

# Good Manufacturing Practices: Is It Possible in Developing Countries?

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## 1. OBJECTIVES

- ▶ Help manufacturers in developing countries overcome economic and technical challenges to produce medicines in compliance with internationally accepted Good Manufacturing Practices (GMP)
- ▶ Increase local production and availability of quality-assured medicines to treat priority diseases



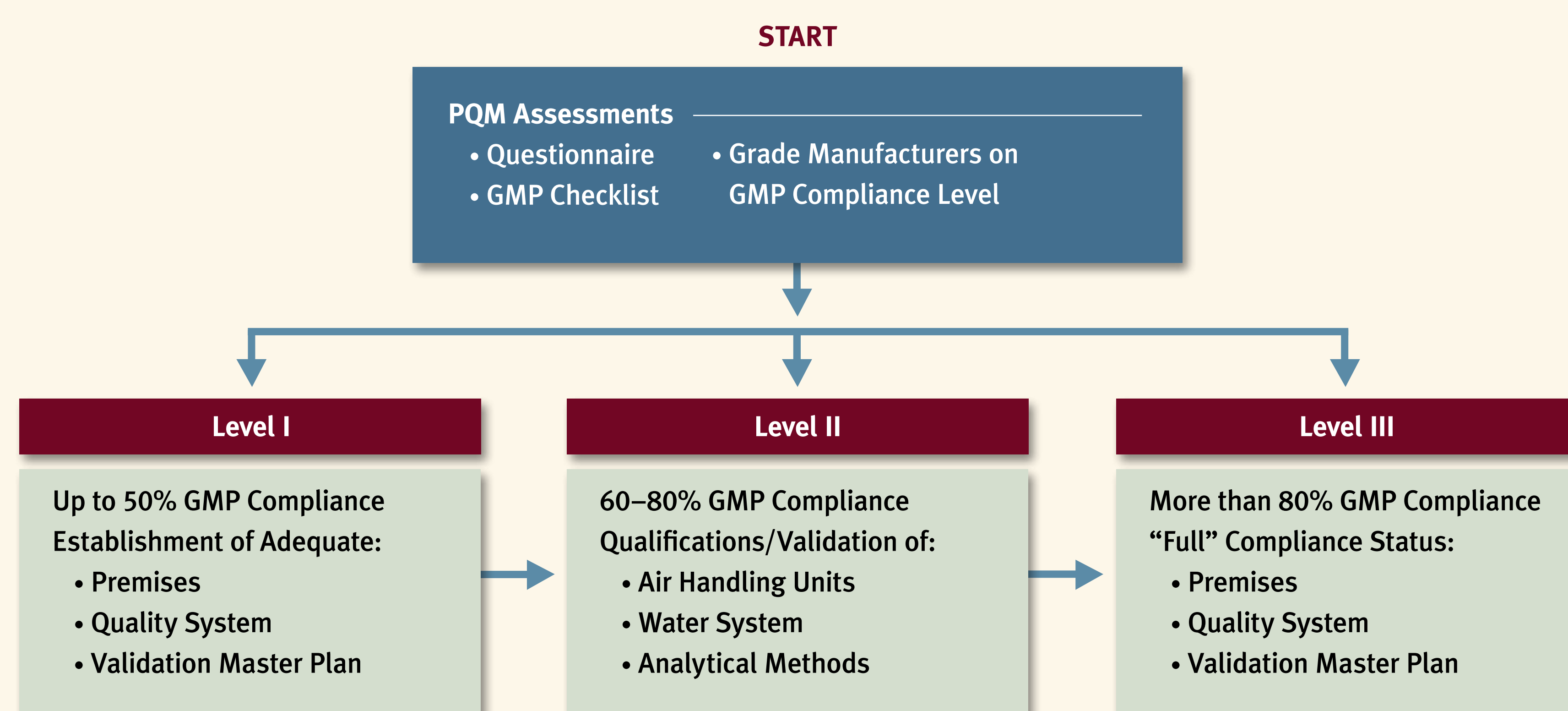
## 2. BACKGROUND

The lack of infrastructure, quality management systems, and trained personnel greatly hampers manufacturers in most developing countries from following stringent GMP. For many, their institutional capacity and resources are limited—they have inadequate pharmaceutical management systems, outdated equipment, and insufficient expertise in medicines quality. Weak regulation of quality assurance and quality control (QA/QC) of medicines contributes to inadequate enforcement of even national GMP compliance standards.

While traditionally there has been little incentive for manufacturers to produce quality-assured medicines, Promoting the Quality of Medicines (PQM) case studies demonstrate that where the demand exists and technical assistance is provided, compliance with international GMP is an achievable goal. Improving their adherence to GMP to meet more stringent standards opens up opportunities for local manufacturers to expand into the area of national and international procurement by the Global Fund, UNICEF, and UNITAID, among others.

## 3. METHODS

PQM, funded by the United States Agency for International Development (USAID) and implemented by the U.S. Pharmacopeial Convention (USP), works with manufacturers interested in improving their quality systems in order to produce medicines that meet requirements of the World Health Organization (WHO) Prequalification Programme. PQM guides manufacturers through the complex process and prepares them for WHO audits of documentation and facilities.



PQM staff perform an initial evaluation of qualifying companies to determine their level of compliance with critical GMP elements. After meeting with the manufacturer’s management team and assessing their facilities, PQM helps them prepare a plan and timeline to reach their goal for WHO Prequalification. PQM offers continuing technical assistance on assembling product dossiers, preparing for GMP inspections, testing samples for quality, and facilitating discussions with WHO.



Manufacturer (country)	Product	Questionnaire	Baseline GMP Assessment	Dossier Compliance	Dossier Review Stage 1	Dossier Review Stage 2	Dossier Sent to WHO	Dossier Accepted by WHO	WHO Comments Addressed	PQM Mock Audit	Site Inspection Conducted	Pre-qualified

## 4. RESULTS

PQM has successfully provided technical assistance to manufacturers of zinc sulfate and anti-tuberculosis (TB) medicines. PQM was instrumental in developing USP quality standards for zinc sulfate—used to control childhood diarrheal disease—to meet treatment guidelines recommended by WHO and UNICEF.

To help manufacturers achieve WHO Prequalification for zinc sulfate, PQM helped them strengthen their QA systems and compliance to meet international GMP standards. To date, one manufacturer has reached WHO Prequalification for zinc formulations, two others are one step away, and five more are making progress toward that goal.

In 2008, USAID approached PQM to assist TB medicine manufacturers on QA measures at the initial stage of the prequalification process, as well. PQM is assisting 21 manufacturers of TB medicines in nine countries to achieve WHO Prequalification.



## 5. CONCLUSION



The technical assistance that PQM provides to manufacturers is proving instrumental in their journey to reach WHO Prequalification. The demand for WHO-prequalified products by procurement agencies and PQM’s technical assistance to manufacturers are increasing the availability of quality-assured medicines. The advances made by participating manufacturers and their dedication to improvement have demonstrated that it is possible for manufacturers in developing countries to achieve compliance with international GMP standards.

The knowledge PQM has gained from each experience working with manufacturers in developing countries has helped build its “road map” for GMP compliance—a phased approach, with incremental steps a company can realistically attain along the way. This strategy also helps regulators set a timetable for when local manufacturers might comply with GMP guidelines, reach WHO Prequalification, and make quality-assured medicines available in the market.

Achieving compliance with WHO GMP standards presents manufacturers with an exceptional opportunity and an optimistic future. They will have access to additional markets, bringing increased revenue that can be reinvested in quality systems and also advance sustained production of quality-assured pharmaceuticals.