



LabTrain

Strengthening capacity and infrastructure building in drug quality assurance in African countries: A contribution by BfArM to WHO standards and good laboratory practice

Context

Low-quality drugs pose a substantial threat to individual and public health. Issues include incorrect labelling, potentially toxic or wrong active ingredients and unacceptably high levels of impurities. Low-quality anti-infective medicines, in particular, pose a potentially global concern as they can lead to the development of antimicrobial resistance, making the therapy ineffective or even toxic. Medicine control laboratories play an important role in detecting low-quality medicines and preventing them from circulating on the market. LabTrain builds on previous projects under which laboratory staff were trained in quality control for anti-infective medicines and in advanced analytical techniques and a research network was developed. The project addresses the need to continuously train laboratory staff, develop national policies and strategies for laboratory services, exploit funding opportunities and draft and improve quality assurance and control protocols in Ghana, Liberia, Sierra Leone and The Gambia. In cooperation with multiple partners at the international and local level, LabTrain strengthens the capacities of the staff of national medicines authorities involved in drug quality control in the participating countries. LabTrain provides a basic training programme and guidance on infrastructure building which equip staff to establish quality control laboratories.

Objective

Increasing the expertise of selected African national medicines regulatory authorities in drug quality assurance and in establishing quality control laboratories.

Key facts

Duration

1 January 2023 to 31 December 2025

Budget

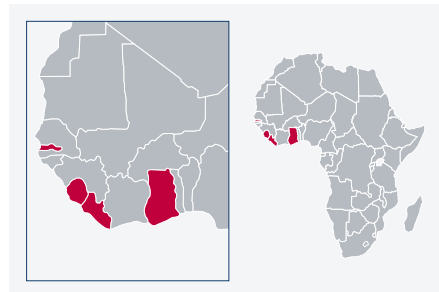
~ EUR 1.3 million

Partner countries

Ghana, Liberia, Sierra Leone, The Gambia

Region

Western Africa



Implemented by

Federal Institute for Drugs and Medical Devices (BfArM)

Commissioning party

German Federal Ministry of Health (BMG)

Thematic focus

Strengthening of public health systems

Marketing authorisation and safety of medicinal products

Activities



STAFF DEPLOYMENT AND EXCHANGE

Training the staff of partnering quality control laboratories to meet quality standards and achieve international accreditations; supporting the staff of national medical authorities involved in drug quality assurance in the participating countries in establishing and improving quality control laboratories and laboratory quality management systems



CAPACITY DEVELOPMENT

Supporting capacity and infrastructure building in the field of drug quality assurance in Ghana, Liberia, Sierra Leone and The Gambia and in other sub-Saharan African countries; enhancing laboratory management structures



RESEARCH AND PROVISION OF EVIDENCE

Joint research activities by BfArM, WHO and the University of Würzburg to develop quality testing procedures and specifications for lipid derivatives used as excipients in mRNA vaccines based on the results of laboratory testing; preparing monographs for medicinal products that treat leishmaniasis and amoebiasis



NETWORKING AND COOPERATION

Professional consultation by BfArM and InphA; promoting the implementation of WHO guidelines

In cooperation with

- World Health Organization (WHO), Switzerland
- Institute for Pharmaceutical and Applied Analytics (InphA), Germany
- University of Würzburg (JMU), Institute for Pharmacy and Food Chemistry, Germany
- Food and Drugs Authority (FDA), Ghana
- Liberia Medicines and Health Products Regulatory Authority (LMHRA), Liberia
- Pharmacy Board of Sierra Leone (PBSL), Sierra Leone
- Medicines Control Agency (MCA), The Gambia

Contact

Prof. Britta Hänisch / Dr The-Hung Vu

German Federal Institute for Drugs and Medical Devices (BfArM)

Kurt-Georg-Kiesinger Allee 3,
53175 Bonn, Germany

GHPP.Labtrain@bfarm.de

GHPP, the Global Health Protection Programme of the German Federal Ministry of Health, promotes networking, exchange and cooperation between specialized German and international public health actors. By reducing health risks and strengthening health systems at the national, regional and international level, in particular relating to pandemic and epidemic preparedness and response, the GHPP fosters public health protection – worldwide.



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