



## **Press Release**

Brussels (Belgium), 26 September 2022

The International Pharmaceutical Excipients Council Federation (IPEC Federation) and the Pharmaceutical Quality Group (PQG) are pleased to announce the availability of the revised International Pharmaceutical Excipient Council – Pharmaceutical Quality Group Good Manufacturing Practices Guide for Pharmaceutical Excipients (version 5).

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.

This updated version becomes the sole reference for IPEC-PQG GMP, and previous versions are obsolete. We recommend that users of the guide study its contents carefully. This will enable any existing descriptions of how an excipient manufacturer's quality system aligns with the IPEC-PQG GMP requirements to be re-presented according to the guide's new structure.

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

For further information contact the IPEC Federation or PQG Secretariat at:

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