international excipients certification

NEWS RELEASE

CARBAGAS DOMDIDIER SITE IN SWITZERLAND RECEIVES EXCiPACT GMP CERTIFICATION AS PHARMACEUTICAL EXCIPIENT SUPPLIERS

Brussels, 14 March 2017

EXCiPACT asbl is delighted to announce that the **Carbagas Domdidier site** has recently been awarded an EXCiPACT Certificate from AJA, one of EXCIPACT's internationally-recognised Certification Bodies.

The Certificate demonstrates that the Carbagas site in Domdidier, Switzerland, manufactures pharmaceutical excipients according to the EXCiPACT Good Manufacturing Practice (GMP) Certification Standard. Its scope covers manufacturing (filling) of pharmaceutical grade gases (nitrogen, oxygen, argon, carbon dioxide) in cylinders and bundles. For full details of all sites that have been EXCiPACT certified to date in 14 Countries (Canada, China, Belgium, France, Germany, The Netherlands, India, Israel, Saudi Arabia, Singapore, Spain, Switzerland, UK and USA), see http://www.excipact.org/certification/certificates/

Both AJA and their auditors had to undergo a rigorous assessment process in order to be EXCiPACT Registered. This required the successful completion of the EXCiPACT Training Programme and post-course examination followed by an independently witnessed audit to verify that their competency was to the required standard. AJA also had to have their auditor's report verified by an independent certification board prior to issuing the certificate.

EU and U.S. pharmaceutical regulations require drug manufacturers to conduct either their own or commission 3rd party physical audits of all their starting material suppliers to demonstrate GMP and/or GDP compliance thus increasing the audit burden. Using GMP and GDP standards designed for excipients, the independent, high quality 3rd Party EXCiPACT Certification Scheme is already helping excipient users and suppliers to reduce their audit burden, save costs and assure quality.

Notes for the Editor

EXCiPACT asbl provides management oversight for a high quality, voluntary 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 will ensure 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, customers and regulators. For further information see www.excipact.org or contact info@excipact.org.