PQM Promoting the Quality of Medicines

Promoting the Quality of Medicines Program

INVENTORY OF TECHNICAL RESOURCES

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About PQM

The Promoting the Quality of Medicines program is a cooperative agreement between USAID and USP. The PQM program provides technical assistance to strengthen medicines regulatory authorities and quality assurance systems and supports manufacturing of quality-assured priority essential medicines for malaria, HIV/AIDS, tuberculosis, neglected tropical diseases, and maternal and child health.

Cover Photo

Scientists at Myanmar's Food and Drug Administration listen as PQM Program Manager, Yanga Dijiba, reviews tools used for performance verification tests.

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INTRODUCTION

Financed by the U.S. Agency for International Development (USAID) and implemented by the U.S. Pharmacopeial Convention (USP), the Promoting the Quality of Medicines (PQM) program works to improve the quality of essential medicines in low- and middle-income countries (LMICs) to help prevent and treat HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, and threats to maternal, newborn, and child health. To achieve this important goal, the program supports the adoption of effective and enforceable policies and legislation; strengthens the regulatory and quality assurance workforce to effectively manage product quality; and harnesses information to increase evidence-based decision-making at all levels. Through these activities and related actions, PQM strengthens regulatory systems and improves the ability of manufacturers to produce quality-assured medicines.

The PQM program has been providing technical assistance to governments and pharmaceutical manufacturers since 2009. Since that time, it has developed or contributed to a significant number of resources that can be useful to implementers of medicines quality assurance programs and to decision makers who must consider the value of investments in medicines regulatory systems and quality manufacturing for LMICs. The purpose of this inventory is to provide easy access to these resources through a regularly updated document.

This inventory consists of four main chapters that span the PQM program's primary technical areas: regulatory systems strengthening, manufacturing, laboratory strengthening, and quality surveillance. These chapters are preceded by a section of resources that introduce the project and its intervention zone, and are followed by a collection of resources that cut across multiple themes. Those resources are grouped by type and displayed chronologically based on their publishing date in each grouping.

Resource types mainly include:

Policies and guidelines

providing direction on the necessary procedures, processes, and decisions to implement an activity.

Reports

detailing the implementation and results of key activities.

Success stories

highlighting factors that led to impact in the implementation of technical approaches and activities.

Fact sheets and briefs

summarizing PQM's achievements through short texts and tables, bullet points, graphs, and other data visualization and presentation techniques.

Journal articles

written entirely or in part by PQM staff members.

Media articles

that cover PQM activities or cite program expertise or opinions.

Presentations

made at conferences and other external events.

Videos

that raise awareness about fundamental program themes.

eCourses

provide online learning opportunities on critical quality assurance topics.

Titles of all resources listed in the chapters of document are linked to online, downloadable versions of those resources. The annex provides a linked, alphabetical listing of the same resources and also includes a URL and a citation to facilitate attribution by authors who quote or excerpt information therein.

ABOUT THE PROJECT

Program Overview

Strengthening medicines quality assurance systems for sustainable health outcomes (2018)

This fact sheet describes PQM's work in strengthening medicines quality assurance systems.

Promoting the Quality of Medicines: program approach and technical areas (2017)

This document describes the PQM approach and technical service areas. PQM's approach reflects a holistic view of medicines quality assurance to strengthen and improve the systems, structures, and processes that promote product quality. This approach recognizes the dynamic and cross-cutting relationships among different components of the health system, and therefore seeks to address product quality issues in a sustainable manner using systems-based thinking and solutions.

Results Framework and Indicators

PQM Results Framework and Indicators (2017)

The Results Framework is a graphic representation of a strategy to achieve a specific objective that is grounded in cause-and-effect logic. The PQM results framework has three Intermediate Results (IRs) and sub-results under each IR linked in a cause-and-effect relationship.

Country and Regional Program Briefs

PQM activities in sub-Saharan Africa (2015)

This brief lists PQM activities in sub-Saharan Africa. PQM supported activities in 13 African countries—Angola, Burundi, Ethiopia, Ghana, Guinea, Kenya, Liberia, Mali, Mozambique, Nigeria, Senegal, Tanzania, and Zimbabwe—that continue to build their capacity to safeguard medicines. PQM activities center on strengthening medicines regulatory authorities and their national quality control laboratories to maintain the quality control of medicines, from registration to distribution and sales. The typical activities carried out by PQM are then listed and explained: monitoring medicines quality, building the capacity of medicines quality control laboratories, raising awareness about the dangers of falsified and substandard medicines, and promoting good manufacturing practices.

Promoting the Quality of Medicines (PQM) program in Nigeria (2015)

This document highlights the accomplishments of the PQM program in Nigeria. These include reinforcing the National Agency for Food and Drug Administration and Control's (NAFDAC) regulatory capacity (primarily by assisting its Central Drug Quality Control Laboratory to attain ISO 17025 accreditation), strengthening quality assurance of medicines nationally, and assisting manufacturers in meeting international standards and reaching World Health Organization prequalification for maternal, newborn, and child health medicines.

Promoting the Quality of Medicines program in the Philippines (2015)

The Philippines is listed as 1 of the 22 countries with the highest burden of tuberculosis in the world. This brief presents the activities conducted by PQM in partnership with the Philippines Food and Drug Administration (Philippines FDA) and the National Tuberculosis Control Program–Department of Health (DOH) since 2008 to strengthen the country's capacity in assuring the quality of anti-tuberculosis medicines. Highlights include establishing a medicines monitoring management program; disseminating information and mobilizing of policymakers, regulators, and health professionals; strengthening the FDA's quality assurance/quality control systems; and providing support to local manufacturers.

Promoting the Quality of Medicines (PQM) program in Southeast Asia (2014)

This brief describes PQM's efforts to tackle the proliferation of substandard and falsified medicines in Southeast Asia. While this initiative has had some positive results, certain issues persist, such as the prevalence of poor-quality antimalarials, where artemisinin-resistant malaria has emerged, the limited number of staff adequately trained in quality assurance/quality control of medicines, and the lack of public awareness about substandard and falsified medicines. The primary recommended solutions are building the capacity of medicines regulatory authorities and conducting research and surveys to determine medicines quality.

PQM support in Burma (2013)

This document summarizes a 2012 PQM mission to Burma, which identified several areas in which the country's quality assurance/quality control systems required attention: weak premarket product evaluation for registration, weak quality management system and inadequately equipped quality control laboratories, limited post-marketing surveillance, and ineffective control of imports/exports and supply and distribution of medicines.

Briefing on the Promoting the Quality of Medicines program in Indonesia (2013)

PQM provides technical assistance to Indonesian medicines manufacturers to ensure that locally produced medicines meet World Health Organization (WHO) quality standards. Additionally, the PQM program is strengthening the capacity of the national system to improve and sustain quality assurance and quality control of essential infectious disease medicines. Indonesia is considered a high-burden tuberculosis country by WHO, with 1.8 percent of all newly diagnosed cases estimated to be multidrug-resistant tuberculosis (MDR-TB). PQM aims to assist local anti-tuberculosis medicines manufacturers to achieve WHO prequalification status. This achievement would help the National TB Control Program to manage MDR-TB in Indonesia, strengthen the National Agency of Drug and Food Control capacity in improving the quality assurance and quality control of medicines, and build capacity for operational research and surveys to determine medicines quality at strategic sentinel sites.

Promoting the Quality of Medicines: Cambodia (2012)

This brief lists the achievements of PQM's activities in Cambodia, which focus mainly on improving detection of poor-quality anti-infective medicines through monitoring medicines quality; strengthening medicines quality assurance/quality control systems; improving access to medicines quality information; and raising awareness about medicines quality issues among regulators, healthcare professionals, and the public.

Ensuring the quality of malaria medicines in Amazon Malaria Initiative (AMI) countries (2011)

This brief describes the role PQM plays in AMI, which aims to ensure the quality of antimalarial medicines in South American countries. PQM contributes to AMI through a three-pronged approach: building country capacity to ensure the supply of quality-assured antimalarial medicines, enhancing sustainable South–South collaborations, and optimizing quality control testing capability for sustainable impact and providing transparency of results.

Annual Reports

Submitted to the USAID Agreement Officer's Representative (AOR), annual reports provide an overview of PQM's key activities for the fiscal year. In addition to key activities, the reports also document success and challenges faced by the program in the given year.

Promoting the Quality of Medicines Program Annual Report: Project Year 2018

Promoting the Quality of Medicines Program Annual Report: Project Year 2017

Promoting the Quality of Medicines Program Annual Report: Project Year 2016

Promoting the Quality of Medicines Program Annual Report: Project Year 2015

Promoting the Quality of Medicines Program Annual Report: Project Year 2014

Promoting the Quality of Medicines Program Annual Report: Project Year 2013

Promoting the Quality of Medicines Program Annual Report: Project Year 2012

Promoting the Quality of Medicines Program Annual Report: Project Year 2011

Promoting the Quality of Medicines Program Annual Report: Project Year 2010

REGULATORY SYSTEMS STRENGTHENING

Policies and Guidelines

A risk-based resource allocation framework for pharmaceutical quality Assurance for medicines regulatory authorities in low- and middle-income countries (2018)

This document proposes a framework to assist medicines regulatory authorities in low- and middle-income countries in managing and sustainably supporting pharmaceutical quality assurance to achieve maximum health impact and efficiencies. The framework is specifically intended as a guide for the development of country-specific resource allocation tools and consists of six core elements: (1) risk analysis, (2) analysis of the pharmaceutical market, (3) analysis of country characteristics, (4) assessment of the regulatory and quality assurance environment, (5) risk management, and (6) assessment of the impact of resource allocation.

Guidelines for good storage practices, good distribution practice, and pharmaceutical product recall: Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) (2015)

These guidelines address the negative effects that lack of control during storage and poor compliance with good storage practices have on the quality and integrity of pharmaceutical products and materials. The objective of this guide is to describe the minimum requirements considered appropriate for the storage and transportation of pharmaceuticals products and materials to avoid the safety, efficacy, and quality problems caused by improper storage of pharmaceutical products and materials.

Guidelines for submission of post-approval variation medicine applications: Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) (2015)

This is a guideline for handling variation applications to medicines registered by EFMHACA. Its purpose is to provide applicants/manufacturers with information about documentation to be submitted for approval variations to the medicine previously registered by EFMHACA. In order to facilitate the classification of the different types of variations, the guideline explicitly defines the classification of variations.

Guidance on waiver of in vivo bioequivalence requirements: Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) (2015)

This guidance on bioavailability/bioequivalence enumerates the requirements for waiver of in vivo bioavailability/bioequivalence requirements for immediate release solid oral dosage forms, dose-proportionality formulation, and significant post-approval changes. The term biowaiver is applied to a regulatory finished pharmaceutical product approval process where the efficacy and safety part of the dossier (application) is approved based on evidence of in vitro equivalence other than through in vivo equivalence testing (i.e., use of in vitro testing as a reliable surrogate for an in vivo bioequivalence study).

National Quality Assurance Policy for medicines and other health products (NQAP): Nigerian Federal Ministry of Health (2015)

This policy paper outlines the NQAP, a crucial component in the development of the national health sector toward ensuring that health products in Nigeria are not only quality assured but also effective, affordable, and safe. The NQAP is offered primarily as a tool—to be used in whole or in part—to facilitate establishment of systems for quality assurance in organizations where no such formal systems exist, or for improvement of existing systems. Where resources or other constraints limit the immediate application of some of the principles outlined in the policy, it is hoped that this document can serve as a "road map" for the future.

Guideline for registration of medical devices: Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) (2014)

This guideline introduces the In Vitro Diagnostic (IVD) Medical Device Classification, Summary Technical Documentation (STED), and Essential Principles Checklist for Medical Device Safety and Conformity Assessment. The document reviews general registration requirements for all medical devices, medical device conformity assessments other than IVD, conformity assessments for IVD medical devices, reregistration of medical devices, applications for variation and amendments to a registered device, and requirements for application of a medical device with stringent regulatory authority procedure.

Guideline for registration of medicines: Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) (2014)

This guideline provides recommendations on the quality, safety, and efficacy information for both active pharmaceutical ingredients (API) and finished pharmaceutical products (FPP) that should be submitted to support product dossiers for the registration of medicines in Ethiopia. The guideline applies to product dossiers for products containing an API of synthetic, semisynthetic, or biotechnological origin; an API that has previously been authorized through an FPP by a stringent regulatory authority; and/or an API or its finished formulation officially included in a pharmacopoeia. APIs from fermentation, biological, or herbal origin are covered by other guidelines. In situations where the documentation requirement of a particular application is not addressed, the matter will be resolved on a case-by-case basis in consultation with EFMHACA.

Fact Sheets and Briefs

Strengthening Indonesia's pharmaceutical post-marketing surveillance capacity (2018)

This brief summarizes how the PQM program supported Indonesia's Ministry of Health and the National Agency for Drug and Food Control to improve intra-government communication and develop regulations to ensure that a robust quality assurance system was not only in place but also being implemented across the public and private sectors.

Building foundations for robust quality assurance systems in Myanmar (2018)

This brief summarizes how the PQM program used its systems-strengthening approach to support the Government of Myanmar in building capacity to properly ensure the quality of antimalarial medicines, with major focus on improving capacity within the country's network of Quality Control laboratories to accurately and reliably test the quality of medicines and, ultimately, achieve ISO accreditation.

Strengthening regulatory systems to improve medical product quality in low- and middle-income countries (2018)

This document reviews key regulatory challenges in LMICs, the key areas in which PQM aims to build or strengthen regulatory capacity, and shares lessons learned from the program's extensive implementation experience. Strengthening the capacity of MRAs requires in-depth and ongoing consideration of the broader country context and health system components that interact and influence MRA operations. As such, PQM relies on strategies and interventions rooted in systems thinking to sustainably strengthen regulatory capacity.

PQM support for regional medicines regulatory harmonization and reliance in Africa (2017)

PQM supports multiple initiatives to promote the harmonization of regulatory standards for medical products. The approach for supporting these initiatives focuses on strengthening regional economic communities' (REC) technical competency and capacity for joint good manufacturing practices inspection and dossier review so they can efficiently and promptly approve priority essential medicines, as well as providing technical guidance for regional collaboration in risk-based post-marketing surveillance. PQM's efforts build technical capacity for reliance, reduce duplication, and improve efficiency in achieving RECs' objectives for regional medicines regulatory harmonization.

Media Articles

Alliance to fight counterfeit malaria drugs in Kenya (2015)

This article announces the partnership between Kenyan Mission for Essential Drugs and Supplies, the Pharmacy and Poisons Board, and PQM to ensure the safety of all marketed medical products.

Kenyans cautioned against purchasing medicine from hawkers (2015)

This article reports the Kenya Pharmacy and Poison Board's press statement advising public schools not to purchase medicine from street vendors because the quality of such goods may be compromised. With the help of PQM, the root problem of the spread of falsified and substandard medicines in Kenya can be effectively addressed.

Reports

Mitigating cross-contamination in shared production facilities using risk-based cleaning validation methods: considerations and case study (2018)

This report provides guidance to pharmaceutical manufacturers on using a risk-based approach to cleaning validation in order to prevent cross-contamination of medicines during production. Applying this approach can provide a cost-effective alternative to building a dedicated facility for manufacturing essential medicines and thus may help motivate manufacturers to produce these priority products.

Success Stories

African medicines quality forum: an Africa-led network protecting consumers from poor-quality medicines (2019)

This success story documents the path that the African Medicines Quality Forum (AMQF) is taking to evolve from a donor support to self-reliance. AMQF is a powerful continental collaborative that helps national quality control laboratories strengthen their capacity for medicines quality testing and supports countries to institute programs that prevent falsified and substandard medicines from reaching consumers.

Bangladesh implements updated standards for medicines testing (2019)

This success story summarizes early adoption of the ISO/IEC 17025:2017 standard by the Bangladesh Directorate General of Drug Administration's National Control Laboratory.

Guinea updates its pharmaceutical regulatory law (2019)

This success story reviews the process Guinea followed to update its 24-year-old pharmaceutical regulatory law in 2018. The new law, which stipulates that quality control is required for all health products in Guinea at all stages, gives authority to the National Directorate of Pharmacies and Medicines for medicines quality assurance and surveillance of medicines in circulation.
Click here for French version

Pakistan acts quickly to recall contaminated medicines (2018)

This success story documents how the 2018 recall of certain medications for treating hypertension and heart disease in Pakistan was facilitated by the country's decision one year earlier to require pharmaceutical manufacturers to declare the source of the active pharmaceutical ingredients they use.

Pakistan adopts international standards for assessing and registering medicines (2018)

This success story describes the process that the Drug Regulatory Authority of Pakistan followed to implement the Common Technical Document (CTD), a standard format for medicines registration applications that is facilitating the Authority's efficient and timely use of globally accepted good review practices.

Building medicines quality assurance systems helps protect Liberians from poor-quality antimalarials (2017)

Created in 2010, Liberia's medicines regulatory authority—the Liberia Medicines and Health Products Regulatory Authority (LMHRA)—is a critical step forward in reducing the country's vulnerability to the proliferation of poor-quality medicines. The PQM program received financial support from the U.S. President's Malaria Initiative and began collaborating with Liberia in 2009 to help build stronger medicines quality assurance systems. The work began with studies assessing the proliferation of poor-quality medicines and helping to draft legislation that established LMHRA. Findings showed that half of the antimalarial medicine samples from 2010 and 2011 were of poor quality. The findings prompted LMHRA to recall failed lots and, in collaboration with National Malaria Control Program, push for a ban on oral artemisinin-based monotherapies, which was passed in 2011.

Nigeria builds capacity for data-driven decision-making in medicines quality assurance (2017)

Monitoring the effectiveness of programs can help provide the data needed to make informed decisions about investment priorities. Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) took a major step forward in its efforts to incorporate monitoring and evaluation (M&E) systems into program planning. In collaborating with PQM, NAFDAC made a significant investment by sharing the cost of a first-of-its-kind, 3-day intensive workshop on M&E capacity building. Participants included NAFDAC staff working on medicines approvals, as well as those conducting quality control and surveillance of medicines on the market.

Strengthening quality assurance systems for antimalarials in Nigeria (2017)

In Nigeria, PQM helps regulators improve their technical skills and strengthen laboratory capacity so they can survey and test medicines in their own market. To improve the reliable availability of medicines closer to patients, manufacturers in Nigeria work with PQM to enhance their capability to produce antimalarial medicines according to international standards. In addition, PQM supports regulatory agencies in adopting expedited approval processes for medicines, which then help antimalarial medicines manufacturers that meet medicines quality standards bring them to market faster.

Strengthening Nigeria's medicines quality assurance system by building capacity, sustainability and partnerships (2016)

Nigeria's National Agency for Food and Drug Administration and Control is collaborating with the PQM program to strengthen Nigeria's health system in sustainable ways and bolster its technical capacity in regulation and manufacture of quality-assured medicines.

PPB expands medicines quality surveillance in Kenya (2015)

In order to help Kenya's Pharmacy and Poisons Board (PPB) establish its first program to monitor the quality of antimalarial medicines, PQM provided extensive quality control training to health workers at PPB, the National Quality Control Laboratory, and the National Malaria Control Program. The trainings enhanced skills and knowledge in post-marketing surveillance of medicines and use of innovative, field-based technologies, called Global Pharma Health Fund (GPHF) Minilabs™, to evaluate medicines quality at the additional sentinel sites.

Videos

Protecting patients from bad drugs: A risk-based approach to medicines quality surveillance (part 1) (2019)

Poor-quality medicines can cause treatment failure and adverse reactions, increase morbidity and mortality, and contribute to the development of drug resistance. They also waste resources that could otherwise be used to benefit public health. These videos explain how designing and implementing programs that monitor medicines quality through a risk-based approach allows countries to tailor activities according to local needs, optimize limited resources, and focus efforts on areas that present the greatest risks to public health.

Protecting patients from bad drugs: A risk-based approach to medicines quality surveillance (part 2) (2019)

Poor-quality medicines can cause treatment failure and adverse reactions, increase morbidity and mortality, and contribute to the development of drug resistance. They also waste resources that could otherwise be used to benefit public health. These videos explain how designing and implementing programs that monitor medicines quality through a risk-based approach allows countries to tailor activities according to local needs, optimize limited resources, and focus efforts on areas that present the greatest risks to public health

eCourses

Strengthening quality assurance systems for medical products

This e-course provides an overview of essential aspects of medical product quality assurance, reviews common challenges, and discusses key interventions and approaches that can help improve the quality of medical products in low- and middle-income countries. The course also presents several lessons learned and recommendations from implementation experience to increase knowledge, awareness, and effective discourse across the diverse set of stakeholders working in this arena and related areas.

MANUFACTURING

Policies and Guidelines

Strengthening manufacturing capacity to improve access to quality-assured essential medicines (2017)

PQM works to strengthen the capacity of pharmaceutical manufacturers to produce quality-assured medicines and collaborates with manufacturers globally to address critical shortages or gaps in the supply of essential medicines. This technical report describes the support PQM provides to manufacturers and the technical approach employed.

Good manufacturing practice guideline for pharmaceutical products: main principles. Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) (2014)

PQM supports EFMHACA's efforts to devise and implement a comprehensive quality system model. This model allows manufacturers to support and sustain robust, modern quality systems that are consistent with current good manufacturing practice regulations.

Reports

GSK Chlorhexidine Digluconate (7.1%) Gel Technology Transfer Report (2019)

This technology transfer report is intended to serve as a guidance document on the development and manufacture of Chlorhexidine (CHX) gel. The report addresses the development of the formulation, including analytical testing along with manufacturing and primary packaging processes. The report also provides guidance for the commercial manufacturing and primary packaging of CHX gel into 3g sachets.

Revisiting the stability and storage specifications of oxytocin injection: a literature review (2018)

Oxytocin is used to manage postpartum hemorrhage. Although it is effective in preventing maternal deaths, significant challenges limit access to oxytocin, particularly for women in developing countries. This review explores the effects of various factors that compromise the quality of oxytocin injection available in low- and middle-income countries. It begins with a basic introduction to oxytocin as an active pharmaceutical ingredient and as an injection formulation, followed by a compilation of research studies to establish its solution-state stability.

Media Articles

Generation next: ensuring quality medicines for newborns (2017)

Over the past 30 years, great strides have been made globally to address child mortality, especially in the poorest countries. However, statistics for newborn deaths have not kept pace with the overall reduction in child mortality since the start of the new millennium. Low medicines production capacity, limited laboratory facilities, and weak regulatory frameworks mean many low- and middle-income countries import essential medicines, despite the fact that some medications can be produced locally at low cost. To address this matter, the PQM program works to develop local capacity to produce essential medicines in country, thus bringing down costs, increasing the speed of distribution, driving up use, and saving newborn lives.

Increasing the sources of quality medicines in LMICs: challenges and strategies (2017)

According to the World Health Organization, roughly one-third of the world's population lacks access to even the most basic essential medicines—a figure that climbs to nearly half the population in the poorest parts of Asia and Africa. In many cases, even when essential medicines are available for purchase, access to treatment can be limited due to cost, as brand-name pharmaceuticals are often more expensive, while generic medicines are not always widely available. As a result, people may be inclined to procure medicines from informal sources, such as markets, which typically contain medicines of unknown origins. These medicines are often falsified and substandard, and therefore may be less effective, toxic, or even lethal. Through activities such as working closely with pharmaceutical manufacturers, correcting for market failures, and addressing supply chain issues, PQM helps development stakeholders to increase the sources and supply of quality-assured medicines to low- and middle-income countries.

How to curb "fake" food products in Nigeria by PQM (2015)

This article quotes Chimezie Anyakora, Chief of Party for the PQM program, about the program's activities in Nigeria. These include PQM's assistance to local manufacturers in international good manufacturing practice standards, as well as to Nigeria's National Agency for Food and Drug Administration and Control and to the Ministry of Health, particularly in the area of quality control laboratories.

Fact Sheets and Briefs

Good manufacturing practice/chemistry, manufacturing, and controls technical assistance (2016)

The PQM program provides technical assistance to support pharmaceutical manufacturers in their efforts to achieve World Health Organization prequalification and/or approval of their product in a stringent regulatory market. PQM also supports national regulatory authorities to develop and strengthen their regulatory functions. Through technical assistance in both administrative and technical regulatory functions, including policy, legislation, marketing authorization, good manufacturing practices, quality control, inspections, licensing, standards setting, specifications, guidelines, and procedures, PQM enables regulatory authorities to ensure timely approval of high-quality medicines imported into their countries. Assistance is made available through a series of workshops held in various regions around the world.

Chlorhexidine for umbilical cord care: a new, low-cost intervention to reduce newborn mortality (2014)

This brief examines the positive impact chlorhexidine can have on reducing infant mortality that results from poor hygiene and antisepsis at birth and in the first week of life. Chlorhexidine is a safe, feasible, and cost-effective intervention, recommended by the World Health Organization during umbilical cord care in both home and facility births. Use of chlorhexidine is recommended as a replacement for harmful traditional substances, such as cow dung, to the cord stump. Research trials conducted in Nepal, Bangladesh, and Pakistan have shown positive results.

PQM technical assistance for manufacturers of second-line TB medicines (2012)

This document describes PQM assistance to the Global Drug Facility in its efforts to increase the availability of quality-assured second-line anti-tuberculosis medicines at affordable prices. To expedite the process of World Health Organization prequalification—and thereby expand the pool of viable manufacturers—PQM provides technical assistance to interested companies at no cost to the manufacturer in preparing medicines dossiers, evaluating manufacturing practices, providing gap analysis, and guiding them through the facility inspection process.

Success Stories

Helping save mothers and children in Indonesia: increasing the supply of quality-assured essential medicines (2017)

PQM supported an Indonesian manufacturer to achieve good manufacturing practices (GMP) standards, which resulted in World Health Organization (WHO) prequalification for oxytocin injection. In addition, the facility in which it manufactures amoxicillin 250 DT was found by WHO to be operating at an acceptable level of compliance with GMPs for pharmaceutical products. Soon, increased availability of quality-assured oxytocin and amoxicillin DT in Indonesia may save thousands of lives.

Protecting newborns by expanding locally manufactured quality-assured medicines (2017)

This success story documents PQM's help to two local manufacturers in Pakistan to become the first to receive government authorization to produce chlorhexidine. For years, global health workers and government officials in Pakistan advocated for a local source of chlorhexidine, with little success. However, recognizing the high rate of newborn mortality in Pakistan and the opportunity to leverage its global experience helping low- and middle-income countries to produce quality medicines, PQM identified and supported two manufacturers of chlorhexidine gel in Pakistan work toward market authorization. With this authorization, a dose of chlorhexidine is now available for a low cost; as a result, locally produced, affordable, quality-assured chlorhexidine is expected to reach health facilities across the country, dramatically expanding chlorhexidine's availability and reducing the price of an essential medicine for newborns.

Saving newborn lives with scale up of quality-assured chlorhexidine (2017)

This success story documents the effectiveness of quality-assured 7.1% chlorhexidine digluconate in preventing hundreds of thousands of newborn deaths caused by infections in low- and middle-income countries. Since 2013, PQM has participated in the Chlorhexidine Working Group, an international collaboration of organizations committed to advancing use of 7.1% chlorhexidine digluconate for umbilical cord care through advocacy and technical assistance. PQM has also equipped local manufacturers and regulators with technical expertise in quality assurance to meet increased local, regional, and global demands for 7.1% chlorhexidine digluconate. Two countries of focus have been Pakistan and Nigeria.

Presentations

Strengthening quality assurance systems of pharmaceutical manufacturers to ensure availability of affordable TB medicines on the global market (2016)

The presentation describes PQM's approach to providing technical assistance to manufacturers of medicines for tuberculosis to improve good manufacturing practice compliance and successfully apply for World Health Organization (WHO) prequalification or stringent regulatory authority approval. The presentation also reports the results of PQM's technical assistance to manufacturers of anti-tuberculosis medicines, as measured by the number of different products that have attained WHO prequalification or stringent regulatory authority approval and became available on the public health market.

Good manufacturing practices: is it possible in developing countries? (2011)

This presentation addresses ways to assist low- and middle-income countries in complying with internationally accepted good manufacturing practices (GMP). After receiving this assistance, individual manufacturers should attain Full Compliance Status, meaning over 80-percent compliance with GMP.

Videos

True impact: helping babies thrive in Nigeria (2017)

In newborns, chlorhexidine reduces severe infections by 68 percent and deaths by 28 percent. Prior to 2013, chlorhexidine gel was not manufactured in sub-Saharan Africa. The PQM program partnered with Drugfield Pharmaceuticals Ltd. to build its capacity to produce this essential medicine. Today, Drugfield continues to produce chlorhexidine and is now exporting to other parts of the world.

LABORATORY STRENGTHENING

Policies and Guidelines

Strengthening national quality control laboratories in low- and middle-income countries to improve the quality of medicines (2018)

This document describes PQM's technical approach: building the managerial and technical capabilities of national quality control laboratories to strengthen local capacity to detect substandard and falsified medicines. This approach has guided PQM in supporting national quality control laboratories to develop stronger laboratory quality management systems, comprehensive laboratory quality assurance policies and practices, medium- and long-term instrument maintenance plans, and risk-based sampling and testing activities.

Analytical Instrumentation support for national quality control laboratories (2018)

This document outlines PQM's approach to supporting national quality control laboratories in managing and maintaining their analytical instrumentation and outlines strategies for building in-house expertise of laboratory staff, strengthening the capacity of national metrology institutes, and strategically partnering with contract service providers to share resources and calibration reference standards.

Success Stories

Building capacity for laboratory equipment maintenance in Liberia (2019)

This success story describes how the Liberia Medicines and Health Products Regulatory Authority has approach capacity-building for maintenance of laboratory equipment, notably including team members who are traditionally not trained for such tasks.

Increasing the sustainability of Ethiopia's medicines quality assurance system by building local service capacity (2019)

This success story provides describes how the PQM program helped build the capacity National Metrology Institute of Ethiopia (NMIE) to provide calibration services to the Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA). This contributed to EFMHACA's organizational sustainability by significantly reducing service costs through local contracting and helped NMIE expand the range of services it can offer in Ethiopia.

Protecting patients from poor-quality medicines in Mozambique (2019)

This success story details Medicines Quality Monitoring in Mozambique and explains how it fits into Post-Marketing Surveillance.

Supporting medicines quality testing laboratories in Nigeria on the path to self-reliance (2019)

This success story summarizes the PQM program's experience supporting five Nigerian public sector quality control laboratories in achieving and maintaining ISO/IEC 17025 accreditation and discusses how this contributes to sustainable national regulatory capacity.

Using mobile technologies to detect poor-quality medicines in Benin (2018)

This success story provides details on how Benin's National Laboratory for the Quality Control of Medicines and Medical Consumables has been using two mobile testing tools, GPHF-Minilab™ and the Raman spectrometer, to screen suspicious pharmaceuticals in the country's commodity pipeline. **Click here for French version**

Reducing quality assurance costs by building Ethiopia's capacity to calibrate laboratory instrumentation (2017)

In the past, the Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) outsourced laboratory instrumentation calibration to international contractors because there were no local accredited providers. The cost of using such providers was extraordinarily high and put a financial drain on the laboratory's limited resources, making international outsourcing an unsustainable solution. With supplemental funding from USP, PQM provided tailored technical assistance and training to the National Metrology Institute of Ethiopia. This resulted in an expansion of the Institute's scope of services to include accreditation for the calibration of pressure and temperature instrumentation. To date, this expanded capacity has decreased EFMHACA's use of international contract service providers by two-thirds and reduced annual calibration costs by 58 percent.

Strengthening Burma's capacity to test for quality medicines (2017)

Despite making strides to improve medicines quality, Burma's national laboratory experienced low staff retention and struggled with reliable data management, leaving Burma unable to consistently perform quality tests on products coming into the country or perform surveillance activities of medications already in circulation. PQM trained staff from laboratories in Nay Pyi Taw, Mandalay, and Yangon and also trained pharmacists on various testing procedures and inspection methods. The success of PQM's work to build the capacity of Burma's national laboratory helped the laboratory to receive ISO/IEC 17025:2005 accreditation. Burma can now rely on its own national laboratory to test the quality of medicines in the country.

Reducing the risk of HIV transmission in Ethiopia (2017)

This success story records PQM's support to Ethiopia's national quality control laboratory (NQCL). Ethiopia's NQCL is the first USAID-supported laboratory in sub-Saharan Africa to hold accreditation for testing of male condoms. The laboratory is now able to test antiretroviral medicines and the quality of male condoms, and monitor and eliminate sources of falsified and substandard medicines. In 2016, the NQCL was able to identify and halt the distribution of 69 million defective condoms from a single manufacturer. After having identified the defective condoms, Ethiopia's medicines regulatory agency took regulatory actions to prevent the distribution of the substandard condoms in the market, and the manufacturer was blacklisted.

Building local laboratory capacity to improve health outcomes (2017)

This success story documents PQM's work to ensure that testing capacity is sustainable by developing local expertise. In both Ethiopia and Indonesia, the national quality control laboratories have maintained their ISO/IEC 17025:2005 accreditation in part because PQM trained staff to maintain and calibrate their equipment. With the success of PQM and the government's initiative in both countries, local staff members were instructed on maintenance, calibration, and qualification of laboratory equipment, which contributed to the laboratories' continued ability to provide accurate quality testing to protect the population from poor-quality medicines.

Why lab accreditation matters for public health (2017)

When addressing poor-quality medicines is not made a priority for national regulatory authorities, the cost of medicines increases, supply chains become vulnerable, shortages of quality medicines become more frequent, and the presence of substandard medicines expands. These outcomes have adverse effects on preventive and treatment efforts and reduce the public's faith in the national health system. This success story documents PQM's support in helping laboratories achieve internationally recognized accreditations that help ensure only quality medicines reach patients. Once accredited, national quality control laboratories can confidently provide quality verification of medicines that are entering or currently circulating within a country, allowing a more effective and quality-assured response to HIV/AIDS, malaria, tuberculosis, and other public health threats.

Building capacity at borders to help protect medicine quality (2017)

In sub-Saharan Africa, cross-border trafficking of poor-quality medicines is a major problem. PQM is working with the Liberia Medicines and Health Products Regulatory Authority to ensure that only quality medicines reach the Liberian people. Training of border officers can empower cross-border security agencies to rapidly detect and confiscate falsified and substandard medicines in the market, thereby saving lives.

Applying a Collaborative Learning Model to sustainably build staff capacity: experiences from Nigeria, Burma, and Kazakhstan (2017)

This success story records PQM's piloted innovative approach to laboratory-strengthening activities. PQM's Collaborative Learning Model allows for standardized, sustainable learning and encourages collaboration among country laboratories. In Nigeria, the Collaborative Learning Model was applied to trainings for two laboratories, Agulu and Kaduna. Performed at the Agulu laboratory, the Kaduna team was able to transfer lessons learned back to their laboratory. Similar approaches were adapted for two other laboratories in Burma that leveraged support from the Nay Pyi Taw laboratory. Furthermore, staff from three laboratories in Kazakhstan attended each laboratory assessment in order to learn from each other's experience and facilitate consistent progress across the three sites.

Protecting patients from poor-quality medicines by boosting laboratory capacity– Nigeria (2017)

This success story documents how PQM's assistance helped Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) Agulu Zonal Laboratory achieve ISO 17025 accreditation in just 1 year. NAFDAC initially lacked adequate capacity and competency to meet quality control testing needs in eastern Nigeria. This left NAFDAC without the means to fulfill its full mandate to help address serious health threats, including those posed by informal markets located in the region. To address this problem, PQM assessed the gaps and collaborated with NAFDAC and Agulu leadership to develop a capacity-building plan that included hands-on training and demonstrations. As a result, in December 2016, the Zonal Laboratory received ISO/IEC 17025:2005 accreditation for multiple pharmaceutical testing methods. PQM's efforts enabled the laboratory to ensure the quality of antimalarial medicines available in eastern Nigeria, contributing to positive treatment outcomes for millions of Nigerians.

Guatemala's lab attains ISO 17025 accreditation (2015)

This success story documents PQM's assistance to the Medicines Unit of the National Health Laboratory, which allowed the laboratory to perform high-performance liquid chromatography, ultraviolet visible spectroscopy, and dissolution the tests within the accreditation scope for all medicines by October 2015.

Official medicines laboratory of Ethiopia re-accredited for ISO 17025 (2014)

This success story attests to the reaccreditation of the Product Quality Assessment Directorate (PQAD) in Ethiopia after its move to a new laboratory space in 2013. The PQAD serves as the technical arm of the Ethiopian Food, Medicine and Health Care Administration and Control Authority's (EFMHACA) quality management system, establishing which medicines submitted during the medicine registration process conform to their claimed specifications. PQM began working with the USAID/Ethiopia Mission in 2009 to help strengthen EFMHACA's quality assurance and quality control systems. To help the laboratory reach its goal of achieving ISO 17025 accreditation, PQM provided training for the laboratory staff on major analytical and testing techniques; supplied reference standards, chemicals, instruments, and reference books; guided the development of laboratory standard operating procedures; established a quality management system; and instructed the staff on the maintenance, calibration, and qualification of laboratory equipment.

Ethiopia's lab certifies condom testing capabilities (2012)

In 2012, the Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) suspected problems with its ability to reliably test the quality of condoms. USAID tapped the experts at PQM to help devise a solution. To strengthen EFMHACA's quality assurance capacity, PQM trained EFMHACA staff, prepared and enhanced the condom testing machines—everything from missing parts to calibration—and instituted a much-needed quality management system.

Fact Sheets and Briefs

Monitoring the quality of medicines with the GPHF Minilab (2018)

This fact sheet describes the uses and limitations of the GPHF-Minilab™ product. The product consists of a series of low-cost screening methods assembled as a self-contained kit ready-packed for worldwide delivery by air and medicines testing in the field. Approximately 80 products can be tested with the GPHF-Minilab™ outside of a laboratory environment by properly trained personnel who do not have an extensive background in analytical chemistry. However, GPHF-Minilab™ tests are not as comprehensive as compendial analysis, nor are they intended to replace laboratory testing of registration specifications.

QUALITY SURVEILLANCE

Policies and Guidelines

Guidance for implementing risk-based post-marketing quality surveillance in low- and middle-income countries (2018)

Strong national post-marketing surveillance programs capable of monitoring the overall quality and safety of medical products (e.g., medicines, vaccines, devices, and diagnostic kits) and responding to public health risks can help protect populations from the threats posed by substandard and falsified medicines. Through extensive consultation with international experts, the PQM program has developed this document to guide the implementation of comprehensive risk-based post-marketing surveillance programs in low- and middle-income countries.

Guideline to establishing a medicines quality monitoring program (2010)

The purpose of the quality surveillance guidance document is to help authorities create a uniform protocol for all procedures undertaken in quality surveillance programs, including medicines sampling, testing, and reporting. The guide and annexed forms are designed to be adapted as needed by the individual country.

Reports

Baseline survey on the quality, presence and source of priority antimalarial medicines in select geographical areas of Burma/Myanmar (2015)

The primary objectives of this baseline survey were to identify the pharmaceutical quality of the antimalarial medicines in Burma, their availability (dosage forms, strengths, and brands), and their source (country of origin, manufacturer/supplier, health facility and/or retailer), as well as to formulate recommendations for improving quality assurance/quality control for the country. This study was designed as a descriptive, cross-sectorial survey using simple random sampling methodology for the locations and antimalarial medicines in Tier 1 under the Myanmar Artemisinin Resistance Containment project (MARC). The study sites were limited to 11 townships within the MARC Area/Tier 1.

Post-market quality surveillance project maternal healthcare products (oxytocin and ergometrine) on the Ghanaian market (2013)

This report focuses only on the sampling and testing of the maternal healthcare products oxytocin and ergometrine. The objective of the study was to determine whether all oxytocin injection and ergometrine (tablets and injections) products distributed and sold on the Ghanaian market conformed to the specifications and standards listed by the manufacturer—and upon which their marketing authorizations were granted. The study also sought to uncover whether there were unregistered and/or falsified products within this therapeutic group circulating in Ghana’s markets.

Journal Articles

Medicines quality assurance to fight antimicrobial resistance (2017)

This paper suggests that product quality surveillance and other quality assurance measures should be thoroughly addressed in efforts to contain antimicrobial resistance. Including such measures in national action plans and key normative guidance documents for antimicrobial resistance is critical to containment, especially for low- and middle-income countries, where weak regulatory controls may increase the potential for poor-quality antimicrobials to be widely available.

Cost benefit of investment on quality in pharmaceutical manufacturing: WHO GMP pre- and post-certification of a Nigerian pharmaceutical manufacturer (2017)

This article primarily evaluates benefits against the cost of investing in good manufacturing practices (GMP) using a Nigerian pharmaceutical company, Chi Pharmaceuticals Limited, as a case study. The article also discusses how to drive more local manufacturers to invest in quality to attain GMP compliance and proffers practical recommendations for local manufacturers that want to invest in quality to meet ethical and regulatory obligations.

Assessment of the effectiveness of the CD3+ tool to detect counterfeit and substandard anti-malarials (2016)

A total of 84 antimalarial medicines test samples comprising artemether–lumefantrine tablets and artesunate–amodiaquine tablets were used. The technologies were evaluated for sensitivity in determining falsified/substandard medicines, specificity in determining authentic products, and reliability of the results. Authentic samples obtained from manufacturers were used as reference standards. High-performance liquid chromatography analysis data were used as the “gold standard” for decisions regarding a sample being authentic or substandard/falsified.

Monitoring the quality of medicines: results from Africa, Asia, and South America (2015)

Medicines quality monitoring (MQM) plays a crucial role in an integrated medicines quality assurance system. In a publicly available medicines quality database, USP reports results of data collected from MQM activities spanning the period 2003–2013 in 17 countries in Africa, Asia, and South America. The Medicines Quality Database (MQDB) contains information on 15,063 samples collected and tested using Minilab™ screening methods and/or pharmacopeial methods. Approximately 71 percent of the samples came from Asia, 23 percent from Africa, and 6 percent from South America. The samples collected and tested include mainly antibiotic, antimalarial, and anti-tuberculosis medicines. A total of 848 samples (5.6% of total samples) failed the quality test. The failure proportion per region was 11.5 percent, 10.4 percent, and 2.9 percent for South America, Africa, and Asia, respectively. Eighty-one falsified medicines were reported, 86.4 percent of which were found in Asia and 13.6 percent in Africa.

Potential use of handheld Raman devices as tools for screening medicines for quality (2014)

This paper promotes the Raman device as a useful tool to detect falsified medicines. Raman devices have been shown as potential screening tools for detecting products lacking or having the wrong active pharmaceutical ingredient. These devices consistently discriminate between different finished pharmaceutical products with different active pharmaceutical ingredients or, in some cases, even between different brands. While Raman devices have proven helpful in detecting falsified medicines, substandard medicines—which are more prevalent—represent an even bigger issue. In addition to treatment failure as a potential effect, use of poor-quality medicines may contribute to the emergence of drug resistance. The use of handheld Raman spectrometers to test substandard medicines would require tedious modeling, which is neither affordable nor practical for routine testing. On the other hand, integrating chemometrics into the device as an application may lead to quantitative use in the future. In addition, researchers from the U.S. Food and Drug Administration have demonstrated that the transfer of spectral library and chemometric-based Raman methods across different Raman handheld devices is feasible.

The Three-Level Approach: a framework for ensuring medicines quality in limited-resource countries (2014)

Regulators from countries at all levels of income struggle to protect the public from the dangers of poor-quality (falsified and substandard) medicines. In particular, countries with limited resources are at higher risk because of weak regulations, insufficient personnel, or laboratories with poor infrastructure and a lack of equipment required for performing quality control analysis. A systematic approach is needed to address these gaps. A stepwise process was used to design medicines quality monitoring programs in numerous countries in Africa, South America, and Southeast Asia. The experience gained in these countries resulted in the development of the Three-Level Approach for performing quality control of medicines throughout the supply chain. The approach consists of three successive, complementary, and increasingly complex levels of analysis. The first level includes visual and physical inspection to assess package and insert conditions and information as well as the physical characteristics of the actual medicines. The second level consists of rapid analytical tests that assess a limited number of quality attributes and can easily be performed in the field by trained personnel. The third level involves quality control testing according to the product's registration specifications and is performed in an appropriate laboratory setting by experienced and trained analysts.

Cambodian Ministry of Health takes decisive actions in the fight against substandard and counterfeit medicines (2014)

From 2005 to 2012, legal private sector facilities and illegal outlets in 12 Cambodian provinces were targeted for routine surveillance of medicines quality through sample collection and testing of various anti-infective medicines, the majority of which were antimalarial medicines and antibiotics. The medicines quality monitoring program samples from the field were analyzed through a Three-Level Approach that included field and advanced laboratory testing. During this time, 4,381 medicines were collected and tested: 106 failed quality testing (resulting in an overall failure rate of 2.4%), and 28 of the failed samples (26.4%) were falsified. The medicines most commonly found to be falsified were chloroquine, artesunate, mefloquine, ampicillin, and penicillin. Through the Inter-Ministerial Committee to Fight against Counterfeit & Substandard Medicines (IMC), by the end of November 2011, Cambodia had closed more than 99 percent of illegal pharmacy outlets.

Were medicine quality and pharmaceutical management contributing factors in diminishing artemisinin efficacy in Guyana and Suriname? (2014)

Recent studies in Guyana and Suriname unveiled diminished efficacy of artemisinin derivatives based on day-3 parasitemia. The migrant characteristics of the population at risk and the potential development of resistance pose a serious health threat in the region. Assessment of factors that may have contributed to this situation was warranted, and analysis of the data generated in those countries on quality and pharmaceutical managements of antimalarials contributed to a better understanding of this occurrence. Data on malaria medicine quality and pharmaceutical management, generated in the context of the Amazon Malaria Initiative, were reviewed and discussed.

Poor quality medicines pose a danger to patients (2014)

This article describes PQM's Medicines Quality Database (MQDB). The free, publicly available online database, established in 2011, contains results of medicines quality testing from 17 countries in Africa, Asia, and South America. This database has proven useful to track and arrest counterfeiters, ban poor-quality antimalarial medicines produced by a number of companies, and seize stocks of falsified medicines.

The quality of antimalarial medicines in Eastern Thailand: a case study along the Thai–Cambodian border (2013)

This study examined the prevalence, availability, and use of antimalarial medicines (AMLs) along the Thai–Cambodian border. The study was divided into two parts: the first looked at the quality of AMLs available in six Thai provinces, and the second obtained information about the availability and use of AMLs. A randomized sampling methodology was used to select locations and collect samples, which were screened using GPHF-Minilabs™. A subset of samples was sent to quality control laboratories for verification testing. For the second part of the study, face-to-face interviews were conducted with members of randomly selected households and the staff of health facilities in villages with the highest malaria incidence to find out where they acquired their AMLs and which was used most frequently. The results of quality testing showed an overall failure rate of 1 percent (7 of 709 samples) for active pharmaceutical ingredients, which varied from 0.0 percent to 2.2 percent by location, and the overall failure rates of samples by province varied from 0.0 percent to 3.4 percent.

The quality of antimalarial medicines in Western Cambodia: a case study along the Thai–Cambodian Border (2013)

The prevalence, availability, and use of antimalarial medicines (AMLs) were studied in six Cambodian provinces along the Thai–Cambodian border. The study was divided into two parts: the first looked at the quality of AMLs available in Pursat, Pailin, Battambang, Bantey Meanchey, Oddar Meanchey, and Preah Vihear; the second obtained information about the availability and use of AMLs. A randomized sampling methodology was used to select locations and collect samples, which were screened using GPHF-Minilabs™. A subset of samples was sent to quality control laboratories for confirmatory testing. For the second part of the study, face-to-face interviews were conducted using standardized surveys with members of randomly selected households and staff of health facilities in the villages with highest malaria incidence to find out where they acquired their AMLs and which were most frequently used. The results showed an overall failure rate of 12.3 percent (n=46 of 374 total AML samples). The causes of medication sample failure were low active pharmaceutical ingredient content, failed dissolution properties, and unacceptably high levels of impurities.

Quality of anti-malarials collected in the private and informal sectors in Guyana and Suriname (2013)

To assess the quality of circulating antimalarial medicines, samples were purchased in the private and informal sectors of Guyana and Suriname in 2009. The sampling sites were selected based on epidemiological data and/or distance from health facilities. Samples were analyzed for identity, content, dissolution or disintegration, impurities, and uniformity of dosage units or weight variation according to manufacturer, pharmacopeial, or other validated method.

Assessment of the performance of a handheld Raman device for potential use as a screening tool in evaluating medicines quality (2013)

The TruScan™ handheld Raman device is used for testing finished pharmaceutical products in the field to detect falsified and substandard medicines. The paper reported on the device's ability to discriminate between a specific product and similar products from different manufacturers, unrelated medicines, and medicines with different strengths. This investigation evaluated Raman's ability to differentiate among similar medical products of similar or different strengths, focusing on the specificity and precision of the testing. First, several units of the same medicine's dosage form were compared; then, comparisons were made among unrelated products, similar products, and products with different strengths. The six pharmaceutical products used in testing were from commonly used analgesic, antimalarial, and antidiarrheal medicines. The results showed that the performance of the TruScan™ device depends on the nature and strength of the dosage form tested. While the device could be suitable for authentication of some finished pharmaceutical products and could therefore be used to detect some falsified medicines, it could not be used to detect substandard medicines.

Implementation of basic quality control tests for malaria medicines in Amazon Basin countries: results for the 2005–2010 period (2012)

Ensuring the quality of antimalarial medicines is crucial in working toward malaria control and eventual elimination. Unlike other validated tests that can assess all critical quality attributes, which is the standard for determining the quality of medicines, basic tests are significantly less expensive and faster, and they require less skilled labor—yet these tests provide reproducible data and information on several critical quality attributes, such as identity, purity, content, and disintegration. Visual and physical inspections also provide valuable information about the manufacturing and labeling of medicines, and in many cases this inspection is sufficient to detect falsified medicines. The PQM program has provided technical assistance to Amazon Malaria Initiative countries to implement the use of basic tests as a key screening mechanism to assess the quality of antimalarial medicines available to patients in decentralized regions.

Malaria 2012: saving lives in the Asia-Pacific (2012)

With the common purpose of combating and eventually eliminating malaria from the Asia-Pacific region, over 300 representatives from 30 countries and 130 organizations, mostly from the region, gathered in Sydney, Australia, from October 31 to November 2, 2012.

Media Articles

NAFDAC has successfully reduced fake anti-malaria drugs in Nigeria to 4%, says Paul Orhii (2015)

In collaboration with PQM, Nigeria's National Agency for Food and Drug Administration and Control contributed to a drastic reduction of falsified antimalarial medicines from 19.6 percent in 2012 to 3.6 percent in 2015.

The Medicines Quality Database: a free public resource (2014)

This editorial appearing in the Bulletin of The World Health Organization describes the need for the Medicines Quality Database (MQDB), the protocols it uses to gather data, and the structure and content of the database itself. The necessity to improve certain aspects of MQDB is also highlighted.

Countering the problem of falsified and substandard drugs (2013)

This report brief summarizes the root causes and factors behind the proliferation of substandard and falsified medicines and emphasizes the importance of strengthening medicines distribution and international cooperation. The report advocates for an emerging consensus on once-contentious terms and lays out a plan to invest in quality to improve public health.

Countering unregistered and illegal antimalarial drugs in Ethiopia (2013)

The Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) conducted surveillance of antimalarial medicines on the market and found that 34 percent were not registered with regulatory authorities. Hotspots for illegal drug smuggling were also identified. The Ministry of Health, the Ministry of Customs and Revenue, EFMHACA, regional regulatory offices, law enforcement, and community members convened a workshop to discuss the results of these antimalarial medicines surveillance activities. At the workshop, participants agreed to continue monitoring antimalarial medicines on the market, use various media to raise community awareness about the dangers of falsified medicines, and increase collaboration with neighboring countries, such as Kenya.

Focus on drug quality: improving global health initiatives for lasting impact (2011)

Uncertainty in funding and the spread of falsified and substandard medicines have a devastating impact on public health. The article suggests building capacity in affected countries so public health programs become locally self-sustaining. This is not a new concept, but well-meaning people and programs often veer off course in striving toward this larger goal. The article presents PQM as a source of funding and highlights the medicines quality monitoring program as an effective means of combating the proliferation of falsified and substandard medicines.

Presentations

The Medicines Quality Database (MQDB): successfully sharing information about poor quality medicines for infectious diseases in Asian countries (2014)

The poster presents the objectives, methods, and results of the Medicines Quality Database as it pertains to Asia. It also documents the total number of samples collected in the continent by therapeutic indication and by country, along with the number and percentage of medicines that failed quality testing.

Ensuring the quality of medicines in the Greater Mekong Sub-region to protect the public health (2012)

This poster presents the different facets of PQM initiatives in the Greater Mekong Sub-region, including building the capacity of medicines regulatory authorities, conducting research and surveys on medicines quality, strengthening quality control laboratories to meet international standards, monitoring medicines quality, and raising awareness about falsified and substandard medicines.

Three-Level Approach: a risk-based, cost-effective approach to medicines quality monitoring in low-and middle-resource countries (2011)

This presentation describes the need for the Three-Level Approach to medicines quality monitoring activities, along with its pros and cons. The application and results of this approach in two countries, Cambodia and Ghana, are examined.

USP Promoting the Quality of Medicines program (PQM) activities in Southeast Asia 2010–2011 (2011)

This poster addresses PQM's key activities, especially medicines quality monitoring, in Southeast Asia. Medicines quality trends in the region between 2005 and 2009, as well as various means of raising awareness about falsified medicines, are also examined.

Three-Level Approach for ensuring the quality of medicines in resource-limited countries (2010)

This poster explains the rationale and various elements of the Three-Level Approach. It also illustrates its position in the quality assurance framework and its application at the procurement, distribution, and medicines quality monitoring stages.

Medicine Quality Monitoring in Cambodia (2009)

This poster outlines PQM's medicines quality monitoring activities in Cambodia, detailing testing methods and results. Several other related initiatives are mentioned, such as public awareness campaigns and product recalls.

Fact Sheets and Briefs

Improving public safety using risk-based post-marketing surveillance (2018)

This document details PQM's practical strategy for implementing risk-based post-marketing surveillance programs in low- to middle-income countries. Some key components of PQM's approach include sampling and testing priorities, national post-marketing surveillance planning and data analysis, dissemination, and regulatory action.

Promoting the Quality of Medicines (PQM) program: Lao People's Democratic Republic (PDR) (2017)

In partnership with USAID's Regional Development Mission for Asia (RMDA), PQM activities in Southeast Asia focus on post-marketing surveillance, quality control laboratory support toward international standards, and advocacy and leveraging of funds for combating poor-quality medicines. In Laos between 2005 and 2013, post-marketing surveillance activities drastically reduced the number of poor-quality antimalarial medicines. This was made possible thanks to funding from the government and implementation by the Bureau of Food and Drug Inspection and the Food and Drug Department. Other key PQM partners in combating poor-quality antimalarial medicines were the Ministry of Health, the Food and Drug Quality Control Centre, and the Center for Malariology, Parasitology and Entomology.

Monitoring the quality of medicines (2015)

PQM helps low- and middle-income countries strengthen their medicines quality assurance/quality control systems so they can better monitor medicines quality throughout the supply chain and prevent substandard and falsified medicines from reaching patients. This brief specifies the steps involved in setting up this medicines quality monitoring program: assessing existing quality assurance/quality control systems; selecting sites to monitor medicines quality based on criteria (e.g., epidemiology, geography, border region, history of trafficking falsified medicines); training field staff in sampling; testing with Minilab™ methods; reporting data; training national medicines quality control laboratory staff in advanced analytical test methods; performing sampling and testing; analyzing results and reporting to authorities; and recommending action based on evidence.

PQM Medicines Quality Database (2014)

Medicines regulatory authorities, as well as international agencies and programs involved in procuring medicines and managing the supply chain, usually do not have access to a continuously updated source of reliable information on poor-quality medicines. To address this need, PQM created the Medicines Quality Database (MQDB), a free, publicly available, online database that contains medicines quality testing results from various countries in Africa, Asia, and Latin America. This fact sheet presents basic information about the database.

Promoting the Quality of Medicines program in Vietnam (2013)

PQM efforts in Vietnam mainly focus on building the capacity of the National Institute of Malariology, Parasitology and Entomology; Drug Administration of Vietnam; and National Institute of Drug Quality Control to improve the quality of medicines they register, supply, and use in the priority health programs; supporting post-marking surveillance through the medicines quality monitoring program for antimalarial, anti-tuberculosis, antibiotic, and avian influenza medicines and opportunistic infection products; strengthening quality control laboratories through trainings and provision of essential laboratory equipment, reference substances and materials, chemical reagents; and supporting local pharmaceutical manufacturers to operate with internationally accepted good manufacturing practices to produce methadone.

Success Stories

Reducing the supply and demand of illegal medicines in Senegal (2018)

Like many low- and middle-income countries, Senegal struggles with the problem of poor-quality medicines. This story details the seizure of illegally imported medicines and shows how Senegal has taken significant steps to protect its people from poor-quality medicines.

Safer skies: helping Ethiopian airlines protect medicines quality while in transit to Ethiopia and other African countries (2017)

Transporting medicines may sound simple, but it requires more than merely getting products from point A to point B. Many medicines are very sensitive to environmental factors, such as temperature and humidity, which can change beyond acceptable limits during transport in an airplane's cargo hold. To protect medicines quality, Ethiopia's Food, Beverage and Pharmaceutical Industry Development Institute asked PQM to train Ethiopian Airlines cargo staff on how to follow important procedures, such as good distribution practices and good storage practices.

Peru strengthens its medicine quality control approach (2016)

This success story details Peru's efforts to improve its Medicine Quality Control initiatives in 2015. The General Directorate of Medicines, Supplies and Drugs (DIGEMID) and the National Center for Quality Control (CNCC) convened a training workshop in Cuzco with the participation of six universities and six Regional Health Directorates (DIRESAs). During the workshop, stakeholders decided to adopt PQM's Three-Level Approach to medicines quality control. The Three-Level Approach is a proven methodology to detect substandard and falsified medicines in a rapid and cost-effective manner. It consists of preliminary visual and physical inspection (Level 1), rapid screening field tests (Level 2), and compendial or other validated laboratory tests (Level 3).

CROSS-CUTTING THEMES

Media Articles

Falsified medicine—tackling a serious threat to public health (2017)

Falsified medical products, which include medicines and medical devices and equipment, could account for as much as 30 percent of the market in some countries in Asia, Africa, and Latin America. Anti-infectives such as antimalarial medicines and antibiotics are particularly prone to falsification, given the weak regulatory and enforcement mechanisms in countries where these diseases are present. The PQM program is addressing this challenge by taking a holistic approach to the problem. PQM collaborates with countries to build the capacity of medicines regulatory authorities, strengthen the testing capability of national quality control laboratories, and provide technical assistance to manufacturers that supply local and international markets to ensure sustainable production of quality-assured essential medicines. PQM assists countries in setting up medicines quality assurance systems that make it easier for authorities to identify and remove poor-quality medicines from the market.

Poor-quality medicine: a global pandemic (2017)

Cracking down on the proliferation of falsified and substandard medicines is a daunting task involving the cooperation and coordination of many different stakeholders, from regulators to legislators, manufacturers, distributors, and suppliers. The challenges posed by poor-quality medicines are increasingly global, requiring international cooperation on all levels. By creating strong country plans; empowering regulators, auditors, and enforcers; providing technical assistance to global manufacturers; and raising awareness among healthcare workers and local populations, stakeholders can begin to tackle this unwieldy issue and ensure that only quality medicines reach the market.

USP committed to quality assurance of medicines (2016)

This is an interview with Chimezie Anyakora, the Chief of Party of the PQM program in Nigeria. He explains the mission of the PQM program in Nigeria, the challenges it faces, and its achievements thus far. Challenges include the large volume of medicines in Nigeria that need quality testing and evaluation, as well as the technical, infrastructure, and human resources components that have not been able to completely fulfill this considerable task. However, thanks to PQM's collaborative efforts, significant achievements have been made in the areas of medicines quality surveillance, monitoring and evaluation, policy, regulation, and local manufacturing of essential medicines.

Journal Articles

Fake anti-malarials: start with the facts (2015)

This meeting report presents the key findings and discussion points of a 1-day meeting called "Fake anti-malarials: start with the facts" held on May 28, 2015, in Geneva, Switzerland, to disseminate the findings of the artemisinin combination therapy consortium's medicines quality program.

Videos

Good quality medicines mean health, quality of life, productivity & social stability (2017)

This video reviews the fundamental principles that guide the PQM program.

Quality medicines save lives (2017)

This video summarizes the consequences of poor-quality medicines and the challenge of reinforcing the systems that are meant to ensure people's access to quality-assured medicines in low- and middle-income countries.

Pharmacide Mekong documentary (2012)

Published on YouTube by a group of governmental and nongovernmental agencies, *Pharmacide Mekong* tracks the issue of falsified medicines trafficking from a public health perspective, with a focus on countries with limited resources to tackle this enormous challenge. It also features the GPHF-Minilab™, a non-sophisticated and affordable mini-laboratory to boost testing capacities in Asia, Africa, and Latin America.

Counterfeit drugs can kill (2011)

More than 50 percent of the medicines sold over the internet are falsified. This video depicts the harsh reality of purchasing medicines from vendors that are not trustworthy.

Counterfeit medicines trailer (2010)

This video shows PQM's support to Cambodia in combating the proliferation of falsified medicines that are imported illegally from pharmaceuticals.

ANNEX

Alphabetical listing of PQM resources by title, including technical area, resource type, URL, and citation

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
African medicines quality forum: an Africa-led network protecting consumers from poor-quality medicines	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2l1mfub**	Promoting the Quality of Medicines program. African Medicines Quality Forum: An Africa-Led Network Protecting Consumers from Poor-Quality Medicines. Rockville (MD): U.S. Pharmacopeial Convention; 2019.
Alliance to fight counterfeit malaria drugs in Kenya	Regulatory Systems Strengthening	Media Article	**https://bit.ly/2JhbLNl**	Alliance to fight counterfeit malaria drugs in Kenya. The Standard. 2015 May 3.
Analytical Instrumentation support for national quality control laboratories	Laboratory Strengthening	Guideline	**https://bit.ly/2uSutX5**	Hernandez S, Nkansah P. Analytical Instrumentation Support for National Quality Control Laboratories. Rockville, (MD): U.S. Pharmacopeial Convention, Promoting the Quality of Medicines Program; 2017.
Applying a Collaborative Learning Model to sustainably build staff capacity: experiences from Nigeria, Burma, and Kazakhstan	Laboratory Strengthening	Success Story	**https://bit.ly/2mLNBBM**	Promoting the Quality of Medicines program. Applying a collaborative learning model to sustainably build staff capacity: experiences from Nigeria, Burma, and Kazakhstan. Rockville (MD): U.S. Pharmacopeial Convention, Promoting the Quality of Medicines Program; 2017.
Assessment of the effectiveness of the CD3+ tool to detect counterfeit and substandard anti-malarials	Quality Surveillance	Journal Article	**https://bit.ly/2OgKz53**	Batson JS, Bempong DK, Lukulay PH, Ranieri N, Satzger RD, Verbois L. Assessment of the effectiveness of the CD3+ tool to detect counterfeit and substandard anti-malarials. Malaria Journal. 2016 Feb 25;15(119).
Assessment of the performance of a handheld Raman device for potential use as a screening tool in evaluating medicines quality	Quality Surveillance	Journal Article	**https://bit.ly/2AcP0e9**	Hajjou M, Qin Y, Bradby S, Bempong D, Lukulay P. Assessment of the performance of a handheld Raman device for potential use as a screening tool in evaluating medicines quality. J Pharm Biomed Anal. 2013 Feb 23;74:47–55.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Bangladesh implements updated standards for medicines testing (2019)	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2lcr2sv**	Promoting the Quality of Medicines program. Bangladesh Implements Updated Standards for Medicines Testing. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Baseline survey on the quality, presence and source of priority antimalarial medicines in select geographical areas of Burma/Myanmar	Quality Surveillance	Report	**https://bit.ly/2mNhSjw**	Phanouvong S, Kyaw Tin Oo LL, Lane Barlow C. Baseline survey on the quality, presence and source of priority antimalarial medicines in select geographical areas of Burma/Myanmar. Rockville (MD): U.S. Pharmacopeial Convention, Promoting the Quality of Medicines Program; 2015.
Briefing on the Promoting the Quality of Medicines program in Indonesia	About the Project	Brief	**https://bit.ly/2NNTtG5**	Promoting the Quality of Medicines program. Briefing on the Promoting the Quality of Medicines program in Indonesia. Rockville (MD): U.S. Pharmacopeial Convention; 2013.
Building capacity at borders to help protect medicine quality	Laboratory Strengthening	Success Story	**https://bit.ly/2uSahom**	Promoting the Quality of Medicines program. Building capacity at borders to help protect medicine quality. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Building capacity for laboratory equipment maintenance in Liberia	Laboratory Strengthening	Success Story	**https://bit.ly/2kASVu2**	Promoting the Quality of Medicines program. Building Capacity for Laboratory Equipment Maintenance in Liberia. Rockville (MD): U.S. Pharmacopeial Convention; 2019.
Building foundations for robust quality assurance systems in Myanmar	Regulatory Systems Strengthening	Brief	**https://bit.ly/2mCrD7b**	Promoting the Quality of Medicines program. Building Foundations for Robust Quality Assurance Systems in Myanmar. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Building local laboratory capacity to improve health outcomes	Laboratory Strengthening	Success Story	**https://bit.ly/2NNamAI**	Promoting the Quality of Medicines program. Building local laboratory capacity to improve health outcomes. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Building medicines quality assurance systems helps protect Liberians from poor-quality antimalarials	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2Ae8E9E**	Promoting the Quality of Medicines program. Building medicines quality assurance systems helps protect Liberians from poor-quality antimalarials. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Cambodian Ministry of Health takes decisive actions in the fight against substandard and counterfeit medicines	Quality Surveillance	Journal Article	**https://bit.ly/2v4xh2E**	Krech LA, Lane-Barlow C, Lang S, Phanouvong S, Yuan WE, Heng B, et al. Cambodian Ministry of Health takes decisive actions in the fight against substandard and counterfeit medicines. Trop Med Surg. 2014 Mar 1;2(2).

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Chlorhexidine for umbilical cord care: a new, low-cost intervention to reduce newborn mortality	Manufacturing	Brief	**https://bit.ly/2OiVATa**	Promoting the Quality of Medicines program. Chlorhexidine for umbilical cord care: a new, low-cost intervention to reduce newborn mortality. Rockville (MD): U.S. Pharmacopeial Convention; 2014.
Cost benefit of investment on quality in pharmaceutical manufacturing: WHO GMP pre- and post-certification of a Nigerian pharmaceutical manufacturer	Quality Surveillance	Journal Article	**https://bit.ly/2mK0bkM**	Anyakora C, Ekwunife O, Alozie F, Esuga M, Ukwuru J, Onya S, Nwokike J. Cost benefit of investment on quality in pharmaceutical manufacturing: WHO GMP pre- and post-certification of a Nigerian pharmaceutical manufacturer. BMC Health Services Research. 2017;17(665).
Counterfeit Drugs Can Kill	Cross Cutting Themes	Video	**https://bit.ly/2JYVEnJ**	Promoting the Quality of Medicines program. Counterfeit drugs can kill. Rockville (MD): U.S. Pharmacopeial Convention; 2011.
Counterfeit Medicines Trailer	Cross Cutting Themes	Video	**https://bit.ly/2Adl4OX**	Promoting the Quality of Medicines program. Counterfeit medicines trailer. Rockville (MD): U.S. Pharmacopeial Convention; 2010.
Countering the problem of falsified and substandard drugs	Quality Surveillance	Report	**https://bit.ly/2AcIy6H**	IOM (Institute of Medicine). Countering the problem of falsified and substandard drugs. Washington (DC): The National Academies Press; 2013.
Countering unregistered and illegal antimalarial drugs in Ethiopia	Quality Surveillance	Media Article	**https://bit.ly/2LDf0DS**	U.S. President's Malaria Initiative. Countering unregistered and illegal antimalarial drugs in Ethiopia. 2013 Nov. Available from: https://www.pmi.gov/news/stories-from-the-field/stories-from-the-field---detail/countering-unregistered-and-illegal-antimalarial-drugs-in-ethiopia
Ensuring the quality of malaria medicines in Amazon Malaria Initiative (AMI) countries	About the Project	Brief	**https://bit.ly/2Ac8b7F**	Promoting the Quality of Medicines program. Ensuring the quality of malaria medicines in Amazon Malaria Initiative (AMI) countries. Rockville (MD): U.S. Pharmacopeial Convention; 2011.
Ensuring the quality of medicines in the Greater Mekong Sub-region to protect the public health	Quality Surveillance	Poster	**https://bit.ly/2LU1KHJ**	Promoting the Quality of Medicines program. Ensuring the quality of medicines in the Greater Mekong Sub-region to protect the public health. Rockville (MD): U.S. Pharmacopeial Convention; 2012.
Ethiopia's lab certifies condom testing capabilities	Laboratory Strengthening	Success Story	**https://bit.ly/2Lr7Hjp**	Promoting the Quality of Medicines program. Ethiopia's lab certifies condom testing capabilities. Rockville (MD): U.S. Pharmacopeial Convention; 2012.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Fake anti-malarials: start with the facts	Cross-Cutting	Journal Article	**https://bit.ly/2OajQXn**	Kaur H, Clarke S, Lalani M, Phanouvong S, Guérin P, McLoughlin A, Wilson BK, Deats M, Plançon A, Hopkins H, Miranda D, Schellenberg D. Fake anti-malarials: start with the facts. Malaria Journal, 2016;15(86).
Falsified medicine—tackling a serious threat to public health	Cross Cutting Themes	Media Article	**https://bit.ly/2ueK2bz**	Devex Editor. Falsified medicine—tackling a serious threat to public health. 2017 July. Available from: https://www.devex.com/news/sponsored/falsified-medicine-tackling-a-serious-threat-to-public-health-90266.
Focus on drug quality: improving global health initiatives for lasting impact	Quality Surveillance	Media Article	**https://bit.ly/2AmsyPD**	Lukulay P. Focus on drug quality: improving global health initiatives for lasting impact. Monthly Developments Magazine. 2011 Sep.
Generation next: ensuring quality medicines for newborns	Manufacturing	Media Article	**https://bit.ly/2tS35qB**	Devex Editor. Generation next: ensuring quality medicines for newborns. 2017 Jul. Available from: https://www.devex.com/news/sponsored/generation-next-ensuring-quality-medicines-for-newborns-90268
Good manufacturing practice guideline for pharmaceutical products: main principles. Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA)	Manufacturing	Guideline	**https://bit.ly/2vfrPKz**	Ethiopian Food, Medicine and Health Care Administration and Control Authority. Good manufacturing practice guideline for pharmaceutical products: main principles. Addis Ababa, Ethiopia: Ethiopian Food, Medicine and Health Care Administration and Control Authority; 2014.
Good manufacturing practice/chemistry, manufacturing, and controls technical assistance	Manufacturing	Fact Sheet	**https://bit.ly/2mltVP3**	Promoting the Quality of Medicines program. Good manufacturing practice/chemistry, manufacturing, and controls technical assistance. Rockville (MD): U.S. Pharmacopeial Convention; 2016.
Good manufacturing practices: is it possible in developing countries?	Manufacturing	Poster	**https://bit.ly/2LQpJrz**	Promoting the Quality of Medicines program. Good manufacturing practices: is it possible in developing countries? Rockville (MD): U.S. Pharmacopeial Convention; 2011.
Good quality medicines mean health, quality of life, productivity & social stability	Cross Cutting Themes	Video	**https://bit.ly/2xa5OOW**	Promoting the Quality of Medicines program. Good Quality Medicines Mean Health, Quality of Life, Productivity & Social Stability. Rockville (MD): U.S. Pharmacopeial Convention; 2017.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
GSK Chlorhexidine Digluconate (7.1%) Gel Technology Transfer Report	Manufacturing	Report	**https://bit.ly/2kTH76v**	Promoting the Quality of Medicines program. GSK Chlorhexidine Digluconate (7.1%) Gel Technology Transfer Report. 2018. U.S. Pharmacopeial Convention. The Promoting the Quality of Medicines Program. Rockville, Maryland.
Guatemala's lab attains ISO 17025 accreditation	Laboratory Strengthening	Success Story	**https://bit.ly/2AeL8cu**	Promoting the Quality of Medicines program. Guatemala's lab attains ISO 17025 accreditation. Rockville (MD): U.S. Pharmacopeial Convention; 2015.
Guidance for implementing risk-based post-marketing quality surveillance in low- and middle-income countries	Quality Surveillance	Guideline	**https://bit.ly/2JYqYmw**	Nkansah P, Smine K, Pribluda V, Phanouvong S, Dunn C, Walfish S, Umaru F, Clark A, Kaddu G, Hajjou M, Nwokike J, Evans L. Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries. Rockville (MD): U.S. Pharmacopeial Convention, Promoting the Quality of Medicines Program; 2018.
Guidance on waiver of in vivo bioequivalence requirements: Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA)	Regulatory Systems Strengthening	Guideline	**https://bit.ly/2NPolGj**	Ethiopian Food, Medicine and Health Care Administration and Control Authority. Guidance on waiver of in vivo bioequivalence requirements. Addis Ababa, Ethiopia: Ethiopian Food, Medicine and Health Care Administration and Control Authority; 2015.
Guideline for registration of medical devices: Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA)	Regulatory Systems Strengthening	Guideline	**https://bit.ly/2AeMDYa**	Ethiopian Food, Medicine and Health Care Administration and Control Authority. Guideline for registration of medical devices. Addis Ababa, Ethiopia: Ethiopian Food, Medicine and Health Care Administration and Control Authority; 2014.
Guideline for registration of medicines: Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA)	Regulatory Systems Strengthening	Guideline	**https://bit.ly/2mMnPwU**	Ethiopian Food, Medicine and Health Care Administration and Control Authority. Guideline for registration of medicines. Addis Ababa, Ethiopia: Ethiopian Food, Medicine and Health Care Administration and Control Authority; 2014.
Guideline to establishing a medicines quality monitoring program	Quality Surveillance	Guideline	**https://bit.ly/2mKaeGz**	Promoting the Quality of Medicines program. Guideline to establishing a medicines quality monitoring program. Rockville (MD): U.S. Pharmacopeial Convention; 2010.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Guidelines for good storage practices, good distribution practice, and pharmaceutical product recall: Ethiopian Food, Medicine and Health Care Administration and Control Authority	Regulatory Systems Strengthening	Guideline	**https://bit.ly/2mJLn5H**	Ethiopian Food, Medicine and Health Care Administration and Control Authority. Guidelines for good storage practices, good distribution practice, and pharmaceutical product recall. Addis Ababa, Ethiopia: Ethiopian Food, Medicine and Health Care Administration and Control Authority; 2015.
Guidelines for submission of post-approval variation medicine applications: Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA)	Regulatory Systems Strengthening	Guideline	**https://bit.ly/2uQF4BX**	Ethiopian Food, Medicine and Health Care Administration and Control Authority. Guidelines for submission of post-approval variation medicine applications. Addis Ababa, Ethiopia: Ethiopian Food, Medicine and Health Care Administration and Control Authority; 2015.
Guinea updates its pharmaceutical regulatory law (French version also available)	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2mov41i**	Promoting the Quality of Medicines program. Guinea Updates its Pharmaceutical Regulatory Law. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Helping save mothers and children in Indonesia: increasing the supply of quality-assured essential medicines	Manufacturing	Success Story	**https://bit.ly/2LscCAo**	Promoting the Quality of Medicines program. Helping save mothers and children in Indonesia: increasing the supply of quality-assured essential medicines . Rockville (MD): U.S. Pharmacopeial Convention; 2017.
How to curb "fake" food products in Nigeria by PQM	Manufacturing	Media Article	**https://bit.ly/2LoWU9o**	Muanya C. How to curb "fake" food products in Nigeria by PQM. The Guardian Nigeria. 2015 Aug 6.
Implementation of basic quality control tests for malaria medicines in Amazon Basin Countries: results for the 2005–2010 period	Quality Surveillance	Journal Article	**https://bit.ly/2NMZWkx**	Pribluda VS, Barojas A, Anez A, Lopez CG, Figueroa R, Herrera R, et al. Implementation of basic quality control tests for malaria medicines in Amazon Basin countries: results for the 2005–2010 period. Malaria Journal. 2012 Jun 15;11(202).
Improving public safety using risk-based post-marketing surveillance	Quality Surveillance	Fact Sheet	**https://bit.ly/2LIcLiw**	Promoting the Quality of Medicines program. Improving public safety using risk-based post-marketing surveillance . Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Increasing the sources of quality medicines in LMICs: challenges and strategies	Manufacturing	Media Article	**https://bit.ly/2sQGlFn**	Devex Editor. Increasing the sources of quality medicines in LMICs: challenges and strategies. 2017 Jul. Available from: https://www.devex.com/news/sponsored/increasing-the-sources-of-quality-medicines-in-lmics-challenges-and-strategies-90267.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Increasing the sustainability of Ethiopia's medicines quality assurance system by building local service capacity	Laboratory Strengthening	Success Story	**https://bit.ly/2mVY68R**	Promoting the Quality of Medicines program. Increasing the Sustainability of Ethiopia's Medicines Quality Assurance System by Building Local Service Capacity. Rockville (MD): U.S. Pharmacopeial Convention; 2019.
Kenyans cautioned against purchasing medicine from hawkers	Regulatory Systems Strengthening	Media Article	**https://bit.ly/2Lr44dm**	Thio'go J. Kenyans cautioned against purchasing medicine from hawkers. The Standard. 2015 Oct 14.
Malaria 2012: Saving Lives in the Asia-Pacific	Quality Surveillance	Conference Summary	**https://bit.ly/2mHGeuW**	Phanouvong S. Malaria 2012: Saving Lives in the Asia-Pacific
Medicine quality monitoring in Cambodia	Quality Surveillance	Poster	**https://bit.ly/2LScp5Z**	Promoting the Quality of Medicines program. Medicine Quality Monitoring in Cambodia. Rockville (MD): U.S. Pharmacopeial Convention; 2009.
Medicines quality assurance to fight antimicrobial resistance	Quality Surveillance	Journal Article	**https://bit.ly/2v6SskI**	Nwokike J, Clark A and Nguyen P , Medicines quality assurance to fight antimicrobial resistance, Bulletin of the World Health Organization 2018;96:135-137.
The Medicines Quality Database (MQDB): successfully sharing information about poor quality medicines for infectious diseases in Asian countries	Quality Surveillance	Poster	**https://bit.ly/2K0rtN9**	Promoting the Quality of Medicines program. The Medicines Quality Database (MQDB): successfully sharing information about poor quality medicines for infectious diseases in Asian countries. Rockville (MD): U.S. Pharmacopeial Convention; 2013.
The Medicines Quality Database: a free public resource	Quality Surveillance	Media Article	**https://bit.ly/2LO7aYk**	Krech LA, El-Hadri L, Evans L, Fouche T, Hajjou, M, Lukulay P, et al. The Medicines Quality Database: a free public resource. Editorial. Bulletin of the World Health Organization 2014;92(2).
Mitigating cross-contamination in shared production facilities using risk-based cleaning validation methods: considerations and case study	Regulatory Systems Strengthening	Report	**https://bit.ly/2muKf92**	Mehta J, Nkansah P, Clark A. Mitigating Cross-Contamination in Shared Production Facilities Using Risk-Based Cleaning Validation Methods: Considerations and Case Study. 2018. Promoting the Quality of Medicines (PQM) Program. US Pharmacopeial Convention. Rockville, Maryland.
Monitoring the quality of medicines	Laboratory Strengthening	Fact Sheet/Brief	**https://bit.ly/2NJkmeb**	Promoting the Quality of Medicines program. Monitoring the quality of medicines. Rockville (MD): U.S. Pharmacopeial Convention; 2015.
Monitoring the quality of medicines with the GPHF Minilab	Quality Surveillance	Fact Sheet	**https://bit.ly/2LFAeRp**	Promoting the Quality of Medicines program Monitoring the quality of medicines with the GPHF Minilab. Rockville (MD): U.S. Pharmacopeial Convention; 2016.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Monitoring the quality of medicines: results from Africa, Asia, and South America	Quality Surveillance	Media Article	**https://bit.ly/2uPuJpY**	Hajjou M, Krech, L, Lane-Barlow C, Roth L, Pribluda VS, Phanouvong S, et al. Monitoring the quality of medicines: results from Africa, Asia, and South America. Am J Trop Med Hyg. 2015;92 Suppl 6:S68–74.
NAFDAC has successfully reduced fake anti-malaria drugs in Nigeria to 4%, says Paul Orhii	Quality Surveillance	Media Article	**https://bit.ly/2NI0cRC**	Twer M. NAFDAC has successfully reduced fake anti-malaria drugs in Nigeria to 4%, says Paul Orhii. National Accord. 2015 Aug 12.
National Quality Assurance Policy for medicines and other health products (NQAP): Nigerian Federal Ministry of Health	Regulatory Systems Strengthening	Policy	**https://bit.ly/2vbzQQm**	Federal Ministry of Health. National quality assurance policy for medicines and other health products. Abuja, Nigeria: Federal Ministry of Health; 2015.
Nigeria builds capacity for data-driven decision-making in medicines quality assurance	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2mNjh9S**	Promoting the Quality of Medicines program. Nigeria builds capacity for data-driven decision-making in medicines quality assurance. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Official medicines laboratory of Ethiopia re-accredited for ISO 17025	Laboratory Strengthening	Success Story	**https://bit.ly/2LLk9tP**	Promoting the Quality of Medicines program. Official medicines laboratory of Ethiopia re-accredited for ISO 17025. Rockville (MD): U.S. Pharmacopeial Convention; 2014.
Pakistan Acts Quickly to Recall Contaminated Medicines	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2mnUlDu**	Promoting the Quality of Medicines program. Pakistan Acts Quickly to Recall Contaminated Medicines. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Pakistan adopts international standards for assessing and registering medicines	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2lrDsNt**	Promoting the Quality of Medicines program. Pakistan Adopts International Standards for Assessing and Registering Medicines. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Peru strengthens its medicine quality control approach	Quality Surveillance	Success Story	**https://bit.ly/2A9jhKA**	Promoting the Quality of Medicines program. Peru strengthens its medicine quality control approach. Rockville (MD): U.S. Pharmacopeial Convention; 2016.
Pharmacide Mekong documentary	Cross Cutting Themes	Video	**https://bit.ly/2OjyA6w**	Promoting the Quality of Medicines program. Pharmacide Mekong documentary. Rockville (MD): U.S. Pharmacopeial Convention; 2012.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Poor-quality medicine: a global pandemic	Cross Cutting Themes	Media Article	**https://bit.ly/2sthDdM**	Devex Editor. Poor-quality medicine: a global pandemic. 2017 July. Available from: https://www.devex.com/news/sponsored/poor-quality-medicine-a-global-pandemic-90265
Poor quality medicines pose a danger to patients	Quality Surveillance	Publication	**https://bit.ly/2NPCH9B**	Marshall S. Poor quality medicines pose a danger to patients. Pharm Journal. 2014 Sep 26;12(43).
Post-market quality surveillance project maternal healthcare products (oxytocin and ergometrine) on the Ghanaian market	Quality Surveillance	Report	**https://bit.ly/2uTeKXN**	Karikari-Boateng E. Post-market quality surveillance project maternal healthcare products (oxytocin and ergometrine) on the Ghanaian market. Accra, Ghana: Ghana Food and Drugs Authority; 2013.
Potential use of handheld Raman devices as tools for screening medicines for quality	Quality Surveillance	Journal Article	**https://bit.ly/2v5kOvJ**	Hajjou M, Lukulay P. Potential use of handheld Raman devices as tools for screening medicines for quality. BioPharma Asia 2. 2014 Jan/Feb;1:14–21.
PPB expands medicines quality surveillance in Kenya	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2uPBlVi**	Promoting the Quality of Medicines program. PPB expands medicines quality surveillance in Kenya. Rockville (MD): U.S. Pharmacopeial Convention; 2015.
PQM activities in sub-Saharan Africa	About the Project	Brief	**https://bit.ly/2AadRiM**	Promoting the Quality of Medicines program. PQM activities in sub-Saharan Africa. Rockville (MD): U.S. Pharmacopeial Convention; 2015.
PQM Medicines Quality Database	Quality Surveillance	Fact Sheet	**https://bit.ly/2NLpGlQ**	Promoting the Quality of Medicines program. PQM Medicines Quality Database. Rockville (MD): U.S. Pharmacopeial Convention; 2014.
PQM results framework and indicators	About the Project	Graphic	**https://bit.ly/2OhGw8q**	Promoting the Quality of Medicines program. PQM Results Framework and Indicators. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
PQM support for regional medicines regulatory harmonization and reliance in Africa	Regulatory Systems Strengthening	Brief	**https://bit.ly/2AdaUOt**	Promoting the Quality of Medicines program. PQM support for regional medicines regulatory harmonization and reliance in Africa. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
PQM support in Burma	About the Project	Brief	**https://bit.ly/2AeOyfp**	Promoting the Quality of Medicines program. PQM support in Burma. Rockville (MD): U.S. Pharmacopeial Convention; 2013.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
PQM technical assistance for manufacturers of second-line TB medicines	Manufacturing	Fact sheet	**https://bit.ly/2mJyush**	Promoting the Quality of Medicines program. PQM technical assistance for manufacturers of second-line TB medicines. Rockville (MD): U.S. Pharmacopeial Convention; 2012.
Promoting the Quality of Medicines (PQM) program in Nigeria	About the Project	Brief	**https://bit.ly/2LH19ME**	Promoting the Quality of Medicines program. Promoting the Quality of Medicines (PQM) program in Nigeria Rockville (MD): U.S. Pharmacopeial Convention; 2015.
Promoting the Quality of Medicines (PQM) program in Southeast Asia	About the Project	Brief	**https://bit.ly/2OjyIDd**	Promoting the Quality of Medicines program. Promoting the Quality of Medicines (PQM) program in Southeast Asia. Rockville (MD): U.S. Pharmacopeial Convention; 2014.
Promoting the Quality of Medicines (PQM) program: Lao People's Democratic Republic (PDR)	Quality Surveillance	Brief	**https://bit.ly/2v998Ip**	Promoting the Quality of Medicines program. Promoting the Quality of Medicines (PQM) program: Lao People's Democratic Republic (PDR). Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Promoting the Quality of Medicines Program Annual Report: Project Year 2018	About the Project	Annual Report	**https://bit.ly/2Ip1OY1**	Promoting the Quality of Medicines program. Annual Performance Report: FY 2017. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Promoting the Quality of Medicines Program Annual Report: Project Year 2017	About the Project	Annual Report	**https://bit.ly/2LufI7m**	Promoting the Quality of Medicines program. Annual Performance Report: FY 2017. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Promoting the Quality of Medicines Program Annual Report: Project Year 2016	About the Project	Annual Report	**https://bit.ly/2v8QNuW**	Promoting the Quality of Medicines program. Annual Performance Report: FY 2016. Rockville (MD): U.S. Pharmacopeial Convention; 2016.
Promoting the Quality of Medicines Program Annual Report: Project Year 2015	About the Project	Annual Report	**https://bit.ly/2v5q8iH**	Promoting the Quality of Medicines program. Annual Performance Report: FY 2015. Rockville (MD): U.S. Pharmacopeial Convention; 2015.
Promoting the Quality of Medicines Program Annual Report: Project Year 2014	About the Project	Annual Report	**https://bit.ly/2LvSC00**	Promoting the Quality of Medicines program. Annual Performance Report: FY 2014. Rockville (MD): U.S. Pharmacopeial Convention; 2014.
Promoting the Quality of Medicines Program Annual Report: Project Year 2013	About the Project	Annual Report	**https://bit.ly/2v9Kw1V**	Promoting the Quality of Medicines program. Annual Performance Report: FY 2013. Rockville (MD): U.S. Pharmacopeial Convention; 2013.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Promoting the Quality of Medicines Program Annual Report: Project Year 2012	About the Project	Annual Report	**https://bit.ly/2LvTiCA**	Promoting the Quality of Medicines program. Annual Performance Report: FY 2012. Rockville (MD): U.S. Pharmacopeial Convention; 2012.
Promoting the Quality of Medicines Program Annual Report: Project Year 2011	About the Project	Annual Report	**https://bit.ly/2NQSZ1P**	Promoting the Quality of Medicines program. Annual Performance Report: FY 2011. Rockville (MD): U.S. Pharmacopeial Convention; 2011.
Promoting the Quality of Medicines Program Annual Report: Project Year 2010	About the Project	Annual Report	**https://bit.ly/2LTIl4x**	Promoting the Quality of Medicines program. Annual Performance Report: FY 2010. Rockville (MD): U.S. Pharmacopeial Convention; 2010.
Promoting the Quality of Medicines program in the Philippines	About the Project	Brief	**https://bit.ly/2R2hGe9**	Promoting the Quality of Medicines program. Promoting the Quality of Medicines in the Philippines. Rockville (MD): U.S. Pharmacopeial Convention; 2015.
Promoting the Quality of Medicines program in Vietnam	Quality Surveillance	Fact Sheet	**https://bit.ly/2LTiJtM**	Promoting the Quality of Medicines program Promoting the Quality of Medicines program in Vietnam. Rockville (MD): U.S. Pharmacopeial Convention; 2013.
Promoting the Quality of Medicines: Cambodia	About the Project	Brief	**https://bit.ly/2mPavIp**	Promoting the Quality of Medicines program. Promoting the Quality of Medicines: Cambodia. Rockville (MD): U.S. Pharmacopeial Convention; 2012.
Promoting the Quality of Medicines: program approach and technical areas	About the Project	Overview	**https://bit.ly/2Lt8wlh**	Promoting the Quality of Medicines program. Promoting the Quality of Medicines: program approach and technical areas. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Protecting newborns by expanding locally manufactured quality-assured medicines	Manufacturing	Success Story	**https://bit.ly/2mMEZuw**	Promoting the Quality of Medicines program. Protecting newborns by expanding locally manufactured quality-assured medicines. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Protecting patients from bad drugs: A risk-based approach to medicines quality surveillance (part 1)	Regulatory Systems Strengthening	Video	**https://bit.ly/2mnr9lw**	Promoting the Quality of Medicines program. Protecting Patients from Bad Drugs: A Risk-Based Approach to Medicines Quality Surveillance. Rockville (MD): U.S. Pharmacopeial Convention; 2019.
Protecting patients from bad drugs: A risk-based approach to medicines quality surveillance (part 2)	Regulatory Systems Strengthening	Video	**https://bit.ly/2mtVoXK**	Promoting the Quality of Medicines program. Protecting Patients from Bad Drugs: A Risk-Based Approach to Medicines Quality Surveillance. Rockville (MD): U.S. Pharmacopeial Convention; 2019.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Protecting patients from poor-quality medicines in Mozambique	Laboratory Strengthening	Success Story	**https://bit.ly/2leGk0a**	Promoting the Quality of Medicines program. Protecting Patients from Poor-Quality Medicines in Mozambique. Rockville (MD): U.S. Pharmacopeial Convention; 2019.
Protecting patients from poor-quality medicines by boosting laboratory capacity–Nigeria	Laboratory Strengthening	Success Story	**https://bit.ly/2LUrOCO**	Promoting the Quality of Medicines program. Protecting patients from poor-quality medicines by boosting laboratory capacity–Nigeria. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Reducing the supply and demand of illegal medicines in Senegal	Quality Surveillance	Success Story	**https://bit.ly/2DliMca**	Promoting the Quality of Medicines program. Reducing the supply and demand of illegal medicines in Senegal. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Quality medicines save lives	Cross Cutting Themes	Video	**https://bit.ly/2p6xobq**	Promoting the Quality of Medicines program. Quality Medicines Save Lives. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Quality of anti-malarials collected in the private and informal sectors in Guyana and Suriname	Quality Surveillance	Journal Article	**https://bit.ly/2LFdlh1**	Evans L, Coignez V, Barojas A, Bempong D, Bradby S, Dijiba Y, et al. Quality of anti-malarials collected in the private and informal sectors in Guyana and Suriname. Malaria Journal. 2012 Jun 15;11(203).
The quality of antimalarial medicines in Eastern Thailand: a case study along the Thai–Cambodian border	Quality Surveillance	Journal Article	**https://bit.ly/2NNvqae**	Phanouvong S, Dijiba Y, Vijaykadga S, Raymond S, Krech L, Lukulay P, et al. The quality of antimalarial medicines in Eastern Thailand: a case study along the Thai–Cambodian border. Southeast Asian J Trop Med Public Health. 2013 May;44(3):363–373.
The quality of antimalarial medicines in Western Cambodia: a case study along the Thai–Cambodian Border	Quality Surveillance	Journal Article	**https://bit.ly/2LtXen9**	Phanouvong S, Raymond C, Krech L, Dijiba Y, Mam B, Lukulay P, et al. The quality of antimalarial medicines in Western Cambodia: a case study along the Thai–Cambodian Border. Southeast Asian J Trop Med Public Health 4; 2013 May;44(3):349–362.
Reducing quality assurance costs by building Ethiopia's capacity to calibrate laboratory instrumentation	Laboratory Strengthening	Success Story	**https://bit.ly/2vbIFdb**	Promoting the Quality of Medicines program. Reducing quality assurance costs by building Ethiopia's capacity to calibrate laboratory instrumentation. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Reducing the risk of HIV transmission in Ethiopia	Laboratory Strengthening	Success Story	**https://bit.ly/2vcASM7**	Promoting the Quality of Medicines program. Reducing the risk of HIV transmission in Ethiopia. Rockville (MD): U.S. Pharmacopeial Convention; 2017.

TITLE (Linked to Description)	TECHNICAL AREA	RESOURCE TYPE	URL (Linked)	CITATION
Revisiting the stability and storage specifications of oxytocin injection: a literature review	Manufacturing	Report	**https://bit.ly/2Ml3U2K**	Thakral S, Suryanarayanan R, Evans L, Nkansah P. Revisiting the stability and storage specifications of oxytocin Injection: a literature Review. Rockville (MD): U.S. Pharmacopeial Convention, Promoting the Quality of Medicines Program; 2018.
A risk-based resource allocation framework for pharmaceutical quality assurance for medicines regulatory authorities in low- and middle-income countries	Regulatory Systems Strengthening	Guidance	**https://bit.ly/2x9ww9I**	Babigumira JB, Stergachis A, Kanyok TK, Evans L, Hajjou M, Nkansah PO, Pribluda V, Garrison LP, Nwokike JI. A risk-based resource allocation framework for pharmaceutical quality assurance for medicines regulatory authorities in low- and middle-income countries. Rockville, (MD): U.S. Pharmacopeial Convention, Promoting the Quality of Medicines Program; submitted to USAID June 2018.
Safer skies: helping Ethiopian airlines protect medicines quality while in transit to Ethiopia and other African countries	Quality Surveillance	Success Story	**https://bit.ly/2LHtFxH**	Promoting the Quality of Medicines program. Safer skies: helping Ethiopian airlines protect medicines quality while in transit to Ethiopia and other African countries. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Saving newborn lives with scale up of quality-assured chlorhexidine	Manufacturing	Success Story	**https://bit.ly/2mKAxfU**	Promoting the Quality of Medicines program. Saving newborn lives with scale up of quality-assured chlorhexidine Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Strengthening Burma's capacity to test for quality medicines	Laboratory Strengthening	Success Story	**https://bit.ly/2Lqg0fn**	Promoting the Quality of Medicines program. Strengthening Burma's capacity to test for quality medicines. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Strengthening Indonesia's pharmaceutical post-marketing surveillance capacity	Regulatory Systems Strengthening	Brief	**https://bit.ly/2m9UmQM**	Promoting the Quality of Medicines program. Strengthening Indonesia's Pharmaceutical Post-Marketing Surveillance Capacity. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Strengthening manufacturing capacity to improve access to quality-assured essential medicines	Manufacturing	Guideline	**https://bit.ly/2LJPX1Z**	Roth L, Clark A, Nkansah P. Strengthening manufacturing capacity to improve access to quality-assured essential medicines. Rockville (MD): U.S. Pharmacopeial Convention, Promoting the Quality of Medicines program; 2017.

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Strengthening medicines quality assurance systems for sustainable health outcomes	About the Project	Overview	**https://bit.ly/2NNGC6E**	Promoting the Quality of Medicines program. Strengthening medicines quality assurance systems for sustainable health outcomes. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Strengthening national quality control laboratories in low- and middle-income countries to improve the quality of medicines	Laboratory Strengthening	Guideline	**https://bit.ly/2LWVAqC**	Charles D, Umaru F, Nkansah P. Strengthening national quality control laboratories in low- and middle-income countries to improve the quality of medicines. Rockville (MD): U.S. Pharmacopeial Convention, Promoting the Quality of Medicines program; 2017.
Strengthening Nigeria's medicines quality assurance system by building capacity, sustainability and partnerships	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2LVzZij**	Promoting the Quality of Medicines program. Strengthening Nigeria's medicines quality assurance system by building capacity, sustainability and partnerships. Rockville (MD): U.S. Pharmacopeial Convention; 2016.
Strengthening quality assurance systems for antimalarials in Nigeria	Regulatory Systems Strengthening	Success Story	**https://bit.ly/2NQJMGU**	Promoting the Quality of Medicines program. Strengthening quality assurance systems for antimalarials in Nigeria. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Strengthening quality assurance systems for medical products	Regulatory Systems Strengthening	E-course	**https://bit.ly/2kUN9nr**	Promoting the Quality of Medicines program. Strengthening Quality Assurance Systems for Medical Products. Rockville (MD): U.S. Pharmacopeial Convention; 2019.
Strengthening quality assurance systems of pharmaceutical manufacturers to ensure availability of affordable TB medicines on the global market	Manufacturing	Poster	**https://bit.ly/2K1zDEU**	Promoting the Quality of Medicines program. Strengthening quality assurance systems of pharmaceutical manufacturers to ensure availability of affordable TB medicines on the global market .Rockville (MD): U.S. Pharmacopeial Convention; 2016.
Strengthening regulatory systems to improve medical product quality in low- and middle-income countries	Regulatory Systems Strengthening	Brief	**https://bit.ly/2l9glqD**	Promoting the Quality of Medicines program. Strengthening Regulatory Systems to Improve Medical Product Quality in Low- and Middle-Income Countries. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
Supporting medicines quality testing laboratories in Nigeria on the path to self-reliance	Laboratory Strengthening	Success Story	**https://bit.ly/2lau1BV**	Promoting the Quality of Medicines program. Supporting Medicines Quality Testing Laboratories in Nigeria on the Path to Self-Reliance. Rockville (MD): U.S. Pharmacopeial Convention; 2019.

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Three-Level Approach for ensuring the quality of medicines in resource-limited countries	Quality Surveillance	Poster	**https://bit.ly/2Lt5Pqk**	Promoting the Quality of Medicines program Three-Level Approach for ensuring the quality of medicines in resource-limited countries. Rockville (MD): U.S. Pharmacopeial Convention; 2010.
The Three-Level Approach: a framework for ensuring medicines quality in limited-resource countries	Quality Surveillance	Journal Article	**https://bit.ly/2Afoi4n**	Pribluda VS, Barojas A, Coignez V, Bradby S, Dijiba Y, El-Hadri L, et al. The three-level approach: a framework for ensuring medicines quality in limited-resource countries. Pharmaceut Reg Affairs. 2014;3(1).
Three-Level Approach: a risk-based, cost-effective approach to medicines quality monitoring in low-and middle-resource countries	Quality Surveillance	Poster	**https://bit.ly/2NQM5JV**	Promoting the Quality of Medicines program. Three-Level Approach: a risk-based, cost-effective approach to medicines quality monitoring in low-and middle-resource countries. Rockville (MD): U.S. Pharmacopeial Convention; 2011.
True impact: helping babies thrive in Nigeria	Manufacturing	Video	**https://bit.ly/2vcNJxE**	Promoting the Quality of Medicines program. True impact: helping babies thrive in Nigeria. Rockville (MD): U.S. Pharmacopeial Convention; 2017.
Using mobile technologies to detect poor-quality medicines in Benin (French version also available)	Laboratory Strengthening	Success Story	**https://bit.ly/2kUM3bj**	Promoting the Quality of Medicines program Using Mobile Technologies to Detect Poor-Quality Medicines in Benin. Rockville (MD): U.S. Pharmacopeial Convention; 2018.
USP committed to quality assurance of medicines	Cross Cutting Themes	Media Article	**https://bit.ly/2LGUulW**	Muanya C. USP committed to quality assurance of medicines. The Guardian Nigeria. 2016 Sep 8.
USP Promoting the Quality of Medicines program (PQM) activities in Southeast Asia 2010–2011	Quality Surveillance	Poster	**https://bit.ly/2NRyMZL**	Promoting the Quality of Medicines program USP Promoting the Quality of Medicines program (PQM) activities in Southeast Asia 2010–2011. Rockville (MD): U.S. Pharmacopeial Convention; 2011.
Were medicine quality and pharmaceutical management contributing factors in diminishing artemisinin efficacy in Guyana and Suriname?	Quality Surveillance	Journal Article	**https://bit.ly/2LZ4ofi**	Pribluda VS, Evans L, Barillas E, Marmion J, Lukulay P, Chang J. Were medicine quality and pharmaceutical management contributing factors in diminishing artemisinin efficacy in Guyana and Suriname? Malaria Journal. 2014 Mar 3;13(77).
Why lab accreditation matters for public health	Laboratory Strengthening	Success Story	**https://bit.ly/2v6hDUq**	Promoting the Quality of Medicines program. Why lab accreditation matters for public health. Rockville (MD): U.S. Pharmacopeial Convention; 2017.