

## **Press Release**

Brussels (Belgium), 12 November 2020

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of the new International Pharmaceutical Excipient Council GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients. The guide was developed for excipient users (e.g. pharmaceutical manufacturers) to qualify both certification bodies (CB) that issue excipient GMP and GDP certificates and audit reports as well as Certification Scheme Owners. The use of the guide is intended to facilitate sharing pertinent information from the CBs and Scheme Owners to excipient users in a standardized way.

The guide and its associated "sample" template were designed to facilitate the provision of standardized information from the CB or Scheme Owner to the excipient user. This will accelerate communication between all parties, helping consistency in the level and type of information/documentation required avoiding multiple diverse questionnaires/information requests from different excipient users.

Qualifying the CB and/or the Scheme Owner should facilitate the acceptance of excipient GMP and GDP certification schemes, audit reports and certificates which may substitute for audits otherwise performed by the excipient users.

A template for the certification body is included.

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

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## **IPEC Federation asbl**

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