ProBioGen
Intelligent Biopharmaceutical Solutions

PRESS RELEASE

ProBioGen Receives Manufacturing Authorization for Viral Vectors and Vaccines

Berlin, Germany – November 10, 2026

ProBioGen today announced that its dedicated viral manufacturing facility in Berlin has received extended manufacturing authorization and an updated GMP certificate from the Berlin State Office for Health and Social Affairs (Lageso). This confirms compliance with Good Manufacturing Practice (GMP) requirements and establishes the regulatory foundation for the manufacture of sterile biological drug substances and investigational medicinal products, including viral vectors, viral vaccines, and advanced therapy medicinal products (ATMPs). The milestone extends the company's GMP manufacturing services for therapeutic proteins to viral vectors and vaccines, connecting its proprietary technologies and process development expertise with clinical supply.

Designed specifically for viral products, the facility combines drug substance production capacity of up to 200L with in-house aseptic filling and adjacent quality control laboratories. Our integrated services support timely testing and handling of sensitive products and intermediates. For customers this provides continuity from process development through GMP manufacturing to filled vials, without the need to transfer between different partners.

Qualification was carried out in accordance with EU GMP Annex 1 requirements for sterile medicinal products and included three successful aseptic process simulations. Drug product filling uses an L1 system with restricted access barrier system (RABS) technology. The contamination-control approach also includes pre-use post-sterilization integrity testing (PUPSIT) for filters used to prepare sterile media and buffers. These aseptic capabilities are particularly relevant to viral products for which sterilizing filtration is not suitable.

"This milestone builds on ProBioGen's proven track record of more than two decades in GMP manufacturing of protein-based biopharmaceuticals, now combined with our deep expertise in viral vector technologies," said Dr. Simon Bulling, Chief Operating Officer at ProBioGen. "With the authorization of our dedicated viral facility, we can offer an integrated service covering process development, GMP drug substance manufacturing and aseptic drug product filling for clinical supply. For our customers, this means greater continuity, fewer handovers and one integrated path from development to GMP supply—with quality, reliability and speed at its core."

The facility will also manufacture GMP drug substance for the Minapharm-led program to advance a Bundibugyo ebolavirus vaccine candidate based on ProBioGen's proprietary MVA-CR19 platform towards clinical evaluation. The program combines ProBioGen's vaccine development and drug substance manufacturing expertise with Minapharm's commercial drug product manufacturing capabilities in Egypt.

This authorization also provides an important foundation for ProBioGen's future activities at the Berlin Center for Gene and Cell Therapies (BC GCT), a major biotechnology hub currently under construction in Berlin. ProBioGen will operate the future GMP facility at the center, which is intended to expand manufacturing capabilities for innovative biological medicines, viral vectors, and advanced therapies.

About ProBioGen

ProBioGen is a Berlin-based expert in the development and manufacturing of biopharmaceuticals, viral vectors, and vaccines, powered by proprietary technologies that enhance product quality and features. It has developed multiple innovative vaccine platforms, including Lenti.RiGHT®, AGE1 host cell lines and the IP-protected MVA-CR19 strain, which has a unique genomic signature. Operating for over 30 years, ProBioGen runs three manufacturing lines in Berlin, where 300 employees contribute to advancing next-generation therapies and global biotech innovation.

For more information about ProBioGen, follow us on LinkedIn.

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