assisted many companies achieve regulatory/ERP approval or quality assurance requirements for UNICEF procurement for 20 products. The technical assistance provided by the PQM GMP/CMC group is at no cost and focuses on many disciplines within regulatory compliance, such as the preparation/review of product dossiers, assessments and auditing of manufacturing facilities, and preparation for inspection by WHO and stringent regulatory authorities.

http://uspgo.to/qualitymeds

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PQM Promoting the Quality of Medicines

Good Manufacturing Practice/Chemistry, Manufacturing, and Controls Technical Assistance

USP U.S. Pharmacopeial Convention

USAID FROM THE AMERICAN PEOPLE

The Promoting the Quality of Medicines (PQM) program is the result of a cooperative agreement between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention. The PQM Good Manufacturing Practices (GMP)/Chemistry, Manufacturing, and Controls (CMC) Technical Assistance program assists manufacturers and regulators in low-to middle-income countries in achieving compliance with the regulatory expectations of stringent markets such as the United States, Europe, Japan, and the WHO Prequalification program. Since 2009, PQM has

Technical Assistance to Manufacturers

The PQM program is a resource to pharmaceutical manufacturers, supporting their bid to achieve WHO prequalification and/or approval of their product in a stringent regulatory market. PQM GMP staff collaborate closely with each manufacturer to

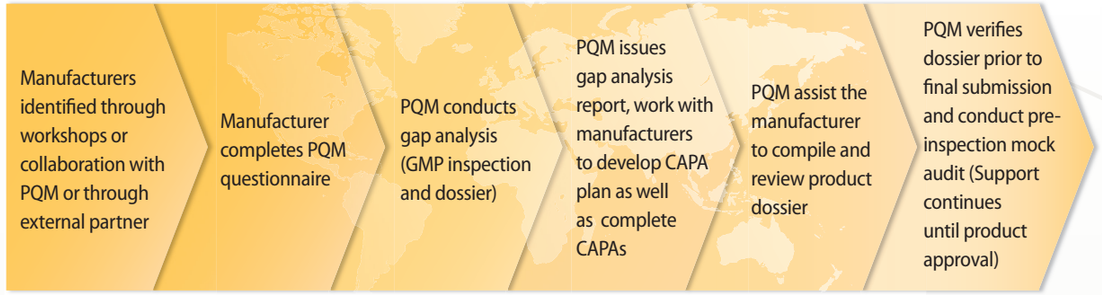
- Support product research and development, scale-up, and technology transfer
- Conduct on-site GMP assessment and mock audits
- Develop an effective CAPA plan
- Provide technical training in support of dossier and GMP-related activities and processes
- Review product dossier prior to submission
- Assess the compliance of clinical research organizations to conduct bioequivalence studies
- Review bioequivalence study protocols
- Provide technical assistance after the product dossier has been submitted to WHO or other regulatory authorities. PQM assistance includes review of regulatory inquiries and preparation of responses on dossier and inspection, until the product receives final approval. PQM also provides post-approval assistance with product registration.

Strengthening Regulatory Capacity

The PQM program also provides assistance to National Regulatory Authorities in order to develop and strengthen regulatory functions. PQM provides technical assistance in both administrative and technical regulatory functions, including policy, legislation, marketing authorization, GMP, quality control, inspections, licensing, setting standards, specifications, guidelines, and procedures. PQM also provides training to regulatory staff in the areas of

- Inspection of manufacturers and distributors
- Product assessment and registration
- Medicines quality monitoring and surveillance.

PQM GMP/CMC Work Flow



Medicines Approved with PQM GMP/CMC Technical Assistance

Medicine	Indication	Regulatory Approval	Public Health Impact
Azithromycin FPP	HIV	WHO PQ	-
Capreomycin API	Tuberculosis	WHO PQ	First source for public health market
Capreomycin API	Tuberculosis	WHO PQ	Second source
Capreomycin FPP	Tuberculosis	WHO PQ	First Capreomycin FPP on public health market; led to 50% price decrease
Cycloserine API	Tuberculosis	WHO PQ	-
Cycloserine FPP	Tuberculosis	WHO PQ	Led to global price decrease of 30%
Isoniazid API	Tuberculosis	WHO PQ	WHO prequalification achieved just in time to address global shortage in 2013
Kanamycin API, non-sterile	Tuberculosis	U.S. FDA Approval & WHO PQ	First source for public health market
Kanamycin API, sterile	Tuberculosis	WHO PQ	First source for public health market
Kanamycin FPP	Tuberculosis	Global Fund ERP	First source for public health market; led to 30% price decrease
Levofloxacin API	Tuberculosis	WHO PQ	First source for public health market
Mebandazole API	Neglected Tropical Disease	CEP	First source for public health market
Mebandazole API	Neglected Tropical Disease	WHO PQ	First source for public health market
Moxifloxacin API	Tuberculosis	WHO PQ	-
ORS	Diarrhea	UNICEF Procurement	-
Rifampicin API	Tuberculosis	WHO PQ	Addressed public health shortage
Streptomycin API	Tuberculosis	Spanish Regulatory Approval	-
Streptomycin API	Tuberculosis	WHO PQ	First source for public health market
Zinc Sulfate FPP	Diarrhea	UNICEF Procurement	-
Zinc Sulfate FPP	Diarrhea	WHO PQ	First source for public health market

Why Does PQM Provide Free Technical Assistance?

The main purpose of the PQM technical assistance program is to increase the availability of quality-assured, essential priority medicines for the public health market. Regulatory authorities in many countries have challenges in meeting the stringent requirements for reviewing product dossiers and inspecting manufacturing facilities. By receiving assistance from PQM, regulatory authorities can ensure timely approval of high quality medicines imported into their countries. As a result of the technical assistance provided by PQM, many pharmaceutical manufacturers in low-to middle-income countries produce medicines that meet international GMP standards and can achieve WHO prequalification, SRA approval, or ERP approval of their product. These manufacturers become eligible to participate in procurement programs operated by UN agencies, such as UNICEF and UNOPS, as well as other donor-funded mechanisms, like The Global Fund.

How Does PQM Make This Assistance Available to Manufacturers?

PQM reaches out to manufacturers through a series of workshops held in various regions of the world where pharmaceutical manufacturers are working to improve their GMP compliance and obtain stringent regulatory approval of their products. At these workshops, participants can interact with PQM facilitators and receive clarification on key technical issues.

For further information

on PQM GMP/CMC Technical Assistance, visit **http://uspgo.to/qualitymeds** or contact PQM at **PQMGMPGroup@usp.org**