



Quality Infrastructure for the Health Sector

Every person is entitled to the best possible health care. To achieve this, medication has to be effective, medical equipment accurate and laboratories reliable. This is not guaranteed everywhere. To this end, a corresponding quality infrastructure is helpful as a precondition for improved health care – e.g. by monitoring whether medications contain the correct amounts of active ingredients or whether the measuring instruments are correctly calibrated.

Only healthy people can participate in social and economic life and contribute to the development of their country. Therefore, *Sustainable Development Goal 3* – “Ensure healthy lives and promote well-being for all at all ages” – of the United Nations and several others expressly refer to the improvement of the

health care situation in developing countries: improving health care for mothers, reducing childhood mortality, combating Aids, malaria and other severe diseases.

In many newly developed countries and in most of the developing countries, the majority of the people do not have access to adequate health care. Therefore, one focus of German technical cooperation is on building up the health care systems of its partner countries; the respective quality infrastructure is an important component for this. The task of the *International Cooperation* of PTB Braunschweig is to develop this quality infrastructure in partner countries in accordance with their needs.

Our Contribution

The *International Cooperation* of PTB concerns itself – world-wide within the framework of bilateral or regional projects – with the establishment of a suitable quality infrastructure that makes an important contribution to health protection. Cooperating partners here are national authorities, laboratories, manufacturers and their associations as well as international organizations such as the World Health Organization (*WHO*).

PTB offers training programmes and advises personnel at all levels from the laboratory to the Ministry of Health, it promotes the networking of important stakeholders, organizes and finances study trips and training programmes abroad and supports the carrying out of comparison measurements and the conducting of studies.

A functioning quality infrastructure – and thus the contributions of PTB – are especially relevant for three topics of the health sector:

- medication,
- medical laboratories and
- medical equipment.

MEDICATION

National authorities must be able to control and monitor the effectiveness and safety of drugs and medicines. This requires institutions with functioning quality management systems that are used in daily work.

By means of a comprehensive market monitoring, inspectors of the regulatory authorities protect the general public against inferior and falsified drugs and medicines.

The manufacturers of drugs and medicines and the monitoring laboratories of the regulatory authorities have to prove that they work with calibrated and validated instruments. Moreover, they have to compare the ingredients with certified reference materials.

An important basis for the manufacture and testing of drugs and medicines are international standards: Good Manufacturing Practice (*GMP*), standards of the International Organization for Standardization (*ISO*) and guidelines of the World Health Organization (*WHO*).



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The *GMP* guidelines lay down the measures for the production environment and processes which are a part of quality assurance for the manufacture of pharmaceutical products and active ingredients. A requirement for obtaining a permit to manufacture pharmaceutical products is to follow these guidelines. The national authorities' task is to regularly inspect and to certify the production facilities in accordance with the *GMP* guidelines. When control laboratories are accredited according to the *ISO 17025* quality management system, they improve their processes, prove their reliability and achieve international recognition. A similar effect is provided by the so-called *WHO pre-qualification* with which independent international experts certify the competence of manufacturers of drugs and medicines and of monitoring laboratories.

MEDICAL LABORATORIES

The services of medical laboratories are important in order to evaluate the health condition of patients and to make correct diagnoses. They have to fulfil the needs of patients and of hospital personnel.

These services include provisions for the examination, the clear identification of the patients, the taking of samples and their transport, preparation and testing, up to their validation and evaluation. This also encompasses the writing of reports and advising patients. The work in the medical laboratory must take safety and ethical aspects into consideration. This includes the responsible handling of the samples and the comprehensive protection of patients' data.

Testing methods and analysis procedures in medical laboratories form the basis for diagnostics and treatment in the health sector. Unreliable measurements and analyses can have serious consequences for the patients. The international standard *ISO 15189* lays down the specific requirements for medical laboratories. Its purpose is to guarantee the competence and quality of the laboratory services and the unchangingly valid test results. Accreditation bodies base their work on this *ISO* standard when they evaluate medical laboratories.



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MEDICAL EQUIPMENT

Modern medicine depends on reliable and accurate measurements – this is just as true for a correct diagnosis as it is for effective treatment.

Here, too, quality infrastructure plays an important role: Medical products such as thermometers, blood pressure monitors or X-ray apparatuses have to be tested in numerous ways. Measurements for diagnostics and therapy monitoring have to be carried out in exactly defined methods.

Only equipment, tests and measurement methods that meet internationally recognized standards can deliver results which are reliably the same, independent of practice or laboratory.

This requires having corresponding laws at national level and having a quality management system in the medical institutions which is practically implemented. Medical equipment must be calibrated and traced back to international standards and the staff must be trained for working with this equipment.

Increasingly, health care also resorts to measurements for early diagnosis in the case of risk factors, e.g. for cardiovascular diseases, cancer or diabetes. In this way, quality infrastructure also contributes to improved prevention and helps to reduce the costs of a national health system.

Impacts

Through PTB projects in the field of health protection, the quality infrastructure present in the partner countries is strengthened and demand-oriented, competent and internationally recognized services are made available for the health sector.

Thus, laboratories can work in a qualified and reliable manner, accurate measurements help avoid diagnostic errors, and there is effective protection against ineffective or falsified medicines. All people who have to rely on the national health system in their country will benefit from this.



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