A commercial-scale viral vector manufacturing facility

Synergies between viral vector and mRNA technology

The NSW Government has committed to expand and operate a world-leading viral vector manufacturing facility in the Westmead Health and Innovation District in western Sydney. The first of its kind in Australia, the facility will meet the growing demand in Australia and internationally for clinical-grade viral vectors, which are a key component of gene therapies and vaccines.

There are many advantages associated with locating viral vector manufacturing and mRNA technology development within one precinct. They both require a highly educated and skilled workforce, share some raw materials and employ similar logistics infrastructure.

Viral vector and mRNA technology

NSW is home to nationally and globally significant programs of genomic medicine development, particularly in the fields of gene therapy, gene-modified cell therapy and RNA therapy. (Ribonucleic acid (RNA) is a single-stranded molecule similar to DNA. Messenger RNA (mRNA) holds the information needed to create proteins.) These therapies treat a wide range of conditions including genetic diseases, cancers, infectious diseases and cardiac conditions.

The state has capabilities in the advanced manufacture of viral vectors, plasmids and short-form RNA, which are key technologies used for these therapies. Supporting advanced biomanufacturing will significantly strengthen local research and development programs.

NSW is providing major support to NSW's leading universities, research institutions and hospitals to further advance gene therapies and RNA research, development and manufacturing capabilities.

> "Supporting our advanced biomanufacturing industry will make NSW a world-leader in the development of technology and therapeutics to combat everything from pandemics to cancer and genetic diseases."
>
> – Hugh Durrant-Whyte
> NSW Chief Scientist & Engineer

Viral vectors and viral vector vaccines

Viral vectors are integral to the development of cell and gene therapies and represent major pharmaceutical investment worldwide. Viral vectors can deliver genetic material to a cell's nucleus: a fundamental step in therapies that rely on inserting new genetic code to replace faulty genes or switch off disease-causing genes. They can be used to treat many genetic disorders and cancers. There are hundreds of cell and gene therapies in early-to late-stage clinical trials, with enormous potential to improve the lives of patients.

Viral vector-based vaccines use the body's cells to produce antigens. They do this by using a modified virus (the vector) to deliver the genetic code for the antigen (e.g. a spike protein) into the nucleus of your cells. Before being used as a vector, the virus is physically altered so that it can't cause infection. Once inside the nucleus, your cell makes an mRNA copy of the antigen gene. The mRNA exits the nucleus, and your cell uses the protein-building machinery in its cytoplasm to follow the instructions to build the antigen.

There are viral vector-based vaccines for many infections including adenovirus (a cause of the common cold), measles and smallpox. Viral vectors also represent an effective way of developing and producing vaccines to treat infections such as COVID-19. The Oxford AstraZeneca and Johnson & Johnson Janssen vaccines rely on viral vector technology.

mRNA vaccines

mRNA vaccines provide your cells with the instructions for how to make a particular antigen. The usual process of turning genetic code into a protein is DNA to mRNA (in the nucleus) then mRNA to protein (in the cytoplasm). By skipping the first step in this process, mRNA vaccines don't have to enter the cell nucleus; the vaccine just has to enter the cytoplasm. Delivering genetic material to the cytoplasm is much simpler than getting it deep into the nucleus, which requires a viral vector.

The challenge for mRNA vaccines is their instability. They require very cold temperatures for distribution and administration.

"Establishing viral vector and mRNA facilities represents a real boost to Australian jobs and intellectual property. The facilities will attract world-leading researchers and bring experienced expats back to NSW. It represents a great investment in education and in developing a highly skilled workforce for the future."

– Dr Leszek Lisowski
Leader of the Translational Vectorology Group at the Children's Medical Research Institute

History of vaccination

Edward Jenner is widely considered the founder of vaccinology for recognising that viruses can teach your immune system to fight antigens. In May 1796, Jenner took pus from cowpox lesions on a dairymaid's hands and scratched it into the skin of an 8-year-old boy. The boy developed a mild fever, fully recovered, and didn't develop the deadly disease smallpox when later exposed to it.

The immune system is your body's defence against infection. When a germ invades your body, your immune system is activated. First, it identifies the germ as foreign based on parts of the germ's structure (such as spikes sticking out of its surface) called antigens. Next, your immune system makes antibodies: special tags that lock on to these antigens and neutralise the germ. Vaccines are a clever way to train your immune system to fight a specific germ without you ever falling ill.

Viral vector vaccines and mRNA vaccines: What's the difference?

During the past decades, scientists have developed new types of vaccines including viral vector vaccines and mRNA vaccines. Rather than containing antigens (dead germs or germ fragments, such as spike proteins), these vaccines contain the instructions – in the form of genetic code – for how to make these antigens. Your cells can read these instructions and build the antigen, which then activates your immune system. The viral vector-based vaccines use the body's cells to produce antigens. They do this by using a modified virus (the vector) to deliver the genetic code (instructions) for the antigen into the nucleus of cells. Like viral vectors vaccines, mRNA vaccines also provide cells with the instructions for how to make a particular antigen, but in another way using a different technology.

Manufacturing synergies

The manufacturing processes and requirements for viral vector vaccines and mRNA vaccines are very different. However, there are myriad benefits in locating both facilities within the Westmead Health and Innovation District.

There are similar requirements for connection with universities and hospitals, workforce expertise, quality control and supporting infrastructure. There are some common raw materials (such as plasmids, which are small DNA strands used for gene manipulation), shared ancillary products (such as vaccine ingredients and culture media), and similar logistics infrastructure for packaging and distribution.

Giving Australian researchers access to both viral vectors and mRNA to conduct clinical trials means the extent of the research they can achieve is increased. This further develops the research, industry and education ecosystem in NSW.

The new biomanufacturing industry precinct combining world-leading viral vector manufacturing and mRNA capacity will bring considerable benefits. It represents a powerhouse of medical science developments for decades to come, an education hub and a major economic contributor.

NSW GOVERNMENT

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