

HALIX Enters Collaboration with the University of Oxford for GMP Manufacturing of a COVID-19 Vaccine

15 April 2020 | News | By Ankit Kankar

Alliance for the scale-up of a GMP manufacturing process and production of a coronavirus (SARS-CoV-2) vaccine (ChAdOx1 nCoV-19) formed



COVID-19 Vaccine Trial







<u>HALIX B.V.</u> has joined a consortium of partners under the guidance of the University of Oxford, to provide GMP manufacturing services supporting the large scale production of a COVID-19 vaccine (ChAdOx1 nCoV-19), being developed by the University's Jenner Institute. This GMP manufacturing scale-up is taking place alongside early phase clinical trials. The trials are crucial in testing whether the vaccine is proven to be effective.

The nCoV-19 vaccine is based on the Jenner Institute's adenovirus vaccine vector (ChAdOx1) technology, which was chosen as the most suitable candidate for a SARS-CoV-2 (COVID-19) vaccine as it can generate a strong single dose immune response, and is not a replicating virus, so it cannot cause infection in the vaccinated individual.

Under the collaboration, HALIX B.V. will utilise its brand new state-of-the-art GMP facilities with capacity up to 1,000 L SUB scale, applying its viral vector bioprocessing expertise, to transfer an industrial scale drug substance process from Pall in the UK, supporting the manufacture of ChAdOx1 nCoV-19 clinical trial material. Based on this transfer, HALIX B.V. and the consortium will be in a position to manufacture at a larger scale. This is a key step in decreasing the time it would normally take to make the vaccine available for deployment and could help to halt the further spread of this pandemic.

The large-scale manufacturing project is a collaborative effort, led by Dr Sandy Douglas at the Jenner Institute. The ChAdOx1 coronavirus vaccine alliance encloses viral vector manufacturing and regulatory compliance experts from the University of Oxford's Jenner Institute and Clinical Biomanufacturing Facility, the Vaccine Manufacturing and Innovation Centre (VMIC), Pall Biotech and Cobra Biologics.

Alex Huybens, Chief Operations Officer of HALIX, states: "We are committed to working as one team across the industry bringing our collective expertise, track record and manufacturing capabilities, to support the Jenner Institute's rapid clinical development of this nCoV-19 vaccine candidate to combat this evolving crisis as quickly as possible."

HALIX has an established technical and quality track record for the development and GMP manufacture of viral vectors used against infectious diseases, such as HIV, ZIKA, chikungunya and the flu. Our brand new 6,700 m² BSL2 GMP facility, located in Leiden (the Netherlands), provides both clinical and commercial scale manufacturing capabilities in fully independent, self-contained Grade B and C cleanrooms for virus products.

The clinical trial program, led by Professor Sarah Gilbert at the Jenner Institute and Professor Andrew Pollard of the Oxford Vaccine Group, will recruit up to 510 volunteers, who will receive either the ChAdOx1 nCoV-19 vaccine or a control injection for comparison. Since March 23, 2020, The University of Oxford is recruiting individuals in the UK to take part in trialing the vaccine. For further information on the vaccine