Date: 27 March 2023 (Monday)
Venue: Korea University Medicine

MEDICAL DEVICE REGULATORY

Time (SGT)	**Time (KST)**	Sub-Topic	**Speakers**
0800	0900	Registration	
0830	0930	Opening	• IL-HO PARK, Director for office of Clinical Trials of Korea University Medicine • Song Kwok Yuen , Director, School of Engineering, Temasek Polytechnic. • May Ng , CEO of ARQon Group • Dae Hee Hong, CEO of Mediguide
0900	1000	The role of Industry Associations and partners in regulatory convergence and healthcare innovation • The effective network of industry associations across the ASEAN, ASIA, EU, US, GLOBAL • The importance of association's role for its stakeholders i.e. local industry and the national authorities/agencies	• Gabriel Sim, APACMed • May Ng, ARQon & ATTOPOLIS • Marc Perut, Swiss Ventures • Hakan, Requalite Europe • Dae Hee Hong, CEO of Mediguide
0945	10:45	Clinical trial for Innovation Products • What are funding available and criteria • Single or Multi-centre trial • Plan and conduct of Clinical trial • Differences between Clinical trial vs clinical evaluation	• Dong Ho, Hong, Mediguide
1030	1130	Tea Break	
1045	1145	The trends of Medical Device Industry in Korea	• Dae Hee Hong, CEO of Mediguide
1115	1215	APAC regulatory requirements - South Korea	• Chan Yo (CY) Won, Mediguide and ARQon Korea
1140	1240	APAC regulatory requirements - ASEAN, Greater China	• May Ng, ARQon Group
1200	1300	Lunch	
1300	1400	MDR & IVDR CE mark regulatory requirements – Introduction & Conformity assessment Routes • MDD and the New MDR, Other related Directives eg Combination products • IVDD and the New IVDR • Conformity assessment routes for CE Marking • Post Market: Vigilance, PMPF, PMCF, PSUR • Further changes eg Eudamed, Clinical Evaluation	• Hakan, Requalite Europe
1345	1445	Korea Q&A	
1400	1500	End of IMDS KR	