

A commercial-scale viral vector manufacturing facility



Frequently Asked Questions

Viral vectors save lives

What are gene therapies?

Genes, found within our body's cells, provide the instructions for our cells to produce proteins. These are required to make parts of our body, such as muscles, bones, and blood, and support most of our body's functions, such as digestion, producing energy, and growing. Missing or defective genes can disrupt how proteins are made, resulting in genetic disease.

Gene therapies treat genetic diseases by replacing a faulty gene that is causing disease, adding genes to help the body fight or treat disease, or switching off genes that are causing disease.

What are viral vectors?

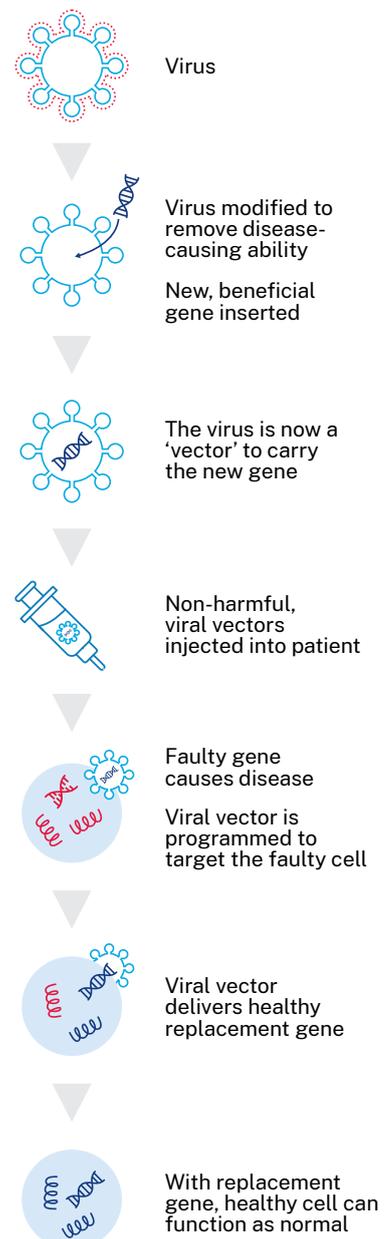
Viral vectors are modified viruses that are a tool used to safely deliver gene therapies into the cells of a patient with a genetic disease. Before being used as a vector, the virus is altered so that it can't cause infection. By inserting working genes into the target cells, viral vectors provide the instructions the cell needs to function normally.

What diseases can viral vectors help cure?

Viral vectors can treat inherited genetic disorders, such as cystic fibrosis, spinal muscular atrophy (SMA) and blood disorders. They do this by introducing working genes into a patient's cells to replace the defective or missing ones (this is called gene therapy).

Patients with cancer can benefit from viral vector therapy, too. For example, genes delivered by viral vectors can reprogram the patient's immune system to fight cancerous cells. Viral vectors also can deliver other genes into cancer cells that instruct them to self-destruct.

What are viral vectors?





Viral vectors are emerging as an effective method to treat infectious diseases. They can be used in the development of vaccines to treat infections such as COVID-19 by delivering target genes into cells to trigger an immune response.

Can viral vectors help to address COVID-19 and similar viruses?

Viral vectors are emerging as an effective method to produce vaccines. They can be used in the development of vaccines to treat infections such as COVID-19 by delivering target genes into cells to trigger an immune response.

Notably, the development of the Oxford/AstraZeneca and Johnson & Johnson/Janssen COVID-19 vaccines rely on viral vector technology.

What are the differences and synergies between viral vector vaccines and mRNA vaccines?

While both viral vector vaccines and mRNA vaccines use a similar concept of delivering instructions to our cells, there are differences in the manufacturing requirements between the two methods. Viral vector vaccines are produced using mammalian cells, whereas mRNA vaccine production relies on microbial cells. The processes also have different purification methods, necessitating physically separate facilities to avoid cross-contamination. Also, mRNA vaccines require different processing compared with traditional viral vector methods, such as the addition of a lipid coating.

The value-add that viral vectors provide over mRNA is in supporting locally and internationally developed gene therapies – cures for genetic diseases, infectious diseases and cancer.

Despite these differences, viral vector and mRNA vaccine manufacturing have several synergies that would benefit from co-location of the facilities within a precinct. These include shared workforce expertise requirements, ancillary products (such as vaccine ingredients and culture media), quality control capabilities, and logistics infrastructure for packaging and distribution.

Manufacturing viral vectors

Does Australia have a viral vector manufacturing facility?

Currently, there are no licensed, Good Manufacturing Practice (GMP) certified viral vector manufacturers in Australia. The NSW Government has committed to build a commercial grade viral vector manufacturing facility that will provide an end-to-end capability that involves collaborative research and development, where intellectual property is retained in Australia.



Stage 1 involved the construction of a pilot facility with a 25-litre capacity. Already operational, the pilot facility has demonstrated the capability and established a track record for viral vector manufacturing, and re-affirmed Sydney's local medical research expertise. The pilot facility has started developing the required workforce and building an initial customer base for the products.

How is the viral vector manufacturing facility expanding?

The currently operational viral vector pilot manufacturing facility (Stage 1) is set to expand from a 25-litre capacity, adding a 550-litre capacity facility (Stage 2). The expansion will include building additional laboratories for quality control and process development.

In addition to capital works, a new, independent company co-funded by NSW Government and a private investor will be established. It will be operationalised to bring together research capability and enable NSW to locally develop and manufacture viral vector vaccines and viral vector-based gene therapies for multiple foreign and Australian markets.

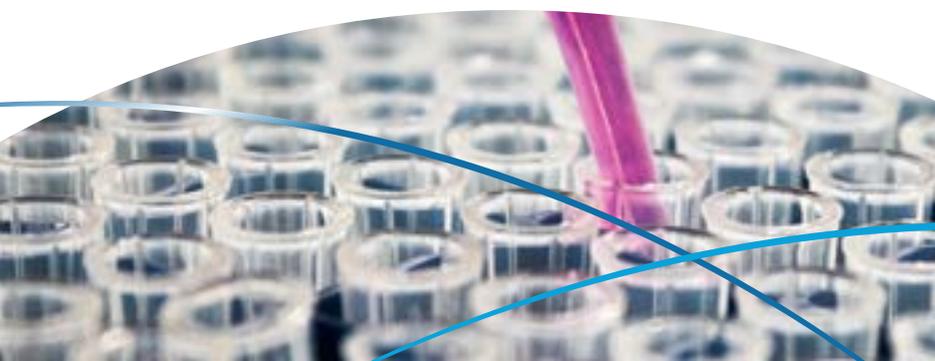
How does large-scale viral vector manufacturing work?

Producing viral vectors at scale begins by inserting the healthy copy of the target gene into a modified virus. The resulting viral vector is grown in large batches in human cell lines, which have the ability to replicate the viral vector. Once infected with the viral vector, these cells begin producing large quantities of the viral vector. The viral vectors are harvested from the cells. These are then purified, sterilised and independently verified to ensure they are working correctly, free of any contamination and are a high-quality product. The final stage is to package the viral vector for use.

Why do we need a viral vector manufacturing facility?

Viral vectors are in demand. With rapid developments in our understanding of genetic diseases, the number of conditions that could be treated or cured using cell and gene therapies is growing. Even a single clinical trial requires a large supply of viral vectors. The viral vector manufacturing facility will support the generation of treatments to improve Australian lives and position Australia as a leader in health research and development.

NSW has the unique opportunity to establish sovereign capability in the development and manufacture of vaccines and other cell and gene therapies. The facility will harness more than 40 years of research capability and knowledge of cell and gene therapies to manufacture other GMP-grade viral vector vaccines and viral vector-based gene therapies, and will export viral vectors to a growing local and international market.



What are the benefits of manufacturing viral vectors locally?

Gene therapies that use viral vectors can be expensive. There is also a very long waiting list to order the viral vectors, making them –and gene therapies– difficult to access.

Manufacturing viral vectors locally will provide Australian patients with faster access to new innovative viral vector-based therapies to treat genetic diseases. Local production of viral vector vaccines will also ensure we are better prepared for health and biosecurity threats in the future.

In addition, establishing local manufacturing infrastructure will accelerate national research into this new technology, by providing important medical tools to support clinical trials across Australia.

Local manufacture will also stimulate the economy and create jobs supporting a wide range of medical, science, engineering, and business skills.



How does the Stage 2 funding assist the work done to date in both manufacturing and therapeutic research & development for disease?

The pilot facility (Stage 1) can produce viral vectors on a small scale, which is sufficient for proof-of-concept testing and laboratory use for the early design and development of new therapeutics. The Stage 2 facility will enable production and purification procedures that will make the larger amounts of viral vectors needed to further develop these therapeutics, for example in important safety and efficacy studies and larger clinical trials. The Stage 2 facility will also enable production levels to meet competitive commercial needs, generating income and increasing the supply of cutting-edge therapies for patients.



What are the capabilities of the viral vector manufacturing facility?

The facility will have the capability to manufacture viral vectors for use in clinical trials for both gene therapies and genetically modified cell therapies. It will draw on Australia's substantial clinical and scientific research talent, with NSW being a leader in the development and delivery of therapies for genetic diseases, cancers, and viral infections. Manufacturing viral vectors will provide jobs in production and supply, and in medical research and clinical trials. As well as research capability, the facility will partner with industry and will contribute to the education of the next generation of medical professionals.

Having the capability to produce enough viral vectors to support local and international clinical trials offers a significant advantage to Australians for health and investment purposes, and will support the development of intellectual property (IP) and attract further private investment.

Who is involved in the viral vector manufacturing facility?

The initial pilot facility (Stage 1) was funded by NSW Health and supported by Sydney Children's Hospitals Network, the Office of Health and Medical Research and the Westmead Health and Innovation District.

NSW Treasury and NSW Health provided further investment to deliver the capital works (by Health Infrastructure) and also establish a new company (owner and operator of the facility). Other stakeholders will include corporate investors and manufacturing partners.

When will the viral vector manufacturing facility be built and how much will the project cost?

It is anticipated the Stage 2 facility will be operational in the first quarter of 2023. The NSW Government committed \$25 million to the project in 2019, and will commit additional funds to expand and operate the facility following private investment partner expressions of interest process. The facility will be co-owned and operated by a new company, with an independent board of directors.

Are there other viral vector manufacturing facilities (are there competitors)?

Currently, there are no licensed viral vector manufacturers in Australia. Although a specific COVID-19 vaccine is being manufactured using viral vector technology in Australia, this product relies on research completed and owned by others. Conversely, the new viral vector manufacturing facility in NSW will provide an end-to-end capability that involves collaborative research and development, selection of the best viral vector for the purpose, description and definition of the product, and validation and commercialisation, so that intellectual property is retained in Australia.

Countries in the northern hemisphere, including Canada, the UK and Germany, are increasing their viral vector manufacturing capacity, while in the Asia-Pacific region there is only a small-scale (15-litre) facility in Singapore. The commercial-scale viral vector manufacturing facility at Westmead is uniquely positioned to fill this market gap. Near-term demand will likely only support one commercial viral vector manufacturing facility locally.

Why is New South Wales the state to support viral vector manufacturing?

Why should the viral vector manufacturing facility be in NSW?

NSW has a highly skilled workforce and has two of Australia's top four highest-ranked research universities.

The state is at the forefront of international gene therapy research. NSW paved the pathway for cell and gene therapies in Australia, conducting the first gene therapy clinical trial for a genetic disease in the country back in 2002.

NSW researchers are globally recognised as leaders in the development and delivery of cell and gene therapies, viral vector engineering, as well as oncology, neuroscience, cardiovascular medicine, infectious diseases and medical devices.

The Australian Government offers significant tax incentives for research and development expenses and intellectual property protections. Sydney has proven itself as a favourable home for foreign and domestic investment. The city offers reliable utilities, affordable infrastructure services, and a thriving central business district.





Why is Westmead the best location for a viral vector manufacturing facility?

The Westmead Health and Innovation District is one of Australia's largest integrated health, education and research and training precincts. It is connected to universities and research facilities, and home to globally recognised research leaders and a strong pipeline of talent.

The precinct includes four hospitals, four world-leading medical research institutes, two multidisciplinary university campuses, the largest clinical school in Australia, and the largest research-intensive pathology service in NSW.

Westmead and the surrounding Parramatta population is highly educated. Over the next decade, this region will account for 50 per cent of Sydney's overall population growth. Building in this precinct offers convenient access to international collaborators via the Western Sydney Airport that is under construction.

Why is the NSW Government investing in the viral vector manufacturing facility?

The NSW Government has invested in the viral vector manufacturing facility to meet the growing demand for viral vectors. Currently, there is a wait of up to two years to source viral vectors from international suppliers.

The NSW Government has identified an opportunity to invest and grow viral vector manufacturing locally not only to help save lives and cure disease, but also to attract jobs, drive investment and foster innovation. The facility has the potential to bring in annual revenue for the state.

The complexity with advanced biomanufacturing often means it takes longer to translate new scientific insights into commercially successful products, therefore requiring government commitment to attract industry investment. The facility will grow capacity, stimulate significant revenue and create jobs in production and supply, medical research and clinical trials, and other science, engineering, and business areas. Developing the technology to manufacture viral vectors locally will support Australia to retain high-value intellectual property.

The viral vector manufacturing facility will position NSW and Australia as a leader in future health research and innovation promoting a culture of medical research and modern manufacturing in partnership with industry.

Why does the NSW Government seek investors for this innovation?

There is a very long waiting list to order viral vectors, so the NSW Government has committed to fund a viral vector manufacturing facility. The government is seeking industry partners to co-invest and help develop the facility. The government's support of modern manufacturing in this specialised domain provides a foundation on which investors can confidently engage in, develop and commercialise emerging technologies.

Comprehensive market engagement has identified strong support for industry partnerships in the viral vector manufacturing facility, with the NSW Government and industry as investors. Private industry bodies have expressed interest in co-investment to leverage NSW research expertise and to access Asia-Pacific markets.

Benefits of a NSW-based viral vector manufacturing facility

What are the economic benefits of a viral vector manufacturing facility?

As well as the benefits to health, research and education in Australia, the viral vector manufacturing facility offers many economic benefits to Australia. It will be the first GMP-licensed viral vector manufacturer in Australia, capturing a significant market share in a fast-growing therapeutic area and creating a new global export market for Australia.

The development of local jobs in manufacturing and science offer additional benefits to the people of NSW. Finally, the viral vector manufacturing facility will provide an important educational platform for researchers across the country, attracting students and high-performance research teams to the facility, further stimulating the local economy.

What are the viral vector manufacturing facility benefits to partners?

Demand for viral vectors is increasing and the facility is the first of its kind in Australia. Partnering with the NSW Government in the facility is an opportunity to invest in a growing sector of medical health research. Australia has strong business relationships with America, Europe and Asia and our research is world-renowned. More than 100 of Australia's medical and research companies are listed on the stock exchange, and the government offers significant tax incentives for research and development.



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