5th Annual Meeting of WHO Prequalification of In Vitro Diagnostics Dossier Assessors and Inspectors

SALLE B, WHO, Geneva, Switzerland
13 – 15 November 2018

Meeting background

Since 2014, the WHO Prequalification Team (PQT) – Diagnostics, has been working towards implementation of operational improvements to the WHO prequalification process to improve its efficiency and to limit resource requirements; while ensuring that WHO norms and standards are sufficiently comprehensive for prequalifying different risk-based categories of in vitro diagnostics and are universally accepted.

The first meeting of prequalification assessors and inspectors was held in March 2014. Although many of the changes to the programme proposed at this meeting have been implemented, there is still the opportunity for further improvement. PQT has committed to donors that the programme will keep improving in terms of efficiency and requirements clarity. The purpose of this meeting is to further streamline PQT work by reviewing in-depth specific activities and processes associated with the dossier assessment and inspection components of prequalification, to ensure a continuous improvement of PQT' s activities. In addition, the meeting aims at educating all experts working with PQT about new stability requirements as well as risk/benefit analyses and their role in product assessment.

This group will discuss specific activities and processes and ensure that proposed actions are aligned internationally. In addition, the group will consider the implications of these actions, both on the manufacturer, so as not to be overly burdensome, and to the programme, to ensure they will enhance efficiency.

Meeting objectives

1. To further improve WHO inspection procedures for in vitro diagnostics (IVDs)
    a. To discuss abbreviated inspections and their main objective
    b. To discuss data integrity
    c. To discuss upcoming risks

2. To further improve WHO dossier assessment procedures for IVDs
    a. To update assessors on the newly published guidance and technical specifications for PQDx
    b. To discuss the new IMDRF Table of Contents reporting format and Collaborative Registration Procedure.
    c. To discuss assessors challenges

Expected meeting outcomes

- Improved WHO PQ dossier assessment and inspection processes that are aligned internationally and that best support a streamlined PQ process.
- Harmonized and consistent assessments and inspections.