Expanding manufacturing capacity

Producing medicines closer to patients to advance health equity

Expanding manufacturing capacity is key to improving access to medical products, averting supply chain shortages, advancing health security, and assuring equitable responses during health emergencies. We work to strengthen **regional and local manufacturing of medicines, vaccines, personal protective equipment, medical devices, and other health products** to provide more equitable access for patients and communities worldwide.

Why it matters

While pharmaceutical supply chains have become increasingly complex, the supply of many essential health products is constrained by a limited number of producers from a handful of major manufacturing hubs. The challenge extends beyond limited sources of finished products, but includes few sources for starting materials, raw materials, and active pharmaceutical ingredients (APIs) as well.

Over-consolidation of the pharmaceutical market makes supply chains vulnerable *to disruptions and impedes access to essential medicines for millions of patients.*

Our Impact

40+ technology transfers facilitated
including 10 fill/finish programs.

40+ products approved
by the WHO's prequalification program or other stringent regulatory authority, including APIs and finished products.

100+ pharmaceutical companies engaged
to strengthen good manufacturing practices.

4,000+ people trained
in good manufacturing practices from 24 countries.

OUR WORK IN ACTION

Facilitated technology transfer between Gilead Sciences Inc. and **Pakistan** manufacturer Ferozsons to expand the supply of essential COVID-19 treatment remdesivir to 16 countries.

In **Nigeria,** we worked to establish new local sources for five essential medicines for maternal and newborn health.

In **Indonesia, Kazakhstan, Philippines,** and **Uzbekistan,** we helped 10 manufacturers produce medicines to combat drug-resistant TB, including the first locally produced anti-TB medicine to receive WHO-prequalification in Indonesia.

Learn more about our work on the USAID PQM+ program and our other programs on our website.

OUR EXPERTISE

Manufacturing Quality

- Quality system development
- GMP, GLP, GCP, and other GxPs
- Bioavailability/bioequivalence
- Corrective and preventive actions
- Quality control/lot release

Technology Transfer

- Feasibility analysis
- Product and process knowledge transfer
- Skills transfer for workforce development

Regulatory Advisory Services

- Dossier preparation/filing
- Product registration
- Mock inspections/audits

Process Optimization

- Capital improvement projects
- Facility design/expansion
- Material sourcing/selection
- Traceability/barcoding
- Advanced manufacturing technologies

Pharmaceutical Sector Strategy

- GMP roadmaps
- Market intelligence
- Predictive analytics

Creating an enabling ecosystem for regional COVID-19 vaccine production

Expanding vaccine production in isolation is insufficient to expand access to COVID-19 vaccines. That is why our efforts are focused on creating an enabling ecosystem for sustainable production that includes collaborating with the following:

- **Regulators** to advance and optimize regulatory review, emergency use, and full approval processes.
- **Local manufacturers** to explore sustainable models of expansion, including feasibility studies and backward integration.
- **Pharmaceutical innovators** to address and bridge capacity gaps for successful technology transfer.
- **Development and finance institutions** to de-risk investments through strategic and technical insights and guidance.

Learn more about our work
https://www.usp.org/global-public-health