IPEC Federation Connect

3 - 2025

Welcome to the third and final edition of IPEC Federation Connect for 2025.
In this edition, we share updates on the latest publications, insights from recent events and workshops, and news from the regional IPECs. We hope you enjoy the read. Please feel free to share this bulletin widely, and as always, we welcome your feedback and suggestions at info@ipec-federation.org.
On behalf of the IPEC Federation Board, we share a 'thank you' to all the key contributors who dedicate their time, expertise, and commitment to developing and contributing to IPEC guidelines and documents. The revision and updating of our guidelines and documents would not be possible without the time and commitment of our volunteers.
Season's Greetings and Happy New Year! - IPEC Federation Secretariat

In this issue

IPEC Federation Members Meeting and AGA February 2026

The IPEC Federation will hold its first face-to-face Members' meeting followed by its Annual General Assembly (AGA) in Torremolinos, Spain, on Tuesday, 3 February 2026.
This first face-to-face meeting of the year will also feature a Members' Meeting with updates from each region. IPEC Federation will take this opportunity to review 2025 achievements and set the strategic direction for 2026. A summary of the discussions and outcomes will be included in the first issue of our 2026 bulletin.

Updated: IPEC Questionnaire on Nitrosamines Webinar

The 2025 revision programme has delivered a new version of the IPEC Questionnaire for the Risk Evaluation of Nitrosamines in Excipients. This tool assists excipient manufacturers in collecting data in a standardised format to support drug product manufacturers in assessing the risk of nitrosamine impurities. First issued in 2023, the IPEC Questionnaire has been updated to reflect recent scientific developments, revised authority guidelines, and growing expectations from MAHs (Marketing Authorisation Holders).
The IPEC Questionnaire is available on the IPEC website. A webinar on 12 November, led by U. Reichert (IPEC Europe, Merck KGaA) and J. Nette (IPEC-Americas, Perrigo), drew more than 100 participants from across the five IPECs and beyond. The high volume of questions made it clear that this topic remains very current.

IPEC Federation-PDG Board/Members meeting Tokyo - October

IPEC Federation met PDG representatives at PMDA in Tokyo on 1 October to review progress on the PDG workplan and the proposed revision of the Polysorbate 20 monograph. PDG also outlined South Korea's next step: the Korean Pharmacopoeia will enter the Observing Phase as it prepares to adopt PDG-harmonised texts, strengthening the group's global reach.

Priscilla Zawislak presented IPEC's proposal on excipient nomenclature and composition, prompting a constructive exchange on how pharmacopoeial standards can better account for excipient-specific needs. The meeting confirmed strong momentum between IPEC and PDG (i.e. Polysorbate 20), with both sides keen to continue joint work on monographs and excipient standards.

IPEC Federation also held its second Members' meeting and a Board meeting in Tokyo to advance the 2025 strategy and set priorities for 2026.

IPEC China Excipient Conference 2025 November – Chongqing

The IPEC China Annual Conference 2025 brought together pharma and excipients experts in Chongqing, China on 12 and 13 November. The annual conference welcomed delegates and speakers from authorities including WHO and EDQM, Drug Control Institutes in China. IPEC Federation was also present at this important gathering, providing insights on matters such as supply chain security, excipient registration requirements in Japan, and excipient stability with Frank Milek (Hedinger/IPEC Federation Past President), Hiroshi Watanabe (IPEC Japan/IPEC Federation Treasurer) and Adrian Bone (IPEC Federation Executive Secretary) attending. Congratulations to IPEC China for this great event!

Visit this page with a summary and video clips of the event.

IPEC Federation meets with regulators

In recent months, IPEC Federation leaders have significantly increased their engagement with authorities worldwide. On 20 August, Frank Milek (Hedinger, former IPEC Federation President) and Morad Amadji (Sanofi, EXCiPACT President) met the Shanghai MPA in Paris to introduce IPEC Federation and EXCiPACT and discuss topics of mutual interest, including support for manufacturers preparing for China's new excipient GMP requirements.

This outreach continued in Asia. Priscilla Zawislak (IPEC Federation Vice President, Roquette, IPEC-Americas) contributed to a BADAN POM and WHO excipient GMP workshop on 31 July and 1 August, followed by presentations from IPEC Federation President Kevin Hughes (Colorcon, IPEC Europe) on implementing excipient GMP at an ISPE Indonesia workshop on 21 October.

On 27 October, IPEC Europe hosted the Shanghai Centre of Drug Evaluation and Inspection (SCDEI). The meeting focused on IPEC Federation's GxP guidance and its relevance to China's upcoming excipient GMP regulations, with EXCiPACT also participating.

IPEC Federation at ICH

Janeen Skutnik-Wilkinson (Lilly/IPEC-Americas) and Priscilla Zawislak (Roquette/IPEC-Americas) attended the latest ICH meetings on behalf of IPEC Federation in Singapore in mid-November. The Assembly welcomed authorities from Nigeria and South Africa as Full Members, and authorities from Philippines and Dominican Republic as new Observers, expanding ICH's global representation to 25 Members and 41 Observers.

Updates were provided on ongoing projects, including MedDRA developments, operational improvements, and the implementation of AI and digitalisation in guideline processes.

Progress was reported across several working groups, covering topics such as Q1 Stability (Priscilla is IPEC's representative), Q6(R1) Specifications, M13 Bioequivalence, M15 Model-Informed Drug Development, and S13 Non-clinical Safety of Oligonucleotide-based Therapeutics. Draft guidelines and training materials are being developed, with many groups targeting milestone completions between 2026 and 2030. For the M7 addendum on 'Risk Assessment and Control of Nitrosamine Impurities', in which Ulrich Reichert (Merck Life Science KGaA/IPEC Europe) represents IPEC Federation, Step 2 is scheduled for August 2028.

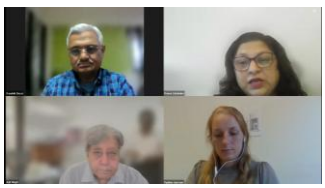
The Assembly also elected new leadership, emphasised the need for enhanced efficiency and secure digital platforms for collaboration, and recognised strong engagement from members and observers in advancing global regulatory harmonisation. The next ICH meeting is planned in early June 2026 in Rio de Janeiro, Brazil.

What's new at IPEC India

by IPEC India

Regulatory developments - On 10–11 October 2025, Dr. Ravleen Singh Khurana, Vishakha Metkar, and Kaushik Desai attended an informal meeting with Dr. A. Ramkishan, Deputy Drugs Controller (CDSCO), at FDA Bhavan in Delhi to discuss the regulation of excipients considering the recent cough syrup tragedy. A draft GMP guideline for excipients was developed and subsequently presented to stakeholders, including manufacturers, distributors, and importers, on 3 November. Dr. Ramkishan, supported by Mr. D. R. Gahane, Maharashtra State Drug Controller and Western Zone Deputy Drugs Controller (CDSCO), outlined the proposed requirements. Stakeholders provided constructive feedback, which was positively received, and several concerns related to imports were also addressed. Notable events recently organised by IPEC India include:

A webinar on Microplastics Regulation, held with DFE Pharma and presented by Dr. Pauline van der Wijst – Janssen on 19 August. Key points included definitions of microplastics, differences in biodegradability testing, variation in polymer chemistries despite identical CAS numbers, and the idea of creating an open-access biodegradability repository. The session concluded with an active Q&A.



IPEC India facilitated the organisation of an Auditor Training Course for EXCiPACT on 7-8 October. The following day, on 9 October, a Seminar on Peptide Delivery was held in which Dr. Alexandre Gil (Gattefossé) discussed the increasing role of lipid-based excipients in improving solubility, absorption, GI stability, and paracellular transport for peptide drugs.

For information on IPEC India activities, please get in touch with admin@ipecindia.org.

IPEC Japan in the spotlight

by IPEC Japan

IPEC Japan organized the IPEC Federation Excipients Workshop in Tokyo on October 2 at Bellesalle Kudan, adjacent to the IPEC Japan office, coinciding with the PDG/IPEC Federation meeting held in the city. Attendance was limited to IPEC Japan members and IPEC Federation guests, and the workshop welcomed approximately 70 participants. The workshop covered topics including Nitrosamines and Excipients Update, Change Control, the Stability Study Guideline, as well as excipient-related updates from China and India. Simultaneous translation was provided to support active discussion and enhance participant engagement. Read more.

In addition, the IPEC Japan GMP Committee has finalized the Pharmaceutical Excipients Self-Imposed GMP Guide 2025 (Japan Version), revised from the 2016 edition and aligned with the IPEC/PQG Joint Pharmaceutical Excipients GMP Guide 2022. An explanatory seminar was held on 18 November 2025, with around 90 attendees from both member and non-member organizations, and a robust Q&A session helped participants to gain a deeper understanding of the updated GMP guide.

For more information, please contact IPEC Japan at office@jpec.gr.jp

Highlights from IPEC China

by IPEC China

On 3 September, a joint EXCIPACT–IPEC China–SPPEA workshop was held in Nanjing, bringing together approximately 60 participants for an in-depth discussion on excipient GMP and risk assessment. The event facilitated active dialogue and strengthened the understanding of best practices across the industry.

On 16 October, IPEC China participated in CPEC, organized by the regulatory authority CCFDIE. IPEC China speakers delivered presentations on excipient-related topics, including risk assessment and ICH Q3D & Q3C considerations for excipients. The conference attracted an audience of more than 500 attendees.

On 7 November, IPEC China organized a visit to the Shanghai Drug Evaluation & Inspection Center, and on 11 November, IPEC China organized a closed door meeting with Chongqing MPA prior to the IPEC China Excipient Conference. Representatives discussed implementation-related questions on China's excipient GMP raised by IPEC China members Representatives discussed implementation-related questions on China's excipient GMP raised by IPEC China members. Risk-based approach for evaluating and addressing these inquiries reached a constructive consensus.

For more details, please get in touch with IPEC China at info@ipec-china.org.

CPHI Frankfurt - Panel on Sustained availability of excipients

by IPEC Europe

IPEC Europe, IPEC-Americas and EXCiPACT representatives discussed the "Challenges to the Sustained Availability of Excipients" during a panel session at CPhI Worldwide in Frankfurt on 29 October. The session highlighted how evolving regulations, cross-sector restrictions, and increasing sustainability demands are impacting excipient availability. Speakers explored the need for novel excipients, the impact of legislative changes such as limitations on recycled plastics, and best practices for strengthening supply chain resilience. They also examined how greener production methods can be incorporated without compromising quality or performance.

Felicity Thomas (The Pharma Navigator) moderated the discussion, drawing sharp insights from a panel of experts: Iain Moore (EXCiPACT asbl), Nigel Langley (gChem, IPEC-Americas), Robert Williams (PSCI), and Bram Baert (Lonza Capsules & Health Ingredients, IPEC Europe).

Updates from IPEC Europe

by IPEC Europe

After the organisation of 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.

In September, IPEC Europe held its Excipient Conference in Heidelberg and co-organised the Lhasa Limited-IPEC Europe Nitrite meeting in October – see the dedicated articles.

In October, IPEC Europe attended the A3P Conference, and welcomed a delegation from the Shanghai Centre for Drug Evaluation and Inspection (SCDEI) in the Brussels office.

IPEC Europe also organised a webinar on 'Securing the Supply Chain' – Rodrigo Arias (DFE Pharma) presented how implementing the IPEC GDP Guide can help prevent contamination risks and strengthen confidence in the global pharmaceutical (excipient) supply chain.

Regular catches-up with Members were also organised in September and December.

For information on IPEC Europe activities, please get in touch with info@ipec-europe.org

Lhasa Limited & IPEC Europe

Nitrites collaborative meeting

More than 100 participants online and in Leeds attended the second Nitrites meeting organised by Lhasa Limited and IPEC Europe. Over the two half-days of insightful discussions, attendees explored practical approaches to nitrite risk mitigation and shared their experiences in excipient analytical testing.

IPEC Europe Excipient Conference September - Heidelberg, Germany

by IPEC Europe

The IPEC Europe Excipient Conference 2025 was held in Heidelberg on 25–26 September, bringing together about 95 participants for two days of regulatory updates, technical insights, and industry discussion. The programme opened with an overview of IPEC Federation's mission and activities, followed by presentations on supplier qualification, China's new excipient GMP requirements effective in 2026, and inspectors' perspectives on risk assessment, quality agreements, and change control. Afternoon workshops explored the EXCiPACT certification, nitrite detection methods in the context of nitrosamine risks, and regulatory expectations for synthetic polymer microparticles (microplastics). Day 1 concluded with a guided tour of Heidelberg's Old Town and a networking dinner.

On Day 2, EDQM and USP shared updates on excipient monographs, impurity control, microbiological standards, and new polymer monographs. EXCiPACT outlined the value of its independent GMP/GDP certification scheme, while further presentations addressed the environmental biodegradability of polymeric excipients, advancements in lipid-based delivery systems, and Laxxon's 3D screen-printing technology enabling customised tablet structures and release profiles.

The next edition of the Conference will be held in Prague, Czechia in September 2026. Save the Date!

IPEC EUROPE Excipients Forum 2026

REGISTER NOW!

5 February 2026

IPEC Europe Excipients Forum 2026

Melia Costa del Sol Hotel, Torremolinos, Spain

Featuring regulators and industry speakers, the IPEC Europe Excipients Forum 2026 is a great opportunity to learn more about the latest developments on pharmaceutical excipients. Many 'hot' topics impacting the excipient world will be covered, where the best practices and insights shared can help your company adapt to current and future challenges. Sister associations can benefit from the 'IPEC Europe Members' rate.

Register now.

News from IPEC-Americas

by IPEC-Americas

IPEC-Americas LATAM Working Group Activities

In 2022, IPEC-Americas formed a Latin America Working Group to focus on trending topics in the LATAM region. During September, the group held a virtual seminar which took place over three consecutive days. The webinar series, presented in Spanish, introduced and explored IPEC's most relevant guides for excipient control and lifecycle management. The sessions discussed excipient quality—from foundational elements to supplier interactions and ongoing compliance with over 70 attendees in attendance.

The recording is available and there is no charge to access it. If you have operations in the LATAM region, view the recording to learn how IPEC guidelines can help ensure consistent, compliant, and collaborative practices across the excipient supply chain. Understanding these principles is essential to protecting product quality and reducing regulatory risk whether you're a user or a manufacturer.

Learn More – Free Recording

IPEC-Americas International Journal of Pharmaceutical Excipients

IPEC-Americas sponsors and publishes a peer-reviewed quarterly journal related exclusively to excipients entitled “The International Journal of Pharmaceutical Excipients”. The Journal publishes original research manuscripts, opinion and commentary, as well as technical notes on topics of interest to the excipient pharmaceutical industry.

The open access journal is indexed in major scientific databases. It provides an opportunity for the excipient industry to disseminate information and opinion through a well-defined peer reviewed scientific model and has a significantly large audience.

Submissions to the journal, review and publication are online via the Scholastica platform.

The Journal accepts ongoing submissions and there are no fees for the authors. This is an opportunity for academics, industry researchers and formulators and regulators to publish their research related to excipients as well as their opinions about regulatory and formulation matters concerning these materials.

Take this opportunity to get recognized for your excipient related research. Submit an Abstract here

For more information on IPEC-Americas activities, please contact ipecamer@ipecamericas.org

Work Plan for IPEC Guides and Positions

IPEC Guidelines

Revision is ongoing for:

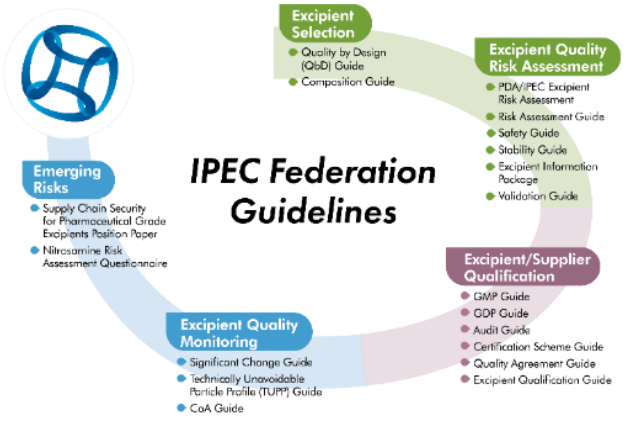
- Excipient Composition
- GMP CS and CB Qualification
- Qualification of Excipients
- Excipient Information Package *(Guide-Templates)*
- GMP Audit
- GDP Audit
- Stability
- IPEC-PDA TR 54-6

Position papers and documents

- Good Manufacturing Practices for Atypical Actives
- Data Integrity for Pharmaceutical Grade Excipients
- Excipient Impurities
- Pharmacopeial Convergence
- Excipients used in Biologicals
- REACH Restrictions on SPM (microparticles)

Recently Published Guides and documents:

Questionnaire Excipient Nitrosamines Risk Assessment	October 2025	Available on the website
Paper on Pharmaceutical Excipients GMP Reference Documents	July 2025	Available on the website
Risk Assessment Guide	May 2025	Available on the website



Download our guidelines and papers

FREE TO DOWNLOAD!

Visit ipec-federation.org

Season’s greetings and happy new year!

ACT NOW

Early registration rates available through January 15, 2026

IPEC Federation newsletter subscribers save an ADDITIONAL $100 with code IPEC100

EXCIPIENTS
The Heartbeat of Pharm Country
Powering Science, Drug Formulation, and Patient Safety

IPEC-AMERICAS

EXCIPIENT WORLD

2026

MAY 4-6

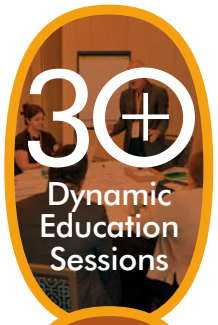
NASHVILLE

HARMONIZE in MUSIC CITY

from leading companies, universities, and regulatory bodies

CELEBRATING IPEC AMERICAS 35 YEARS STRONG

showcasing breakthrough studies and emerging data



covering the latest in formulation science, R&D, quality assurance, and regulatory trends

GAYLORD OPRYLAND RESORT & CONVENTION CENTER
Nasvhille TN

Otilia Koo, PhD, FAAPS
Portfolio Vice President, Novo Nordisk
AAPS President-elect and Fellow

INTERNATIONAL PHARMACEUTICAL IPEC AMERICAS EXCIPIENTS COUNCIL

Conference: May 4-6 | Expo: May 5-6

find out more and register at

ExcipientWorld.org

INFO @