18th International Conference of Drug Regulatory Authorities
Dublin, Ireland | 3–7 September 2018

"Smart Safety Surveillance – a life-cycle approach to promoting safety of medical products"

Pre-ICDRA (open)				
	Monday **September 3**		**Tuesday** **September 4**	
08:00-09:00	**Registration**			
09:00-10:30	**Plenary 1:** Smart Safety Surveillance – a shared responsibility: moderated panel discussion		**Workshop 5:** Enabling access to innovative medical products in resource-limited settings	**Workshop 6:** Changing procurement models: maintaining safety and quality of medical products
Coffee				
11:00-12:30	**Plenary 2:** Regulatory collaboration, convergence and harmonization: "transfer" of regulatory information		**Workshop 7:** Local production of medical products: regulators' role	**Workshop 8:** Regulation of advanced therapies
Lunch				
14:00-15:30	**Workshop 1:** Regulatory preparedness for public health emergencies	**Workshop 2:** Certification of Pharmaceutical Products: is it still "fit for purpose" in a modern environment?	**Workshop 9:** Progress in regulation of medical devices (including IVDs)	**Workshop 10:** Regulation of biosimilars
Coffee				
16:00-17:30	**Workshop 3:** Global Benchmarking of Regulatory Systems: from individual countries to networks	**Workshop 4:** Risk-based inspections: potential for work-sharing	**Plenary 3:** Partnerships to enhance better regulatory outcome	
18:00-20:00	**Pre-ICDRA Welcome Reception**		**ICDRA Welcome Reception**	

ICDRA (regulators only)					
	Wednesday September 5	**Thursday September 6**		**Friday September 7**	
08:00-09:00	**Registration**				
09:00-10:30	**Plenary 1:** Opening Ceremony: - WHO HQ - Key note speaker - WHO EURO	**Plenary 4:** WHO strategic approaches to improving access to safe medical products		**Plenary 5:** Safety of medical products throughout the product life cycle: moderated panel discussion	
Coffee					
11:00-12:30	**Plenary 2:** 17th ICDRA recommendations: how well are we doing?	**Workshop 1:** Benchmarking of Regulatory Systems: towards mature regulatory systems	**Workshop 2:** Regional regulatory networks: progress and challenges	**Workshop 7:** Harmonization, work-sharing and reliance in pharmacovigilance	**Workshop 8:** Promoting medical products safety: supply chain integrity
Lunch	**12:30-13:15**	**12.30-14:00**	**12.30-14:00**	**12.30-14:00**	
	13:15 – 14:45	**14:00 - 15:30**	**14:00 - 15:30**	**14:00 - 15:30**	
	Plenary 3: Future direction of WHO Prequalification Programme: moderated panel discussion	**Workshop 3:** Safety of blood and blood products	**Workshop 4:** Regulators role in containing antimicrobial resistance	**Break-out session:** Consolidation of pre-ICDRA and ICDRA recommendations	
				Group 1	**Group 2**
Coffee	**City tours Starting at 14:45**				
16:00-17:30		**Workshop 5:** Regulation of clinical trials: focus on patient safety	**Workshop 6:** Does facilitated registration accelerate access?	**Plenary 6:** 18th ICDRA recommendations (reporting back from the break-out session) Closing	
18:00-20:00		**Gala Dinner**			