

VVMF, Australia's First Viral Vector CDMO Receives TGA Manufacturing Licence

Regulatory milestone strengthens Australia's sovereign advanced therapeutics manufacturing capability.

Sydney, Australia, 9th September 2026

Viral Vector Manufacturing Facility Pty Ltd (VVMF), Australia's first viral vector Contract Development and Manufacturing Organisation (CDMO) advises that the Therapeutic Goods Administration (TGA) has granted the company a **Licence 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 licence 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.

The facility supports clients developing gene therapies, genetically modified cell therapies and other advanced therapeutics requiring viral vectors. By providing end-to-end process development, analytical development, GMP manufacturing and quality control testing services, VVMF is positioned to support programs from early

development and throughout their clinical translation journey.
VVMF is



Image: VVMF scientists working within the company's viral vector manufacturing facility in Sydney, Australia. Photo credit:

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.

Supported by Australia's robust regulatory environment, internationally recognised clinical trial ecosystem and R&D tax incentives, VVMF provides an attractive, capital efficient manufacturing destination for local and international therapy developers.

Stephen Thompson, VVMF CEO said: "Receiving our TGA Manufacturing Licence is a defining moment for VVMF and an important milestone for Australia's advanced therapeutics sector. This achievement establishes a sovereign capability that will enable innovators to access world-class viral vector manufacturing services locally while supporting the growth of Australia's cell and gene therapy ecosystem, ultimately, helping bring these therapies closer to the patients who need them."

Maria Adesida, Chief Quality Officer said: "The granting of our TGA Manufacturing Licence demonstrates the strength of our quality systems, facility, operational controls and manufacturing capability. This achievement reflects the expertise, dedication and commitment of our team in building these systems from the ground up and establishing a strong quality culture embedded in how we operate. The importance of this moment extends well beyond the licence itself. VVMF can now deliver GMP-compliant viral vector manufacturing services to our clients, enabling us to support the advancement of the next generation of cell and gene therapies."

About VVMF – Unlocking the Future of Medicine

Viral Vector Manufacturing Facility Pty. Ltd. (VVMF) is Australia's only Contract Development and Manufacturing Organisation (CDMO) dedicated to providing services in the research, design, development, and manufacture of viral vectors for advanced therapeutic applications. VVMF partners with researchers, clinicians, and bio-pharma companies to accelerate the path to market for cell and gene therapies to local and global patients.

Viral vectors play a crucial role in delivering genetic material into cells and are central to innovative treatments in areas of medicine including cancers and rare diseases.

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