IPEC Federation Connect

1 / 2021

Welcome

Dear IPEC Federation members and friends,
Welcome to our latest edition of the IPEC Federation bulletin, which we hope you will find interesting. In this edition, we delve into the Federation's objectives for 2021 and news from the IPECs around the world.
Enjoy it, share it and as always, your feedback is most welcome. Contact us for more details!
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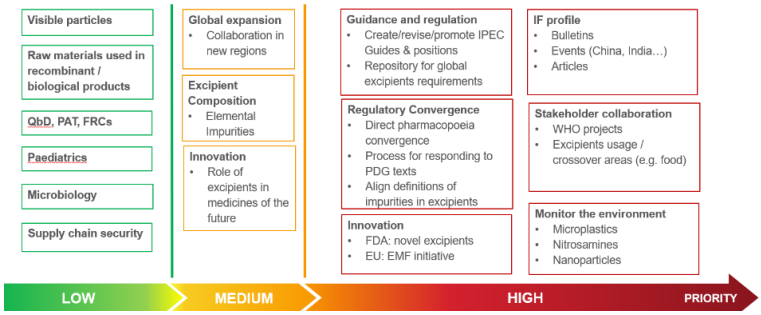
In this issue

Strategic Focus and Priority objectives for 2021

Built around the Federation's area strategic focus, the Board has identified **several high priority objectives** for 2021:

- Guidance and Regulation: Focus on the revision and creation of IPEC Guides; development of a new repository for global requirements;
- Innovation: Novel excipients and EMF;
- 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, process to respond to PDG texts;
- Monitor the environment, with particular attention to Microplastics, Nitrosamines and Nanoparticles



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.
Guide programmes continue to be a significant effort for the Federation and three new revision teams have been created for Stability, CoA (Certificate of Analysis) and Significant Change.
Thanks to the many IPEC members across the world who volunteered to participate in these groups!

IPEC Federation Annual General Meeting

The IPEC Federation organised its Annual General Assembly online on 26 April.
Delegates from all IPECs reunited virtually to discuss the results of the past year and 2021 objectives.
2020 was a constructive year for the Federation, which steered the publication of two position papers on Data Integrity and Good Manufacturing Practices Documents as well as two new guides on GMP Certification Scheme & Certification Body Qualification, and Quality by Design.
Our ambitious revision programme resulted in publishing the updated Qualification Guide, the Excipient Information Package and Composition Guides.
The Federation submitted comments on several draft regulations across the world as well as fulfilling its observer role at the ICH – more on that in the dedicated article on ICH Q13.

In 2021, the Federation is pursuing its aggressive agenda to publish several new and revised guides which feature in the 2021 Strategic Plan. Good news is that so far this year, the new Validation Guide and the updated Glossary have been released, with the GDP Audit Guide planned for publication in the near future. A very exciting development which is in the preliminary stages of exploration is the creation of a database of global excipient requirements.

30 years of IPEC-Americas

by IPEC-Americas

IPEC-Americas celebrated its 30th Anniversary in June, 2021. Thirty years of elevating the relevance of excipients in finished drug products! In February of 1992 the Japan Pharmaceutical Excipients Council (now known as IPEC Japan) was formed; and IPEC Europe was formed shortly thereafter, in April of 1992.

Over the last 30 years, IPEC members have been advocating to increase awareness of the critical role that excipients play in finished drug products. Excipients are not always inactive, and in many cases, are vital components that help to deliver the drug in the most efficient and effective way to its intended target. Excipients help to preserve the efficacy, safety, and stability of active pharmaceutical ingredients (APIs), and help ensure that they deliver their promised benefits to patients.

IPEC-Americas will continue to advance its mission to advocate, educate, innovate and develop best practices for excipients, with a focus on patient safety, and will be celebrating its 30th Anniversary in conjunction with the Excipient World Conference & Expo at the Gaylord National Harbor in the Washington DC Metro area.

EXCLUSIVELY EXCIPIENTS
IPEC-AMERICAS EXCIPIENT WORLD Conference & Expo

ICH Q13 Update

by Brian Carlin, IPEC Federation representative to ICH

The ICH Expert Working Group for the Quality Guideline on the Continuous Manufacturing of Drug Substances and Drug Products (Q13) held a virtual meeting from May 24th – 27th to finalise a draft of the Step 1 Technical Document based on the objectives set out in the Concept Paper, published on the ICH website.

This draft Technical Document will be forwarded in June to the ICH assembly for review and endorsement (Step 2) which will then initiate regional public consultation via the appropriate regulatory authorities. For example, in the USA it will be published as draft guidance in the Federal Register with a request for public comment. In Europe it will publish as a draft CHMP Guideline, and in Japan it will be issued by MHLW/PMDA. Each region's public consultation period may range from 30 days up to 6 months.

The Expert Working Group will now commence development of complementary training materials.

Japan – Risk Assessment

by IPEC Japan

The revision of GMP Ministerial Ordinance by Ministry of Health, Labour and Welfare of Japan (MHLW) was promulgated on 28 April 2021 and will come into effect on August 1.

The key issue in the revision for excipients manufactures that MHLW recommends to refer the guideline of PIC/S PI 045-1 Guidelines on the Formalised Risk Assessment For Ascertaining the Appropriate Good Manufacturing Practice for Excipients of Medicinal Products for Human Use/

Global events of IPECs around the world

IPEC Federation – Validation for Pharmaceutical Excipients – webinar – 21 July 2021
IPEC Europe – IPEC Europe Excipients Conference 2021 – online - 22-23 September 2021
IPEC-Americas – Excipient World – National Harbor, MD, US – 27-29 September 2021