

Workshop for Asian manufacturers of IVDs: from QA to procurement

20 to 23 January 2025

Westin Jakarta Hotel, Jakarta, Indonesia

DAY 1 : WHO TESTING GUIDELINES, DONORS' PERSPECTIVES ON LOCAL PRODUCTION AND PROCUREMENT		Chair S Braniff, WHO
9:00 - 9:30	<ol style="list-style-type: none"> 1. Welcoming remarks 2. Introduction and tour de table 3. Meeting objectives and expected outcomes 4. Housekeeping information 	WR, CO Indonesia I Prat, WHO
9 :30 – 10 :00	5. WHO WPRO perspective on regional manufacturing of IVDs	TBD, WHO WPRO
10 :00 – 10 :30	6. WHO SEARO perspective on regional manufacturing of IVDs	TBD, WHO SEARO
10 :30 – 11 :00	<i>Tea and coffee break</i>	
11 :00 – 11 :30	7. WHO guidelines : HIV testing guidelines	TBD, HHS/HIV pre-recorded
11 :30 – 12 :00	8. WHO guidelines : TB testing guidelines	TBD, WHO/GTB pre-recorded
12 :00 – 12 :30	9. WHO guidelines : malaria testing guidelines	TBD, WHO/GMP pre-recorded
12 :30 – 13 :30	<i>Lunch break</i>	
13 :30 – 14 :00	10. WHO guidelines : STIs testing guidelines	TBD, HHS/STI pre-recorded
14 :00 – 14 :30	11. WHO guidelines : NCDs testing guidelines	TBD, WHO/NCD pre-recorded
14 :30 – 15 :00	12. WHO guidelines : NTDs testing guidelines	TBD, WHO/NTD pre-recorded
15:00 – 15:30	<i>Tea and coffee break</i>	
15 :30 – 17 :00	13. Donors perspectives on local manufacturing in Asia: <ul style="list-style-type: none"> • Gates Foundation • Unitaid 	M Yang, Gates Foundation TBD

	14. Q&A	Moderated by S Braniff
17 :00	15. Day 1 Wrap Up	S Braniff, WHO

DAY 2 : PREQUALIFICATION OF IVDs		Chair : I Prat, WHO
9 :00 – 9 :10	16. Introduction to day 2	I Prat, WHO
09 :10 – 10 :00	17. Overview of WHO PQDx	I Prat, WHO
10 :00 – 10 :30	18. PQDx product dossier assessment: Overview of processes and key principles	S Braniff, WHO
10 :30 – 11 :00	<i>Tea and coffee break</i>	
11 :00 – 12 :00	19. PQDx Technical Specifications	U Ströher, WHO
12 :00 – 12 :30	20. PQDx performance evaluations	A-L Page, WHO
12 :30 – 13 :30	<i>Lunch break</i>	
13 :30 -14 :15	21. PQDx site inspections	TBD, WHO
14 :15 – 14 :30	22. Labelling review	TBD, WHO
14 :30 – 15 :00	23. PQDx product dossier assessment: useful tips	S Braniff, WHO
15 :00 – 15 :30	<i>Tea and coffee break</i>	
15 :30 – 16 :00	24. Collaborative registration procedure for PQ-ed IVDs	S Braniff, WHO
16 :00 – 16 :30	25. Quiz on PQDx	S Braniff, WHO
16 :30– 17 :30	26. Q&A on PQDx	Moderated by I Prat, WHO
17 :30	27. Day 2 Wrap Up	I Prat, WHO

DAY 3 : EXPERT REVIEW PANEL FOR DIAGNOSTICS, SUPPORT TO MANUFACTURERS AND PROCUREMENT		Chair: TBD
9:00 – 9:10	28. Introduction to day 3	Day 3 chair TBD

	<ul style="list-style-type: none"> 32. Expert Review Panel for Diagnostics (ERPD): Global Fund/Unitaid coordinated ERPD ERPD for other IVDs Preparing for an ERPD submission: useful tips Q&A 	O Ducamp/D Karenye, Global Fund D Healy, WHO D Healy and F Gruszka, WHO
10 :30 – 11 :00	<i>Tea and coffee break</i>	
11 :00 – 12 :30	29. Manufacturers' support projects : <ul style="list-style-type: none"> WHO LPA (30 min) FIND (30 min) PATH (30 min) 	TBD TBD TBD
12 :30 – 13 :30	<i>Lunch</i>	
13 :30 – 14 :15	30. Manufacturers' support projects: lessons learnt – Panel discussion and Q&A	
14 :15 – 15 :00	31. Health technology transfer: principles and opportunities	TBD, WHO HTAP
15 :00 – 15 :30	<i>Tea and coffee break</i>	
15:30 – 17 :00	32. QA policy and procurement of IVDs: <ul style="list-style-type: none"> Global Fund USAID Q&A 	Moderated by I Prat, WHO
17 :00	Day 3 wrap up and end of workshop	I Prat, WHO

DAY 4: CLINIC FOR MANUFACTURERS		
9:00 – 10:30	33. Product dossier: case study 1	S Braniff, WHO
10 :30 – 11 :00	<i>Tea and coffee break</i>	
11 :00 – 11 :45	34. ERPD case study	D Healy, WHO and O Ducamp/D Karenye Global Fund
11:45 – 12:30	35. Inspection case study	TBD, WHO
12 :30 – 13 :30	<i>Lunch</i>	

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