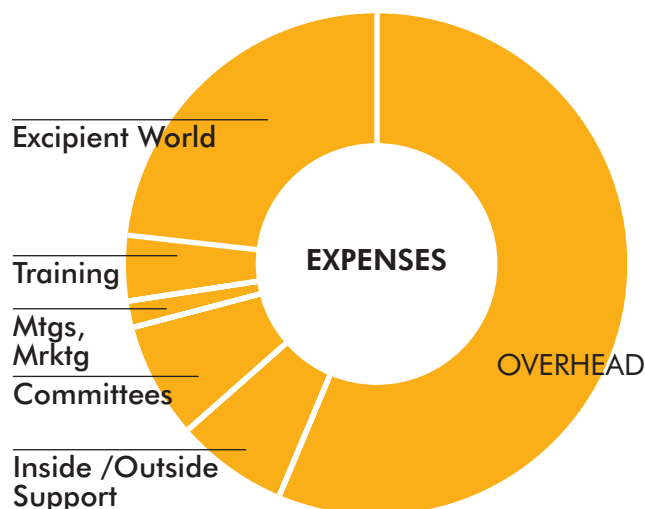
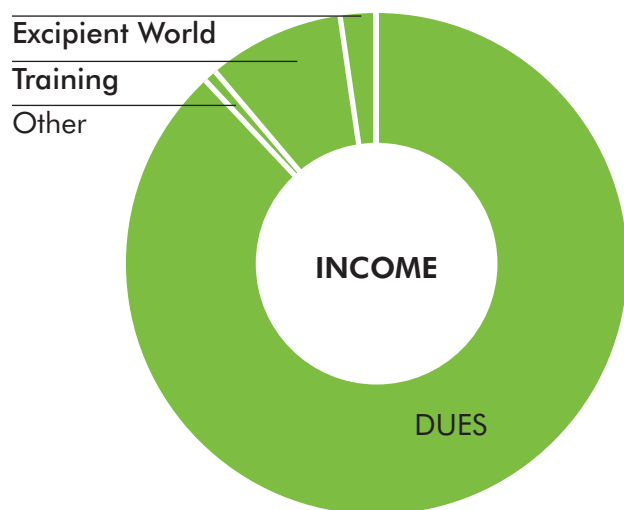
Dues	\$ 883,788
Other Income	\$ 8,307
Training	\$ 87,539
Excipient World	\$ 22,500
<b>Total Income</b>	<b>\$ 1,002,134</b>

### EXPENSES

Overhead	\$ 637,158
Inside/Outside Support	\$ 78,973
Standing Committees	\$ 86,516
Other meetings/marketing	\$ 18,705
Training Expenses	\$ 47,515
Excipient World Expenses	\$ 260,829
<b>Total Expenses</b>	<b>\$ 1,129,696</b>

**Net Cash From Operations**

**-\$ (127,562)**





## 2020 EXECUTIVE COMMITTEE

### ● CHAIR

**Janeen Skutnik-Wilkinson**

Director, Global Regulatory CMC Policy & Intelligence Head,  
Biogen

### ● Chair-Elect

**Nigel Langley, Ph.D., MBA**

Global Technology Director – Pharma Solutions, BASF

### ● Vice-Chair for Administrative Affairs

**Meera Raghuram**

Director, Regulatory Strategy and Policy, Personal  
Home and Health Care Lubrizol Advanced Materials, Inc.

### ● Vice Chair for Harmonization and Compendial Monographs

**Douglas G. Muse**

Consultant – Compendial Affairs, Global Quality  
Laboratories, Eli Lilly and Company

### ● Vice-Chair for Membership

**William Dale Carter**

Head of Quality Business Line Silica, NA Evonik

### ● Vice-Chair for Science & Regulatory Policy

**David R. Schoneker**

Black Diamond Regulatory Consulting

### ● Vice Chair for User Relations

**Heather Sturtevant**

Associate Director, Global Consumer Health,  
J&J Family of Consumer Companies

### ● Elected Executive Committee Members

**George Collins**

Vice President Vanderbilt Mineral Co.

**Ron C. Kelly**

Senior Principal Scientist, Drug Product Technologies,  
Amgen

**Gina Marsee**

Director, Compendial Compliance and Advocacy, Merck

**Joseph Zeleznik**

Technical Product Manager, IMCD

### ● Immediate Past Chair

**Priscilla Zawislak**

Global Regulatory Affairs Advocacy Manager, IFF

## COMMITTEES

### ● CRC-Compendial Review

### ● EQ-Excipient Qualification

### ● GMP - Good Manufacturing Practices

### ● QbD-Quality by Design

### ● RA-Regulatory Affairs

### ● Scientific Affairs

### ● Users Network





IPEC  
AMERICAS



30  
YEARS  
OF EXCIPIENT  
LEADERSHIP

IPEC-Americas members are finished pharmaceutical manufacturers, excipient producers, distributors, and other suppliers of specialized services related to pharmaceutical use of excipients.

For more information about IPEC-Americas and to learn how your company can advance its future through membership and committee involvement, you are invited to contact:

IPEC-Americas  
3138 10th Street N.  
Suite 500  
Arlington, VA 22201

571-814-3449

**ipecamerica.org**

ipecamer@ipecamerica.org



@ipec-americas @ipecamer



## Have a seat at the table...

## Join the leader in advancing excipient relevance.

## Contact us today!

