



## Welcome

Dear Members and friends,  
welcome to the second IPEC Federation Connect for 2026, sharing the latest updates from the Federation and the five regional organisations. Enjoy reading it, share it widely, and of course, we welcome your feedback: [info@ipec-federation.org](mailto:info@ipec-federation.org).  
IPEC Federation Secretariat

## In this issue

### **IPEC Federation News**

- 🌐 *IPEC Guides: Stability, Composition and more*
- 🌐 *IPEC Federation at ICH*
- 🌐 *Document revision plans for 2026*

### **News from Regional IPECs**

## New IPEC Guides: Stability, Composition and more

As part of IPEC's ongoing guide revision programme, several key publications have been reviewed and updated to reflect current industry practices and expectations.

Recent revisions include:

### **IPEC Stability Guide**

Provides guidance on planning and conducting excipient stability studies, covering storage conditions, testing intervals, and interpretation of results.

The guide was presented during two webinars held in May from the U.S. and Europe.

### **IPEC GMP Certification Scheme and Certification Body Qualification Guide**

Offers a framework for excipient users to assess and qualify third-party GMP certification schemes and certification bodies.

### **IPEC Qualification of Excipients for Use in Pharmaceuticals Guide**

Describes a risk-based approach to qualifying excipients from both new and existing suppliers.

### **IPEC Excipient Composition Guide**

Helps excipient users understand the full composition of excipients, including processing aids and residual substances.

IPEC members benefit from three months of exclusive access to newly published guides. Once the access period concludes, guides are made available through the IPEC Federation website and regional IPEC association websites.

For questions, please get in touch with [info@ipec-federation.org](mailto:info@ipec-federation.org).

**THANKS TO THE MANY IPEC MEMBERS ACROSS THE FIVE REGIONS WHO VOLUNTEER TO PARTICIPATE IN DELIVERING OUR IPEC DOCUMENT OBJECTIVES!**

*Did you know? You can find the list of contributors in the section 'Acknowledgements' of our guides.*

**The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl**

Rue Marie de Bourgogne 52 – 1000, Brussels, Belgium – <https://www.ipec-federation.org> - +32 (0)2 213 74 40 – [info@ipec-federation.org](mailto:info@ipec-federation.org)

VAT: BE 0823931361 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region

## IPEC Federation at ICH

Janeen Skutnik-Wilkinson and Priscilla Zawislak (IPEC-Americas) represented the IPEC Federation at ICH meetings in Rio de Janeiro, Brazil in early June.

The Assembly approved two new Observers, DRAP (Pakistan) and Medsafe (New Zealand), expanding ICH's global representation to 25 Members and 43 Observers. The Assembly also endorsed a proposed ICH Strategic Vision and received an update on the development of a multi-year Strategic Roadmap for future guideline work. Progress was reported across a broad portfolio of ongoing harmonisation activities, including work on ICH Q1 (Stability Testing), ICH Q3E (Extractables and Leachables), ICH Q6(R1) (Specifications), and several efficacy, safety and multidisciplinary guidelines. The Assembly also adopted ICH E6(R3) Annex 2: Guideline for Good Clinical Practice as a final guideline (Step 4).

IPEC Federation continues to participate in the ICH Q1 (Guideline on stability testing of drug substances and drug products) Expert Working Group, which was among the working groups reporting progress at the Rio de Janeiro meeting.

## Highlights from IPEC Japan

by IPEC Japan - [www.ipec.gr.jp](http://www.ipec.gr.jp)

### CPHI Japan 2026: Japan Pharmaceutical Excipients Pavilion

CPHI Japan 2026 took place from 21-23 April at Tokyo Big Sight. IPEC Japan hosted the Japan Pharmaceutical Excipients Pavilion, bringing together eight exhibiting companies and presenting IPEC Japan activities, publications, and IPEC Federation guides to visitors from Japan and abroad.

The pavilion was well attended, with active exhibitor booths and strong interest in the accompanying seminars. CPHI Japan 2027 is scheduled for 21-23 April 2027 at Tokyo Big Sight, where IPEC Japan will organise the pavilion again. Interested member companies are invited to contact the IPEC Japan Secretariat.



### Internal Governance Meetings

IPEC Japan held several internal governance meetings during spring. At the end of April, the semi-annual Committee Chairpersons Meeting reviewed 2025 fiscal year activities and discussed planning for 2026, with key committees reporting on progress and priorities.

The semi-annual Board Meeting was held on 29 May to review agenda items for the Annual General Meeting, which took place on 17 June at the Bellesalle Kudan Conference Center. Two new Board Directors were approved, and a temporary Board Meeting was subsequently held to elect the new President of IPEC Japan for the period up to 2027. Mr Akihiro Kato of Asahi Kasei was elected in this role.

## IPEC India in the spotlight

by IPEC India – [www.ipecindia.org](http://www.ipecindia.org)

### Regulatory engagement

From April to June 2026, IPEC India contributed to regulatory dialogue and technical exchange on issues relevant to excipients and pharmaceutical quality. On 16 April, Kaushik Desai represented IPEC India at an invitation-only roundtable on antimicrobial awareness, organised by the US Consulate in Mumbai with Dr Ashley Styczynski, CDC and FDA expert.

Members were also invited to review and comment on draft Indian Pharmacopoeia monographs for Carboxymethylcellulose and for rice, wheat, corn and potato starches. This consultation supports continued input from industry on pharmacopeial texts affecting excipient manufacture, control and use.



**The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl**

Rue Marie de Bourgogne 52 – 1000, Brussels, Belgium – [www.ipec-federation.org](http://www.ipec-federation.org) - +32 (0)2 213 74 40 – [info@ipec-federation.org](mailto:info@ipec-federation.org)

VAT: BE 0823931361 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region

## Events and outreach

IPEC India participated as an association partner at PharmaCore India 2026, jointly organised by the Indian Drug Manufacturers' Association and Messe Muenchen India from 22 - 24 April. The association presented its activities at an exhibition booth and delivered the technical session "Excipients – Value Contributor to the Pharmaceutical Industry," attended by more than 80 delegates from excipient manufacturers, pharmaceutical companies and academia.



## IPEC India Annual Conference

The IPEC India Annual Conference 2026 will be held on 23 July at the Westin Garden City, Goregaon, Mumbai, under the theme "Excipients Redefined: From Inactive Ingredients to Therapeutic Enablers." The programme will address the evolving contribution of excipients to drug performance, innovation and advanced formulation, with updates on regulatory expectations and market trends. International speakers will include Adrian Bone, Senior Advisor, IPEC Federation, and Dr Iain Moore, Senior Advisor Operations, EXCiPACT.

## News from IPEC China

by IPEC China – <http://ipec.tb21.cn/>

Throughout spring 2026, IPEC China organised several activities to support member engagement, regulatory dialogue and knowledge exchange on pharmaceutical excipients.

On 24 April, IPEC China held a Member Salon at Merck's Shanghai office, bringing together more than 30 representatives from member companies. Discussions focused on practical challenges in excipient registration, regulatory best practices, and updates on the IPEC–ChP Microbial Control Project and the ICH Q3C/Q3D project.

IPEC China also contributed to two major industry events in Shanghai.

On 13 May, the IPEC Technical Seminar on Pharmaceutical Excipient Application and Regulatory Compliance was held alongside API Shanghai 2026, covering IPEC guidelines on stability, ICH Q3D, new excipients and co-processed excipients. On 16 June, the IPEC Forum on Global Pharmaceutical Excipient Regulatory Development and Technology took place during CPHI Shanghai 2026, addressing GMP implementation, excipients for 3D-printing and paediatric medicines, FDA inspection expectations, and nitrosamine mitigation. The two events attracted more than 150 participants in total, followed by an exhibition tour involving 23 member companies.



Following the publication of the draft "[Rules for the Compilation of Drug Production Site Codes](#)" by the NMPA Center for Information on 7 May, IPEC China coordinated member discussions and consolidated feedback into a formal comment letter. A Chinese translation of the IPEC Federation position was also prepared and submitted together with the original English version.

Upcoming events include the 3rd EXCiPACT-IPEC China-SPPEA Excipients GMP Workshop on 8 September 2026 at the Hilton Suzhou (Suzhou, Jiangsu Province) and the IPEC China Excipients Conference on 11–12 November 2026 in Wuhan International Expo Centre (Wuhan, Hubei Province).

For further information, please contact IPEC China Secretariat: [info@ipec-china.org](mailto:info@ipec-china.org)

**The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl**

Rue Marie de Bourgogne 52 – 1000, Brussels, Belgium – [www.ipec-federation.org](http://www.ipec-federation.org) - +32 (0)2 213 74 40 – [info@ipec-federation.org](mailto:info@ipec-federation.org)

VAT: BE 0823931361 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region



## News from IPEC Europe

by IPEC Europe – [www.ipec-europe.org](http://www.ipec-europe.org)

IPEC Europe is turning its Agenda 2030 into action, with progress across key priorities including excipient education, stakeholder engagement and the role of excipients throughout the pharmaceutical supply chain.

A highlight was the Multicompendial Compliance webinar, which welcomed around 80 participants and combined updates on the [revised best-practice document](#) with practical implementation exercises.

Regulatory and compendial work also advanced delivering the publication of the [DEG-EG position paper](#), the release of the [French translation of the IPEC-PQG GMP Guide](#) and submissions to authorities for comments.

IPEC Europe also contributed to Making Pharma in Coventry, UK, with presentations on IPEC guidelines relating to stability studies and to restrictions on microplastics.

Looking ahead, preparations are underway for the [IPEC Europe Excipient Conference 2026](#) in Prague on 22–23 September, bringing together regulators, industry experts and academics to discuss current challenges, emerging opportunities and practical experience.

IPEC Europe will take part in a [CPHI Milan panel discussion](#) on 7 October exploring whether innovation and excipients are mutually exclusive as well as representatives being present to meet existing and potentially new members.

Further activities include a GDP for Pharmaceutical Excipients training programme planned for November and the IPEC Europe Excipients Forum 2027, taking place on 4 February in Aix-en-Provence, France, to mark the association's 35th anniversary.

## Updates from IPEC-Americas

by IPEC-Americas – [www.ipecamericas.org](http://www.ipecamericas.org)

Excipient World Conference (EW26) and Expo were hosted by IPEC-Americas on 4–6 May 2026 in Nashville, Tennessee. Under the theme “Harmonize in Music City,” the three-day event brought together more than 300 professionals for focused learning, technical exchange and networking.

The education programme, “Excipients: The Heartbeat of Pharm Country,” highlighted the essential role of excipients across the drug lifecycle, from formulation development to patient safety and product performance. Sessions addressed scientific progress, regulatory expectations and manufacturing practice, with contributions from FDA, USP and industry speakers.

Programme highlights included workshops, technical sessions, keynote presentations and on the first day of the Fourth Annual Biologics Summit, a joint programme led by the Controlled Release Society and IPEC-Americas. The exhibition area featured 40 exhibitors and 30 posters, providing opportunities to exchange knowledge and build partnerships across the pharmaceutical supply chain. EW26 also marked IPEC-Americas' 35th anniversary, celebrated with an evening reception at the Grand Ole Opry.

[Excipient World Conference & Expo 2027](#) will take place from 17 to 19 May 2027 at the Gaylord National Resort & Convention Center in National Harbor, Maryland.



IPEC-Americas will participate and exhibit in the following events: [PDA/FDA Joint Regulatory Conference](#), 14-16 September 2026, Washington, DC - Booth 226; and [AAPS PharmSci 360](#), 25-28 October 2026, New Orleans, LA - Booth 1025.

The IPEC Foundation supports research, education, and safety initiatives that advance the science and application of pharmaceutical excipients. Its programs include research funding and scholarships that encourage innovation and knowledge sharing across the industry. Visit [ipecfoundation.org](http://ipecfoundation.org) for more information. Late submissions are being considered.



The International Journal of Pharmaceutical Excipients publishes peer-reviewed research on excipients used in pharmaceutical development and drug delivery. The industry-sponsored journal does not charge publication fees for accepted manuscripts. Submissions welcome!

[Access here the latest volume.](#)

## Document revision plans for 2026

### IPEC Guidelines

#### Under revision:

- 🌐 Co-processed Excipients
- 🌐 GMP Guide
- 🌐 PDA-IPEC TR on Formalized Risk Assessment
- 🌐 Excipient Information Package  
*inclusion of Sustainability chapter*
- 🌐 GDP Audit

#### Recently Published Guides and documents:

- 🌐 Excipient Composition Guide
- 🌐 IPEC-PQG Good Manufacturing Practices (French language)
- 🌐 Qualification of Excipients for Use in Pharmaceuticals
- 🌐 Excipient Stability Guide
- 🌐 GMP Certification Scheme and Certification Body Qualification Guide

### Position papers and documents

- 🌐 Good Manufacturing Practices for Atypical Actives
- 🌐 Data Integrity for Pharmaceutical Grade Excipients
- 🌐 Pharmaceutical Grades of Lactose used in oral preparations is a low-risk excipient
- 🌐 Use of industrial grade ingredients as excipients
- 🌐 Use of Artificial Intelligence (AI)

May 2026

May 2026

April 2026

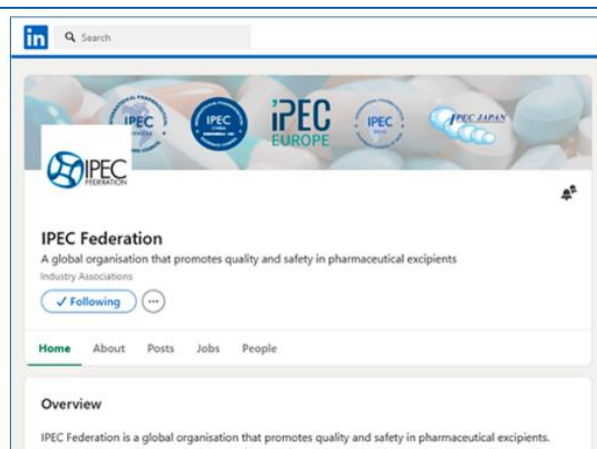
March 2026

March 2026

*IPEC members benefit from three months of exclusive access to newly published guides.*

**Follow  
IPEC Federation  
on LinkedIn** 

*Stay updated on news  
events and guidelines*



**The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl**

Rue Marie de Bourgogne 52 – 1000, Brussels, Belgium – [www.ipec-federation.org](http://www.ipec-federation.org) - +32 (0)2 213 74 40 – [info@ipec-federation.org](mailto:info@ipec-federation.org)

VAT: BE 0823931361 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region