



19 June 2026

Draft agenda Annex 22 Expert Workshop - Day 1 Session with Interested Parties

Meeting Time and date: 09:00 CET – 18:00 CET 30th June 2026.

Virtual Teams Meeting + Web Broadcast + Room 0B

Chair: R. Conocchia

Item	Preliminary draft agenda	Initials	Mins
1.	Opening of the meeting Welcome from the Meeting Chair Welcome from Chair GMDP IWG Welcome from Chair QIG Welcome from Rapporteur Annex 22 Drafting Group Opening comments from industry	Roberto Conocchia (EMA) Brendan Cuddy (EMA) Marcel Hoefnagel (MEB) Ib Alstrub (DKMA) Lori Otto (EFPIA)	09:00-09:30
2.	Agenda Review and aim of the meeting	RC	09:30-09:40
3.	Topic 1: Regulatory Pathways for Adaptive/probabilistic AI models in GMP	Michael Schousboe (EFPIA)	09:40-10:20
4.	Q&A on topic 1	all	10:20-10:40
5.	Topic 5: Strategic Risk & Compliance Limits	Volkan Kocak (EFPIA)	10:40-11:20
6.	Q&A on topic 5	all	11:20-11:40



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7.	<i>Coffee Break</i>	all	11:40- 11:55
8.	Topic 3: Human Oversight & Accountability	Andrea Kurz (EFPA)	11:55- 12:30
9.	Q&A on topic 3	all	12:30- 12:50
10.	<i>Lunch Break</i>	all	12:50- 13:50
11.	Topic 2: Technical Reliability & Incident Response	Toni Manzano (PDA)	13:50- 14:50
12.	Q&A on topic 2	all	14:50- 15:10
13.	Topic 4: Validation & Lifecycle Management	Martin Heitmann (ISPE)	15:10- 16:25
14.	Q&A on topic 4	all	16:25- 16:45
15.	<i>Coffee Break</i>	all	16:45- 17:00
16.	Topic 6: Cybersecurity and Outsourced activities	Toni Manzano (PDA)	17:00- 17:25
17.	Q&A on Topic 6	all	17:25- 17:45
18.	Next Steps	RC	17:45- 17:50
19.	Closing Remarks Closing remarks from the chair Closing remarks from industry	RC Gert Thurau and Linda Wilding	17:50- 17:55 17:55- 18:00
20.	Meeting End.	RC	18:00