

Training African National Drug Quality Control Laboratories (NDQCLs) in Quality Assurance and Quality Management in the Context of Combating Antimicrobial Resistance

DQA

Long-Term Training Activities for NDQLs in Quality Assurance and Quality Management in the Context of Combating Antimicrobial Resistance

Duration

2016 – 2021

Budget

total approx. 3.2 million EUR

Partner countries

Botswana
Burkina Faso
Cameroon
Ethiopia
Ghana
Malawi
Namibia
Nigeria
Sierra Leone
Senegal
Zambia
Zimbabwe

Challenges addressed by the project

Patient safety is an essential component of high-quality healthcare. Maintaining widespread availability, quality and integrity of medicinal products worldwide remains a critical challenge for healthcare systems. DQA responds to the growing need for quality assurance of medicines. The training programme has been developed in close and coordinated cooperation with the WHO. Long-Term training activities facilitate transfer of know-how in accordance with international standards. DQA PLUS complements DQA to strengthen competencies and capacity necessary for the efficient monitoring of drug quality. Both projects aim to empower partner countries to advance regulatory competence and to implement effective regulatory measures. The projects facilitate networking and guide the development of a multinational competency framework, thereby supporting access to and use of high-quality medicines.

Objectives

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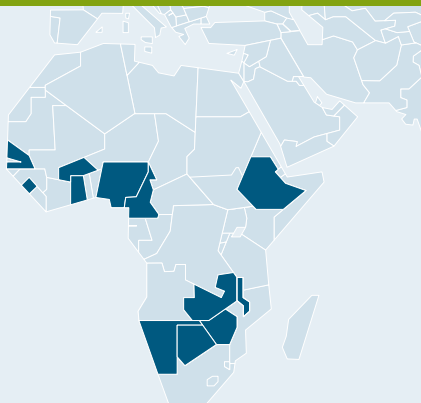
Comprehensive training activities in DQA will facilitate:

- » Advancement of know-how needed to operate, maintain and employ technology to full capacity
- » Further understanding of means and processes to monitor quality of selected medicinal products
- » Increased awareness and current strategies for improving compliance with ISO (International Organization for Standardization) and an advanced overall operational capacity needed to address and/or meet WHO prequalification requirements

Training areas are continuously tailored to address the needs of the participating laboratories because the development of further strategies and measures when dealing with the constantly increasing complexity of evaluating technologically sophisticated products is and will remain a particular challenge for the future.

DQA PLUS

The extension project DQA PLUS will further strengthen regulatory competencies and laboratory capacities essential for the efficient monitoring of the quality of medicinal products by:



Supported by:



on the basis of a decision
by the German Bundestag



Celebrating togetherness – Participants at the First GHPP DQA Alumni Meeting, Cape Town, South Africa, 2020



Meeting participants report on the impact of their training programme, Cape Town, South Africa, 2020



Group work to build collaborative multinational teams – First GHPP DQA Alumni Meeting, Cape Town, South Africa, 2020



The DQA7 team from Malawi, Botswana and Zimbabwe working in the laboratory at the Institute for Pharmaceutical and Applied Analytics in Bremen (Photo ©InphA)

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- » Facilitating further training through the incorporation of thematically extended training topics into the programme
- » Extending training actions as well as reaching out to more partner countries
- » Supporting alumni engagement and connecting the DQA alumni community of analysts from NDQCLs at the regional level
- » Fostering engagement through dissemination of the core aims and impact of project activities

The projects will substantiate access to collaborative know-how and thereby support partners/national quality control laboratories in addressing and meeting prequalification and or accreditation requirements more effectively. All in all, DQA and PLUS aim to make an important contribution to advancing sustainable processes and activities in alignment with laboratory needs and in compliance with international norms.

Overview of activities

BfArM cooperates closely with the WHO REG and the Institute for Pharmaceutical and Applied Analytics (InphA GmbH), Germany's largest Official Medicines Control Laboratory (OMCL). To date, DQA has facilitated training for drug analysts/specialist laboratory staff from NDQCLs in African countries. Since its launch, GHPP DQA has established partnerships with 12 countries: Botswana, Burkina Faso, Cameroon, Ethiopia, Ghana, Malawi, Namibia, Nigeria, Senegal, Sierra Leone, Zambia and Zimbabwe. Within the PLUS project, more countries may be invited to attend the range of training activities. This includes transfer of know-how with regard to topics of high interest such as drug analysis, analytical method development and validation, troubleshooting and equipment operation, as well as the methods, pharmacopoeia regulations and standards. DQA and PLUS aim to advance compliance with international norms so that NDQCLs may address and meet the WHO prequalification and/or ISO accreditation requirements more effectively. Participation in this long-term training programme will enable the partners to transfer, apply and pass on knowledge acquired to others, advance overall operational capacities as well as strengthen knowledge and understanding of quality assurance procedures. The DQA alumni network is to be strengthened so that sustainable support and established regulatory structures can be further promoted. In January 2020, BfArM and the WHO hosted the first GHPP DQA alumni meeting entitled "Life-long learning, sharing, impact and relevance towards advancing public health". Current, ongoing virtual activities are connecting our alumni community through the facilitation of joint actions which are playing an important role in the continuous development of a multinational competency framework for the wider access to and appropriate use of medicines of ensured quality.

Partner institutions

- » National Regulatory Authorities and their quality control laboratories (NDQCLs) in the following African partner countries: Botswana, Burkina Faso, Cameroon, Ethiopia, Ghana, Malawi, Namibia, Nigeria, Sierra Leone, Senegal, Zambia, Zimbabwe
- » WHO – Regulation and Safety (WHO-REG), Switzerland
- » Institute for Pharmaceutical and Applied Analytics (InphA), Germany¹

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1 WHO prequalified Official Medicines Control Laboratory (OMCL)