Catalyst GLOBAL

Capability Statement

Global Regulatory Affairs and Quality Assurance

Catalyst Global

Catalyst Global is a US-based 501(c)(3) committed to increasing access to critical, quality-assured health products and services in low-and middle-income countries. Our team of experts in the public health, social marketing, pharmaceutical, and medical device industries provide comprehensive technical assistance to product developers, manufacturers, and governments to create access to high-quality health products in global markets. Since 2010, Catalyst Global's strategic and practical technical assistance to partners has resulted in over **160 registrations** of health commodities in **90 countries** in Africa, Asia, and Latin America, and supported product prequalification through the WHO Prequalification Program.

Catalyst Global supports product developers and manufacturers in the pre-and post-market introduction of new health commodities, including the development of regulatory lifecycle management and quality management systems in alignment with applicable National Regulatory Authority (NRA) requirements. We work closely with manufacturers to improve their quality management systems and supplier audits, aligning their quality standards with Good Manufacturing Practice (GMP) regulations and assisting with the establishment of Pharmacovigilance (PV) policies and procedures between manufacturers and distributors.

Catalyst Global provides capacity building support to regulators by improving their pharmaceutical management systems to assure the quality, safety, and efficacy of quality-assured health commodities. This includes regulatory systems strengthening and technical assistance to improve regulatory processes, reduce costs, and clarify national guidelines with the goal of accelerating the introduction of reliable commodities.

Catalyst Global also acts as a product-neutral convener, identifying strong partners and building strategic teams that work comprehensively along the value chain to introduce new health commodities. Catalyst Global leads the $21M, USAID-funded **Expanding Effective Contraceptive Options (EECO)** project (2013-2023), designed to pilot innovative contraceptive technologies in low-and middle-income countries and to develop roadmaps for the successful introduction of new and underused commodities to contribute to knowledge within the broader reproductive health community. Catalyst Global's credentials in product introduction, global regulatory affairs, and quality assurance have made it a preferred partner of organizations seeking to move products from laboratories and manufacturing plants to the women who need them.

160 registrations of health commodities

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Catalyst Global's functional regulatory and quality systems support

Technical Assistance in Regulatory Systems Strengthening

- Support National Regulatory Authorities (NRAs) to optimize their clinical trial oversight, registration, licensing, advertising, and promotion control;
- Conduct regulatory landscape assessments to gather critical market data and develop thorough regulatory strategies;
- Provide support for pre-market and post-market regulatory lifecycle management and commitments;
- Compile, review and publish regulatory dossiers;
- File regulatory dossiers for local market authorizations and through regional harmonization mechanisms;
- Support products undergoing the WHO prequalification process;
- Liaise with NRAs and key local stakeholders to garner support for new product registration and introduction;
- Provide scientific advice and clinical trial oversight to products in this stage of development;
- Support regulatory advertising and promotion;
- Compile and publish reports.

Technical Assistance in Quality Management Systems

- Support country NRAs' pharmaceutical quality systems to apply best practices to their inspection procedures, post-marketing surveillance and pharmacovigilance;
- Provide compliance auditing/inspection (internal and external);
- Support the development of quality management systems;
- Assist manufacturers to improve quality assurance and quality control;
- Oversee quality control testing and batch release;
- Stability program support;
- Technology transfer support.

Catalyst Global's regulatory training and capacity building publications include:

- "African Medicines Regulatory Harmonization Initiatives," published in the TOPRA Regulatory Rapporteur. Non-copyright version available here.
- *Product Registration Basics for Global Health Program Managers*, available here.
- *Learning about Expanded Access and Potential of the Levonorgestrel Intrauterine System* (LEAP LNG-IUS), available here.
- "Donation of Contraceptive Products Through Special Import Permits: A Case Study of Zambia and Nigeria," published in the International Journal of Drug Regulatory Affairs (IJDRA), available here.
- Product Registration Toolkit, available here.

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