IPEC Federation Connect

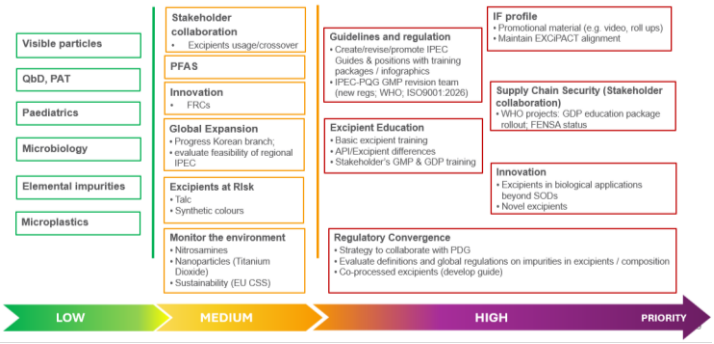
1 - 2026

Welcome

Dear Members and friends,
welcome to the first IPEC Federation Connect for 2026. This edition outlines our objectives for the year and provides updates from the five regional organisations.
Enjoy reading it, share it widely, and of course, we welcome your feedback and suggestions at info@ipec-federation.org.
IPEC Federation Secretariat

In this issue

Strategic Focus and Priority objectives for 2026



At the IPEC Federation members' meeting held on 3 February in Spain, accomplishments were reviewed and the work plan for 2026 developed. Highlights include:

- **Guidelines and Regulation:** Revision and creation of multiple IPEC Guides and positions with accompanying training packages is fundamental to our mission. With the proliferation of excipient GMP requirements, a Team will be established to ensure that the IPEC-PQG GMP Guide remains the leading document for excipient manufacturers and users.
- **Regulatory Convergence:** Dialogue with PDG continues on matters of common interest; excipient composition and impurities remain a focus area for further discussion. Work has started on developing a guideline on co-processed excipients, as regulatory perspectives have become clearer.
- **Innovation:** The evolving use of certain raw materials as *de facto* excipients is changing expectations. This raises the question whether our guides and positions are reflecting the needs of innovative uses of excipients in pharmaceutical development.
- **Supply Chain Security (Stakeholder collaboration):** the work with WHO, particularly to strengthen knowledge and education on securing excipient supply chains, continues. In parallel, the education package on GDP will be deployed.
- **IPEC Federation profile:** New promotional materials developed to support the Federation's brand.
- **Excipient education:** Developing an introduction to excipient training to increase the understanding of excipients among stakeholders, is only increasing in importance. Highlighting differences between API and excipients will be a key part of our message.

For questions, please get in touch with info@ipec-federation.org.

THANKS TO THE MANY IPEC MEMBERS WHO VOLUNTEER TO PARTICIPATE IN DELIVERING OUR OBJECTIVES!

IPEC Federation AGA 2026 - Torremolinos, Spain

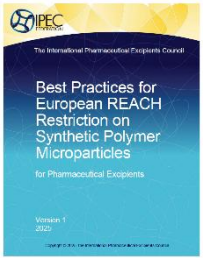
The IPEC Federation held its 2026 Annual General Assembly on 3 February.
Delegates representing the five IPEC regions met to review the association's activities and achievements in 2025 and to define strategic priorities and next steps for the coming years.

During the Assembly, elections were held for the Management Body for the 2026–2027 term.
The newly appointed officers are:
President: IPEC-Americas, Priscilla Zawislak
Vice-President: IPEC Europe, Kevin Hughes
Treasurer: IPEC Japan, Hiroshi Watanabe
Board Member: IPEC China, Cloris Tian
Meet the Board on our website.

In the picture, from left to right.
Standing: Takako Yoshihara (Higuchi/IPEC Japan), Prema Saldanha (IPEC India), Tsutomu Nakagawa (IPEC Japan), Yufan Zhao (IPEC China), Cloris Tian (Merck/IPEC China), Priscilla Zawislak (Roquette/IPEC-Americas), Janeen Skutnik-Wilkinson (Lilly/IPEC-Americas), Frank Milek (Hedinger/IPEC Europe); Dr. Ravleen Singh Khurana (Nitika/IPEC India), Kaushik Desai (IPEC India), Adrian Bone (IPEC Federation) and Dr. Sunil Bambarkar (Gattefossé/IPEC India).
Seated: Carole Capitaine (IPEC Federation Secretariat), Hiroshi Watanabe (IPEC Japan), Kevin Hughes (Colorcon/IPEC Europe), Dr. Ajit Singh (ACG/IPEC India).

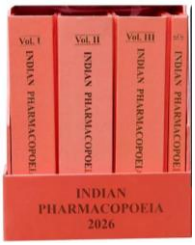
IPEC Best Practices on SPM restrictions - Guide and webinars

The IPEC Best Practices Guide for European REACH Restriction on Synthetic Polymer Microparticles (SPM) for Pharmaceutical Excipients was published in December 2025. It provides practical recommendations for makers and users, to prepare and share microparticle data needed to support potential excipient derogations under the European Union REACH SPM restriction. Read more.
The guide was presented at two webinars, one in the US by Meera Raghuram (Lubrizol) on 25 February, and also in Europe by Kevin Hughes (Colorcon) on 18 March.



IPEC India in the spotlight

by IPEC India – www.ipecindia.org



Regulatory Updates

The 10th Edition of the Indian Pharmacopoeia (IP 2026) was released on 2 January 2026 and will enter into force on 1 July 2026. This edition includes 18 General Chapters and 22 excipient monographs, harmonised based on PDG discussions. In addition, Dr. Rajeev Singh Raghuvanshi has been reappointed as Drugs Controller General of India (DCGI) for one year, effective 1 March 2026.

IPEC India activities

On 20 December 2025, IPEC India hosted scientific sessions on “Excipients as Enablers: Compliance, Safety and Innovation in Drug Development” at the 74th Indian Pharmaceutical Congress in Bangalore.

Updates from IPEC-Americas

by IPEC-Americas – www.ipecamericas.org

IPEC-Americas Latin America Working Group (LAWG) activities

In 2022, IPEC-Americas formed a Latin America Working Group to focus on trends in the LATAM region. The group recently published a position paper titled, “Clarification of Definitions and Non-Applicability Regarding the Regulations of Active Ingredients Classified as Atypical Actives”. The position paper “clarifies the definitions and non-applicability of CADIFA (Letter of Adequacy of the Active Pharmaceutical Ingredient Dossier defined by ANVISA) and CBPF (Good Manufacturing Practices (GMP) certification issued by ANVISA) regarding the regulation of excipients when used as Atypical Actives in Brazil.”

The paper is available in the Public Library of the IPEC-Americas website at www.ipecamericas.org. (registration required).
The group meets bi-monthly and new members are welcome to attend. If your company has operations in Latin America interested in participating, please notify IPEC-Americas: ipecamer@ipecamericas.org.

The goals of the working group are:

- Advocate, educate, contribute and develop best practices for excipients
- Encourage international standards and best practices for excipients to be adopted and recognised in the region
- Support the harmonisation of drug approval and pharmacopeial standards for excipients
- Address regional-specific hot topics and trends
- Offer training and share latest industry knowledge
- Facilitate and strengthen scientific and regulatory collaborations in the region (e.g. Sindusfarma, SAFYBI, and other trade associations)

IPEC Foundation Now Accepting Award Applications for 2026

The IPEC Foundation (the charitable arm of IPEC-Americas, a 501(c)3 organization) is now accepting applications for 2026.

The drugs of tomorrow cannot be developed with yesterday’s excipients and processes. Energise research in excipients through the IPEC Foundation.
By supporting research, education, and safety through programs and scholarships, our partners and donors can shape the future of excipients. Apply or nominate someone soon.

Deadline: June 15, 2026.
Visit www.ipecfoundation.org to learn more.

Highlights from IPEC Japan

by IPEC Japan - www.ipec.gr.jp

Pharmaceutical Excipients Self-Imposed GMP Standard 2025 Japan Version Explanatory Seminar

The IPEC Japan GMP Committee has finalised the "Pharmaceutical Excipients Self-Imposed GMP Standard 2025 version", updating the 2016 edition. This revision aligns with the latest IPEC-PQG GMP Guide (2022).

To introduce the updated standard, the GMP Committee held an explanatory seminar on 18 November 2025, attended by approximately 70 participants from both member and non-member companies. The seminar featured an active Q&A session, allowing participants to deepen their understanding of the revised GMP requirements.

Following the seminar, the GMP Committee has begun preparing a Guidebook to support implementation of the 2025 GMP Standard.

Annual Pharmaceutical Excipients Seminar held in Tokyo

On 20 February, the IPEC Japan Annual Pharmaceutical Excipients Seminar was held at Rengo Kaikan, attracting over 170 participants.
A cross-sector review highlights recent regulatory updates from MHLW and PMDA, emerging academic research from Hoshi University and Tokushima University, and industry initiatives addressing excipient quality and nitrosamine control from Sawai Pharmaceutical, Santen Pharmaceutical, and Towa Pharmaceutical.
Following the presentations, a business card exchange session provided participants with an opportunity to network and share insights.

CPHI Japan in April

IPEC Japan will be exhibiting at CPHI Japan, held in Tokyo on 21-23 April 2026.
Meet IPEC Japan representatives at booth 1J-29, category Ingredients - Japan Pharmaceutical Excipients Council Pavilion. Learn more at https://www.cphi.com/japan/.

IPEC China in the spotlight

by IPEC China – http://ipec.tb21.cn/

Release of the IPEC China 2025 Annual Report

IPEC China has summarised 2025 activities in its Annual Report, which has been shared with members and stakeholders. The report highlights the work of four sub-committees - Regulatory Affairs, Pharmacopeia, GMP, and Industry Liaison - as well as task forces covering China Excipient GMP / IPEC PQG GMP comparison, ICH Q3C and Q3D, and microbial risk assessment and control for

excipients. IPEC China experts also participated in multiple industry events, addressing regulatory and quality issues such as the newly effective China Excipient GMP and ChP 2025 implementation for excipients. The organisation continues to provide a platform for members to exchange best practices, discuss challenges, and explore solutions. Sincere gratitude is extended to the volunteers who actively contributed to all IPEC China activities.

Translation of China Excipient GMP and the IPEC-PQG GMP Guide Q&A

The Chinese translation and proofreading of this document have been completed and shared with the IPEC Federation, IPEC China members, and stakeholders. This effort helps member companies better understand and implement the requirements of the China Excipient GMP, supporting effective compliance and risk management.

Feedback on ICH Q3C-related regulatory requirement on excipient

Following the release of the Draft for Common Issues on Risk Assessment and Control of Residual Solvents in Chemical Drugs (Draft for Public Comment) by the Center for Drug Evaluation (CDE), NMPA, on 26 January 2026, the IPEC China Regulatory Affairs Subcommittee organised an online discussion with members. Based on industry practices, the committee compiled formal feedback and officially submitted a response letter, helping shape regulatory implementation and industry alignment.

IPEC China at IPEC Europe Forum

On 5 February, Cloris Tian, Chair, presented on China's new Excipient GMP at the IPEC Europe Forum.

Updates from IPEC Europe

by IPEC Europe – www.ipec-europe.org

A new strategy for IPEC Europe: Agenda 2030

IPEC Europe's Agenda 2030 was unveiled at the association's Annual General Meeting on 4 February, the overarching goal being recognition as the 'go-to partner' for excipients with European stakeholders. Objectives have been structured in four pillars:

Pillar 1 – Innovation - *Provide essential resources to advance excipient use across all applications.*
Pillar 2 – Impact - *Strengthen and grow our stakeholder network.*
Pillar 3 - Added-value - *Quantify the importance of excipients in the pharmaceutical value chain.*
Pillar 4 – Knowledge - *Drive education and engagement within the excipient community.*

IPEC Europe Excipients Forum 2026

The IPEC Europe Excipients Forum held on 5 February focused on regulatory convergence and the evolving role of excipients within a complex global framework.

Preceded on 4 February by Committee meetings and the Annual General Meeting of the association, the IPEC Europe Forum opened with a welcome address from Chair Karine Roth who introduced Agenda 2030 and its four pillars.

The morning featured key regulatory updates, beginning with EDQM Director Dr Petra Doerr, who outlined developments within the European Pharmacopoeia, including the launch of a new Environmental Sustainability Working Party, revised pharmaceutical water texts, and progress toward a dedicated CEP for excipients. A presentation was then delivered by I. Tasevska, a member of European Medicines Agency's Quality Working Party, on the EMA Q&A for co-processed excipients, effective from August 2026.

Global perspectives followed, with insights into China's newly implemented mandatory GMP framework for excipients and WHO's efforts to combat substandard and falsified medical products through a revised Certification Scheme covering APIs and high-risk excipients.
The afternoon panel explored regulatory divergence, sustainability pressures, excipient substitution risks, and supply continuity challenges. The programme concluded with a dual user/maker presentation on practical perspectives on change management, and a forward-looking session on pharmaceutical 3D printing and personalised medicine.

Recent events and conferences

In addition to the IPEC Europe Forum in February, IPEC Europe continues its efforts to engage with regulators and other industry associations, contributing to leading events across Europe - this includes attendance at Making Pharma Spain (February) and Making Pharmaceuticals (April).
IPEC Europe hosted a 'Question Time' on the EMA Q&A on co-processed excipients in oral solid dosage forms. This new format provides members with the opportunity to ask questions and exchange experiences with experts and fellow members on 'hot' topics. The IPEC Europe Excipients Conference 2026 will be hosted in Prague, Czechia on 22-23 September, covering aspects such as bioburden in excipients, innovative drug delivery systems, and updates from pharmacopoeias. The Conference features three workshops, each repeated twice.
Registrations are now open, with early bird rates available until 30 June.

Document revision plans for 2026

IPEC Guidelines

Planned for revision:

- Co-processed Excipients
- GMP Audit

Under revision:

- PDA-IPEC TR on Formalized Risk Assessment
- Excipient Information Package
  User Guide & Templates ; incl. Sustainability chapter
- Excipient Composition
- GDP Audit

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)

The IPEC Stability guide, IPEC GMP Certification Scheme and CB Qualification guide, and Qualification of Excipients guide are pending final approval and will be made available to members soonest.

Recently Published Guides and documents:

Best Practices for European REACH Restriction on Synthetic Polymer Microparticles (SPM) for Pharmaceutical Excipients	December 2025
Questionnaire for Excipient Nitrosamines Risk Evaluation	October 2025
Position on Pharmaceutical Excipients GMP documents	July 2025