



## Welcome

Dear IPEC Federation members and friends,  
 Welcome to our first issue of the year of the IPEC Federation bulletin, which we hope you will find interesting. In this edition, we delve into the priority objectives for 2022 and the recent meeting with PDG. 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)

## IPEC Federation Board

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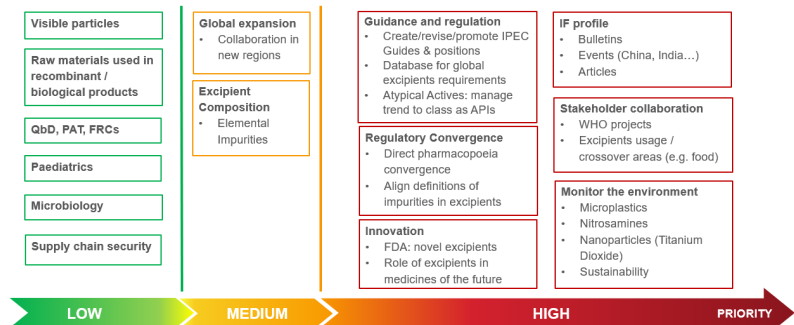
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## Strategic Focus and Priority objectives for 2022

Built around the Federation’s areas of strategic focus, the Board has identified **several high priority objectives** for 2022:

- 🌐 **Guidance and Regulation:** Focus on the revision and creation of IPEC Guides; development of a database for global requirements; address the trend to classify Atypical Activities as APIs;
- 🌐 **Innovation:** Novel excipients and role of excipients in medicines of the future;
- 🌐 **IF Profile:** Bulletins, articles, events;
- 🌐 **Stakeholder collaboration:** Contribute to WHO projects, cooperate on excipient use in crossover areas (e.g. food);
- 🌐 **Regulatory Convergence:** Direct pharmacopoeial convergence, alignment of definitions of impurities in excipients;
- 🌐 **Monitor the environment,** with special attention to Microplastics, Nitrosamines, Nanoparticles and Sustainability.

### 2022 Strategic Focus and 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 three revision teams are now active for Stability, CoA (Certificate of Analysis) and Significant Change guides. Thanks to the many IPEC members across the world who volunteered to participate in these groups!

## IPEC Federation Annual General Assembly and Election

The IPEC Federation will organise its Annual General Assembly in Brussels in June. Hopefully, delegates from all IPECs will be able to reunite to discuss the results of the past year and 2022 objectives. Elections for the two-year mandate of the Management Body will also take place. 2021 was a very positive year for the Federation despite the pandemic challenges, which steered the publication of a position paper on Lactose used in oral preparations, as well as four guides, of which two are new guidelines, on Validation and Safety for Pharmaceutical Excipients. The Federation submitted comments on several draft regulations across the world as well as fulfilling its observer role at the ICH.

## Meeting with the Pharmacopoeial Discussion Group (PDG)

On 1 December 2021, IPEC met with PDG to discuss common areas of interest related to the harmonisation of excipient monographs and general chapters. This event took place virtually, hosted by EDQM and was attended by IPEC representatives from the Americas, Europe and Japan.



PDG announced recently that it is preparing a pilot to integrate additional world pharmacopoeias into its membership. This is a critical step in the PDG's commitment to expand the recognition of harmonised pharmacopoeial standards with a view to achieving global convergence. The publication of the Harmonised General Chapter Chromatography (G-20) was also highlighted.

The agenda included follow up on a list of 'priority' excipients and general methods submitted by IPEC to PDG at an earlier meeting. IPEC would like PDG to consider these candidates for inclusion on the PDG workplan. PDG had gone to great lengths to evaluate the feasibility of harmonising the identified materials and methods; the latter IPEC feels will have important impact globally, particularly with reference to PDG's expansion plans. IPEC agreed to provide additional data to support the rationale for further analysis and therefore, for evaluations to be concluded.

IPEC attendees agreed that the meeting was conducted in a positive and constructive manner and we look forward to further exchanges with PDG in 2022.

## IPEC Position Paper on Nitrosamines

On 1 March, IPEC announced the availability of a new position paper, "The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products". 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. [The position paper](#) is available on the website [www.ipec-federation.org](http://www.ipec-federation.org)

A huge Thank You to the team that developed this Position Paper for your tremendous effort, delivered in a record time. Your efforts are very much appreciated!

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

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## Excipient World Conference & Expo - May 2-4 2022

by IPEC-Americas



Excipient World Conference & Expo  
May 2-4, 2022 - Orlando, Florida, USA

[Excipient World Conference & Expo](#) – IPEC-Americas flagship event – is the only U.S. event focused exclusively on excipients. This year, the event is expecting 200+ participants representing the entire excipient supply chain – formulators, R&D, engineering, operations, regulatory and compliance, quality assurance/ control, supply chain, scientists, and other manufacturing professionals.

The Excipient World educational program will feature 30+ excipient subject matter experts discussing issues related to the pharmaceutical manufacturing process – including FDA speakers and [featured keynote speaker Katherine Eban](#). The program includes one day of in-depth preconference workshops and two days of education sessions totaling over 25 presentations across 3 days. Topics include elemental impurities, excipient regulations, novel excipients, content uniformity, supply chain security, excipient sourcing, and the FDA's Inactive Ingredient Database. Try out the [interactive schedule builder](#) to view sessions by track, target audience, etc.

Attendees will have 10+ hours of opportunities to connect with peers and exchange ideas, best practices and lessons learned. In addition to lunches and breaks between education sessions, Excipient World will host three evening networking events. The featured event will be [IPEC-Americas 30<sup>th</sup> anniversary celebration](#) on the evening of Tuesday, May 3 (access is included in registration). The optional “Plus One”

## Co-processed excipients, TiO<sub>2</sub> and Microplastics activities

by IPEC Europe

These three topics currently feature heavily on IPEC Europe's agenda. Here a short summary of the actions being undertaken by IPEC Europe and others:

### Co-Processed Excipients

Efforts are being made to address regulatory perceptions that CPEs are not excipients, but rather drug product intermediates. IPEC Europe is collating its arguments for future discussions with regulatory stakeholders to reassure that the current approach to the control of CPEs meets regulatory expectations.

### Titanium Dioxide

Following its ban in foods in the European Union, the evolution of the situation on titanium dioxide as a food additive is being closely monitored in other parts of the world (Republic of Korea, Switzerland and UK) and for its future as a pharmaceutical excipient. Collaboration with other stakeholders to promote the safety aspects of E171 is ongoing.

### Microplastics

IPEC Europe and IPEC-Americas worked together to develop a “How To” document to summarise the core elements of the restriction proposal of the ECHA's EU-wide Restriction on Intentionally Added Microplastics.

This dynamic document intends to provide guidance for excipient manufacturers and users on how to prepare for compliance and will be amended as the legislation is finalised.

The document can be retrieved in the [IPEC Europe](#) and [IPEC-Americas](#) websites.

## IPEC Europe Forum 2022

by IPEC Europe

IPEC Europe is delighted to announce that the IPEC Europe Forum is back and will take place as a face-to-face event in Brussels, on 23 June 2022! This eagerly-awaited Forum will be an opportunity to celebrate IPEC Europe's 30th Anniversary.

[Learn more and register.](#)

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networking pass allows attendees to bring a significant other to all evening networking events.

Education continues in the Excipient World exhibit hall – a center for collaboration and information exchange between all industry stakeholders (excipient users, makers, distributors, etc.). This year 35+ industry suppliers will be exhibiting and 20+ posters will be on display showcasing the latest excipient research and innovations. In addition, the new Exhibit Hall Theater will feature interactive “Quick Talks” on topics including atypical actives, TiO<sub>2</sub>, sustainability, and more! [Learn more and register.](#)  
(Housing deadline: March 31, 2022)

## English version of JP available

by IPEC Japan

IPEC Japan informed that the English version of the 18<sup>th</sup> edition of Japanese Pharmacopoeia has been published on the homepage of MHLW, accessible here.

The association has a full calendar of events coming up this year, including CPhI Japan on 20-22 April, an Introductory course on Excipients on 8 July. IPEC Japan celebrates its 30th Anniversary on 28 October. Many congratulations to our colleagues in Japan!

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## IPEC India and knowledge sharing activities

by IPEC India

IPEC India continues to be very active on virtual platforms during this pandemic period. A series of knowledge-sharing webinars are planned in the coming months. Save the Date for these future events:

- 🌐 April 2022 - Launch of upgraded IPEC India website - <http://ipecindia.org/>
- 🌐 May 06 & 07, 2022 - National Conference on 'Pharmaceutical Excipients: Formulation Backbone' in partnership with School of Pharmacy, RK University, Rajkot, Gujarat
- 🌐 May 31, 2022 - Webinar on 'Breaking Down Barriers to Bioavailability - Overcoming Insolubility issues' by Ruchir Shah, Senior Manager-Technical, AZELIS India
- 🌐 June 24, 2022 - Webinar on 3D Printing, speaker TBC from DFE Pharma

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## Global events of IPECs around the world

20-22 April 2022 – IPEC Japan – [CPhI Japan, Tokyo, Japan](#)

26-27 April 2022 – IPEC Europe – [Making Pharmaceuticals, Coventry, UK](#)

2-4 May 2022 – IPEC-Americas – [Excipient World, Orlando, FL, US](#)

6-7 May 2022 – IPEC India - National Conference on 'Pharmaceutical Excipients: Formulation Backbone' in partnership with School of Pharmacy, RK University, Rajkot, Gujarat

23 May 2022 – IPEC-Americas - [Excipient GMP Compliance Workshop](#)

13-15 May 2022 – IPEC-Americas - [Excipients: Compliance with Compendial and GMP Requirements](#)

23 June 2022 – IPEC Europe – [IPEC Europe Excipients Forum 2022, Brussels, Belgium](#)

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