

Sartorius launches new services for mammalian cell bank manufacturing

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Sartorius Stedim Biotech (SSB), a leading partner of the biopharmaceutical industry has announced the launch of new services for mammalian cell bank manufacture under GMP conditions. These services are offered by its subsidiary, Sartorius Stedim BioOutsource, an experienced contract testing organization (CTO) based in Glasgow, UK, and in Cambridge, Massachusetts, USA.

Based on these new services, Sartorius Stedim Biotech now offers the manufacture of GMP master and working cell banks (MCB/WCB) for mammalian suspension cells. This activity will be conducted in a custom-designed 260 m² GMP clean room facility that has been audited and approved in 2018 by the Medicine and Healthcare Products Regulatory Agency (MHRA) according to the latest guidelines.

Exclusively dedicated to mammalian suspension cell lines, the facility uses selected equipment that enables closed-system manufacture of GMP-compliant cell banks, from vial thaw to automated filling. For maximum process reliability and assurance of sterility, this entire manufacturing service is offered as a fully qualified broth technology platform.

The GMP manufacture of master cell banks is a critical step during the development of biopharmaceutical drugs where time is always key. To ensure the best possible timelines, Sartorius Stedim Biotech cell bank manufacturing is offered in a package along with cell bank characterization services that the company has been providing for more than ten years. The combination of its new manufacturing services and its established characterization service for mammalian cell banks allows clients to work with SSB as a single-source provider from vial thaw to released cell banks.

Up to 500 cell bank vials are produced during a manufacturing run, followed by full characterization, genetic stability assessment in compliance with EU and FDA guidelines, and release by the respective qualified person. The cell bank vials produced are then shipped to the client or transferred to a long-term storage facility. In addition, these cell bank manufacturing and characterization services are a perfect match for the cell line development services based on Sartorius Stedim Cellca's CHO expression platform. With all three services combined – cell line development, cell bank manufacturing, and cell bank characterization – Sartorius Stedim Biotech supports clients as a total solutions provider from DNA to released GMP cell bank within a 10-month timeline.