

# IPEC-AMERICAS 2025 YEAR IN REVIEW

## NAVIGATING THROUGH CHANGE

### GUIDES & PAPERS

#### 6 Published

- IPEC Best Practices for European REACH Restriction on Synthetic Polymer Microparticles
- IPEC Questionnaire for Excipient Nitrosamines Risk Evaluation
- IPEC Risk Assessment Guide Revision
- IPEC QbD Guide Revision
- IPEC Clarification of Definitions and Non-Applicability Regarding the Regulations of Active Ingredients Classified as Atypical Actives
- Third Party Audit and Certification Programme

#### 11 In Development

(N=new; R=revision)

- R IPEC GDP Audit Guide
- R IPEC Composition Guide
- R IPEC Qualification of Excipients Guide
- R IPEC Excipient Information Guide
- R PDA-IPEC TR 54-6 Risk Assessment for Excipient Report
- N Annex/Guidance for Parenteral Applications
- R IPEC Stability Guide
- N Excipient Interchangeability Guide
- N Atypical Actives How To Guide
- N Best Practice Guide for New Excipient
- R IPEC GMP Certification Scheme and Certification Body Qualification Guide

17

5

### PUBLICATIONS

#### 4 Issues

International Journal of Pharmaceutical Excipients

#### 1 Poster

State of the Industry: QC Lab Instrument Survey

26

### EDUCATION

10 Excipient Learning Lab Presentations

8 Joint Industry Presentations

6 Videos

2 Infographics

2

### SPECIAL EVENTS

IPEC Foundation Awards

Excipient World Conference & Expo

10

### ORGANIZATIONAL REACH

5 New members (88 Total)

5 Collaborations with associations

14

### GLOBAL COMMENTS

5 FDA Official

5 USP Official

1 ICHA

1 WHO

1 ECHA

1 NMPA, China



find out more: [ipeccamericas.org](http://ipeccamericas.org)

