



## Welcome

Dear IPEC Federation members and friends,  
Welcome to the second and final issue of the year of the IPEC Federation bulletin. In this edition, we provide you with updates from the latest publications, our participation to events and workshops, and news from the regional IPECs. Enjoy it, share it and as always, your feedback is most welcome! Contact us for more details.

IPEC Federation Secretariat – [info@ipec-federation.org](mailto:info@ipec-federation.org)

## In this issue

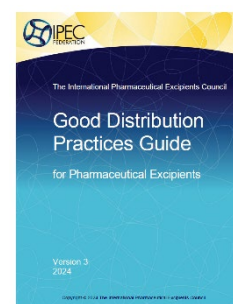
- 🌐 *IPEC Guides: updated GDP Guide*
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## IPEC Guides: updated Good Distribution Practices (GDP) Guide

Following the issue of new revisions of the Quality Agreement and TUPP guides, the 2024 programme has delivered an updated IPEC Good Distribution Practices Guide for Pharmaceutical Excipients.

The 2024 GDP guide, previously updated in 2017, incorporates examples and practical guidance to apply GDP in alignment with WHO's GTDP. Also, this version aligns with the Joint IPEC-PQG GMP Guide (2022), EXCiPACT and NSF/IPEC/ANSI standards to ensure consistency in quality practices.

The updated IPEC GDP Guide will be available to the public on [IPEC websites](#) in early January.



## Infographics: Supply Chain Security, Nitrosamines, Quality Agreement

IPEC Federation published three new infographics to reinforce its messages on key topics. Presented for the first time at the WHO International Conference of Drug Regulatory Authorities (ICDRA) event/exhibition in India in October, the three infographics focus on:

- 🌐 **IPEC Quality Agreement:** illustrating the importance of a standardised Quality Agreement and the IPEC Quality Agreement Guide and templates
- 🌐 **Supply Chain Security:** highlighting key points from the IPEC Federation position published earlier in 2024
- 🌐 **The role of excipients in determining N-Nitrosamine risks:** the infographic illustrates the corresponding position paper

In addition, the general infographic of IPEC Federation was also updated.

You can find the infographics on the [IPEC Federation](#) and regional IPEC websites.



## IPEC Federation Board, Annual General Assembly 2025

The IPEC Federation will organise its Annual General Assembly in Aix-en-Provence on Tuesday 4 February. Delegates from the five IPECs will convene in Aix, where a Board meeting with updates from the different regions and a strategic review of the priorities for the coming year(s) will also be organised.

A summary of the outcomes of this meeting will be included in the next issue of Connect.

## IPEC Federation flying the flag at ICDRA

led by APIs of 17 countries sourced from certified sources will be accepted for review



At the invitation of WHO, Priscilla Zawislak (IFF/IPEC Federation Vice President) and Vishakha Metkar (Colorcon/IPEC India) attended a panel session on behalf of IPEC Federation at the 19th International Conference of Drug Regulatory Authorities (ICDRA) hosted by CDSCO in New Delhi, India on Monday 14 and Tuesday 15 October. The contributors presented their perspectives on addressing critical challenges surrounding the quality of starting materials,

particularly excipients.

The IPEC Federation was also an exhibitor at the same event, showcasing the latest infographics and guidelines to an audience of more than 1500 regulators from across the world.

Important connections were made from delegates in countries where sharing IPEC programmes could have high impact on good manufacturing and distribution practices.



## IPEC Federation meets PDG



For the first time since 2019, IPEC Federation and PDG met in-person in Strasbourg, France, at EDQM's headquarters, on 3 October 2024. The day started with a PDG stakeholder meeting, followed by the annual IPEC Federation/PDG meeting. Amongst other items, the agenda included progress on the PDG workplan, IPEC's proposals for the revision of Polysorbate 20, and the latest developments on DEG/EG issues. The Federation took this opportunity to organise its second members' meeting of year on 2 October to progress on the 2024 strategy and prepare priorities for 2025.

## IPEC Federation and ICH

The latest Assembly of the International Council for Harmonisation (ICH) took place on 5 & 6 November 2024, in Montréal, Canada. The meeting was held in parallel with 11 Working Groups and 1 Discussion Group, and was preceded by meetings of the ICH Management Committee and the MedDRA Management Committee. IPEC Federation has an Observer organisation status at ICH. In 2024, IPEC Federation participated in ongoing ICH activities including several Working Groups (Q13 Continuous Manufacturing; Q1 Stability) and the ICH Assembly / Quality Discussion Group (QDG). The meeting was attended by Janeen Skutnik-Wilkinson (Moderna/IPEC-Americas) and Priscilla Zawislak (IFF/IPEC-Americas). In this meeting, ICH accepted IPEC Federation's request to have an observer on the newly-authorized ICH M7 for Nitrosamines: congratulations to Ulrich Reichert (Merck KGaA/IPEC Europe) who will represent IPEC Federation in this group.

## IPEC Federation webinar on Nitrosamines



### THE ROLE OF EXCIPIENTS IN DETERMINING N-NITROSAMINE RISKS FOR DRUG PRODUCTS

Elizabeth Tocce, IFF and Ulrich Reichert, Merck KGaA  
16-17 July 2024

An IPEC Federation Webinar

More than 250 attendees joined the two sessions of the IPEC Federation webinar on "The role of excipients in determining N-nitrosamine risks for drug products" held in July and presented by Elizabeth Tocce (IFF/IPEC-Americas) and Ulrich Reichert (Merck KGaA, Darmstadt, Germany/IPEC Europe). The webinar attracted many questions from members of the five IPECs across the world and beyond, reflecting the high level of interest in this topic.

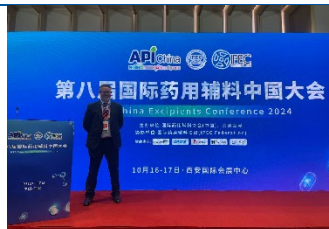
The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl

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## IPEC China Excipients Conference 2024 – Xi'an, China - October

Kevin Hughes (Colorcon/IPEC Federation President) and Adrian Bone (IPEC Federation Executive Secretary) represented IPEC Federation at the IPEC China Conference in Xi'an, People's Republic of China on 16-18 October 2024. Presentations featured an overview of the IPEC position on improvements to excipient supply chain security and "Nanomaterials: Current Regulatory Position and Public Opinion".

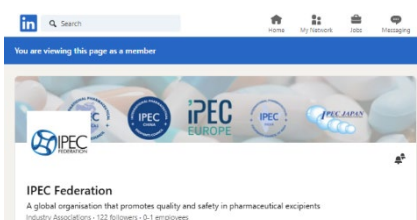


Discussions were also held with representatives of Chinese Pharmacopoeia and its upcoming 2025 edition.

## IPRP Workshop: focus on Supply Chain security initiatives

Adrian Bone (IPEC Federation Executive Secretary) presented on the topic of the latest fatal incidents with contaminated medicinal syrup and on the IPEC Federation initiatives on Supply Chain Security of pharmaceutical grade excipients at the IPRP (International Pharmaceutical Regulators Programme) stakeholder workshop, hosted by HSA (Singapore's Health Sciences Authority) and held in hybrid form on 13 September.

## A LinkedIn page for IPEC Federation



IPEC Federation launched its official LinkedIn page in October.

Follow our page and join our growing online community, engage and stay informed about our work and initiatives. Whether you are a current or potential member of IPEC, or simply interested in our professional domain, our new LinkedIn presence offers a great channel for staying connected and informed about IPEC Federation activities.

Follow us on <https://www.linkedin.com/company/ipec-federation>

## Updates from IPEC China

by IPEC China

IPEC China is pleased to report on an eventful year, marked by several key activities and collaborations. In May and June, IPEC China forums were held alongside the API and CPHI exhibitions, attracting more than 150 participants.

In July, the NMPA issued a draft for Excipient GMP guidelines for public comments. In response, IPEC China actively engaged its members, collected feedback globally through IPEC Federation, organized a meeting to discuss concerns and suggestions, and submitted consolidated comments to the NMPA in August.

On 24 September, a joint event focused on "Excipient GMP/GDP" was held in collaboration with EXCiPACT and SPPEA (Jiangsu Excipient Association). October marked the return of the Excipient Conference in Xi'an after a five-year hiatus, bringing together around 100 participants, and included the 16<sup>th</sup> Annual General Assembly,

## Updates from IPEC Japan

by IPEC Japan

IPEC Japan's activities have been marked by significant progress and key milestones.

The 3<sup>rd</sup> Supplement of JPE (Japanese Pharmaceutical Excipients) 2018 and the 2<sup>nd</sup> Supplement of JP (Japanese Pharmacopoeia) 18 were both published. June saw the return of IPEC Japan's in-person General Annual Meeting after five years of virtual gatherings, featuring a dedicated lecture on nitrosamines. In July, IPEC Japan hosted its 4<sup>th</sup> Introductory Course webinar for newcomers, which attracted over 120 participants.

The GMP Committee has been diligently working on revising the IPEC Japan's Self-imposed GMP standard based on the IPEC-PQG GMP Guide 2022, aiming for completion by spring 2025. Meanwhile, the monthly GMP column on our homepage continues to provide valuable insights to our members.

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where a new board was elected. In the beginning of December (3-5), IPEC China is participating in the China Pharmaceutical Engineering Conference (CPEC) in Nanjing, co-hosted by CCFDIE and CFDI, with speakers from authorities such as NMPA, CDE, ChP, and CFDI, alongside industry and academic experts; IPEC China contributed with three presentations.

## Updates from IPEC Europe

by IPEC Europe

Over the past months, IPEC Europe has been actively engaging with industry stakeholders and contributing to key events.

In October, IPEC Europe our first in-person meeting with EDQM since 2019, marking the return to face-to-face interactions. We attended the EDQM 60<sup>th</sup> Anniversary in June, represented in Strasbourg by Lotte Kok (Novo Nordisk/IE Board Member and Compendial Convergence Committee Chair), and participated in important events such as IPEC Europe/APV Conference, CPHI Worldwide, APIC, and A3P Conferences, all held in September-October.

Our contributions extended to delivering presentations at external meetings.

Collaborative efforts were highlighted by co-organizing a Nitrite-focused meeting with Lhasa in March, while our knowledge-sharing initiatives included webinars on Nitrosamines PP in July (via IPEC Federation) and Supply Chain Security in October. IPEC Europe also held quarterly member Catches-up in February, May, September, and November. Looking forward, IPEC Europe is finalising preparations for the forthcoming IPEC Europe Excipients Forum, on 6 February 2025 in Aix-en-Provence, France.



Collaboration with MHLW (Ministry of Health, Labor and Welfare of Japan) on revising the JPE monograph is underway, work is planned to be completed by 2026.

## Updates from IPEC India

by IPEC India

IPEC India's 2024 was a year marked by significant events and contributions to the pharmaceutical excipient industry. IPEC India's Annual Conference took place on 31 May 2024, under the theme "Safe Pharmaceuticals Through Quality Excipients", featuring IPEC Federation President Kevin Hughes as Guest of Honour.



On 6 July, IPEC India hosted a session at the 73<sup>rd</sup> Indian Pharmaceutical Congress, focusing on "Excipients – Your Partner in Delivering Quality Medicines," which engaged both industry professionals and academia.



In August, IPEC India organized exclusive seminars for academia on

"Excipient Insights" in collaboration with Principal K. M. Kundhani, College of Pharmacy in Mumbai. Additionally, IPEC India contributed to regulatory progress by reviewing a list of excipients from the Indian Pharmacopoeia Commission for standardizing IP Monographs.

The Regulatory Committee identified excipient categories, avoided brand name use, and submitted recommendations to the Commission after review by the IPEC Federation.

Looking ahead, IPEC India is preparing for its next Annual Conference, scheduled for Q2 2025.

## IPEC Federation and PDG Collaborate on Polysorbate 20 Harmonization

by IPEC-Americas

The IPEC Federation is working with the Pharmacopeial Discussion Group (PDG) to draft a harmonized monograph for Polysorbate 20 (PS20). The proposal to harmonize the monographs from the four PDG members; the European Pharmacopeia (Ph.Eur.), Indian Pharmacopeia (IP), Japanese Pharmacopeia (JP), and the United States Pharmacopeia- National Formulary (USP-NF), was a topic of discussion at the October 3rd IPEC Federation – PDG face to face meeting in Strasbourg France.

The IPEC Federation project team is reaching out to any IPEC member companies that manufacture polysorbates with a request to join the harmonization process. Analytical data is an important part of the compendial process, and companies that manufacture PS20 are needed to share data and help evaluate the new proposed PS20 monograph. If you are interested in learning more about this exciting project, please contact the following associations:

IPEC-Americas at [ipecamer@ipecamericas.org](mailto:ipecamer@ipecamericas.org)

IPEC Europe at [info@ipec-europe.org](mailto:info@ipec-europe.org)

IPEC China at [info@ipec-china.org](mailto:info@ipec-china.org)

IPEC Japan at [office@ipec.gr.jp](mailto:office@ipec.gr.jp)

IPEC India at [admin@ipecindia.org](mailto:admin@ipecindia.org)

## IPEC-Americas Latin America Working Group Hosts First Seminar

by IPEC-Americas

On 19 November 2024, the Latin America Working Group hosted its first seminar focused on current hot topics, Nitrosamines, GMPs for Excipients, atypical API's. More than 600 professionals from 22 countries were connected both in person and on-line to exchange knowledge relevant to the field of excipients.

Speakers included Gabriel Marcelín Jiménez, Rivelino Flores, Priscilla Zawislak, Arthur Lopes da Silva (ANVISA), Enrique Vargas, Iain Moore, Liliane Soriano Saadi, Ellen Grippi.



The group's mission is to advocate, educate, innovate and develop best practices for pharmaceutical excipients in the region, prioritizing patient safety and drug product efficacy.

Working members include manufacturers, importers and distributors of pharmaceutical excipients as well as finished drug manufacturers with operations in Latin America. In addition, this group shares guidance and best practices for pharmaceutical excipients, promotes training opportunities and advocates with local authorities and government agencies aimed at harmonizing and adopting international practices for pharmaceutical excipients in the region.

LAWG participation is a limited membership for companies whose primary business consists of sales in South America. If your company has operations in Latin America and is not currently a member of IPEC-Americas, they may be eligible for participation in this working group.

Please notify IPEC-Americas staff at [ipecamer@ipecamericas.org](mailto:ipecamer@ipecamericas.org) to learn more.

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**EARLY REGISTRATION ENDS 31 JANUARY 2025**

## Excipient World

12-14 May 2025

Gaylord National Resort & Convention Center,  
National Harbor, MD (DC Metro Area)

Join us from 12-14 May at the Gaylord National (National Harbor, MD) for the only U.S. event exclusively focused on excipients.

### Why Register Early?

- > Discounted Pricing: Save 20% on your registration fee.
- > Priority Booking: Secure your hotel room at the Gaylord National.

### Your 3-Day Pass Includes:

**Education:** Keynote Sessions – Workshops - Break-Out Sessions - Quick Talks

**Innovation:** Exhibits showcasing industry leaders - Posters featuring excipient research

**Networking:**

- > Lunch each day Welcome Reception – 11 May
- > Exhibit Hall Happy Hour – 12 May
- > Excipient World Celebration – 13 May

**We can't wait to see you at Excipient World 2025! [FIND OUT MORE](#)**

## IPEC Europe Excipients Forum 2025

Join us in Aix-en-Provence, France on Thursday 6 February 2025 to discover, experience and engage in stimulating discussions about the latest innovations and developments in the pharmaceutical excipients sector.

Featuring high-level presenters from leading authorities such as WHO, EDQM and MHRA, this event offers a unique opportunity to explore the latest advancements in pharmaceutical excipients.

The seminar will address key topics shaping the excipient industry, providing valuable insights and best practices to help your company navigate current and future challenges.

[Register now on the IPEC Europe website.](#)

forum  
2025

## IPEC Guides work plan

### IPEC Guides being revised:

- |  |  |
|--|--|
| 🌐 IPEC Quality-by-Design Guide           | 🌐 IPEC Risk Assessment Guide   |
| 🌐 IPEC Excipient Stability program Guide | 🌐 PDA-IPEC Technical Report 54.6 – Formalized Risk Assessment for Excipients |

### Recently Published Guides and date of publication:

- |   |               |                                 |
|---|---------------|---------------------------------|
| 🌐 IPEC Good Distribution Practices (GDP) Guide    | October 2024  | General availability in January |
| 🌐 Quality Agreements Guide and Templates          | February 2024 | Available on website            |
| 🌐 Technically Unavoidable Particle Profile (TUPP) | February 2024 | Available on website            |
| 🌐 Position Paper on Nitrosamines                  | February 2024 | Available on website            |

Information accurate at the time of publishing – December 2024. For comments, [info@ipec-federation.org](mailto:info@ipec-federation.org).

*IPEC Federation wishes you happy holidays and best wishes for 2025.*

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