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Redefining Vaccine Manufacturing: mRNA technology and global collaboration to advance health security and vaccination equity

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Josephine Cheng, Senior Modality Leader, Process Solutions, Life Science Business, Merck Ms Chang illuminates strategies for conquering technological challenges and empowering LMICs with mRNA production capabilities



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The global pharmaceutical and biotechnology industries have experienced significant transformations, driven by vaccine technological advancements. In the pandemic era, messenger RNA (mRNA) platforms have gained eminence for enabling faster development timelines and scalable production than traditional approaches like attenuating viruses or protein subunits. Flexibility enables rapid vaccine design and adaptation to emerging diseases and variants. Following the trend, the Asia-Pacific (APAC) region is witnessing a significant shift in vaccine manufacturing, largely driven by evolving messenger RNA (mRNA) technology platforms. Key markets such as Japan, South Korea, and India are actively pursuing mRNA innovation, supported by government initiatives and investments. To effectively harness the mRNA potential, manufacturers emphasize a skilled workforce, reliable supply chains, and mRNA-specific regulatory frameworks. Manufacturers recognize that these factors are crucial for ensuring successful mRNA platform integration. This shift underscores the broader evolution in vaccine science, as mRNA platforms offer an efficient and adaptable alternative. Embracing industry dynamics, global biopharma players such as Merck are actively placing industry needs on a trajectory by accelerating the development and equitable accessibility of mRNA therapies.

A recent study by Merck, a global leader in life science & healthcare innovations, reveals that in the Asia-Pacific (APAC) region, mRNA technology is seen as a "game-changer," with 87% of vaccine manufacturers recognizing its potential. Industry players view mRNA as a key modality for the future, citing its short development timelines, templated production processes, and flexibility in addressing various diseases and variants. Furthermore, over 60% of surveyed manufacturers plan to recalibrate and optimize their facilities for mRNA production over the foreseeable future, while building capacity alongside traditional and cell-based vaccine production. **Josephine Cheng, Senior Modality Leader, Process Solutions, Life Science Business of Merck** further dives into potential strategies for mRNA production capabilities to empower LMICs.

- **How critical is it to address vaccine inequity, overcome technological diffusion challenges, and develop mRNA vaccines and therapeutics to effectively combat looming pandemics and endemic diseases?**

COVID-19 was a catalyst that highlighted the stark disparities in global health access, where high-income countries secured vaccine supplies quickly, while low- and middle-income countries (LMICs) were often left waiting. Furthermore, during the COVID-19 pandemic, the supply of raw materials, technology transfer, and knowledge sharing was limited, leading to bottlenecks in local production.

When vaccines are not equally distributed, pandemics/endemics can last longer, mutate faster, and become harder to contain. In LMICs, this can cause delays in economic recovery as well as a disproportionate healthcare burden as LMICs often lack adequate health systems. It is imperative to build health security in LMICs, especially in the event that a variant emerges in an under-vaccinated region, it can become a global threat within weeks. Over-reliance on external sources for essential health products means having to deal with possible breakdowns in global supply chains.

In line with the need for in-region-for-region supply, Merck has invested over €2 billion since 2020 in expanding its Life Sciences manufacturing footprint to meet growing demand for life-saving therapies across Europe, China, and the United States.

- **How significant is the global mRNA technology transfer program for acquiring advanced mRNA technology and the capabilities necessary to achieve low-cost, high quality vaccines and therapeutics?**

Many LMICs lack access to cutting-edge science, skilled workforces, and industrial-scale production methods. The programme helps close this gap by sharing technical know-how, protocols, and manufacturing blueprints. It provides LMICs with the tools, knowledge, and autonomy to produce effective, low-cost vaccines and therapeutics, for a broad range of diseases, in a self-sufficient manner. Its success could redefine how the world prepares for and responds to pandemics - more responsibly, more sustainably, and more effectively.

Instead of relying on imports or donations, LMICs can design, produce, and distribute their own vaccines. This reduces the cost per dose, minimizes delays during crises, and improves responsiveness to local disease burdens.

- **How does Merck Life Sciences' support for Afrigen's Center of Excellence and training initiatives empower 15 LMIC with localized mRNA production capabilities to thwart future outbreaks? How do these countries identify potential roadblocks and overcome regulatory bottlenecks?**

The partnership between Afrigen and Merck KGaA, Darmstadt, Germany, on the mRNA Technology Transfer Programme was initiated to empower LMICs to be more self-sufficient in the development and manufacturing of mRNA vaccines and therapeutics through technology and knowledge transfer.

Merck supports Afrigen’s Center of Excellence and training initiatives aimed at building capacity in LMICs to produce mRNA vaccines and therapeutics. The mRNA Technology Transfer Programme, co-led by the World Health Organization (WHO) and the Medicines Patent Pool (MPP), is based on a South African consortium establishing and validating an mRNA manufacturing platform at a central site and transferring the technology platform to partners.

The Afrigen-based mRNA vaccine tech transfer program will provide sufficient transfer of know-how to allow the current 15 recipient manufacturers in the program to produce and release mRNA vaccines at scale to support clinical development, national/regional marketing authorisation, and WHO prequalification, and sustainable supply to meet local and regional vaccine demand.

- **How to address regulatory bottlenecks in vaccine manufacturing?**

Experts from MPP supervise this mRNA Technology Transfer Programme and provide support on regulatory pathway mapping, stakeholder engagement, regulatory capacity building, and streamline the process from a global perspective. On the other hand, Merck Life Science supports manufacturers through its quality system, Emprove® program. Merck's Emprove® program is designed to support regulatory filing processes for molecules in various countries. It provides comprehensive documentation and quality information to help ensure compliance with regulatory requirements, thereby facilitating the registration and approval of pharmaceutical products and biotechnological substances.

- **Describe Merck's approach to advancing mRNA technology transfer and optimizing manufacturing processes? How is the stability and efficacy of vaccines demonstrated under this program?**

Merck plays a pivotal role in supporting Afrigen, which is extended to the LMIC partners in the program. Merck established a partnership with Afrigen before the WHO initiative, highlighting our commitment to enhance mRNA manufacturing capabilities in LMICs. We provide assistance through training and customized designs for key process steps such as tangential flow filtration, bioburden control, mixing, and single-use assemblies. These efforts aim to facilitate the production of development and technical batches of mRNA products, ensuring the process remains ready for GMP-compliant scale-up activities in the future.

The mRNA COVID-19 vaccine candidate AfriVac 2121 (Wuhan) developed under this Program was produced in 2022 under the WHO/MPP mRNA Technology Transfer Program. AfriVac 2121 was evaluated in a hamster model for immunogenicity and efficacy against the ancestral B.1 strain of SARS-CoV-2. Administered in two 5 ?g doses, it elicited a protective immune response comparable to the commercial mRNA vaccine mRNA-1273 (Spikevax®, Moderna). Additionally, AfriVac 2121 induced robust humoral immune responses and effectively protected hamsters from viral challenges.

- **How does Singapore add value to Merck's technology transfer program with Afrigen and serve as an integrated training and skill development hub?**

Singapore is home to one of eleven M Lab™ CollaboraBon Centers that allow pharmaceutical and biopharmaceutical manufacturers to explore ideas, learn innovative techniques, and work side-by-side with our scientists and engineers to solve critical process development and production challenges. The M Lab™ is a non-GMP lab designed for manufacturers of all therapeutic types, offering the flexibility to troubleshoot and test in our facility without impacting your production line.

The "FundaBonal Training" specifically tailored to the mRNA Tech Transfer Programme stakeholders was held in Singapore earlier this year. We hosted 14 participants from 5 global partners of the WHO mRNA Technology Transfer Programme, and the objective was to provide comprehensive technical training on the Core Technologies used in mRNA manufacturing, complementing the process of technology transfer on-site with Afrigen (the Centre for mRNA technology development and transfer), including normal flow filtration, tangental flow filtration, Chromatography, Integrity testing, and Single-use technologies.

As part of Merck's commitment to developing workforce capabilities, this training addressed a gap in the Program. Further, we are exploring the possibility of organizing a second session of the training in Q4 this year in Molsheim's MLab™, to host more global partners of the Program.

- **How does Merck Life Science support public health organizations in APAC in their efforts to advance critical healthcare standards? How does Merck intend to optimize its bioprocessing capabilities to benefit public healthcare?**

Merck's Life Science business supports public health organizations across APAC by providing high quality raw materials and advanced bioprocessing technologies used in vaccines, therapies, and diagnostics. We collaborate with government agencies and public institutions to strengthen R&D and manufacturing capabilities, helping accelerate development and enforcing quality and safety standards to address regional health needs.

To strengthen public health through reliable supply, Merck leverages its global manufacturing network across the Americas, Europe, and Asia to deliver single-use, filtration, and upstream processing solutions. In Asia, our footprint includes Wuxi, China, and an additional site under construction in Daejeon, South Korea, which will house single-use production and upstream cell culture media capabilities. These investments expand capacity, add redundancy, and introduce advanced automation to enhance efficiency and supply resilience.

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