ICMRA 2023 SUMMIT MELBOURNE

ICMRA Session 3 – Advanced Medical Products

Tuesday November 14, 2023 14:00 – 15:40

Co-chairs: MHRA (Dame June Raine) and PMDA (Dr Yasuhiro Fujiwara)

Theme: What have we learnt from the regulatory journey so far, and where are we going?

Time*	Presentation topics	Speaker(Reg Agency)
14:00 – 14:05	Opening Remarks Set the scene – introduce topic and order of session	Co-chairs
14:05 – 14:25	Pre-clinical focus Stem cell technology What are the regulatory challenges from a non-regulator perspective?	Prof Melissa Little, AC Chief Scientist, Group Leader (Kidney Regeneration) Murdoch Children's Research Institute
14:25 – 14:30	The challenges of Gene Therapy	Dr Tony Gill (TGA)
14:30 – 14:40	Focus on Product Quality – how is quality assured and monitored for these products? manufacture – models outside of standard manufacturing models; including point of care, home based, mobile etc. Challenges, controls and regulatory approaches – what is likely to come? What framework change is required? (legal framework updates, links with other regulators e.g hospitals, health professionals) An opportunity to develop internationally harmonised guidelines from the inception	Dr Ian Rees previously Manager for the Inspectorate Strategy and Innovation Unit (MHRA)
14:40 – 14:50	Regulatory decision making Clinical trial design Balancing risks Future proposal for advanced therapies	Dr Yasuhiro Fujiwara - Chief Executive of Pharmaceuticals and Medical Devices Agency (PMDA)
14:50 – 15:00	The role of real-world evidence and observational studies	Turki Bin Hammad - Epidemiologist – Team lead methodology and biostatistics (Saudi FDA)

	Data sharing and advanced therapies registry development (international repository)	
15:00 – 15:05	The promise and the challenges of advanced/gene therapies for LMICs	Moji Christianah Adeyeye, PhD, FAS Director-General (NAFDAC)
15:05-15:35	Panel Discussion – Open Q&A for speakers	All
15:35 – 15:40	Closing remarks Session outcome - where to from here - in a global collaborative sense? What does this mean for regulators? For ICMRA?	Co-chair(s)