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Regulatory milestone strengthens Australiaâ??s sovereign advanced therapeutics manufacturing capability

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VVMF, Australiaâ??s first viral vector CDMO receives TGA manufacturing license

Viral Vector Manufacturing Facility (VVMF), Australia’s first viral vector Contract Development and Manufacturing Organisation (CDMO) has announced that the Therapeutic Goods Administration (TGA) has granted the company a License to Manufacture Therapeutic Goods (GMP licence) for the Sydney facility.

This milestone is significant for Australia's rapidly growing cell and gene therapy sector, enabling VVMF to manufacture viral vectors under GMP conditions to support the development and commercialisation of advanced therapeutic products for Australian and Global clients.

The license authorises the GMP manufacture of replication-incompetent viral vectors using recombinant technology, as either sterile Active Pharmaceutical Ingredients (APIs) or sterile Medicinal Products, together with associated Quality Control (QC) testing.

It follows a comprehensive assessment of VVMF's facilities, quality systems, manufacturing operations and operational capability, demonstrating the company's commitment to meeting the rigorous standards required for GMP manufacturing.

The company’s manufacturing facility, located within Sydney’s Westmead Health and Innovation Precinct, was established to strengthen Australia's advanced therapeutics ecosystem by providing local access to high-quality viral vector manufacturing capabilities. It reduces reliance on overseas suppliers and strengthens domestic capability across the advanced therapeutics’ value chain.

VVMF is expanding access to advanced therapeutics manufacturing across Australia and the Asia-Pacific region, creating new opportunities for biotechnology companies, researchers and therapy developers to access specialist viral vector manufacturing capabilities within a geopolitically stable jurisdiction.