



NEWS RELEASE

VWR'S OHIO SITES RECEIVE EXCIPACT GMP & GDP CERTIFICATION AS PHARMACEUTICAL EXCIPIENT SUPPLIERS

Brussels, 10th January 2017

EXCiPACT asbl is delighted to announce that two **VWR sites in Ohio, USA** have each recently been awarded an EXCiPACT GMP & GDP Certificate from blue inspection body (bmb), one of EXCIPACT's internationally-recognised Certification Bodies.

Separate bmb certificates demonstrate that the **AMRESCO**, **LLC site in Solon**, **OH** and **the VWR Chemicals**, **LLC site in Aurora**, **OH** - both owned by VWR International, LLC of Radnor, PA - operate their facilities according to the EXCiPACT Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) Certification Standards. The scope at both sites covers sourcing, testing, packaging, storage, release and distribution of products for pharmaceutical excipient use; salts, carbohydrates, denaturants and buffers. 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 <u>http://www.excipact.org/certification/certificates/</u>

Both bmb 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. They also had to have their auditor's reports verified by an independent certification board prior to issuing the certificates.

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 specifically 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 <u>www.excipact.org</u> or contact <u>info@excipact.org</u>. **EXCiPACT is a registered trademark**.

minimize risks, maximize benefits

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