



Press Release

Brussels (Belgium), 8 October 2024

The International Pharmaceutical Excipients Council Federation (IPEC Federation) announces the publication and availability of a comprehensive update to the **IPEC Good Distribution Practices Guideline for Pharmaceutical Excipients** (version 3, 2024), jointly developed by a team consisting of members from IPEC Europe and IPEC-Americas.

Excipients play a critical role in the manufacture of medicines by helping to preserve the efficacy, safety, and stability of active pharmaceutical ingredients (APIs), and help to ensure that they deliver their promised benefits to patients.

The IPEC Good Distribution Practices Guideline has proven to be an important element in the supply chain management and control of pharmaceutical starting materials. The updated guide provides a comprehensive tool for companies operating within the supply chain of pharmaceutical excipients. Several serious incidents in the past, and more recently over the past two years resulted in the deaths of many children caused by a lack of supply chain security, inappropriate handling of pharmaceutical excipients and falsification of records. This has moved regulators, users, manufacturers and distributors to take action.

It is IPEC Federation's position that those involved throughout the entire supply chain for the distribution of pharmaceutical excipients as well as stakeholders should rigorously promote and apply the principles of **Good Distribution Practices (GDP)** as provided in this updated Guideline.

IPEC Federation strongly believes that the application of GDP by all stakeholders in the excipient supply chain will help to avoid incidents resulting from the use of sub-standard excipients in drug products as described above.

For the purpose of this document "distributors" includes for example, those parties involved in trade and distribution, re-processors, re-packagers, transport and warehousing companies, forwarding agents, brokers, traders, and suppliers other than the original manufacturer.

Please refer also to the IPEC Federation Position Paper on Latest fatal incidents with contaminated medicinal syrup during 2022/2023 published in August 2023 (<https://ipec-federation.org/supply-chain-security/>).

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The guide will be available, initially exclusively to IPEC members for a three-month period, on the IPEC Federation and national/regional members' websites. Thereafter, the guide will be made available to the general public.

For further information contact the IPEC Federation Secretariat at:

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About IPEC Federation

The IPEC Federation is a global organization that promotes quality in pharmaceutical excipients. The IPEC Federation represents the five current regional International Pharmaceutical Excipient Councils (IPECs) - IPEC-Americas, IPEC Europe, IPEC Japan, IPEC China and IPEC India - and provides a unified voice to promote the best use of pharmaceutical excipients in medicines as a means of improving patient treatment and safety.

Further details are available on the IPEC Federation website <http://www.ipec-federation.org> .

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