

Sustaining Vaccine Manufacturing (SVM)

A PATH program to strengthen low- and middle-income country (LMIC) vaccine manufacturing

<https://www.path.org/who-we-are/programs/center-for-vaccine-innovation-and-access/strengthening-the-global-vaccine-supply/>

A photograph of two scientists in a laboratory setting. They are both wearing white lab coats, blue surgical masks, and safety glasses. The scientist on the left is also wearing blue gloves and is holding up a small, clear plastic bottle with an orange cap, examining its contents. The scientist on the right is looking at the bottle. The background is filled with various laboratory equipment, including shelves with bottles, a centrifuge, and other labware. A large blue hexagon is overlaid on the left side of the image, containing the text 'PATH'S MISSION' and 'Advance health equity through innovation and partnerships.'

PATH'S MISSION

Advance health
equity through
innovation and
partnerships.

SVM is a one-stop-shop for **technical assistance** and problem solving that increases the **availability of lifesaving vaccines**.



We advance critical resources and state-of-the-art technologies that are **strengthening manufacturer knowledge** and the LMIC manufacturing ecosystem.

The SVM program improves global access to essential, high-quality, affordable vaccines

What does SVM do?

- Provides technical expertise and regulatory support
- Strengthens quality and manufacturing systems
- Drives accessibility of innovative technologies
- Improves supply chain and material access
- Generates landscape intelligence to guide investments

What does SVM achieve?

- Improved vaccine manufacturing capacity in LMICs
- Accelerated WHO prequalification and market entry
- Expanded global access to lifesaving vaccines

What is SVM's impact?

- Reliable and sustainable vaccine supply in LMICs
- Enhanced global equity and preparedness
- Lower costs and improved affordability
- Lower-risk investments in local manufacturing



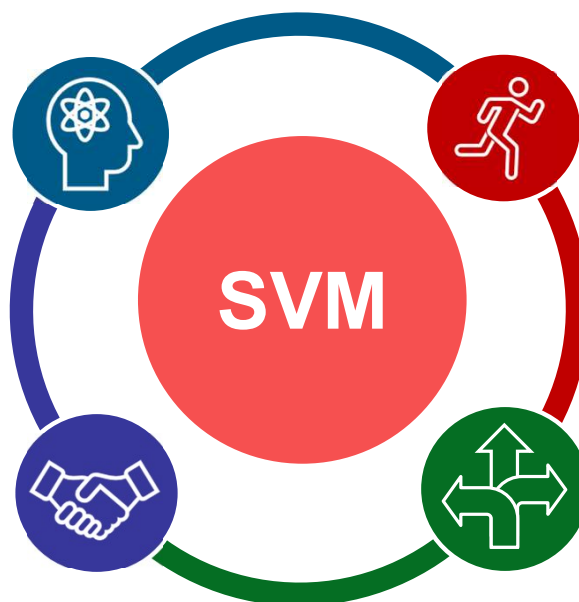
SVM's design enables impactful, timely support

Broad technical experience

- Extensive expertise across all vaccine technologies and platforms
- Deep knowledge of quality management and GMP manufacturing
- Excellence in material logistics and supply chain management

Collaborative and transparent

- Trusted partner to LMIC vaccine manufacturers
- Worldwide geographic presence



Agile and responsive

- Quick initiation of new support activities
- Rapid response to time-sensitive challenges
- Low administrative burden and lean processes

Adaptive and flexible

- Ready to take on projects
- Dynamic team structure tailored to each project

Our technical experience domains



Analytical

- Analytical methods development
- *In vitro* potency development and validation
- In-process assays
- Animal immunogenicity testing
- Reagent generation and screening
- Potency method transfer
- Extractables and leachable studies



CMC Regulatory

- Regulatory strategy (WHO, US FDA, China NMPA)
- WHO prequalification of viral vaccines
- Country registration



Quality management & audit

- GMP compliance
- Quality audit
- Quality by design
- Project risk assessments
- Root cause investigations



Drug substance & drug product

- Process development
- Formulation development
- GMP manufacturing
- Upstream and downstream purification
- Scale up
- Yield improvement
- Cell banking
- Technology transfer
- Process validation
- Fill/finish
- Technology transfer
- Gap assessment
- Adjuvants



Facilities

- Facility design
- Equipment qualification
- Process validation



Nonclinical toxicology

- Preclinical and GLP toxicology study design
- IND-enabling toxicology studies in animals



Logistics & supply chain

- Logistics advice
- Supplier research/identification
- Distribution planning and risk mitigation



Management & strategy

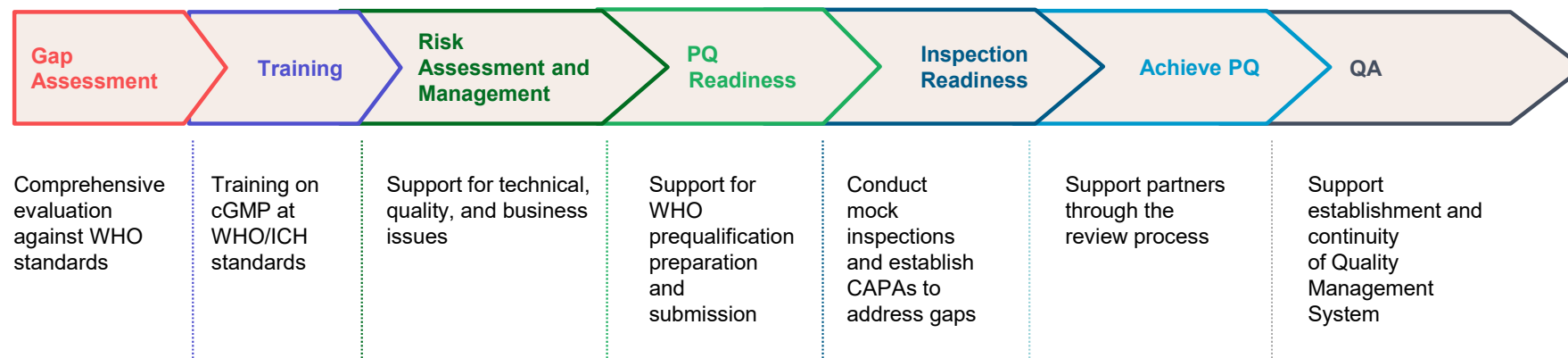
- Global access strategy
- CMC project strategy
- Project management and leadership
- Partnership development
- Management of process and methods for technology transfer
- CMC landscaping assessments



Technology & platforms

- Recombinant protein cell culture
- Subunit
- Bacterial fermentation
- Cell culture
- Live and inactivated viral manufacturing
- mRNA vaccines
- Conjugate vaccines
- Egg-based vaccines
- Antibodies

SVM technical assistance offerings



SVM is transforming the LMIC vaccine manufacturing landscape by:



Accelerating WHO PQ and market entry

300m+

doses of SVM-supported vaccines delivered globally within the last 3 years

11

SVM-supported vaccines have received or maintained WHO PQ over the last 3 years

9

vaccines currently preparing for WHO PQ or licensure with SVM support



Driving access to innovative technologies

18

mAbs developed and scaled-up to support HPV and COVID-19 vaccine release testing

4

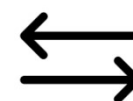
LNP-formation platforms for RNA vaccines evaluated for LMIC use

4

webinars hosted to address manufacturing topics important to LMIC vaccine manufacturers

1

new ELISA-based mRNA vaccine potency assay developed for LMIC use



Facilitating material and information exchange

25

solutions delivered for supply issues experienced by manufacturers and grantees

7

landscaping assessments of the LMIC vaccine manufacturing ecosystem complete

6

diligence assessments of projects or manufacturers conducted

1

logistics hub established to facilitate exchange of hexa-VLP materials between LMIC vaccine manufacturers and academic labs

Thank you!

For more
information contact:

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PATH
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