# IPEC Federation Connect

2 - 2025

Welcome to the second issue of the year of IPEC Federation Connect.
In this edition, we provide updates from the latest publications, our participation in events and workshops, and news from the regional IPECs.
Please enjoy reading it, share the bulletin widely, and of course, your feedback and suggestions are always welcome at info@ipec-federation.org.
IPEC Federation Secretariat

## In this issue



## IPEC Statement on WHO-UNODC Report on Contaminated Medicines

IPEC Federation welcomes the joint report published by the World Health Organization and the United Nations Office on Drugs and Crime (UNODC) to which it contributed through its member associations.
IPEC Federation supports WHO and UNODC's call for stronger regulatory oversight, enhanced quality assurance, and improved transparency and traceability across the pharmaceutical supply chain, including excipients. IPEC Federation remains committed to working closely with WHO, regulators, and stakeholders safeguarding the use of excipients in medicines.
The full statement is available on our website.

## IPEC Guides: updated Risk Assessment Guide

Following the issue of new revisions of the Quality-by-Design guide, the 2025 programme has delivered the IPEC Risk Assessment Guide for pharmaceutical excipients – Risk Assessment for excipient manufacturers.
The IPEC Risk Assessment Guide helps excipient manufacturers, distributors, and users evaluate and manage quality risks consistently. It explains key methodologies and tools for identifying and mitigating risks and supports the application of the risk principles referenced in the IPEC-PQG GMP and IPEC GDP Guides.
The IPEC Risk Assessment Guide is available on IPEC websites.

The revision and updating of our guidelines would not be possible without the time and commitment of our volunteers. We extend a special 'thank you' to the key contributors whose expertise has been vital in delivering this important document.
*Did you know? You can find the list of contributors in the section 'Acknowledgements' of our guides.*

## IPEC Federation meeting with PDG in Tokyo

IPEC Federation will be meeting PDG representatives, at PMDA's headquarters in Tokyo, Japan in the afternoon of 1 October 2025. This yearly meeting is an important opportunity to learn more on the PDG workplan and its progress, discuss IPEC's proposals on harmonisation topics, and for example, the latest developments on DEG-EG issues.

The Federation will also organise its Board meeting on 30 September, and the second members' meeting of year on 1-2 October to monitor progress on the 2025 strategy and prepare priorities for 2026.

The meetings will be followed by a workshop organised by IPEC Japan on the afternoon of 2 October.

## IPEC India Annual Conference 2025 25 July – Mumbai


The IPEC India Annual Conference 2025 brought together more than 230 pharma and excipients experts in Mumbai, India on Friday 25 July. Under the theme 'Quality Excipients: The Foundation for Formulation Excellence' Mr. D. R. Gahane, Drug Controller, FDA Maharashtra, graced the occasion as the Guest of Honour. Ajit Singh, Chairman of IPEC India, opened the conference with welcome remarks. As President of the IPEC Federation, Kevin Hughes served also as Guest of Honour and addressed participants on global excipient challenges from new regulations, rising quality expectations, and social trends. The conference was an excellent platform for excipient and pharma professionals to engage with each other and share knowledge.

## Meetings with USP, Indonesia FDA

IPEC Federation Board members have been representing the IPEC Federation in interactions with several authorities over the past months. On 5–8 May, IPEC Federation President Kevin Hughes attended the U.S. Pharmacopeial Convention as the Federation's official representative, together with over 450 organisations to contribute to discussions on USP's strategic vision and the future of excipient standards.

On 31 July, IPEC Federation Vice President Priscilla Zawislak represented both IPEC Federation and EXCiPACT at a workshop organised by the Indonesian FDA in cooperation (BPOM) with WHO Indonesia on the topic of Good Manufacturing and Distribution Practices for pharmaceutical excipients. The presentation, 'Quality Assurance in GMP Implementation and Certification Mechanism for Pharmaceutical Excipient Manufacturers' covered aspects related to supply chain such as risks and risk assessments, qualification and integrity.

## IPEC Federation at ICH

Janeen Skutnik-Wilkinson and Ulrich Reichert attended ICH meetings on behalf of IPEC Federation in Madrid in mid-May. The Assembly welcomed authorities from Paraguay, Kuwait and El Salvador as new Observers, expanding ICH's global representation to 23 Members and 41 Observers.

The Assembly approved four new topics for future harmonisation efforts, including guidelines on using real-world evidence in regulatory decisions, the utility of comparative efficacy studies in biosimilar development, and manufacturing changes in advanced therapy medicinal products. Progress was reported on several ongoing projects, including the adoption of the revised ICH E6(R3) Guideline on GCP. Several draft guidelines were endorsed, covering diverse areas such as stability testing of drugs, updates to the CTD, and bioequivalence waivers. IPEC Federation is a member of ICH Q1 Working Group which did not meet in

Madrid. However, a draft Q1 Stability Guideline was shared for public consultation over the summer, on which IPEC Federation submitted comments.

## What's new at IPEC India

Kaushik Desai, Secretary General of IPEC India, has been appointed as a member of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) for the 2025–2027 term.
The Government of India has extended Dr. Rajeev Singh Raghuvanshi's tenure as Drug Controller General of India (DCGI) by one year.
Dr. V. Kalaiselvan was appointed as the Secretary-cum-Scientific Director of the Indian Pharmacopoeia Commission (IPC) on June 25, 2025. Kaushik Desai and Ms. Vishakha Metkar represents IPEC India in the Excipients Working Group of Indian Pharmacopoeia Commission.
In parallel, the Indian Pharmacopoeia (IP) has been now recognised by Fiji and Cuba Government in addition to Afghanistan, Ghana, Nepal, Mauritius, Suriname, Nicaragua and Sri Lanka.

## IPEC Japan in the spotlight

*by IPEC Japan*

IPEC Japan exhibited at CPhI Japan on 9-11 April, as hosts of the Excipient Pavilion. Eight excipient manufacturers and importers displayed at the Pavilion, including Asahi Kasei,

San Eigen, Shima Trading, Daido Chemical, DFE Pharma, Nikko Chemicals, Nippon Soda and Shin-Etsu Chemical.
During the exhibition, IPEC Japan publications and IPEC Federation documents and Guidelines were made available.
200 attendees joined the in-person seminar held by Tsutomu Nakagawa, Managing Director of IPEC Japan, titled "Revised Self-Imposed Excipient GMP guideline".

## Highlights from IPEC China

*by IPEC China*

In January 2025, China NMPA issued Excipient and Packaging Material GMP as Annexes to GMP for drug products. The new GMP requirements will be mandatory and will be effective from 1 January 2026.IPEC China translated the notice and Excipient GMP; in March, IPEC China organized a task force with 14 volunteers to compare China IPEC-PQG GMP Guide. At end of May, the task force completed the comparison and shared the Bilingual Comparison Table - China Excipient GMP (2025) vs. IPEC PQG GMP (2022), later made available to all IPEC members.


On April 22, 2025, IPEC China organized an "Excipients GMP Technical Exchange Salon" at the Ashland Shanghai office. The meeting focused on the newly issued China Excipient GMP, to initiate discussions and practice sharing from maker and user perspectives. Over 50 members attended to learn and share to approach the coming regulatory challenges.

On May 29, the IPEC Japan Board meeting was held online. The Agenda activities and financial results of 2024, financial plan of 2025, and a report of current and future activities of the IPEC Japan office in preparation of the Annual General assembly, held on 20 June at the Bellesalle Kudan.

80 participants with voting power were in attendance; the Agenda included activities and financial result of 2024, candidates of directors/auditors and activities and financial plan of 2025. After the AGA, 50 people attended the social gathering.

In July, the popular Excipient Introductory webinar was held with more than 100 participants.
Lectures included General Introduction to excipients, Binders, Disintegrants and Coatings, Lubricant in the dosage formulation, Design of dosage forms by machines and excipients, and Excipients used in the pharmaceuticals and its Regulations.

In May and June, IPEC China forums were held during the API and CPHI exhibitions in Guangzhou and Shanghai respectively, more than 150 participants attended the events.

IPEC China supported, along with SPPEA, a GMP and Risk Assessment Training hosted by EXCiPACT in Nanjing on 3 September.


To conclude the year, the 9th IPEC Excipient Conference will be held on 12th -13th November at the Chongqing International Exhibition Center. With great support from IPEC Federation and sister associations, this Conference will bring international speakers as well as China experts to cover hot regulatory topics, helping excipient users and makers face ever growing stringent regulatory challenges in China and global markets. For more details about this Conference, please contact IPEC China at info@ipec-china.org.

IPEC China also recently published Chinese translations of the IPEC Significant Change guide (version 5, 2023) and of the IPEC-PQG GMP Guide (version 5, 2022) for its Members.

## 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 late March, we presented at the European Conference on Pharmaceutics in Porto, Portugal on the importance of the correct grade of excipients for pharmaceutical drug products.

On 8-9 April, IPEC Europe presented the views on co-processed excipients from regulatory and industrial perspectives at the 6th APV Continuous Manufacturing Conference hosted in Basel, Switzerland.



Later in April, we exhibited and presented at Making Pharmaceuticals in Coventry, UK with a workshop and a presentation on the IPEC GDP Guide, and a presentation on nanomaterials and excipients.
On 11-13 June, we engaged with Italian regulators and experts at the renowned Simposio AFI, where we delivered a presentation on the importance of formalized risk assessment to secure the excipient supply chain.
On 26 June, IPEC Europe attended the workshop on CEP for Excipients organised by EDQM in Strasbourg, France, presenting the association's views and engaging with EDQM and other stakeholders.
In July, IPEC Europe Board members and staff were invited by Novo Nordisk who hosted the Board meeting at its facilities.

Over the summer months, IPEC Europe has also published surveys of which one aimed at gathering information on testing methods for DEG-EG on high-risk excipients.
Coming up, the IPEC Europe Conference in September, and participation in events such as the LHASA-IPEC Europe Nitrite meeting, CPHI Worldwide, and the A3P Conference in October.

## IPEC Europe Excipient Conference 25-26 September - Heidelberg, Germany


Join experts from the pharmaceutical industry, academics, authorities as well as with manufacturer and distributors of pharmaceutical excipients, at the IPEC Europe Excipient Conference on pharmaceutical excipients taking place on 25-26 September 2025 in Heidelberg, Germany.
The conference will be held on two days (Thursday 25 – Friday 26 September) and will focus on regulatory topics relating to pharmaceutical excipients and technology.
Three regulatory workshops aim to provide detailed practical information on current topics, and will be held twice and in parallel, covering topics such as how to get EXCiPACT Certification, Microplastics and Methods to evaluate nitrite levels in pharmaceutical excipients.
IPEC Europe

IPEC-AMERICAS EXCIPIENT WORLD 2026 NASHVILLE

**SAVE THE DATE!** 4-6 May 2026
## Excipient World 2026
**Harmonize in Music City**
*Gaylord Opryland Resort & Convention Center*
*Nashville, Tennessee*
Submit your abstract by 26 September 2025.

# IPEC Foundation Announces 2025 Award Winners

The IPEC Foundation is pleased to announce the 2025 award winners. The winners will be recognized during the IPEC Foundation's annual awards ceremony that will take place Tuesday, November 11 at the Grand Hyatt, San Antonio, Texas.
Congratulations to the award winners for their efforts and contributions to the field of excipients!

**Ralph Shangraw Memorial Award** for individuals who have provided outstanding research contributions in the study of excipients or excipient-related technology: **Dr. Paul Heng, National University of Singapore**

**Henk de Jong Industrial Research Award** recognizes individuals working in an industrial setting who have made significant contributions in the field of excipient technology: **Dr. Örn Almarsson, AXELYF**

**Patrick DeLuca Emerging Researcher Award** recognizes a beginning career scientist (post Ph.D.) who has demonstrated interest and dedication to the area of excipients: **Dr. Khanh Tran, Massachusetts Institute of Technology (MIT)**

**Graduate Student Award Winners:**

**Ms. Yijing Huang, Purdue University**
**Mr. Chanakya Patil, Purdue University**
**Mr. Tianyi Xiang, University of Minnesota**
**Mr. Nileshkumar Malavia, UCONN**
**Mr. Vishvesh Raje, St. John's University**

IPEC-Americas helps shape the future of medicines by energizing research in excipients through education and scholarship.

# Work Plan for IPEC Guides and Positions

## IPEC Guidelines

- Co-processed Excipients

Revision is ongoing for:

- Excipient Composition
- GMP CS and CB Qualification
- Qualification of Excipients
- Excipient Information Package
  *User Guide & Templates*
- GMP Audit
- GDP Audit
- Stability

## Position papers and documents

- Good Manufacturing Practices for Atypical Actives
- Data Integrity for Pharmaceutical Grade Excipients
- Excipient Impurities
- Pharmacopeial Convergence
- Excipients used in Biologicals
- IPEC-PDA TR 54-6

## Recently Published Guides and documents:

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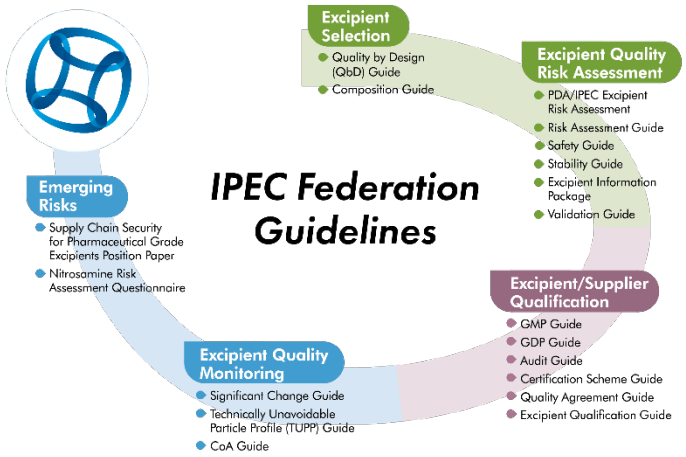
|---|---|---|
| Paper on Pharmaceutical Excipients GMP Reference Documents | July 2025 | Available on the website |
| Risk Assessment Guide | May 2025 | Available on the website |
| Quality-by-Design Guide | February 2025 | Available on the website |

## Lhasa Limited & IPEC Europe

### Nitrites collaborative meeting

Following the success of last year's meeting, join on 7 - 8 October at Lhasa Limited (Leeds, UK) for a collaborative event bringing together industry experts and regulators to advance understanding and share insights on nitrites in excipients.

Register now (IPEC Europe members)


## Download our guidelines and papers

**FREE TO DOWNLOAD**

IPEC-PQG Good Manufacturing Practices (GMP) guide
IPEC Good Distribution Practices (GDP) guide
IPEC Significant Change guide
IPEC Qualification of Excipients guide
IPEC Certificate of Analysis Guide
IPEC Quality Agreement Guide

Visit ipec-federation.org


## IPEC-Americas webinars

All webinars can be accessed on demand: https://education.ipecamericas.org/courses

### Next webinars

- Risk Assessment How To – Practical Application of Guides and Tools – 23 October – 9am-12pm EST
- Excipient GMP Differences, Risk Assessment, and Audit Findings – 11 November – 11am-1pm EST