

EPiC Auditors Virtual Symposium 2023

Beyond the Basics: Mastering GMDP Compliance and Inspection Readiness

AGENDA

Tuesday 5th December 2023 (09:00 to 17:00 GMT)

START TIME – END TIME	SESSION
09:00 – 09:10 (10 mins)	Welcome and Introductions (Richard Andrews)
9:10 – 9:30 (20 mins)	Recent Updates to Guidance & Regulations (Richard Andrews)
9:30 – 10:10 (40 mins)	Inspection Readiness: How do you know you are MHRA inspection ready? (Michelle Yeomans)
10:10 – 10:50 (40 mins)	MHRA Deficiency Data: Interpretation and Root Cause Analysis (Lewis Corbett)
10:50 – 11:10 (20 mins)	Coffee Break
11:10 – 11:40 (30 mins)	Innovation and ATMP : Panel Discussion (Richard Andrews, Ian Rees & Philip Rose)
11:40 – 12:30 (50 mins)	Annex 1 – Contamination Control Strategy (CCS) Gap Assessment – Part 1 (Darren Jones & Philip Rose)
12:30 – 13:30 (1 hour)	Lunch
13:30 – 14:10 (40 mins)	Annex 1 – Contamination Control Strategy (CCS) Gap Assessment – Part 2 (Darren Jones & Philip Rose)
14:10 – 14:50 (40 mins)	Risk Assessment and the Application of ICH Q9(R1) (Lewis Corbett & Richard Andrews)
14:50 – 15:10 (20 mins)	Coffee
15:10 – 15:50 (40 mins)	GDP Masterclass – An Expert’s view on current Challenges and Opportunities (Tony Orme)
15:50 – 16:20 (30 mins)	Q&A Panel Session
16:20 – 16:30 (10 mins)	Closing Remarks (Richard Andrews)