World Health Organization

Workshop for Asian manufacturers of IVDs: from QA to procurement

20 to 22 January 2025

Westin Jakarta Hotel, Jakarta, Indonesia

DAY 1 : WHO TESTING GUIDELINES, DONORS' PERSPECTIVES ON LOCAL PRODUCTION AND PROCUREMENT, ACCELERATING ACCESS TO MARKETS (COLLABORATIVE REGISTRATION AND RISK-BASED REVIEWS)		**Chair** **S Braniff, WHO**
8:00 – 9:00	Participants registration	
9:00 – 9:30	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 strengthening diagnostic capacity	J Shin, WHO WPRO
10:00 – 10:30	6. WHO SEARO perspective on regional manufacturing of IVDs	M Shirdhar, WHO SEARO
10 :30 – 11 :00	*Tea and coffee break*	
11:00 – 11:30	7. WHO guidelines : HIV testing guidelines	P Jolivet, WHO/HHS pre-recorded
11:30 – 12:00	8. WHO guidelines: STIs testing guidelines	I Maatouk, WHO/HHS pre-recorded
12:00 – 12:30	9. WHO guidelines: Hepatitis testing guidelines	N Luhmann, WHO/HSS pre-recorded
12 :30 – 13 :30	*Lunch break*	
13:30 – 14 :30	10. Donors perspectives on access and local manufacturing in Asia, QA policy and demand forecast: • BMGF: Enable access to the highest impact diagnostics for 1B people • Global Fund: QA policy for IVDs • Global forecasts of diagnostic demand for HIV, Hepatitis.	M Yang, BMGF O Ducamp, Global Fund B Dongmo Nguimfack, WHO

	11. Collaborative registration procedure for prequalified IVDs	S Braniff, WHO
14:30 – 15:00	Panel discussion, Q and A	Moderated by S Braniff
15:00 – 15:30	*Tea and coffee break*	
15:30 – 17 :00	12. Introduction to Expert Review Panel for Diagnostics: background, partners, expectations and case study 13. WHO Emergency Use Listing Procedure for IVDs	D Healy and F Gruszka, WHO and O Ducamp, Global Fund U Ströher, WHO
17:00 – 17:30	14. Q and A and Day 1 Wrap Up	S Braniff, WHO

DAY 2 : PREQUALIFICATION OF IVDs		**Chair : I Prat, WHO**
9:00 – 9:10	15. Introduction to Day 2	I Prat, WHO
9:10 – 10:00	16. Overview of WHO PQDx	I Prat, WHO
10:00 – 10:30	17. PQDx product dossier assessment: Overview of processes and key principles	S Braniff, WHO
10:30 – 11:00	*Tea and coffee break*	
11:00 – 11:45	18. PQDx Technical specification and Technical guidance series	U Ströher, WHO
11:45 – 12:30	19. PQDx performance evaluations	A-L Page, WHO
12:30 – 13:30	*Lunch break*	
13:30 – 14:15	20. PQDx site inspections	K Richards, WHO
14:15 – 14:30	21. Labelling review	I Prat, WHO
14:30 – 15:00	22. PQDx product dossier assessment: useful tips	S Braniff, WHO
15:00 – 15:30	*Tea and coffee break*	
15:30 – 16:15	23. TSS/TGS deep dive	U Ströher, WHO
16:15– 17:30	24. Interactive quiz on PQDx 25. Q&A	S Braniff, WHO Moderated by I Prat, WHO
17:30	26. Day 2 Wrap Up	I Prat, WHO

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DAY 3 : WHO GUIDELINES, HEALTH TECHNOLOGY TRANSFER AND PQ CASE STUDIES		Chair: I Prat
9:00 – 9:10	27. Introduction to Day 3	I Prat, WHO
9:10 – 10:30	28. Health technology transfer: principles and opportunities	C Mpande, WHO
10:30 – 11:00	*Tea and coffee break*	
11:00 – 11:30	29. WHO guidelines: TB testing guidelines	P Hall, WHO/GTB pre-recorded
11:30 – 12:00	30. WHO guidelines: malaria testing guidelines	J Cunningham, WHO/GMP pre-recorded
12:00 – 12:30	31. WHO guidelines: NCDs testing guidelines	A Cieza, WHO/NCD pre-recorded
12:30 – 13:30	*Lunch break*	
13:30 – 14:00	32. WHO guidelines: NTDs testing guidelines	D Dagne, WHO/NTD pre-recorded
14:00 – 14:30	33. Overcoming challenges for improved global access to quality diagnostic tools	D Boyle, PATH
14:30 – 15:00	34. PQ Changes – introduction to new guidance/case study	F Gruszka, WHO
15:00 – 15:30	*Tea and coffee break*	
15:30 – 16:15	35. Dossier case study	S Braniff, WHO
16:15 – 17:00	36. Q and A	
17:00	Day 3 wrap up and end of workshop	I Prat, WHO

END