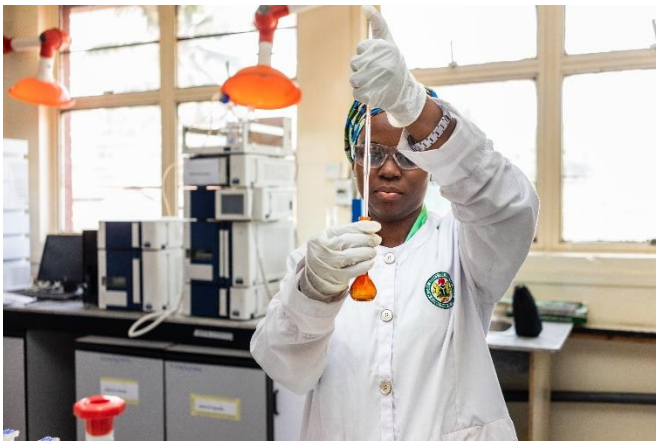
PQM Promoting the Quality of Medicines

Supporting Medicines Quality Testing Laboratories in Nigeria on the Path to Self-Reliance

As part of its efforts to expand access to quality-assured medicines, the Government of Nigeria is working to ensure its ability to efficiently test medical products. Nigeria's partnership with the Promoting the Quality of Medicines (PQM) program, which is funded by the U.S. Agency for International Development (USAID) and implemented by the U.S. Pharmacopeial Convention (USP), has helped five Nigerian public sector quality control laboratories achieve and maintain ISO/IEC 17025 accreditation, adhering to internationally recognized standards for medicines testing.

The PQM program supported three national quality control laboratories (NQCLs), the National Control Laboratory for Vaccines and other Biologicals (NCLVB), and the National Institute for Pharmaceutical Research and Development (NIPRD). Building in-country capacity to test medicines quality using international standards directly contributes to regulatory systems strengthening, explains Victor Abiola, Director of Laboratory Services, Drugs and Biologicals at the National Agency for Food and Drug Administration and Control (NAFDAC). "The real value of ISO/IEC 17025 accreditation comes from institutionalizing a quality management system (QMS) that enables accreditation in the first place," he says, specifying that doing so involves all departments in a laboratory and can mean completely overhauling the way laboratories function. "A good QMS sets the foundation for efficient, cost-effective medicines testing and provides a springboard for expanding a laboratory's scope of services," Abiola adds. He also emphasizes that the results of tests performed by the five accredited laboratories informed NAFDAC's approval of 11,240 new or generic health products for the Nigerian market in 2017.

Supporting these laboratories on the path to self-reliance included identifying their technical and financial needs, determining how the budgetary responsibility for each would be shared between PQM and the Government of Nigeria, and setting a timebound sustainability plan to phase out PQM support as internal capacity and resources increased. From 2015 through 2018, PQM provided approximately 85 percent of total spending on QMS strengthening and testing in the five laboratories, compared to roughly 20 percent in 2019.



An analyst at the Central Drug Control Laboratory in Yaba (Lagos State) prepares a sample for assay determination using high-performance liquid chromatography. This test is used to determine whether a medicine contains the right active pharmaceutical ingredient in the right amount. (Photo credit: PQM program)

National Quality Control Laboratories (NQCLs)

NAFDAC manages seven laboratories, three of which are dedicated to medicines quality testing: Yaba (Lagos State), Agulu (Awka-Anambra State), and Kaduna (Kaduna State). One by one, these laboratories attained their first ISO/IEC 17025 accreditations between 2016 and 2017. To achieve this goal, NAFDAC not only partnered with PQM to assess and subsequently strengthen the laboratories' existing QMS and testing capacity, but also depended on PQM to cover all costs related to having each facility evaluated. These costs included purchasing needed equipment, procuring testing samples and supplies, calibrating devices, and paying evaluation fees. In all, PQM invested around 500,000 USD in the NQCLs during the two years.

By the time the NQCLs came up for mandatory renewal of their accreditations (the Yaba and Agulu NQCLs in 2018 and the Kaduna NQCL in 2019), NAFDAC was ready to assume all costs for the evaluations as well as for new training needs.

"Taking on the price of reaccreditation was one of the major actions designated in the stepwise sustainability plan the PQM program developed with NAFDAC in 2015," says Victor Abiola. "Our ability to now handle these costs has come in large part from the fees we can charge for testing services thanks to the fact that the laboratories are ISO/IEC 17025 compliant," he continues, also noting that further budget flexibility has been gained by switching to qualified local service providers for key services such as equipment calibration.

NAFDAC's sustainability plan also included the establishment of a peer-to-peer collaborative learning program. After achieving certification, Yaba staff assisted colleagues in Agulu to prepare for their certification, and then both NQCLs did the same for the Kaduna NQCL. Such peer support was one reason the Kaduna NQCL opted to seek renewal under ISO/IEC 17025:2017, an updated version of the standard that has been issued but will not become compulsory until 2020. As a result, in 2019 Kaduna became one of the first NQCLs on the African continent to achieve ISO/IEC 17025:2017 accreditation.

National Control Laboratory for Vaccines and other Biologicals (NCLVB)

Also managed by NAFDAC, the NCLVB in Yaba provides the same type of testing support for health product regulation as the NQCLs but does so for vaccines, biologicals (i.e., medicines made from substances found in living organisms), and medical devices. Attaining ISO/IEC 17025 accreditation in February 2019, the NCLVB also benefitted from the peer-to-peer learning program that has been vital to the NQCLs' growing self-reliance. Personnel from the nearby Yaba NQCL trained their peers at the NCLVB and reviewed that laboratory's standard operating procedures, effectively decreasing the amount of technical assistance required from PQM.

NCLVB accreditation is improving Nigeria's ability to assure the quality of its supply of bacille Calmette-Guérin (BCG) vaccines, a mandatory protection for newborns against tuberculosis and a key asset in the effort to address the country's high infant mortality rates. The NCLVB is also instrumental in helping guarantee that test kits used at service delivery points for malaria, HIV, and tuberculosis are quality assured.

National Institute for Pharmaceutical Research and Development (NIPRD)

Established as a parastatal under the Federal Ministry of Science and Technology in 1987 and transferred to the Federal Ministry of Health in 2001, the NIPRD's primary objective is developing medicines, biological products, and pharmaceutical raw materials. However, its mandate includes conducting quality assurance tests for locally manufactured medicines, as well as developing specifications for production of such commodities. As part of meeting the requirements for permission to market new or generic products in Nigeria, pharmaceutical manufacturers bring those products to the NIPRD for testing and receive a certificate of previous analysis that is recognized by NAFDAC and is a prominent element of an authorization request.

The NIPRD pursued ISO/IEC 17025 accreditation during the same period as the Yaba and Agulu NQCLs. Similar to those laboratories, the NIPRD's process began in 2016 when the PQM program conducted an assessment to identify gaps between the targeted standards and the facility's QMS and technical capacities. Informed by that assessment, the PQM program provided training to the NIPRD staff on pharmaceutical testing and paid the costs of accreditation. The NIPRD notably achieved ISO/IEC 17025 in August 2018 and quickly transitioned to the 2017 version of the standard in March 2019 through a self-funded reassessment.

The lesson from Nigeria

Whether addressing testing or other aspects of medicines quality assurance systems anywhere in the developing world, strengthening in-country regulatory capacity is fundamental to sustainability. Quality control and quality assurance activities conducted by competent domestic regulatory authorities are timely and cost-efficient. As Nigeria has shown through the accreditation of its five public sector medicines testing laboratories, donor support can be a powerful way to initiate and foster capacity-building, but success comes from country ownership of both the process and results.

The Promoting the Quality of Medicines (PQM) program is funded by the U.S. Agency for International Development (USAID) and implemented by USP. The PQM program supports low- and middle-income countries in strengthening health systems by building capacity for the regulation and manufacture of medical products. This helps increase availability of lifesaving, quality-assured medicines to meet global health priorities, ensuring healthy lives and promoting well-being for all people of all ages. For more information, visit www.usp-pqm.org.