



Welcome

Dear IPEC Federation members and friends, welcome to 2025's first issue of IPEC Federation Connect.

In this edition, we present the priority objectives for this year and regional updates from our five regional IPEC members. This year will be a busy one and, as well as those events detailed herein, the IPEC Federation is looking forward to supporting members' conferences in China, India and Japan.

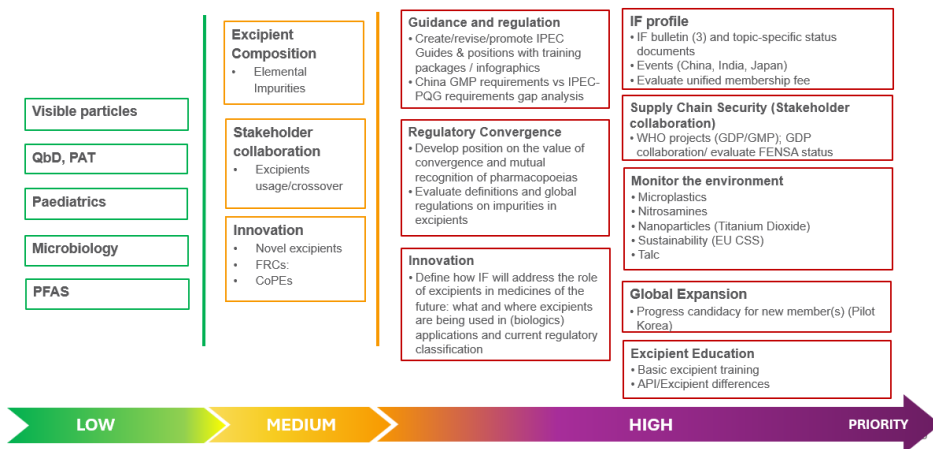
Enjoy reading it, share it widely, and of course, we welcome your feedback and suggestions at info@ipec-federation.org.

IPEC Federation Secretariat

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Strategic Focus and Priority objectives - 2025



At the IPEC Federation members' meeting held in-person on Tuesday 4 February 2024, accomplishments were reviewed to create a work plan for 2025. Built around the Federation's areas of strategic focus, several high priority objectives were identified for action.

Highlights include:

- 🌐 **Guidance and Regulation:** Revision and creation of multiple IPEC Guides and positions, the completion of which will rely heavily on the participation of members for which we will be seeking volunteers soon. Equally, with the recent publication of excipient GMP requirements in China, a gap analysis with the 2022 IPEC-PQG Guide will be invaluable for all members involved in manufacturing and exporting materials there, to ensure compliance is maintained.
- 🌐 **Regulatory Convergence:** while the Federation wishes to make its position on the importance of pharmacopoeial convergence publicly known, a topic of growing *divergence* seems to be how impurities in excipients are defined. There will be an opportunity to open discussion with PDG later this year for which we will prepare our case that this is indeed a matter of concern.

- 🌀 **Innovation:** the way in which excipients are being used and how certain raw materials become *de facto* excipients in medicinal products is changing expectations of them. We need to consider if our guides and positions need repositioning to reflect user requirements.
- 🌀 **Stakeholder collaboration:** working with WHO, particularly to enhance knowledge and education on measures to secure excipient supply chains, is a critical project to attack the recent increase in contamination incidents with tragic consequences.
- 🌀 **Monitor the environment** with special attention to Microplastics, Nitrosamines, Nanoparticles (titanium dioxide), Talc and Sustainability topics. Increasingly, regulations are emerging from other industrial sectors which impact excipients, often significantly, to which we need to react to and inform our members of their responsibilities.
- 🌀 **Global expansion:** The growing focus on excipients globally is stimulating interest in establishing new affiliate associations. The process developed will be piloted in Korea this year.
- 🌀 **Excipient education:** A perceived lack of knowledge on excipients within various stakeholders identified this as a high priority, to develop basic excipient training, and particularly highlighting differences between API and excipients.

At its monthly meetings, IPEC Federation members monitor the **low** and **medium** priorities to see if activity is growing in any of these areas, and whether action is needed. IPEC Federation's core activities are reviewed annually. For further explanation of any of the above, please don't hesitate to get in touch at info@ipec-federation.org.

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

IPEC Federation Annual General Assembly 2025 – Aix-en-Provence

The IPEC Federation organised its Annual General Assembly for 2025 in Aix-en-Provence, France on Tuesday 4 February.

Delegates from the five IPECs were present to discuss the results of activities in 2024 and to define the way forward for the association. During the Annual General Assembly, IPEC India was formally admitted as a full member of IPEC Federation.

The meeting was preceded by a members' meeting with updates from the different regions and a formal endorsement of the review of 2024 activities and priorities for the year(s) to come.



IPEC Quality-by-Design Guide – Free webinar for members

IPEC Federation announces the availability of the revised IPEC Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design (QbD) (version 2).

The guide was first published as an IPEC Federation guide in 2020; however, with this revision, the guide has been updated to include an annex incorporating contents from the 2016 IPEC-Americas QbD Sampling Guide. The Guide is available now for all IPEC members, with a general release in May. [Read more.](#)

A [webinar on this guide was organised on 25 March](#) – the recording is available and free for IPEC members.

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

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IPEC Europe Excipients Forum 2025 - 6 February, Aix-en-Provence, France

by IPEC Europe

More than 120 attendees joined the yearly IPEC Europe Forum held in Aix-en-Provence on Thursday 6 February. Preceded by committee meetings and the Annual General Meeting of the association, IPEC Europe opened its Annual Forum with a welcome speech by Chair Amina Faham.

The theme "Navigating regulatory landscapes and emerging trends" covered several hot topics and with interesting exchanges between attendees and speakers. The morning session featured several regulatory topics, with presentations from the European Pharmacopoeia and WHO's position on the Global challenges and gaps in high-risk excipient supply chain. Representatives of ANSM (French National agency for Safety of Medicines) then provided a thorough overview of the inspections hold in France for excipient manufacturers.

A user-maker real-world on how to provide regulatory information for excipients closed the morning session. The afternoon opened with a panel session on the impact of artificial intelligence/machine learning and its application on excipient selection and formulation. Two presentations followed on the registration of complex raw materials, and microplastics and current challenges with biodegradability testing methods wrapping up the formal proceedings.

During the evening cocktail reception Frank Milek (former Chair of IPEC Europe and IPEC Federation) received an award for his outstanding contribution to the association.

Updates from IPEC-Americas

by IPEC-Americas

IPEC Foundation – Applications for Awards Now Being Accepted!

The IPEC Foundation is now accepting applications for the Ralph Shangraw Memorial Award, Patrick De Luca Emerging Researcher Award, Henk de Jong Industrial Research Award and five graduate student travelships to attend the AAPS PharmSci 360 Meeting in San Antonio Texas, on 9-13 November 2025. The Foundation awards ceremony is scheduled to take place Tuesday evening, 11 November in San Antonio.

[Click here](#) to access the award applications, individuals from around the globe are welcome to apply. **The IPEC Foundation Board with approval from IPEC-Americas' Executive Committee, has increased the value of the awards for 2025.**

The Ralph Shangraw Memorial Award is to be given to any person that has provided outstanding research in the study of excipients or excipient-related technology. **(\$10,000)**

The Henk de Jong Industrial Research Award recognizes individuals in industry for their

Updates from IPEC Japan

by IPEC Japan

24th Excipient Seminar – February

IPEC Japan held its 24th Excipient seminar in-person in February 2025 in Tokyo. More than 180 attendees from pharmaceutical companies, excipient makers, academics and supply chain trading companies joined the seminar. After the seminar, a networking reception was well attended with more than 110 people present.

The seminar included addresses by MHLW, PMDA, and two lectures regarding nitrosamine-related topics. Two presentations featured speakers from academia.

Board meeting - November

IPEC Japan holds semi-annual Board meetings, of which the latest took place in November 2024.

The Board discusses ongoing activities at each working Committee and other topics of interest for IPEC Japan's associates.

CPHI Japan – April

IPEC Japan will be exhibiting on 9-11 April at CPHI Japan, held in Tokyo. Meet IPEC Japan representatives at booth 5H-21, category Ingredients - Japan Pharmaceutical Excipients Council Pavilion.

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outstanding achievements and contributions in excipient research and innovation.

The Patrick DeLuca Emerging Researcher's Award – 2-year award -The IPEC Emerging Researcher Award will be presented to a beginning career scientist post Ph.D. (postdoctoral fellows, research assistant professors and early-stage assistant professors). **(\$15,000 per year)**

Five (5) annual graduate student travel scholarships will be awarded and acknowledged for their excellence in research conducted at the graduate level in the field of Excipients. Students with recent significant contributions to formulation science and technology through innovative research with excipients are eligible for this award. **(\$2,000 each).**

Deadline for 2025 Applications: 15 JUNE 2025



How can you help the Foundation's efforts?

Contributions made to the IPEC Foundation will fund the memorials of individuals who have made significant contributions to the field of excipients.

<http://www.ipecfoundation.org/donate>

Updates from IPEC China

by IPEC China

In January 2025, China NMPA issued its Excipient and Packaging Material GMP as Annexes to GMP for drug products. The new GMP requirements will be mandatory and will need to be implemented by 1 January 2026.

IPEC China provided IPEC Federation members with a translation of the regulation; in parallel, IPEC China established a task force to perform a gap analysis on the requirements of the future China Excipient GMP vs. the IPEC-PQG GMP Guide.

IPEC China also organised two webinars on the topics of China Excipient GMP and ChP 2025 updates, held in January and February. 80 attendees joined the two sessions, respectively.

The drugs of tomorrow cannot be developed with yesterday's excipients and processes. Energize research in excipients through the IPEC Foundation. By supporting research, education, and safety through programs and scholarships, together we can shape the future of excipients.

Grow with us!
INTERNATIONAL JOURNAL OF
PHARMACEUTICAL
EXCIPIENTS

Check out the latest volume



International Journal of Pharmaceutical Excipients

Get recognised by submitting your excipient related research to The International Journal of Pharmaceutical Excipients. This industry sponsored peer reviewed journal is dedicated to excipients and their use in pharmaceutical product development and drug delivery. Submit a manuscript for rapid review and fee-free publication in this exciting new addition to scientific literature.

<https://jefc.scholasticahq.com/>

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IPEC Europe Excipient Conference 2025 – September 2025

25 - 26 September 2025 • Heidelberg • Germany

2025

the future of
excipients
is in our hands

IPEC
EUROPE

IPEC Europe Excipient Conference
– An update on regulatory developments and excipient applications in Drug Delivery –

2025 Work Plan for IPEC Guides and Positions

The calls for volunteers will be made soon!

IPEC Guidelines

- 🌐 Co-processed Excipients
- 🌐 Excipient Composition
- 🌐 GMP Certification Scheme and CB Qualification
- 🌐 Qualification of Excipients
- 🌐 Excipient Information Package
User Guide & Templates
- 🌐 IPEC-PQG GMP Audit
- 🌐 GDP Audit

Stability, IPEC Risk Assessment guide and IPEC-PDA Technical Report 54-6 – Formalised risk assessment for excipient revisions are ongoing.

Position papers and documents

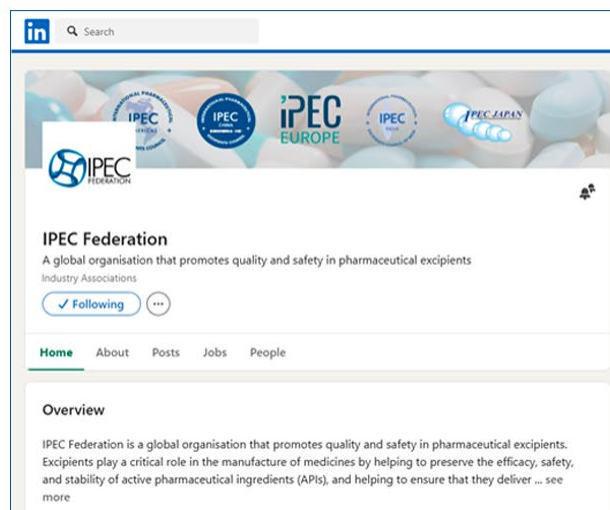
- 🌐 Good Manufacturing Practices for Atypical Actives
(expand scope to include regulatory issues)
- 🌐 Data Integrity for Pharmaceutical Grade Excipients
- 🌐 Pharmaceutical Excipients GMP documents
- 🌐 Excipient Impurities
- 🌐 Pharmacopeial Convergence
- 🌐 Excipients used in Biologicals

Recently Published Guides and documents:

- | | | |
|-------------------------------------------------------|---------------|-----------------------------|
| 🌐 Paper on Third Party Audit Certification Programmes | February 2025 | Available on the website |
| 🌐 Quality-by-Design Guide | February 2025 | General availability in May |
| 🌐 Good Distribution Practices (GDP) Guide | October 2024 | Available on the website |

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*Stay updated on news
events and guidelines*



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EXCIPIENT WORLD

2025
MAY 12-14

★ NATIONAL HARBOR ★

GAYLORD NATIONAL RESORT & CONVENTION CENTER

Located at the edge of Washington, DC!



Conference: May 12-14 | Expo: May 13-14

KEYNOTE

Dr. Andrea Love, Biomedical Scientist, Founder "ImmunoLogic" (science and health communication organization)

FEATURING
FDA OFFICIAL Diana Solana-Sodeinde, CDER, OGD: Inactive Ingredient Database

INCLUDING THE 3RD ANNUAL biologic summit
Advances in Cell and Gene Therapy
a Controlled Release Society and IPEC-Americas joint program



IPEC Members save \$100 on registration with code IPEC100.

find out more and register at **ExcipientWorld.org**



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