

Promoting the Quality of Medicines Plus (PQM+)



Spotlight

Bangladesh Enhances Processes to Ensure the Quality of Personal Protective Equipment (PPE) During the Pandemic

To fight COVID-19, the Government of Bangladesh is expanding access to quality-assured personal protective equipment (PPE). Working with the Directorate General of Drug Administration (DGDA), WHO, and local manufacturers, PQM+ developed visual inspection checklists based on international standards for gowns, coveralls, fabric and surgical masks, and N95/KN95 respirators.



DGDA inspectors use the new checklists to check manufacturing facilities and ensure they are meeting quality standards. PQM+ also developed guidelines for procurement agents to use when inspecting gowns, coveralls, and fabric masks. PPE manufacturers can refer to the guidelines and checklists when selecting materials, defining composition, developing packing material, designing products, and conducting quality control. PQM+ also collaborated with DGDA to develop a database of **local PPE manufacturers** to raise awareness about approved sources of quality-assured PPE.



Learning

Free Course on Good Manufacturing Practices Available Online

Pharmaceutical manufacturers must comply with the regulatory requirements of the countries where they produce and sell medical products. Good Manufacturing Practices (GMP) are critical to ensuring their products are quality-assured. PQM+'s updated online course presents foundational GMP concepts based on World Health Organization and Pharmaceutical Inspections Scheme (PIC/S) principles. The 10 self-paced modules can be

GHTechX Session Explains Emergency Use Authorization

When and how should Emergency Use Authorization (EUA) be used during health emergencies like COVID-19? As part of USAID's Global Health Science and Practice Technical Exchange (GHTechX), Mr. Asim Rauf, Chief Executive Officer of the Drug Regulatory Authority of Pakistan, and PQM+ Director Mr. Jude Nwokike explain EUA and how it can be applied in low- and middle-income countries to facilitate timely, safe access to life-saving medical products. Log in to GHTechX and [watch the video](#) to learn more.

Webinar: Strengthening National Quality Control Labs

National quality control laboratories (NQCLs) are national laboratories that have been mandated to generate quality data for regulatory decision-making. They are known as the "backbone" of the medical products supply chain system for their role in detecting and preventing substandard and falsified (SF) medical products from circulating in local markets. PQM+'s team explains how NQCLs detect SF products, how they support national health programs, and how effective strategies can be applied to strengthen NQCLs to meet international standards. Watch the [webinar](#).



Pharmaceutical Manufacturer in India Earns WHO Approval for NTD Medicine

India's Medopharm Private Limited recently earned WHO prequalification (PQ) for its praziquantel 600mg film-coated tablets, which are used to prevent and treat schistosomiasis. Known as snail fever, schistosomiasis is an acute and chronic disease caused by parasitic worms.

For more than 30 years, praziquantel has been used to prevent and treat this neglected tropical disease (NTD). PQM+ and its predecessor PQM program have been working with Medopharm since 2017 to meet WHO's standards and achieve this goal. By diversifying the [supply source](#) for this #NTD medicine, millions of people will benefit.



Health Elements

Six new maternal, newborn, and child health (MNCH) resources are now available to help regulators and laboratory staff ensure the quality of critical medical products – [Amoxicillin](#), [Chlorhexidine gel](#) and



Oxytocin. PQM+ also developed a [guidance document](#) for implementing risk-based post-marketing surveillance (RB-PMS). RB-PMS monitors the overall quality and safety of medical products and responds to risks posed by SF medical products. These downloadable resources are available in French and English on the PQM+ [homepage](#).



Global Highlights



Resource optimization is an important factor in building the long-term sustainability of national health programs. With PQM+ support, **Nigeria's** National Institute for Pharmaceutical Research and Development (NIPRD) shifted to accreditation by the Nigeria National Accreditation System, a local body, instead of the American National Accreditation Board. NIPRD reduced its annual fee costs by 56 percent or about \$4,500.

Collaboration is a key ingredient to improving governance for medical product quality assurance systems. **Burkina Faso** launched a national PMS Technical Working Group to harmonize activities between L'Agence Nationale de Régulation Pharmaceutique (ANRP) and Laboratoire National de Santé Publique (LNSP). ANRP is the national pharmaceutical regulatory authority and LNSP is the national public health laboratory. The new TWG will also help optimize limited malaria resources by channeling them toward areas with the highest risks to patients.



Substandard and falsified medical products, including those for COVID-19, are proliferating in markets worldwide. Recently, PQM+ and the Global Pharma Health Fund jointly published new **dexamethasone test methods for Minilab™**, an inexpensive field test kit. It uses simple test methods for rapid drug quality verification and to detect counterfeit medicines. The new methods test both dexamethasone tablets and injectable solutions, which are used to

treat COVID-19 intensive care patients. The methods are free to [download](#).

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