

Thank-you Message from EXCiPACT to Shanghai Centre of Drug Evaluation and Inspection

EXCiPACT's core focus is to help assure patient safety though the supply of reliable and highquality excipients which are manufactured to a suitable GMP standard. This is an ambition we share with our Members like IPEC, SEPPEA and PQG, and of course regulatory authorities around the world. In all the work EXCiPACT does to develop higher levels of assurance we always seek constructive feedback from all our stakeholders, including, where possible, the regulatory authorities.

In this respect the inputs of Shanghai Centre of Drug Evaluation and Inspection (SCDEI) to the new EXCiPACT China excipient GMP standard have been especially valuable as these have confirmed we have understood the intent of the existing China Excipient GMP rules and mapped them correctly into the EXCiPACT GMP structure. This new version of EXCiPACT GMP will provide greater access to excipient suppliers, who have based their quality systems on ISO 9001, to manufacture and supply excipients in accordance with the China excipient GMP regulations.

We sincerely thank SCDEI for the time they spent in reviewing our draft, and the explanations provided during that process.

As a result of SCDEI's review we are confident the new EXCiPACT China GMP will contribute to the supply of safe and good quality excipients in China.

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