



PRESS RELEASE

IPEC Federation publishes its position on supply chain security for Pharmaceutical Grade Excipients

Brussels, 23 May 2019

The IPEC Federation has published a new position paper on **Supply Chain Security for Pharmaceutical Grade Excipients** on 23 May 2019.

Supply chain security requires the protection and control of pharmaceutical excipients across the entire supply chain, downstream from the excipient manufacturer to the finished dosage form producer. Throughout, product quality, traceability and integrity must be assured in order to minimize the risk to patients which may result from the use of falsified and sub-standard excipient products.

This paper was written in response to many tragedies, even deaths, caused by the use of falsified excipients in recent decades. Today's increasingly complex global supply chains create additional risk and therefore considerations related to excipient security.

Aimed at providing support to all parties involved in the supply chain, for example pharmaceutical excipient manufacturers, distributors (re-packers, bulk storage and packed storage warehouse providers), traders, brokers, carriers and other service providers, the paper summarizes existing applicable regulations and various tools supporting good practices for supply chain security and ultimately drug safety. These include IPEC Federation's Good Distribution Practices Guide for Pharmaceutical Excipients, IPEC-Americas Risk Assessment Guide and the EXCiPACT and NSF/IPEC/ANSI 363 certifiable GMP and GDP standards for excipient suppliers.

The IPEC Federation specifically emphasises that while overall responsibility remains with the finished dosage form manufacturer, each participant in the supply chain, both up and downstream, has responsibilities for its own specific area of activity. Establishing controls at each interface is imperative, where the level of control required can be determined using IPEC's Risk Assessment Guides. These principles should establish and ensure supply chain security of excipients thereby minimising risk to patients.

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About IPEC Federation

Created in 2010, the IPEC Federation is a global organisation that promotes quality in pharmaceutical excipients. The IPEC Federation represents the five existing regional International Pharmaceutical Excipient Councils (IPECs) – IPEC-Americas, IPEC Europe, IPEC Japan, IPEC China and IPEC India. It provides a unified voice to promote the best use of excipients in medicines as a means of improving patient treatment and safety. Its global membership extends to more than 200 companies.

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The French-speaking Business Court of Brussels Capital Region is competent for dispute resolution and litigation