IPEC Federation Connect

1 / 2023

Welcome

Dear IPEC Federation members and friends,
Welcome to our first 2023 issue of the IPEC Federation bulletin, which we hope you will find interesting. In this edition, we delve into the priority objectives for 2023 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 Board

President **IPEC-Americas** Priscilla Zawislak

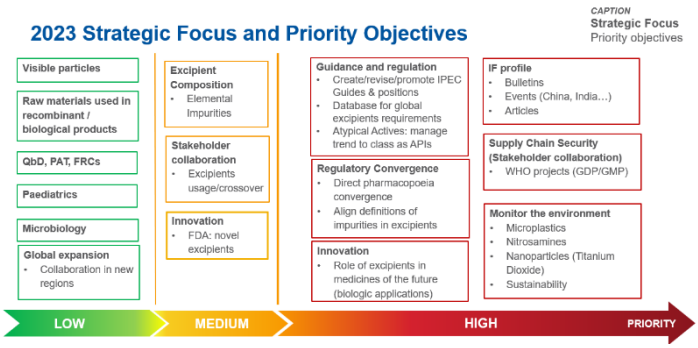
Vice-President **IPEC Europe** Kevin Hughes

Treasurer **IPEC Japan** Hiroshi Watanabe

In this issue

Strategic Focus and Priority Objectives for 2023

Built around the Federation's areas of strategic focus, the Board has identified **several high priority objectives** for 2023:



- Guidance and Regulation: the revision and creation of IPEC Guides; development of a database for global requirements; address the trend to classify Atypical Activities as APIs;
- 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;
- Stakeholder collaboration: Contribute to WHO projects on revision of GDP/GMP guidance;
- Monitor the environment, with special attention to Microplastics, Nitrosamines, Nanoparticles (e.g., titanium dioxide); Sustainability.

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 2023 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 Annual General Assembly

The IPEC Federation organised its Annual General Assembly 2023 virtually on 16 May.
2022 was a positive year for the Federation, which handled the publication of a position paper on Nitrosamines, as well as three revised guides: the Excipient Stability Guide, the Certificate of Analysis Guide and the IPEC-PQG Good Manufacturing Practices Guide.
The Federation submitted comments on several draft regulations across the world as well as fulfilling its observer role at the ICH as in previous years. Hopefully, delegates from all IPECs will be able to reunite face-to-face to discuss the past performance and future strategy.

IPEC-PQG Good Manufacturing Practices Guide

The quality of excipients is critical to assure the safety, quality, and efficacy of medicines. The IPEC-PQG GMP Guide is an invaluable tool in helping to achieve a high level of excipient quality and maintain the integrity of the supply chain for the benefit of patients.

This important revision presents the latest thinking on good manufacturing practices for excipients, and while the fundamental principles of GMP remain the same, the guide has been revised to align with ISO 9001:2015 requirements. This will be of great benefit to the parties responsible for understanding and complying with GMP for pharmaceutical excipients worldwide.
Another significant enhancement is the provision of examples for GMP interpretation and implementation, without adding further requirements. For this reason, this guide is published in two parts:

- Part 1 includes Good Manufacturing Practices for excipients;
- Part 2 includes Good Manufacturing Practices for excipients with notes providing common examples.

The Guide is available on the website www.ipec-federation.org and on regional websites.

A huge THANK YOU to the core team that developed this Guide for their tremendous efforts:

William Dale Carter, Evonik (Co-chair)
George Collins, Vanderbilt Chemicals
Ann Gulau, IFF
Ian McKeown, PQ Silicas *(PQG)*
Astrid Stockrahm-Uhling, DFE Pharma (Co-chair)
Roberto Mastrantonio, Eli Lilly
Beverley Stout, GSK
Jeffrey Brambora, Consultant

The new European Pharmaceutical Strategy

by IPEC Europe

On 26 April 2023, the European Commission unveiled its proposed revisions to pharmaceutical legislation in the European Union (EU). These changes will be implemented through a directive and a regulation, which will replace Directive 2001/83 (the Community code on medicinal products for human use) and Directive 2009/35/EC. The proposed reforms encompass several new and adjusted regulations.
The primary objective of this reform is to enhance the availability, accessibility, and affordability of medicines within the EU. It also seeks to elevate environmental standards, boost the competitiveness and appeal of the pharmaceutical industry in the region. Key aspects of the proposal include streamlining administrative processes, fostering innovation and competitiveness, addressing shortages of pharmaceuticals, ensuring environmental sustainability, and combating antimicrobial resistance.
Overall, this revision aims to establish a more efficient and sustainable pharmaceutical framework that caters to the needs of the EU population, while fostering a thriving and environmentally conscious pharmaceutical sector. A dedicated IPEC Europe task force is analysing the proposals to provide feedback to the European Commission.

Sessions from Excipient World

by IPEC-Americas

TWO HIGH-DEMAND SESSIONS AVAILABLE FOR DOWNLOAD

FDA's Recent Quality Concerns with Excipients
Francis Godwin, Office Director, OMQ, OC, CDER, FDA

During an interactive presentation held on 3 May at Excipient World Conference & Expo, Francis Godwin addressed FDA's recent excipient quality concerns with a highly engaged, "standing room only" audience.
Excipients are subject to Current Good Manufacturing Practice (cGMP) requirements. In the past year FDA has encountered multiple quality concerns with excipients that have led to drug product recalls and adverse events. This talk highlights the regulatory landscape regarding the FD&C act and excipients, as well as presenting recent case examples of FDA regulatory actions taken at various levels in the supply chain when quality concerns with excipients were found.
Purchase the recording here.

Update on FDA's Inactive Ingredient Database
Susan Zuk, Branch Chief, OPQ, CDER, FDA

On the same day, Susan Zuk provided an update on the FDA's Inactive Ingredient Database (IID).
Excipients, the inactive ingredients in pharmaceutical products, are essential drug product components that facilitate drug delivery, promote solubility, improve taste and, in general, allow active pharmaceutical ingredients to be transformed into useable dosage forms. For over 30 years, FDA has published the Inactive Ingredient Database (IID), a publicly available list of the excipients used in FDA approved drug products, as a tool for drug development. Over the years, FDA has made small gradual improvements to the IID in response to requests from industry. In this presentation, FDA provided its vision for the IID as an essential tool for drug development.
The recording of this presentation (including the full Q&A) is now available for on-demand viewing.
Purchase the recording today!

Updates from Japan

by IPEC Japan

Japan's GMP Auditing Board for pharmaceutical excipients (GAB) announced the publication of a GMP Standard for Pharmaceutical Excipients 2022 on their home page. While it references the IPEC-PQG GMP guide 2017 and other international standards, the GAB standard is unique in its requirements. As alignment with the IPEC-PQG document was not possible in this revision, GAB agreed to treat the GAB 2022 standard as 'stand-alone' from IPEC Japan. IPEC Japan will create a voluntary excipient GMP guideline based on IPEC-PQG's 2022 guide.

IPEC Europe Forum 2023

by IPEC Europe

Held in Lisbon (Portugal) on 16 March, the IPEC Europe Forum enabled speakers and attendees to discuss, network and learn about a number of hot topics on pharmaceutical excipients. The programme featured a panel session on the impact of sustainability concepts on excipient supply chains and regulators, updates from EDQM and USP, and mitigation strategies for nitrites and nitrosamines, amongst others.
The next Forum will take place in Bordeaux, France on 8 February 2024.

Updates from China

by IPEC China

The preparation of the Chinese Pharmacopoeia 2025 Edition began in December 2022. Some general chapters, testing methods and monographs have been released already.
The IPEC China Chinese Pharmacopeia Subcommittee summarized all documents for consultation with IPEC China members, the outcome of which will determine which internal task forces will be set up. Change management of pharmaceutical excipients for and excipient GMPs are hot topics in China right now.
Greater attention is being paid to the safety of paediatric medicines and the quality and safety of excipients used in them. This may drive a need for more safety studies on excipients used in dosage forms for children.

IPEC India Annual Conference 2023 – Mumbai

by IPEC India

For the excipient industry to grow, there is a need for focus in five areas in a collaborative and strategic manner: technology, regulatory & compliance, quality of excipients, safety data and supply chain value & cost. There should also be proactive surveillance by industry of the quality of excipients. Validated analytical methods should be used for quality control testing just as is done in research and development. These were the thoughts shared by experts at the International Pharmaceutical Excipients' Council of India Annual Conference 2023 held in Mumbai on 26 May 2023.

IPEC India Managing Committee with Speakers

Conference Participants Overview

2023 IPEC Guides and position papers work plan

Guides and position papers being revised:

- Nitrosamines position paper
- Excipient Stability program Guide
- IPEC Good Distribution Practices (GDP) Guide
- Co-processed excipients Guide
- Technically Unavoidable Particle Profile (TUPP)
- IPEC Glossary of Terms
- Quality Agreements Guide and Templates

Published Guides year-to-date – download available on ipec-federation.org

- Excipient Information Package – Supplementary chapter on sustainability
- Significant Change Guide

Upcoming Events

SAVE THE DATE!

Excipient World Conference & Expo 2024

Collaborating for Sustainable Medicines
May 13 – 15 2024
Gaylord Palms Resort & Convention Center
Kissimmee, FL (Orlando Metro Area)

Register now

IPEC Europe Excipient Conference 2023

An update on regulatory developments and excipient applications in Drug Delivery
Rotterdam, The Netherlands
27/28 September 2023