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. As new vaccine suppliers seek to join the market, PATH is available to partner in achieving vaccine quality and access.

For more than 30 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 a mix of technical support for vaccine manufacturers to ensure life-saving vaccines can be widely available to communities across the world.

Supporting our CMC partners

Our PATH CMC team has worked with vaccine manufacturers in low- and middle-income countries 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 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

To advance our mission of health equity, PATH’s CMC team stands ready to partner with vaccine manufacturers and other organizations at all stages of the vaccine lifecycle. 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.
# PATH CMC’s Vaccine Domain Expertise

## 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, and China National Medical Products Administration [NMPA])
- WHO prequalification (PQ) of viral vaccines
- Country registration

## Drug substance & drug product
- Process development
- Formulation development
- GMP manufacturing
- Upstream and downstream purification
- Scale up of upstream bulk manufacturing
- Process troubleshooting
- Yield improvement
- Cell banking
- Technology transfer
- Process validation
- Fill/finish
- Gap assessment
- Adjuvants

## 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

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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.

path.org