How we shape the global vaccine marketplace

Highlights from PATH's Sustaining Vaccine Manufacturing program to improve global access to essential, high-quality, affordable vaccines

PATH's Sustaining Vaccine Manufacturing (SVM) program improves global access to essential, high-quality, affordable vaccines by supporting low- and middle-income country (LMIC) vaccine manufacturers working toward national licensure and World Health Organization (WHO) prequalification. We provide tailored technical assistance and advance access to knowledge, resources, and new manufacturing technologies that can improve product quality and reduce production costs.

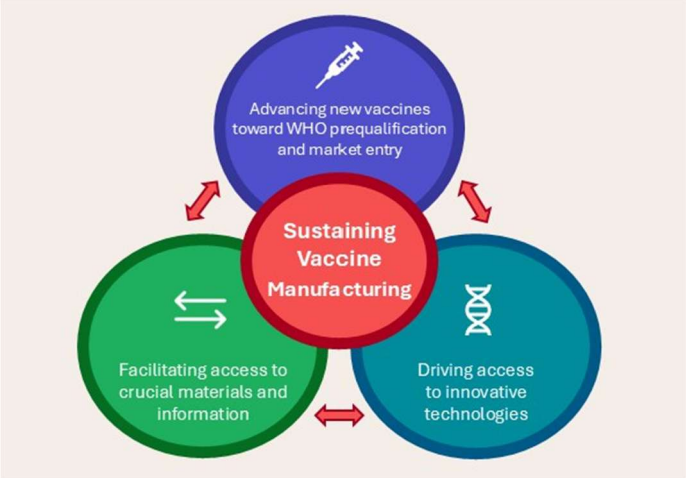
Program successes

SVM support focuses on workstreams essential to LMIC vaccine success: 1) advancing new vaccines toward WHO prequalification and market entry; 2) facilitating access to crucial materials and information; and 3) driving access to innovative technologies. We undertake a wide range of activities in pursuit of those efforts, from focused technical assistance on specific manufacturing steps to activities and collaborations that support a holistic manufacturing environment. Our work has broad impact—we've increased the availability of lifesaving vaccines and have advanced vital resources that are strengthening knowledge and the manufacturing ecosystem. Examples of how SVM drives impact include:

Navigating and achieving WHO prequalification

Since the SVM program began in 2018, we have assisted manufacturers of more than a dozen vaccines meet the rigorous global standards for WHO prequalification and Emergency Use Listing. For instance, we helped usher two new HPV vaccines that were previously licensed in China into the global market: Xiamen Innovax Biotech Co.'s Cecolin® in October 2021 and Yuxi Zerun Biotechnology Co.'s Walrinvax® in August 2024—both of which can help close the global HPV vaccine supply gap.

- We worked with Innovax to improve their quality management system, establish a post-marketing pharmacovigilance system, and collect information on regulatory requirements for registering vaccines in Gavi-eligible countries.



SVM's work focuses on essential workstreams that support LMIC vaccine manufacturing success.

- We worked with Zerun to improve their quality management and pharmacovigilance systems and provide CMC, quality, and clinical advice for the WHO prequalification dossier.

Keeping up with rising regulatory standards

We help manufacturers of WHO prequalified vaccines keep their quality systems and facilities up to standard to ensure strong, sustainable access. For example, the Chengdu Institute of Biological Products' Japanese encephalitis vaccine (JEV), the first-ever Chinese vaccine to be prequalified, has undergone multiple re-inspections by WHO since its 2013 approval; PATH has provided various trainings and supported facility upgrades and site inspection readiness, among other needs—helping to maintain the JEV pipeline and ensure this essential tool for keeping millions of children across Asia safe from disease remains available.

Similarly, in 2025, we helped India-based GCBC Vaccines Pvt. Ltd. prepare for and successfully face a facility audit necessary to maintain WHO prequalification of ShanChol®, an oral cholera vaccine (OCV), following a change in company management. Through mock audits and targeted CMC and quality technical assistance, SVM

support ensured the continued availability of a crucial tool for global health and helped address the significant worldwide shortage of OCVs.

Developing fit-for-purpose vaccine technologies

We're improving access to and affordability of resources and technology that can ensure accurate and reliable vaccine manufacturing in LMICs. For instance, we're developing standardized approaches to mRNA potency assays that can be easily adapted in LMIC settings and by national regulatory authorities. Because existing assays are complex and approaches vary across the field—making methods incompatible with resources available to LMIC manufacturers—standardized approaches for both mono- and multivalent products can ease complexity and promote local manufacturing.

Similarly, we explored different lipid nanoparticle formulations for mRNA vaccine production using resources and techniques that are accessible to LMICs, and discovered options that yield results similar to the ones commonly used today. These new platforms can help strengthen LMIC mRNA programs and reduce reliance on foreign vaccine suppliers—thereby increasing access and reducing costs.

Finding solutions for critical supply issues

We work to ensure LMIC manufacturers can more easily access materials that aren't readily available but that are necessary to advance manufacturing and conduct clinical trials—like reagents, vaccine vials, and even whole vaccines. We explore different avenues for procurement, from working with wholesalers to facilitating exchange between countries and companies to developing and producing important materials or reagents on our own.

For example, we worked with partners to generate supplies of both HPV and COVID-19 monoclonal antibodies that can be made available to LMIC vaccine manufacturers to support development of analytical tests such as potency assays. Improved *in vitro* tests may replace *in vivo* testing, which can lower the cost of goods for manufacturing, thus allowing for a lower price per dose and more manufacturing flexibility through a reduction in time to market for each lot.

Conducting landscape and capacity assessments

We work to understand the LMIC vaccine manufacturing ecosystem to identify challenges and opportunities for growth. For instance, we worked with the Africa Centres for Disease Control and Prevention and the Clinton Health Access Initiative to assess current and planned vaccine manufacturing capacity in Africa. Our work demonstrated that, as of late 2024, Africa faces a significant imbalance between drug substance and drug product manufacturing; uncertain country demand for African-made vaccines; and a strong reliance on non-African vaccine manufacturers for technology transfer. Identifying these gaps and needs can ensure alignment among stakeholders, governments, and funders and lead to more strategic investments and interventions.

Fostering collaboration across borders

We connect manufacturers across the world so they can mutually benefit from exchanged expertise, shared resources, and collaborative learning opportunities. For example, we host an ongoing webinar series that dives into critical aspects of vaccine manufacturing and features global experts as speakers. Past webinars have examined aluminum adjuvants, testing for adventitious egg-based agents, and next-generation sequencing.

Looking forward

Our list of successes is ever-growing and our areas of work ever-expanding. We have our finger on the pulse of innovation, championing the exploration and development of new technologies and strategies that have the potential to improve the global vaccine supply. For example, we're investigating how artificial intelligence might be able to support LMIC manufacturers with tools for different tasks within vaccine development or manufacturing. And we are looking into new vaccine combinations which might reduce the burden of vaccinations over a lifetime.

By keeping an eye on the future and the ways new ideas and technologies can advance vaccine manufacturing, SVM can serve as an advocate for LMIC vaccine manufacturers and champion sustainable vaccine access globally.

PATH

PATH is a global nonprofit dedicated to achieving health equity. With more than 40 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world's most pressing health challenges.

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