

Workshop for African manufacturers of HIV RDTs: from QA to procurement

1 to 3 July 2024

Radisson Blu Hotel, Kigali, Rwanda

1. Background:

In response to the urgent need for substantial action required to achieve the relevant Sustainable Development Goals, the Africa CDC, AUDA-NEPAD, FIND, Global Fund, PATH, Unitaid, PEPFAR/USAID and the World Health Organization (WHO) are working towards scaling up the access to key health commodities, including HIV RDTs, in the African region.

2. Objectives:

The aim of this workshop is to provide manufacturers of HIV RDTs based in Africa with a comprehensive set of information on WHO prequalification and the Expert Review panel, new product introduction implications on national testing algorithms, donors' perspectives on manufacturing in the African region, support projects available to manufacturers and experience from local manufacturers.

3. Agenda:

DAY 1 : REGIONAL PERSPECTIVE AND QUALITY ASSURANCE OF HIV RDTs		Chair I Prat, WHO
9:00 - 9:30	Welcoming remarks 1. Introduction and tour de table 2. Meeting objectives and expected outcomes 3. Housekeeping information	WHO CO Rwanda WHO HQ
9 :30 – 9 :45	4. WHO AFRO perspective on regional manufacturing of HIV RDTs	WHO AFRO
9 :45 – 10 :00	5. AUDA-NEPAD perspective on regional manufacturing of HIV RDTs	<i>AUDA-NEPAD TBC</i>
10 :00 – 10 :15	6. Africa CDC perspective on regional manufacturing of HIV RDTs	<i>Africa CDC TBC</i>
10 :15 – 10 :30	7. Regulation and regional harmonization highlights	P Wairimu, AMDF

10 :30 – 11 :00	<i>Tea and coffee break</i>	
11 :00 – 11 :30	8. Overview of WHO PQDx	I Prat, WHO
11 :30 – 12 :00	9. PQDx Technical Specifications for HIV RDTs	U Ströher, WHO
12 :00 – 12 :30	10. PQDx product dossier assessment: Overview of process and key principles	S Braniff, WHO
12 :30 – 13 :30	<i>Lunch break</i>	
13 :30 – 13 :45	11. PQDx performance evaluation	A-L Page, WHO
13 :45 – 14 :15	12. Site inspection	TBD, WHO PQT/INS
14 :15 – 14 :30	13. Changes to PQ-ed IVDs	F Gruszka, WHO
14 :30 – 15 :00	14. Preparing for PQ assessment	S Braniff, WHO
15:00 – 15:30	<i>Tea and coffee break</i>	
15 :30 – 16 :00	15. Quiz and Q&A	Chaired by I Prat, WHO
16 :00 – 16 :45	16. ERPD	TBD, Global Fund
16 :45 – 17 :15	17. Getting ready to submit for ERPD: useful tips	F Gruszka, WHO
17 :15 – 17 :30	18. Day 1 Wrap Up	WHO RO/CO

DAY 2 : MANUFACTURERS' SUPPORT PROJECTS AND PROCUREMENT		Chair : TBD, WHO RO
9 :00 – 9 :15	19. Introduction to day 2	TBD, Unitaïd
9 :15 – 9 :45	20. Technology transfer: key principles and HTAP project	TBD, WHO
9 :45 – 10 :30	21. HIV testing algorithms and new product introduction	C Lastrucci, WHO
10:30 – 11:00	<i>Tea and coffee break</i>	
11 :00 – 12 :30	22. Donors' perspective on HIV RDTs manufactured in Africa and procurement <ul style="list-style-type: none"> • Unitaïd 20 min • Global Fund 20 min • USAID 20 min • Q&A 30 min 	TBD, Unitaïd TBD, Global Fund TBD, USAID
12:30 – 13:30	<i>Lunch</i>	

		Chair : TBD, USAID
13 :30 – 15 :00	23. Manufacturers' support projects : <ul style="list-style-type: none"> • WHO LPA (30 min) • FIND (30 min) • PATH (30 min) 	TBD, WHO LPA J. Piton, FIND N. Agarwal, PATH
15:00 – 15:30	<i>Tea and coffee break</i>	
15 :30 – 16 :10	24. AUDA-NEPAD support to regional manufacturing (20 min) 25. Africa CDC support to regional manufacturing (20 min)	TBD, AUDA-NEPAD TBC TBD, ACDC TBC
16 :10 – 16 :50	26. Manufacturers' experience : <ul style="list-style-type: none"> • Manufacturer 1 (20 min) • Manufacturer 2 (20 min) 	TBD, Manufacturer 1 TBD, Manufacturer 2
16 :50 – 17 :20	27. Q&A	
17 :20 – 17 :30	28. Day 2 wrap up	TBD, USAID

DAY 3		
9 :00 – 17 :00	29. Face-to-face meetings with : <ul style="list-style-type: none"> • WHO PQ • WHO LPA • WHO HTAP • Global Fund • Unitaid • USAID • PATH • FIND 	All manufacturers as per pre-agreed schedule
10 :30 – 11 :00	<i>Tea and coffee break</i>	
12 :30 – 13 :30	<i>Lunch</i>	
15 :00 – 15 :30	<i>Tea and coffee break</i>	
17 :00	End of meeting	