World Health Organization

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WHO Prequalification Workshop for Chinese manufacturers of IVDs

9 to 11 December 2025,

The Westin Guangzhou, China

Meeting Background

The World Health Organization prequalification of in vitro diagnostics provides a comprehensive assessment of individual IVDs for quality, safety and performance and has over a decade of experience in assessing various IVDs. Many manufacturers of IVDs are based in Asia; some of these are already experienced prequalification applicants while other manufacturers of priority IVDs lack such experience as well as the understanding of WHO Prequalification processes.

This workshop for manufacturers based in China will be a follow up event to the workshop organized in Jakarta in January 2025 which was attended by 150 participants from 8 Asian countries. It also aims to scale-up access to quality-assured IVDs manufactured in China.

Objectives of the meeting:

- Provide manufacturers with a comprehensive understanding of WHO Prequalification (PQ) assessment ;
- Advocate for and provide guidance on evidence-based quality assurance of IVDs;
- Provide support to manufacturers of priority IVDs for preparation of applications for WHO PQ.

Expected outcomes:

- This workshop aims to increase submissions for priority IVDs to PQ assessment, and to scale-up the access to quality-assured IVDs manufactured in China.