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Advanced vaccine manufacturing technologies scaling-up at Pharma Industries

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In conversation with Mr Benoit Opsomer, Vice President & Head of BioProcessing, Asia Pacific, Life Science business who unravelled Merck's commitment towards researchers, developers and manufacturers to combat COVID-19 pandemic



The global vaccine effort is guided by four imperatives: speed, manufacture, deployment scale, and global access. The current pandemic illustrates the need to combine the best-integrated technologies with resilient supply chains at pharma companies to leverage global network and experience. Industries have broadened access to critical supplies and diagnostics to tackle SARS-COV-2 using advanced pharmaceutical manufacturing and testing tools.

APAC Life Science business of Merck develops improved and enhanced technologies from biopharmaceutical therapies to cutting-edge systems for scientific research and production. Responding to COVID-19 outbreak, Merck's BioProcessing unit is engaged in consolidating and supplying raw materials along with characterization and detection of vaccine research products. Merck actively evaluates and leverages business continuity plans for COVID-19 vaccines and therapies development. Merck's SARS-CoV-2 detection, characterization, vaccine and therapy production capabilities are leveraged at the Jenner Institute for the development of Oxford vaccine, **ChAdOx1 nCoV-19**. Prioritizing on crucial timeline Merck's advanced upstream and downstream portfolios target faster yield and productivity to support and expedite the need of an hour. Biospectrum Asia in a recent conversation with a senior regional spokesperson, **Mr Benoit Opsomer, Vice President & Head of BioProcessing at Merck's Asia Pacific Life Science business** explored Merck's commitment towards researchers, developers and manufacturers to combat COVID-19 pandemic.

- **How do you describe the crucial steps and measures in COVID-19 vaccine development?**

A major factor that contributed to the acceleration of vaccine development for the SARS-CoV-2 virus (Covid-19) has been the early and speedy identification of the novel coronavirus' genome sequencing, which contributed to an array of vaccination and treatment development efforts around the world.

Diagnostic tests play a critical role in the global effort to contain and fight the virus. These tests help physicians determine the presence or absence of a disease in patients, and their findings are crucial to making treatment decisions. The spread of

Covid-19 has demonstrated the importance of diagnostics and will have a lasting impact on a national and global level, reshaping how governments and healthcare players deal with future pandemics.

With the global population exceeding 7.5 billion, vaccine developers require unprecedented capabilities for large-scale production of any approved therapies to meet the demand.

While we don't produce vaccines ourselves, Merck has over four decades of experience in supporting customers in vaccine development and manufacturing, which is being leveraged during this critical time. Our biggest value add is our experience, not just in terms of routine business operations, but as a reliable and agile technology partner.

- **Can you elaborate on the significant role Merck is playing at the Jenner Institute and the wider vaccine development ecosystem?**

In partnership with the Jenner Institute, we have laid the foundation for large-scale production of the Institute's Covid-19 vaccine candidate: ChAdOx1 nCoV-19. We are supporting the Institute's development process by scaling up downstream unit operations, preparing for mass production efforts, as well as enabling the seamless technology transfer to the Institute's contract manufacturing organizations.

Prior to the pandemic, our partnership with The Jenner Institute had been going strong for the past two years. Our deep understanding of the organisation's process and development chains allowed us to reduce the process development timeline to just two months – down from the usual timeline of six to 12 months. By speeding up the large-scale manufacturing process, we ensured that Jenner Institute would be in the best possible position to quickly and safely roll out their vaccines to patients, once approved.

The role we play is by finding cost-effective ways to accelerate the vaccine development and manufacturing process and supply chain. We also support emerging economies by sharing our expertise, helping to streamline their manufacturing processes, driven by our mission to help the life science community solve the toughest problems and make healthcare accessible to all.

Merck is currently supplying key products and services to more than 45 Covid-19 vaccine programs around the world. In light of social distancing measures and travel restrictions, we provide both on-site and remote services, including consulting on regulatory and Good Manufacturing Process guidelines to validate the robustness of critical unit operations for these organisations.

- **What are the operational challenges faced by governments and pharmaceutical firms along this journey?**

There are three main challenges to consider namely **(1) safety**, **(2) scaling-up** and **(3) supply**.

As scientists race to develop a life-saving vaccine in record time, **safety** remains the foremost priority. Due to the highly unusual circumstances surrounding this pandemic, there has been strong pressure to expedite the development process and scale-up production within a short period of time. However, vaccines are used on healthy individuals and therefore it is incredibly important that the purity, efficacy and yield of the vaccine process are not compromised by tight timelines.

Scaling-up is another crucial factor in expediting the response. Many pharmaceutical firms have been trying to quickly bring commercial-scale manufacturing capabilities online. Currently, production capability, as well as the capacity to fill and supply vaccines, are concentrated in developed nations with emerging regions having insufficient on-ground production capacity.

As local and regional governments across the world implement social distancing and travel restrictions to reduce the spread of the virus, **supply chains** are ultimately affected hindering the speed of production. To address this, Merck has been working closely with local officials and raw material suppliers to ensure that the essential services our customers provide are not compromised.

- **What are some of the best practices in the effective coordination of the global vaccine development effort?**

Due to the complexity and diversity of vaccine modalities, there is no single standard manufacturing template or process which makes production a challenge for every organization racing to develop a safe and effective Covid-19 vaccine. The close collaboration of the global scientific community regardless of region or nationality is more important than ever to accelerate the discovery of a vaccine or treatment.

- **What role is Merck playing from virus detection and characterisation to vaccine and therapy production?**

The products and services we offer to customers supporting the global Covid-19 effort include:

- More than 25 testing solutions (including RT-PCR and serological diagnostics for both high-throughput centralized and distributed point-of-care settings) including eight of the top 10 In-Vitro Diagnostic (IVD) market leaders
- Bioprocessing manufacturing platforms for more than 45 different vaccine candidates, including DNA, inactivated virus, viral vector, protein subunit and Messenger RNA (mRNA) vaccines
- More than 20 monoclonal antibodies, plasma products and antivirals

We are working around the clock to ensure critical products and services, such as biomanufacturing platforms and biosafety testing services are readily available to accelerate mass manufacturing at the scale required to control this pandemic.

- **What is the advice/suggestions/offerings Merck can extend to pharmaceutical and clinical units in similar ventures**

Our unique position in the pharmaceutical ecosystem is like the engine that powers the global response to the health crisis. Through our strong partnerships with the global scientific community, we are helping bring to life the treatments and therapies plaguing our healthcare system today.

With our extensive experience and a global network of technical experts, we stand ready to help researchers and pharmaceutical firms in their efforts to accelerate the vaccine and treatment process, from optimising the research, testing, process development to scaling the production of vaccines and treatments.

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