

CONCEPT NOTE: Technical Training Workshop on Technology Transfer for IVD Manufacturers in Africa.

26th – 29th MAY 2026

Nairobi, Kenya

Organized by the World Health Organization and [Medicines Patent Pool \(MPP\)](#).

Venue: Pridelnn Azure Hotel

Audience: Manufacturers interested in entering technology transfer partnerships and manufacturers that are already implementing technology transfer projects.

Format: In-person, highly interactive and case-study driven

1. Background and Rationale

Access to quality-assured, affordable *in vitro* diagnostics (IVDs) is critical for disease surveillance, outbreak preparedness, and routine clinical care. Despite growing demand, most countries in Africa remain highly dependent on imported diagnostics, exposing health systems to supply disruptions, and limiting timely access during public health emergencies.

To enable greater health security, strengthening local manufacturing capacity is a strategic priority for the African continent as reflected in WHO resolutions and frameworks on strengthening local production¹ and diagnostic capacity². Technology transfer can enable faster scale-up than de novo product development, particularly where validated technologies, regulatory data, and quality systems are transferred. As such, technology transfer opportunities are increasingly being explored as pathways to accelerate the establishment of manufacturing capabilities for diagnostics.

Why this workshop?

Across the African region, several IVD manufacturers are exploring or are already engaged in technology transfer partnerships - for disease specific test kits, reagents, or in some cases diagnostic platforms that are disease agnostic. While these opportunities can accelerate local production, they also come with technical, operational, and regulatory risks that need to be accounted for to enable optimal execution of the technology transfer plans and eventual market access.

Recent stakeholder forums on diagnostics have focused on specific aspects of the technology value chains such as regulatory and market access enablers. However, consultations with manufacturers have highlighted the need for technical insight and tools to support the implementation of successful technology partnership. This includes but is not limited:

- Assessing technology transfer readiness
- Defining market access and demand signals

¹ [Resolution WHA74.6 - Strengthening local production of medicines and other health technologies to improve access; AFR/RC74/6 - Framework for strengthening local production of medicines, vaccines, and other health technologies in the WHO African region 2025–2035](#)

²; [Resolution WHA67.5 - Strengthening diagnostics capacity](#) and

- Considerations for quality and regulatory requirements

This workshop responds to these needs by focusing on **the considerations manufacturers must make before and during technology transfer**, and on the practical steps required to achieve independent, quality-assured production. It builds on existing initiatives implemented by WHO, including the [WHO Health Technology Access Program](#) and [specialised technical assistance for PQ/EUL; dedicated WHO prequalification \(PQ\) workshops targeted to African manufacturers](#) and [recent workshops organised by AfCDC](#) .

2. Purpose and Objectives

The purpose of the workshop is to equip IVD manufacturers in Africa with **practical tools, frameworks, and real-world insights** to make informed decisions about technology transfer technology transfer agreement, and to successfully implement and complete technology transfer once it begins.

Specific objectives are to enable manufacturers to:

- Assess whether a technology transfer opportunity is technically, commercially, and strategically viable based on demand, market access, and financing considerations.
- Define an appropriate scope of transfer (e.g. contract manufacturing, partial manufacturing, or end-to-end production).
- Assess readiness of facilities, equipment, workforce, and quality systems.
- Prepare for and negotiate technology transfer agreements with a clear understanding of risks and obligations.
- Plan and manage technology transfer as a structured, time-bound process.
- Navigate national, regional, and WHO regulatory pathways following technology transfer.

3. Workshop format:

The workshop is designed to be highly interactive and grounded in real-world experience, the format will include:

- Presentations from global health technical partners and regulators;
- Detailed case studies based on technology transfer experiences in diagnostics;
- Group exercises and problem-solving sessions using realistic scenarios; and
- Dedicated sessions for participants to discuss their own technical challenges.

4. Expected Outcomes: benefit to participants.

By the end of the workshop, manufacturers are expected to:

- Better assess whether a technology transfer opportunity is technically and commercially sound;
- Understand what is realistically required in terms of facilities, equipment, technical knowledge and capabilities of staff, and timelines;
- Integrate quality and regulatory considerations from the start of the transfer process;
- Navigate national, regional, and WHO regulatory pathways with greater confidence; and
- Learn from technology transfer case studies

TENTATIVE AGENDA

DAY	Time	Session
DAY 1: Setting the Foundation: Navigating Ecosystem Enablers for IVD Production.	09:00 – 09:30	Welcome Remarks
	09:30 – 09:45	Agenda overview
	09:45 – 10:15	Overview of Technology Transfer in IVD Manufacturing
	10:15 – 11:30	Initiatives Supporting IVD Manufacturers
	11:30 – 12:00	Break (30min)
	12:00 – 12:30	Understanding Demand Signals for IVDs in Africa
	12:30 – 13:00	Market Access Considerations for IVD Manufacturers
	13:00 – 14:00	Lunch (1:30 hr)
	14:00 – 14:30	Procurement Enablers : Region and Global Procurement Pathways
	14:30 -15:00	Regulatory Sessions
	15:00 – 15:30	Break (30 min)
DAY 2: Executing Technology Transfer: Assessing Readiness, Operational and Quality Considerations	09:00-9:45	Assessing Technology Transfer Readiness: Compatibility and Fit
	9:45-10:30	Technology Transfer Agreements: Key Considerations for Manufacturers
	10:30 – 11:00	Break (30 min)
	11:00-12:00	Practical Exercise: Identifying Risks and Success Factors in Technology Transfer
	12:00 – 12:30	Quality Management System Readiness for Technology Transfer
	12:30 – 14:00	Lunch (1:30 hr)
	14:00 – 14:45	Planning and Executing a Technology Transfer
	14:45 – 15:30	Quality Control Foundations for Successful Technology Transfer
	15:30 – 16:00	Break (30min)
DAY 3: Generating Evidence for Regulatory Submission	09:00-9:45	Verification and Validation Plan
	09:45-10:30	Analytical Studies for Regulatory Submission
	10:30 - 11:00	Break (30 min)
	11:00 - 11:45	<i>Practical exercise: Applying Analytical Study Considerations to a Case Example</i>
	11:45-12:30	Clinical Studies for Regulatory Submission
	12:30 – 14:00	Lunch (1:30 hr)
	14:00-14:45	<i>Practical exercise: Reviewing a Clinical Study Scenario</i>
	14:45-15:30	Building a Regulatory Roadmap for IVDs
	15:30 - 16:00	Break (30 min)
DAY 4: Navigating the Regulatory Landscape for IVD Technology Transfer.	09:00-09:45	WHO Prequalification and ERPD
	09:45 -10:30	Collaborative Registration Procedure
	10:30 – 11:00	Break (30min)
	11: 30-12:15	Continental Listing Procedure for IVDs
	12:15 – 13:00	<i>Practical exercise: Preparation of regulatory submission (TT specific case study)</i>
	13:00 – 14:00	Lunch (1:30 hr)
	14:00-15:00	<i>Panel Discussion – Technology Transfer in Practice – perspectives from regulators</i>
	15:00-15:30	Closing

ANNEX: Description of thematic areas to be covered in the workshop

1. **Overview of key initiatives that aim to support locally manufactured products** across the technology value chains (from technology transfer, production scale-up, regulatory, market access and uptake enablers).
2. **Access considerations to guide selection of technologies:** The session will highlight how aligning health needs with sustainable market opportunities can inform decisions on which technologies to prioritize for technology transfer. Speakers will provide practical insights on how manufacturers can develop manufacturing strategies guided by assessment of public health priorities, demand signals, market access conditions, and procurement dynamics.
3. **Assessing technology transfer readiness:** An overview of different technology transfer models (e.g. contract manufacturing, partial manufacturing, end-to-end production) and considerations when engaging R&D institutions compared to established manufacturers. Discussions will cover what manufacturers should critically assess before committing to agreements, including:
 - The maturity and robustness of the product;
 - Infrastructure, facility, and equipment requirement to absorb the technology;
 - Staffing profiles and skills (engineering, QC, RA, production) requirement to implement the potential technology transfer; and
 - Supply chain considerations.
4. **Considerations for technology transfer agreements:** This session will examine key elements of technology transfer agreements, including:
 - Level of technical guidance to be provided by technology giver;
 - Roles and responsibilities of the technology provider and recipient; and
 - Access to data to support initial implementation phase.
5. **Quality management system readiness for technology transfer:** This session will examine how quality considerations should be embedded throughout the technology transfer process. Topics will include:
 - Quality management systems for IVD manufacturing (including ISO 13485);
 - Aligning transferred processes, documentation, and controls with an existing QMS; and
 - Change management during and after transfer.
6. **Planning and executing a technology transfer:** This session will focus on how manufacturers can translate a technology transfer agreement into a practical and achievable implementation plan. Topics discussed include:
 - Key elements of a realistic technology transfer plan;
 - Transferring know-how and training requirements;
 - How to conduct a risk analysis;
 - Strengthening QC and QMS capabilities;
 - Validation, verification, and process control; samples acquisitions/planning; and
 - Planning and generating data (analytical and clinical data).
7. **Regulatory alignment:** This session will be facilitated with the support of regulators and is aimed to provide manufacturers with tools/resources to develop a regulatory roadmap as a critical activity of the technology transfer process. Topics to be covered include:
 - Overview of regulatory submission pathways (WHO PQ/eRPD and Continental listing);
 - Interaction between WHO PQ and national regulatory processes;
 - Key regulatory consideration technology transferred products; and
 - Discussions on consideration for regulator dossier submission.