

DRAFT AGENDA: WHO Prequalification Workshop for Manufacturers of IVDs
8 to 10 June 2026
WHO Geneva, SALLE C

DAY 1 : The Prequalification process for IVDs		Chair I Prat, WHO
8:00 – 9:00	Participants registration	
9:00 – 9:20	1. Welcoming remarks 2. Introduction and tour de table 3. Meeting objectives and expected outcomes 4. Housekeeping information	PQ Unit Head, WHO I Prat, WHO
9:20 – 10:00	5. Overview of Prequalification Procedure for IVDs	I Prat, WHO
10:00 – 10:30	6. Applying for WHO's PQ Assessment	TBD
<i>10 :30 – 11 :00</i>	<i>Tea and coffee break</i>	
11:00 – 11:30	7. WHO's Performance Evaluation	A-L Page, WHO
11:30 – 12:10	8. PQ Guidance documents: Overview of Technical specification and Technical guidance series	S Braniff, WHO
12:10 – 12:30	9. Panel discussion, Q and A	Moderated by I Prat, WHO
<i>12 :30 – 13 :30</i>	<i>Lunch break</i>	
13:30 – 14 :15	10. PQDx product dossier assessment: Overview of processes and key principles	S Braniff, WHO
14:15 – 15:00	11. Case study: product stability	S Braniff, WHO
<i>15:00 – 15:30</i>	<i>Tea and coffee break</i>	
15:30 – 17 :00	12. Site Inspection 13. Labelling review	TBD C Chiku, WHO
17:00 – 17:30	14. Q and A and Day 1 Wrap Up	I Prat, WHO

DAY 2 : Assessment of Product Dossier and Change Requests		Chair : I Prat, WHO
9:00 – 9:10	15. Introduction to Day 2	I Prat, WHO
9:10 – 10:30	16. Guidance for preparing a product dossier 17. Case study : Label comprehension	S Braniff, WHO
<i>10:30 – 11:00</i>	<i>Tea and coffee break</i>	
11:00 – 11:45	18. Case study : Flex studies	S Braniff, WHO

11:45 – 12:30	19. Debrief of case study, Q and A 20. Common problems in product dossiers	S Braniff, WHO
12:30 – 13:30	<i>Lunch break</i>	
13:30 – 15 :00	21. Overview of Change Request assessment 22. Case study : Change request	F Gruzska, WHO
15:00 – 15:30	<i>Tea and coffee break</i>	
15:30 – 16:45	23. Case study : Change request 24. Debrief of case studies, Q and A	F Gruzska, WHO
16 :45 - 17:00	25. Day 2 Wrap Up	I Prat, WHO

DAY 3 : Expert Review Panel for Diagnostics (ERPD), Emergency Use Listing (EUL), Collaborative Registration Procedure (CRP) and next steps for PQ		Chair: I Prat, WHO
9:00 – 9:10	26. Introduction to Day 3	I Prat, WHO
9:10 – 10:30	27. Introduction to Expert Review Panel for Diagnostics: background, partners, expectations 28. ERPD Case Study	D Healy, WHO
10:30 – 11:00	<i>Tea and coffee break</i>	
11:00 – 11:30	29. ERPD Case Study debrief	D Healy, WHO
11:30 – 12:00	30. Overview of WHO EUL Procedure	S Braniff, WHO
12:00 – 12:30	31. Panel discussion, Q and A	Moderated by I Prat, WHO
12:30 – 13:30	<i>Lunch break</i>	
13:30 – 14:00	32. PQ Interactive Quiz	D Healy, WHO
14:00 – 14:30	33. WHO Public Reports	C Chiku, WHO
14:30 – 15:00	34. Collaborative Registration Procedure	S Braniff, WHO
15:00 – 15:30	<i>Tea and coffee break</i>	
15:30 – 16:00	35. Next steps for WHO Prequalification 36. Q and A	I Prat, WHO Moderated by I Prat, WHO
16:00 – 16:30	37. Day 3 wrap up and end of workshop	I Prat, WHO

END