Building local manufacturing capacity to strengthen the global vaccine supply

How PATH works to support emerging market vaccine manufacturers and build sustainable vaccine supply globally

Historically, much of the world's capacity and capability to manufacture vaccines for global use has been located in high-income countries, which set up huge barriers to access for countries with fewer economic resources. Insufficient supply and high prices can prevent these countries from receiving lifesaving vaccines, sometimes for decades—even though low- and middle-income countries (LMICs) often suffer the highest disease burdens and greatest death tolls.

To address this imbalance in vaccine access, the world needs competitive vaccine markets that include LMIC vaccine manufacturers capable of producing vaccines for global use. When more vaccine manufacturers are able to enter the global market, supply often increases and costs and dependencies often decrease—and access to new and improved vaccines occurs more quickly.

Sustaining Vaccine Manufacturing

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

We work on a wide variety of pathogens and in all corners of the world and, since the program began in 2018, have assisted manufacturers of more than a dozen vaccines meet the rigorous global standards for WHO prequalification and Emergency Use Listing.

Our partnership philosophy hinges on responding to a given manufacturer's specific needs; we listen to the challenges they're having and opportunities they see for growth and together develop a strategy forward.

Who we are

We are an accomplished team of scientists and engineers and quality, regulatory, and logistics specialists. Our team has broad domain expertise across all platforms and aspects of vaccine manufacturing. Our track record of successful and collaborative partnerships has moved vaccines from early phase development to commercial licensure.

SVM staff scientists Jessica White and Manjari Lal examine test samples in PATH's Seattle laboratory. Photo: PATH/Patrick McKern.

What we do

SVM support is wide-ranging, from focused technical assistance on specific manufacturing steps to activities and collaborations that support a holistic manufacturing environment.

Common technical support activities include (but are not limited to): providing facility design reviews; leading subject-specific trainings; conducting site quality audits and gap analyses; supporting technology transfers; and aiding in regulatory applications.

Shaping the global vaccine marketplace

Our work has had broad impact across the vaccine manufacturing spectrum. We've increased the availability of lifesaving vaccines and have advanced critical resources that are strengthening manufacturer knowledge and the manufacturing ecosystem. Some of our successes include:

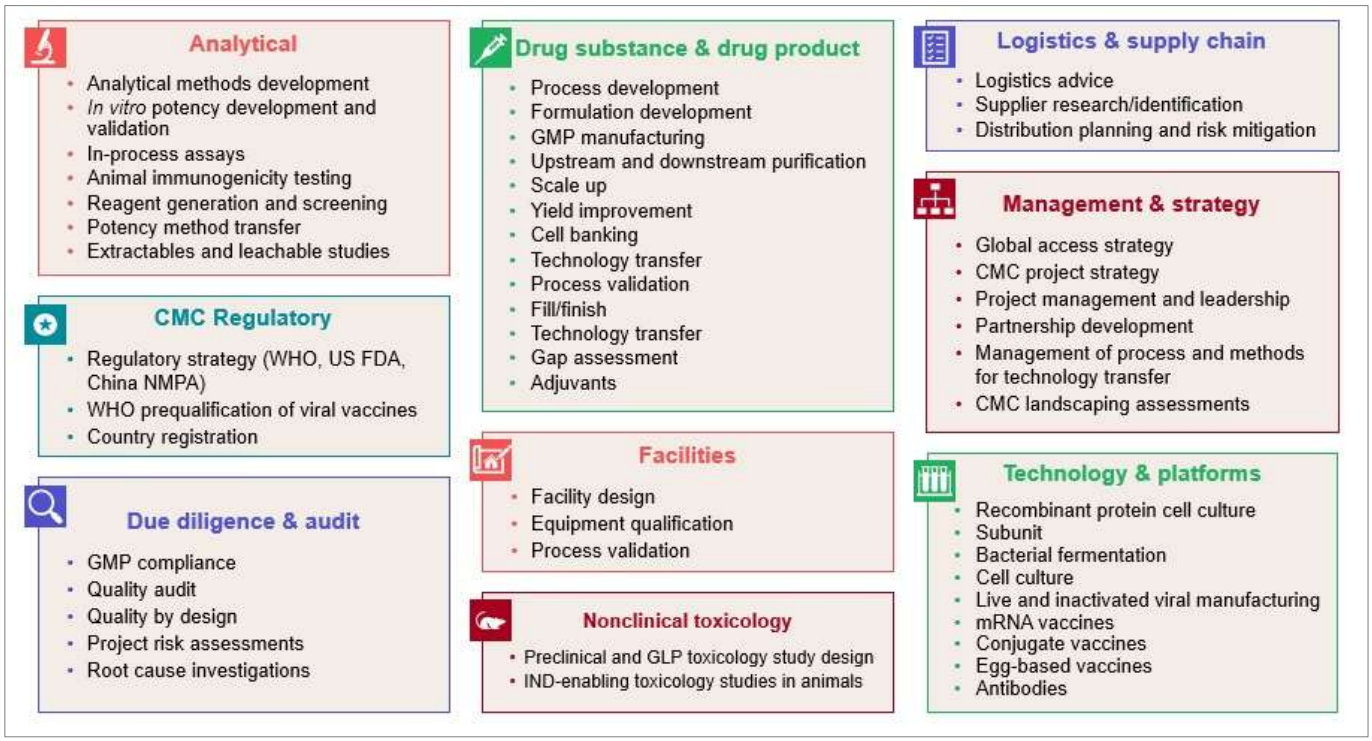
- Eleven WHO prequalified vaccines, three Emergency Use Listed vaccines, and more than 300 million doses of SVM-supported vaccine delivered globally.
- Continued regulatory approval of Japanese encephalitis vaccine, the first Chinese vaccine to be prequalified and an essential too for keeping millions of children across Asia safe from disease.
- A partnership 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.
- A series of webinars that offer a deep dive on critical aspects of vaccine manufacturing, featuring global experts in the field as speakers.
- Providing access to in-depth knowledge of different vaccine platforms and technologies, including lipid nanoparticle formulation platforms for mRNA vaccine production and standardized approaches to mRNA potency assays.
- Increased availability of high-quality HPV and COVID-19 reagents for LMIC vaccine manufacturer use.

We also pursue innovative solutions, 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 (AI) might be able to support vaccine development and manufacturing in LMICs.

Work with us

To advance health equity and to ensure affordable, sustainable vaccine access, PATH's vaccine manufacturing experts and SVM program stand ready to partner with vaccine manufacturers worldwide. Together, we can strengthen the global vaccine supply and save lives.

If you are interested in collaborating or learning more about PATH's manufacturing expertise or SVM program, contact us at CMC@path.org.



Graphic: PATH's chemistry, manufacturing, and controls (CMC) and quality capabilities.

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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