



Welcome

Dear IPEC Federation members and friends,
Welcome to our first issue of the IPEC Federation bulletin for 2024, which we hope you will find interesting. In this edition, we delve into the priority objectives for this year and regional updates.

Enjoy it, share it and as always, your feedback is most welcome! Contact us for more details.

IPEC Federation Secretariat – info@ipec-federation.org

IPEC Federation Management Body

Election held in Bordeaux, France on 6 February 2024

President IPEC Europe Kevin Hughes

Vice-President IPEC-Americas Priscilla Zawislak

Treasurer IPEC Japan Hiroshi Watanabe

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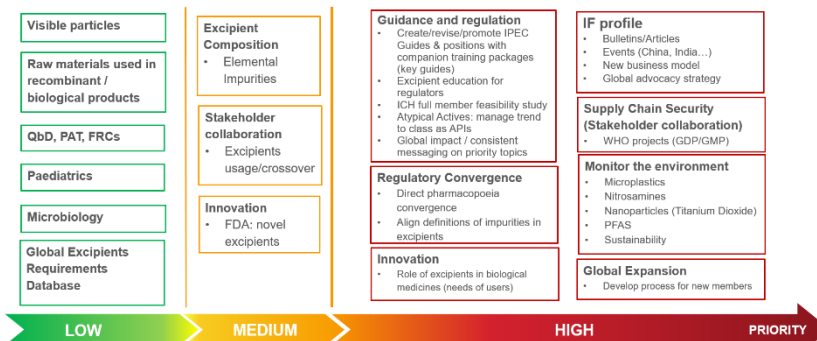
Strategic Focus and Priority objectives

Built around the Federation’s areas of strategic focus, the Board has identified **several high priority objectives** for 2024:

- 🌐 **Guidance and Regulation:** Revision and creation of IPEC Guides and positions with selected corresponding companion training packages; establish the feasibility to apply for an ICH full membership; manage trend to class atypical actives as APIs; ensure consistent messaging on priority topics;
- 🌐 **Regulatory Convergence:** Direct pharmacopoeial convergence; alignment of definitions of impurities in excipients;
- 🌐 **Innovation:** Role of excipients in medicines of the future;
- 🌐 **IF Profile:** Bulletins, articles, support to events in China and India; development of a new business model; initiate the development of a global advocacy strategy;
- 🌐 **Stakeholder collaboration:** Contribute to WHO projects to revise GDP/GMP guidance;
- 🌐 **Monitor the environment** with special attention to Microplastics, Nitrosamines, Nanoparticles (e.g., titanium dioxide), PFAS and Sustainability topics;
- 🌐 **Global expansion** : Development of a process for new members.

2024 Strategic Focus and Priority Objectives

CAPTION
Strategic Focus
Priority objectives



At its monthly virtual meetings, the Federation members monitor the **low** and **medium** priorities to see if activity is growing in any of these areas, and action is needed. The Federation's core activities are reviewed annually. The guide programme continues to be a significant effort for the Federation and teams for those on the 2024 plan will soon be called into action!

THANKS TO THE MANY IPEC MEMBERS ACROSS THE WORLD WHO VOLUNTEERED TO PARTICIPATE IN THESE GROUPS!

IPEC Federation Board, Annual General Assembly & Election 2024

The IPEC Federation organised its Annual General Assembly for 2024 in Bordeaux, France on 6 February. Delegates from the five IPECs were present in Bordeaux for the first face-to-face meeting in five years, leading to many fruitful discussions on the results of the past years, strategic exchanges and future objectives.

The meeting was preceded by a Board meeting with updates from the different regions and a strategic review of the priorities for the year(s) to come.

The Elections for the two-year mandate of the Management Body took place, with the election of representatives and subsequently IPEC Europe representative K. Hughes was named as President and IPEC-Americas representative P. Zawislak as Vice-President. IPEC Japan representative H. Watanabe was confirmed in his role as Treasurer of the association.



IPEC Position Paper on Nitrosamines – Revised version available

A revised version of the IPEC position paper “The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products” is now available. This paper describes IPEC Federation's position on the role of excipients when conducting N-nitrosamine (nitrosamine) risk assessments for drug products.

The presence of N-nitrosamines in drug products continues to be a global concern. Excipients are considered as a potential risk factor during the drug product risk assessment.

The focus of this position paper is to expand on the potential contribution excipients may or may not have on the formation of nitrosamines in final drug products. The presence of nitrites and vulnerable amines in excipients are also considered. This revision highlights the key messages associated with excipients and how they feature in the ongoing debates on the nitrosamines topic and has been updated to reflect current perspectives.

Download the position paper on the [IPEC Federation website](#).

Interview: Keep Your Eye on the Supply

The Medicine Maker hosted an interview with Dr. Frank Milek, Board Member of IPEC Europe and involved in IPEC Federation since its inception, to highlight the importance of ensuring security of the excipient supply chain in light of the recent incidents caused by #DEG contamination in different areas of the world.

The interview follows the publication of the updated position paper on the Supply Chain Security in August 2023 that you can retrieve on the IPEC Federation website.

Almost a quarter of the way through the 21st century, it is hard to believe – and even harder to accept – that the deaths of children can be attributed to cough medicines manufactured with substandard excipients. IPEC Federation is clear: all stakeholders must not suffer complacency when it comes to supply chains.

[Read the interview on The Medicine Maker](#)

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

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IPEC Europe Excipients Forum 2024 – Shaping the future of excipients

by IPEC Europe

More than 100 attendees convened in Bordeaux on 8 February for the yearly IPEC Europe Forum. The theme “Shaping the future of Excipients” covered several hot topics and with interesting exchanges between attendees and speakers. The morning session featured regulatory topics, with presentations from the European Pharmacopoeia and USP and WHO’s views on the impact of medicines contaminated with DEG/EG. A talk on the key quality attributes for excipients used in chemical and biological drug products closed the morning session.

In the afternoon, presentations featured topics such as sustainability expectations from a pharmaceutical company’s perspective, approaches for users/makers of excipients for physical contamination management, how big data analysis approach can help to tackle supply chain variability, and functional excipients in dry powder formulation for nasal/pulmonary drug delivery.

[Save the Date: IPEC Europe Excipient Conference 2024](#) - Vienna, Austria – 24 and 25 September 2024
[An update on regulatory developments and excipient applications in Drug Delivery](#)

Updates from IPEC-Americas

by IPEC-Americas

Did You Know that IPEC-Americas Sponsors the Journal of Excipients and Food Chemicals?

IPEC-Americas sponsors and publishes a peer-reviewed quarterly journal related exclusively to excipients entitled “The Journal of Excipients and Food Chemicals”. 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 (impact factor: 3.4).

IPEC-Americas considers the Journal to represent a significant value added tool to further the organisation’s mission and objectives. The IPEC Foundation sponsors an award for the best article in the journal on an annual basis. Submissions to the journal, review and publication is online.

The Journal is operating under a new editorial board and is now accepting submissions for its 2nd quarter 2024 publication. This is an opportunity for academics, industry researchers and formulators and regulators to publish their

Updates from IPEC Japan

by IPEC Japan

23rd Excipient Seminar – 2 February 2024

After four years of webinars, IPEC Japan held its 23rd Excipient seminar in person on 2 February, 2024 in Tokyo. More than 160 participants attended from pharmaceutical companies, excipient makers, academics and supply chain trading companies. After the seminar, networking reception was also held with 90 people.

The seminar included Recent pharmaceutical regulatory topics by MHLW, Excipient topics in the JP monograph by PMDA, Lipid nanoparticles formulation development, Pharmaceutical formulation development using AI, and two lectures regarding Dissolution enhancement of poorly soluble drugs.

4th Excipient Introductory course webinar for newcomers

IPEC Japan first held an excipient webinar for newcomers in 2021. Nearly 100 people attend then from industry and pharmacy schools covering General guidance of excipients, Binders, Coatings, Disintegrants, and Regulations for excipients when used in solid dosage forms. Another course includes different dosage forms such as injections, and topical preparations.

The 4th course is under preparation to be held in July.

research related to excipients and food chemicals as well as their opinions about regulatory and formulation matters concerning these materials. Submit an abstract soon!

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

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 American Association of Pharmaceutical Scientists (AAPS) 2024 PharmSci 360 Meeting in Salt Lake City, Utah, October 20 – 24, 2024. The Foundation awards ceremony is currently scheduled to take place Tuesday evening, October 22, in Salt Lake City, and individuals from around the globe are encouraged to submit an application.

[Click here to](#) access the award applications:

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.

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

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.

Deadline for Applications: 15 JUNE 2024

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.

Meeting PDG-IPEC Federation

by IPEC Federation

IPEC Federation and the Pharmacopeial Discussion Group (PDG) held a call in December 2023 where representatives from pharmacopoeias (Ph. Eur., USP, JP and IP) presented the current activities of PDG and shared highlights from the PDG October meeting, where the Indian Pharmacopoeia was admitted as a full member of PDG.

Topics included in the meeting included the proposed incorporation of new items into PDG's programme, future expansion plans for PDG and the potential harmonisation of methods for DEG/EG. PDG and IPEC Federation plan to host another meeting in October 2024.

ICH meeting in Prague

by IPEC Federation

Priscilla Zawislak (IPEC-Americas/IFF) represented the IPEC Federation at the International Council for Harmonisation (ICH) in-person meeting on 31 October & 1 November 2023, in Prague, Czechia.

In 2023, IPEC participated in ICH activities including several Working Groups (Q3D Elemental Impurities; Q13 Continuous Manufacturing; Q1 Stability) and the ICH Assembly / Quality Discussion Group (QDG). These representations will continue in 2024.

IPEC Federation Events

by IPEC Federation

Workshop on DEG-EG (Oxford)

IPEC Federation will be in attendance at an in-person workshop on DEG-EG contamination at Jesus College, Oxford University.

The workshop, organised by the Medicine Quality Research Group, will be held on 9-12 April and will discuss devices and methods for detecting diethylene glycol and ethylene glycol in medicines.

Lene Krogh Christensen (IPEC Europe/Novo Nordisk) will represent IPEC Federation in an audience composed of international and national stakeholders.

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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.



Please consider supporting the IPEC Foundation, a 501(c)3 organization qualified to accept tax-deductible contributions.

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

JPEG Seminar on raw materials (London)

On Thursday 21 March, Rodrigo Arias (IPEC Europe/DFE Pharma) presented on the IPEC Federation's initiatives on Supply Chain Security of Pharmaceutical excipients at the Joint Pharmaceutical Analysis Group (JPAG) meeting "Considering the raw materials: API & Excipients" in London, UK.

This symposium presented an overview of testing and risk assessment of these pharmaceutical product components throughout the life cycle, with presentations from MHRA, EXCiPACT and Universities of Manchester and Reading.



REGISTER NOW

Excipient World Collaborating for Sustainable Medicines

May 13 – 15 2024 - Gaylord Palms Resort & Convention Center - Kissimmee, FL (Orlando)

IPEC India Annual Conference 2024 – Hyderabad

by IPEC India

IPEC India will organise its Annual Conference in Hyderabad (Hotel Radisson Banjara) on 31 May 2024.

Under the theme "Safe Pharmaceuticals through Quality Excipients", topics included in the programme include nitrosamines impurities, drug formulation for children, EXCiPACT certification and continuous manufacturing.

The event will feature many high-level speakers, including the Guest of Honour Dr Ramkishan, Deputy Drug Controller, CDSCO, South Zone. IPEC Federation will be represented by Kevin Hughes (President of IPEC Federation) who will provide updates on 'hot topics' such as Titanium Dioxide, Microplastics and Nanoparticles. Iain Moore (EXCiPACT) will be also present to brief about the role of the EXCiPACT certification in maintaining quality of excipients.

Please visit the website of IPEC India to see the full programme and registration details: <https://ipecindia.org/event/ipec-india-annual-conference-2024/>



IPEC Guides work plan

IPEC Guides being revised:

- 🔄 IPEC Good Distribution Practices (GDP) Guide
- 🔄 IPEC Excipient Stability program Guide
- 🔄 PDA-IPEC Technical Report 54.6 – Formalized Risk Assessment for Excipients
- 🔄 IPEC Risk Assessment Guide
- 🔄 IPEC Co-processed excipients Guide
- 🔄 Translation of IPEC-PQG Good Manufacturing Practices (GMP) Guide in French and Spanish

Recently Published Guides and date of publication:

- | | | |
|---|---------------|-----------------------------|
| 🔄 Quality Agreements Guide and Templates | February 2024 | General availability in May |
| 🔄 Technically Unavoidable Particle Profile (TUPP) | February 2024 | General availability in May |
| 🔄 Position Paper on Nitrosamine | February 2024 | Available on website |
| 🔄 IPEC Glossary of Terms | December 2023 | Available on website |
| 🔄 Position Paper on Supply Chain Security | August 2023 | Available on website |

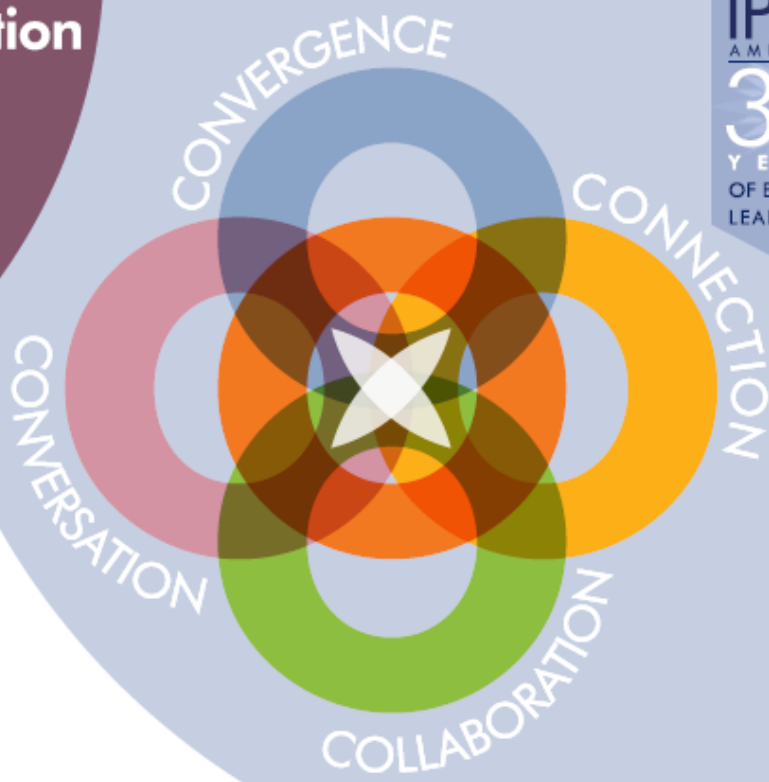
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2024
ORLANDO



FEATURING FDA OFFICIALS—

June Page, CDER, OCQC:
Data Integrity



Amanda Jones, CDER, OGD:
Inactive Ingredient Database

+KEYNOTE

Lee McIntyre, Philosopher
author of

How to Talk to a Science Denier:
Conversations with Flat Earthers, Climate Deniers, and Others Who Defy Reason



ExcipientWorld.org

INCLUDING THE 2ND ANNUAL



a Controlled Release Society and IPEC-Americas joint program:

Drug Delivery Devices
Across Various Administration Routes

Conference & Workshops May 13–15 | EXPO May 13–14
Gaylord Palms Resort & Convention Center (Kissimmee, Florida)

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