

GE's new KUBio box for viral vectors boosts gene therapy manufacturing

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KUBio box leverages expertise in the monoclonal antibody space, accelerates the development of novel drugs and enhances the availability of personalized medicines for an advanced next-generation therapeutics



GE Healthcare Life Sciences is launching KUBio™ box, a fully-integrated, flexible, and adaptable biomanufacturing environment to accelerate the production of viral vector-based gene therapies. The latest addition to the KUBio modular bioprocessing portfolio, KUBio box is expected to speed gene therapies to market and contribute to increased capacity in the viral vector area.

Gene therapies are on the rise in the treatment of a wide range of diseases including cancer. Growing at a compound annual growth rate (CAGR) of 33.3% from 2017 to 2023, the gene therapy market is projected to reach \$4.4 billion by 2023. With more than 700 cell and gene therapies currently in clinical trials, demand exceeds the supply of viral vectors, used in approximately 70% of these therapies under trial. Current market indicators predict that the viral vector manufacturing market will hit \$816 million by 2023.

Olivier Loeillot, General Manager for BioProcess, GE Healthcare Life Sciences, says: "Rapidly adding capacity accelerates the development of novel drugs and enhances the availability of personalized medicines. With KUBio box, we are leveraging our expertise in the monoclonal antibody space to provide biomanufacturers with faster and more cost-effective solutions for advancing next-generation therapeutics."

The first KUBio box on the market is developed in collaboration with Germfree, a Florida-based biotech company globally recognized for its pioneering manufacturing of process ready cleanroom facilities. KUBio box features a Germfree biosafety level 2 (BSL-2) modular bioprocessing environment based on GE Healthcare's proprietary design and equipped with the FlexFactory™ single-use biomanufacturing platform, tailored for the production of viral vectors.

Carol Houts, Germfree's Vice President Quality and Business Strategy says: "Viral vector manufacturing is a strong differentiator for gene therapy companies with products designated for accelerated pathways to commercialization. However, capacity constraints often impede this path. KUBio box provides process-ready solutions that promote product development and production-readiness for delivering viral vector-based gene therapies to patients."

KUBio box supports up to 200-litre scale manufacturing adapted to Good Manufacturing Practice (GMP) standards and is designed to fit into repurposed or retrofitted existing spaces, as well as new facilities. The new modular environment allows for future expansion at different production scales and product technologies. GE Healthcare Life Sciences provides end-to-

end bioprocessing services, including technical process development, qualification and lifecycle support.

GE Healthcare Life Sciences launched the first off-the-shelf KUBio modular facility in 2012 for the biomanufacturing of monoclonal antibodies. The KUBio portfolio has expanded over the years to support the production of vaccines and viral vectors as well. Four KUBio facilities have been deployed globally by Pfizer, Lonza, JHL, and BeiGene for the manufacturing of biopharmaceuticals.

KUBio box for viral vectors is commercially available now.