PRESS RELEASE

BLUE CUBE GERMANY ASSETS SITE IN STADE RECEIVES EXCiPACT GMP AND GDP CERTIFICATION AS PHARMACEUTICAL EXCIPIENT SUPPLIERS

Brussels, 10 May 2019

EXCiPACT asbl is pleased to announce that the **Blue Cube Germany Assets site in Stade** has recently been awarded an EXCiPACT GMP and GDP Certificate from **DQS**, one of EXCIPACT's internationally-recognised Certification Bodies. The Certificate demonstrates that this site manufactures pharmaceutical excipients according to the EXCiPACT Good Manufacturing Practice (GMP) and the Good Distribution Practice (GDP) Certification Standards. Its scope covers manufacturing of excipients (COPTIM™ Glycerine 99,7%, USP/EP, OPTIM™ Plus Glycerine 99,7%, USP/EP. Analytical testing and release of excipients according to pharmacopeia requirements, storage, packaging and supply of excipients.

Both **DQS** and their auditors had to undergo a rigorous assessment process in order to be EXCiPACT Registered. Both have satisfied the additional EXCiPACT competency requirements set out in the EXCiPACT annex to the ISO/IEC 17021-1:2015 standard. These include completion of the 2-day EXCiPACT Auditor Training Course, post-course written examination and an independently witnessed audit to verify their competency to the required standard. **DQS** also had to have their auditor's report verified by their independent certification board prior to issuing the certificate.

For full details of all sites that have been EXCiPACT certified to date in 17 countries (Canada, China, Belgium, France, Germany, India, Israel, Italy, Japan, Romania, Saudi Arabia, Singapore, Spain, Switzerland, The Netherlands, UK and USA), see http://www.excipact.org/certificate-holders.html.

EU and U.S. pharmaceutical regulations require drug manufacturers to conduct either their own or commission third-party physical risk-assessment audits of all their starting material suppliers to demonstrate GMP and/or GDP compliance thus increasing the audit burden. However, using GMP and GDP standards designed specifically for pharmaceutical excipients, the voluntary, independent, high quality, EXCiPACT Certification Scheme helps pharmaceutical excipient users and their suppliers to demonstrate their commitment to GMP/GDP, to reduce their audit burden, to save costs and to assure product quality.

Notes for the Editor

EXCiPACT asbl provides management oversight for the voluntary, high quality, international EXCiPACT Certification Scheme that provides for independent third-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. It has been operational since early 2013 since when there has been considerable interest among pharmaceutical excipient suppliers, their customers and regulators. For further information see www.excipact.org or contact info@excipact.org