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Singapore: On May 10th 2016, JHL Biotech (JHL), opened the world's first KUBio biopharmaceutical manufacturing facility in Wuhan, China. GE Healthcare's KUBio is a fully functional off-the-shelf bioprocessing facility specifically designed to meet cGMP requirements while optimizing manufacturing flexibility and productivity. The facility is pre-fabricated and delivered with a complete ready-to-use production line, based on GE Healthcare's Ready-to-Process single-use technologies.
In an email interaction with us, Mr Jan MÃ?Æ?Ã?Â¤kelÃ?Æ?Ã?Â¤, General Manager for the BioProcess business at GE Healthcare's Life Sciences business, tells us more about this innovative facility. *Edited Excerpts*:

1. **Please throw some light on KUBio manufacturing solution. What is KUBio^{TM}'s core technology and what are its benefits?**
Mr Jan MÃ?Æ?Ã?Â¤kelÃ?Æ?Ã?Â¤: GE Healthcare's KUBio is a prefabricated modular facility based on single-use technologies for monoclonal antibody production.
The facility is installed with the FlexFactory platform, which comprises of bioprocessing equipment from the early stages of cell expansion all the way through to the downstream chromatography steps. This includes technologies such as mixers, bioreactors, filtration and chromatography systems which are integrated through a single automation platform (such as WonderWare or DeltaV).
Using standardized equipment and an optimized layout also provides the bio manufacturer with a facility that can be replicated at multiple sites, for easy tech-transfer and scale-up.
KUBio's key benefit is rapid construction, and corresponding reduction in risk. In comparison to the 2-3 years of design and construction which is typical for conventional stick-built bio manufacturing facilities, KUBio is ready-to-run in 14 to 18 months, translating to a faster time to market. This timeline includes every phase of the build including design, construction and full fit-out with bioprocessing equipment.
Every stage of the project is supported by GE technical expertise, including facility design, procuring and production of process equipment, installation, qualification, staff training, technical support and project management. Financial guidance is also part of the offering.

2. What are some of the most pervasive operating challenges afflicting biopharma manufacturing today? How does KUBio™'s technologies fill the needs of the current bioprocessing manufacturing?

Mr Jan MÃ?Æ?Ã?Â¤kelÃ?Æ?Ã?Â¤: There is an increasing demand for biopharmaceuticals worldwide. Seven of the top 10 selling medicines by revenue are in a new class of drug called biologics, sales of which, over the past six years, have grown at 10% per annum to $170 billion, primarily because of the expansion of new treatments for cancer and demand for insulin. Biopharmaceutical manufacturers are looking for ways to expand their capacity and enter markets that have previously been difficult to access due to location. KUBio was launched to address these needs. The speed and flexibility of single-use components is now well-recognized across the industry - and GE Healthcare's know-how in the sector and global footprint makes us ideally-placed to harness this potential and package it for rapid deployment wherever a customer requires.

3.Can you share with us list of your clients that have utilized KUBio™'s? How has been the reception/feedback by these companies?

Mr Jan MÃ?Æ?Ã?Â¤kelÃ?Æ?Ã?Â¤: This is the world's first KUBio, so JHL Biotech are the only owners of one these facilities at present.

GE is now building another KUBio (purchaser has not yet been publicly announced) and is discussing project opportunities in such countries as Brazil, Mexico, South Korea and Saudi Arabia, among other places.

4. What are the major markets for KUBio™'s in Asia and what is the demand in these countries?

Mr Jan MÃ?Æ?Ã?Â¤kelÃ?Æ?Ã?Â¤: Currently in China, there is a huge unmet need for affordable biologics. China accounts for 20 percent of worldwide cancer incidence, the second-highest rate in the world. In 2015, around 4.3 million new cancer cases were reported in the country. Biologics hold significant promise in their ability to treat cancer, and are especially strong for targeted therapy in specific areas. Today, biologics account only for 4 percent of the medicines prescribed in China (vs. 22 percent in the US).

In a drive to encourage biological medicine and medical device innovation in the region, a number of action plans have been issued by the region, pledging significant funding on the development of new therapeutics and placing a focus on biosimilars. For example China's State Council's 10-year action plan "Made in China 2025" recognizes biological medicines and medical devices as one of its key industrial focus areas. The market is growing rapidly in China and, reaching approximately $350 million in 2019, up from $44 million in 2009.

KUBio offers global biopharmaceutical manufacturers the ability to reproduce world-class quality, standardized facilities, anywhere in the world. There is interest coming from both the developed and developing world.

5. What are the current trends in biopharmaceutical manufacturing industry and how is GE Healthcare positioned to address the changes?

Mr Jan MÃ?Æ?Ã?Â¤kelÃ?Æ?Ã?Â¤: The industry movement towards developing and producing more targeted (personalized) treatments for specific patient groups, has led to a need for more flexible facilities to allow manufacturers to quickly switch from manufacturing one product to another one. FlexFactory uses predominantly disposable, single-use technologies, eliminating cleaning validation steps reducing the risk of cross-contamination, and providing significant time and cost savings.

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6.How is Asia positioned as a hub for biologics manufacturing? Which countries do you think have potential for biologics manufacturing and why?

Mr Jan MÃ?Æ?Ã?Â¤kelÃ?Æ?Ã?Â¤: Due to a large and aging population, coupled with the rising cancer rates and low penetration of biologic medicines, there is a huge demand for biologics in China. A highly skilled workforce as well as the introduction of a number of government funding initiatives to drive biopharmaceutical development provide significant opportunity in the region.

7.Are Asian markets going to influence biopharmaceutical development around the world? How strong is the biopharmaceutical industry in Asia?

Mr Jan MÃ?Æ?Ã?Â¤kelÃ?Æ?Ã?Â¤: The Chinese government has invested heavily in specific initiatives to drive the development of new therapeutics. MNDIP (Major New Drug Innovation Program) was the first initiative to change China from a manufacturing center for drugs to a center of innovation for new drugs. Started in 2009, this initiative has attracted $4.5 billion from 2009 - 2012.

JHL Biotech, owner of the first KUBio, announced earlier this year that it has received authorization from the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) to begin clinical trial for JHL1101, a rituximab biosimilar to treat rheumatoid arthritis. JHL is the first company from the Greater China region to receive European approval for clinical trial of a monoclonal antibody biosimilar. Whether this is the beginning of a larger trend is too early to say.