PRESS RELEASE

DEVELOPMENT OF A NEW CHINESE GMP STANDARD FOR PHARMACEUTICAL EXCIPIENT SUPPLIERS WORLDWIDE

Brussels, 31 March 2021

We are pleased to announce the development of an additional section to our existing GMP Annex for pharmaceutical excipient suppliers to include the mandatory requirements of the present Chinese excipients GMP. Publication in Chinese and English is planned for the first quarter 2022.

The development team is based in China and aimed at including volunteer representatives from the Chinese pharmaceutical excipients suppliers, users, trade associations, local regulatory authorities, expert pharmaceutical industry consultants, Certification Bodies and others involved in auditing excipients suppliers.

Certification against the combination of the existing EXCiPACT GMP Annex with the Chinese GMP Annex would ensure that an excipient supplier is fully compliant with the Chinese excipient GMP (2006) and current regulations. This will allow greater uptake of EXCiPACT GMP Certificates for use in pharmaceutical drug manufacture either in China or elsewhere for importation into China.

China is one of a small number of countries which has legally defined GMP for excipients. Although this regulation is aligned with the IPEC/PQG GMP Guide 2006, and is so aligned with EXCiPACT GMP standard 2017, there are important differences and some increased requirements. In addition, all excipients used in Chinese licenced drug products must have a valid Drug Master File submitted to CDE (Centre for Drug Evaluation) of NMPA (National Medical Products Administration).

Notes for the Editor

EXCiPACT asbl owns and provides management oversight for the voluntary, independent, high quality international EXCiPACT Certification Scheme that provides for independent 3rd party GMP and/or GDP certification of manufacturers, suppliers, and distributors of pharmaceutical excipients worldwide. The Scheme ensures patient safety through supplier quality while minimising the overall costs for assessing the excipient supply chain. Operational from 2013 since when considerable interest has been generated among pharmaceutical excipient suppliers, their customers, and regulators. For further information see www.excipact.org or contact info@excipact.org