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(54) Title: PREVALIDATED, MODULAR GOOD MANUFACTURING PRACTICE-COMPLIANT FACILITY

(57) Abstract: The invention is directed to a ready-to-use modular cleanroom and facility, in particular for the production of drugs and biological substances, which is equipped with pre-approved manufacturing equipment cores. The modular cleanroom is implemented in the interior space of a container, such as a standard shipping container, and includes at least one bioreactor station. The modular facility can be installed on-site from pre-approved cleanroom modules without further regulatory approval. The cleanroom and facility comply with FDA-approved good manufacturing practices (GMP) and good laboratory practices (GLP).



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