

DM Bio's Biopharmaceutical manufacturing
complies with Japanese GMP through PMDA inspection

Meiji Seika Pharma Co., Ltd. (Head office: Chuo-ku, Tokyo, President: Daikichiro Kobayashi, "Meiji") today announced that biopharmaceutical manufacturing at DM Bio Limited (Head office: Incheon, Korea, CEO: Byoung Jo Min, "DM Bio") is complied with Japanese GMP, as a result of GMP compliance inspection of foreign manufacturing sites conducted by the Pharmaceuticals and Medical Devices Agency ("PMDA").

DM Bio Limited, a joint venture company located in Incheon Free Economic Zone in Korea, was established in 2013 under the agreement between Meiji and Dong-A Socio Holdings Co., Ltd. (Head office: Seoul, Korea, CEO: Jong Hyun Han, "Dong-A Socio HD") of September 2011. DM Bio focuses its business on production of biopharmaceuticals, such as therapeutic proteins and monoclonal antibodies. DM Bio provides CDMO services applying cutting-edge hybrid production system to effectively produce various kinds of APIs and finished products.

DM Bio has already established a quality management system that meets the US FDA GMP and PIC/S GMP standards in consultation with Lachman of the United States. Currently, in compliance with Japanese GMP, DM Bio can also manufacture biopharmaceuticals for Japanese market.

DM Bio and Meiji Seika Pharma will continue to improve the quality control system for biopharmaceutical manufacturing and aim to expand the CDMO services.

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