



# Press Release

Brussels (Belgium), 14 September 2021

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of the revised IPEC Good Distribution Practices Audit Guide for Pharmaceutical Excipients (Version 3, 2021).

The revised IPEC Federation Good Distribution Practices Audit Guide has been developed by a team consisting of members from IPEC Europe and IPEC-Americas. This document is a consolidation and revision of IPEC Europe's GDP Audit guideline (2011) and IPEC-Americas GDP Audit Guide for North American distribution of pharmaceutical excipients (2011).

The IPEC Good Distribution Practices Audit guides have been proven as an important element in the supply chain management and control of pharmaceutical starting materials. The revised Audit Guide provides a comprehensive tool for companies auditing the supply chain of pharmaceutical excipients. Several incidents in the past were caused by a lack of supply chain security and inappropriate handling of pharmaceutical excipients. This has moved regulators, users, manufacturers and distributors to take action.

The revised GDP Audit Guide should be used in conjunction with the IPEC Good Distribution Practices Guide. It serves as a valuable tool to help the auditor conduct a complete audit of all relevant GDP principles for pharmaceutical excipients.

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.

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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