

United BioPharma Inc. selects GE Healthcare's FlexFactory manufacturing platform

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United BioPharma Inc. (UBP) has selected GE Healthcare's FlexFactory manufacturing platform to its new facility focusing on late-stage clinical and commercial production capacity of therapeutic monoclonal antibodies in Hsinchu Industrial Park, Taiwan. With this added capacity, UBP will support local healthcare needs by bringing biopharmaceuticals to the Taiwanese and surrounding markets faster, whilst also opening global markets through the FlexFactory's proven track record in meeting global regulations and quality standards.

The project received support from the Taiwanese government to help improve access to biopharmaceuticals and boost the bioprocess market in the region. This is a key priority for the Taiwanese government, which has introduced several policies to create a favorable environment for the development of the biotech, pharma and medical devices industry in the country.

The new facility, including GE's FlexFactory based on integrated single-use technologies, will be dedicated to late-stage clinical and commercial production capacity of biopharmaceuticals, especially a monoclonal antibody, UB-421, which will be used for HIV treatment. GE will also continue to work closely with UBP on the establishment of its contract development and manufacturing organization (CDMO) business.

Dr. Chang Yi Wang, Chairperson of UBP, said: "The completion of this state-of-the-art facility equipped with two of GE's 2,000 liter single-use bioreactors and integrated manufacturing process is a much-anticipated achievement for UBP to enter into commercial-scale current Good Manufacturing Practice (cGMP) -production with international standards. It also resolves the manufacturing bottleneck for UBP's rich pipeline. With the potential expansion to twelve 2,000-liter production lines within this 8-story building, UBP is and will continue to be the largest protein drug manufacturer in Taiwan in the foreseeable future."

The head of Taiwan's Industrial Development Bureau (IDB), Ministry of Economic Affairs (MOEA), said, "In order to improve

the industry's protein drug technology and commercialization capability, the MOEA will assist, through Industry Collaboration Programs, to bring in and transfer GE Healthcare's process optimization and scale-up technology for monoclonal antibodies to United BioPharma (UBP). Through this, we will indirectly assist the establishment of UBP's 2,000L x 2 Biologics Manufacturing Plant. We expect that the successful operation of this plant will further enhance global competitiveness of Taiwan's protein drug industry. We believe this will become the driving force for the growth of Taiwan's biotechnology industry."

Sven Henrichwark, General Manager, Global Commercial BioProcess, GE Healthcare Life Sciences, said: "UBP's Flex Factory will help deliver increased capacity as well as supporting Taiwan's growing pharma industry requirements more rapidly. Taiwan's desire to boost its manufacturing capacity is an industry need we are hearing echoed across the globe. Local production capability is a crucial element in providing national healthcare systems with the vital medicines to address growing patient needs. We are excited to contribute to UBP's development by delivering a robust and flexible biomanufacturing solution, that includes final qualification and training."

UBP's partnership with GE started as a Fast Trak collaboration. GE Healthcare's Fast Trak centers, with their advanced laboratories, provided large scale equipment and process related support for UBP's R&D team members in developing new biopharmaceuticals. The collaboration , under the Industrial Cooperation Program, helped manufacture clinical material and technology transferred the manufacturing process back to the UBP team in Taiwan with complete transparency, while their facility was being built.