PRESS RELEASE

SAFC Biosciences, Inc., sites in Lenexa, USA, RECEIVES EXCiPACT GMP CERTIFICATION AS PHARMACEUTICAL AUXILIARY MATERIALS SUPPLIER

Brussels, 13 September 2024

EXCiPACT is pleased to announce that the **SAFC Biosciences Inc, sites in Lenexa, USA,** has recently been awarded an EXCiPACT GMP Certificate from **SGS**, one of EXCIPACT's internationally recognised Certification Bodies.

The Certificate demonstrates that these sites manufacture custom and catalog cell culture media to be used as Pharmaceutical Auxiliary Materials in upstream bioprocessing. They warehouse raw materials for Pharmaceutical Auxiliary Materials. They also warehouse and ship custom and catalog cell culture media to be used as Pharmaceutical Auxiliary Materials in upstream bioprocessing, according to the 2021 EXCiPACT Certification Standard for Pharmaceutical Excipient Suppliers.

Both **SGS** and their auditors had to undergo a rigorous assessment process 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 EXCiPACT Auditor Training Course, post-course written examinations and independently witnessed audits to verify their competency to the required standard. **SGS** also had to have their auditors' reports verified by their independent certification board prior to issuing the certificates.

For full details of sites currently EXCiPACT certified in 20+ countries (including: Belgium, Canada, China, France, Germany, India, Israel, Italy, Japan, The Netherlands, UK, USA, …), see: http://www.excipact.org/certificate-holders.html.

EU and US pharmaceutical regulations require drug manufacturers to conduct either their own or third-party physical risk assessment audits of all of 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, EXCiPACT's voluntary, independent, high quality Certification Scheme helps pharmaceutical excipient users and their suppliers to demonstrate their commitment to GMP/GDP, reducing their audit burden and costs, to assure product quality.

Notes for the Editor

EXCiPACT 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. It has been operational since early 2013 and there is now considerable interest among pharmaceutical excipient suppliers, customers, and regulators. For further information see www.excipact.org or contact info@excipact.org