

Center for vaccine innovation & access

Vaccine manufacturing: On the critical path to vaccine access

Chemistry, Manufacturing, and Controls at PATH

Chemistry, Manufacturing, and Controls (CMC) plays a pivotal role in the development, licensure, manufacturing, and ongoing monitoring of new and improved vaccines by ensuring product consistency and quality. Consequently, CMC activities are crucial for improving vaccine access globally. However, when vaccine manufacturers have limited CMC experience, it can affect vaccine quality, cost, and access.

For more than 20 years PATH has leveraged scientific and global health know-how, deep connections to communities, and an unparalleled record of successful, multisector partnerships to support countries in advancing immunization equity and vaccine coverage for the people who need it most. As part of PATH’s Center for Vaccine Innovation and Access, the CMC team provides capacity bridging support for vaccine manufacturers to ensure life-saving vaccines can be widely available to communities across the world.

Supporting our CMC partners

For more than a decade, the PATH CMC team has worked with vaccine manufacturers in low- and middle-income countries (LMICs), to address challenges in achieving their production objectives and milestones.

The CMC team regularly works with manufacturing partners, funders, and other organizations to determine how we can best support their needs, whether it’s performing a gap assessment, providing technical assistance, collaborating on assay development and implementation, supporting a technology transfer, troubleshooting supply chain issues, and/or supporting preparation for World Health Organization prequalification inspections.

An experienced global CMC team

We are an accomplished team of scientists and engineers, as well as quality, regulatory, and logistics specialists. Our



Members of PATH’s CMC team. Photo: Courtesy PATH.

team has broad domain expertise across all platforms and aspects of vaccine manufacturing with a successful track record of productive and collaborative partnerships that have moved vaccines from early phase development to commercial licensure.

Work with us

PATH’s CMC team continuously looks for opportunities to partner with vaccine manufacturers and other organizations at all stages of the vaccine lifecycle. We seek collaborations that support PATH’s mission and will have a positive impact on public sector programs in LMICs. Together, we can advance the availability, accessibility, affordability, and sustainability of vaccines for the people who need them most.

If you are interested in collaborating or learning more about PATH CMC, email us at [CMC@path.org](mailto:CMC@path.org).

PATH CMC’s Vaccine Domain Expertise

**Fds**

**Analytical**

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

**CMC Regulatory**

* Regulatory strategy for WHO, US FDA, and China National Medical Products Administration (NMPA)
* WHO prequalification (PQ) of viral vaccines
* Country registration
* Drafting CMC regulatory strategy, including nonclinical sections and Module III (Phase 1 to WHO PQ)

**Drug substance**

* Process development and GMP manufacturing
* Upstream and downstream purification
* Scale up of upstream bulk manufacturing
* Process troubleshooting
* Yield improvement
* Cell banking
* Technology transfer

**Drug product**

* Formulation development
* Process development
* Yield improvement
* Scale up
* Process validation
* Fill/finish
* Technology transfer
* Gap assessment
* Adjuvants

**Due Diligence & Audit**

* GMP compliance and Quality audit
* Quality by design
* Project risk assessments and root cause investigations

**Facilities**

* Facility design
* Equipment qualification, process validation

**Logistics and Supply Chain**

* Logistics advice
* Supplier research/identification for vaccine material supply
* Distribution planning and risk mitigation for clinical supply

**Management and Strategy**

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

**Non-Clinical Toxicology**

* Preclinical and GLP toxicology study design
* IND-enabling toxicology studies in various animal species

**Technology & Platforms**

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