KMDIA Virtual Seminar

- Advancement of Global Medical Device Regulation: Cybersecurity -

Preamble:

• Ministry of Food and Drug Safety(MFDS) has launched Korea IMDRF Working Groups since 2019 to increase its capability for adoption of IMDRF documents by sharing work of IMDRF with industry and academy in Korea. The Korea IMDRF Working Groups are composed of industry, academia, NBs, and etc.: most of members from industry are also KMDIA members.

Seminar Objectives:

• Promote active participation of Korea IMDRF Working Groups in the work of IMDRF and global regulatory harmonization & convergence by introducing DITTA's Working Groups

• Provide KMDIA members with an opportunity to expand their global network, raising KMDIA's competitiveness and creditability

• Provide the Korea IMDRF WGs with IMDRF related information and updates

Program Overview:

• **Date & Time/Venue:** Thursday 29 July 2021, 13:00(KST) / Webinar(Zoom)

• **Zoom link:**

https://us06web.zoom.us/j/84475533999?pwd=WnBDaHN1bjZ3MGFIUUdUbWFpQjk0UT09

ID: 844 7553 3999 / Password: 049115

※ Please join this webinar for free. No registration required.

• Program

Time		Content	Note
13:00~13:05	5’	Opening Remarks	KMDIA Chairman **Cheolwook Yoo**
13:05~13:10	5‘	Greeting Message	DITTA Chair **Masaaki Ohtsuka**
Part 1: Introduction and Current Trend			
13:10~13:50	40‘	- Introduction of DITTA WGs :10 WGs	DITTA Secretary **Uchiyama Susumu**
		- Introduction of DITTA Cybersecurity WG ・ Objectives and mission of the WG, IMDRF collaborative work, DITTA's contribution to IMDRF, and etc. ・ Outline and summary of IMDRF Cybersecurity guideline ・ DITTA's ‘Cybersecurity’ Whitepaper - Current trend of cybersecurity in the global industry(e.g. prospective view, future trend, etc.)	FUJIFILM **Keiichiro Ozawa**
		- Introduction of Korea IMDRF WGs: 12 WGs	KMDIA **Sunny Woo** Manager
		- Introduction of Korea IMDRF Cybersecurity WG ・ Objectives and mission of the WG, IMDRF collaborative work, contribution to MFDS/IMDRF, and etc. - Current trend of cybersecurity in the Korean industry	Cybersecurity WG Chair **Keunhee Han** Professor, Korea University

Part 2: Exchange of Views			
13:50~14:30	40‘	**1. What are we doing to make devices more secure and prevent cyber attacks?**	
		(1) International Standards - Latest developments in international standards on cybersecurity	Philips **Ben Kokx**
		(2) Industry - Root causes and threats in the medical device industry - Responses to current and potential threats - The roles engineers and manufacturers play in cybersecurity	DITTA: Bayer **Ken Zalevsky** KMDIA: H3 System **Min-joon Kim** CEO
		(3) Regulatory authorities: MFDS - Current update on Korea’s regulations of cybersecurity in medical devices - The roles regulators play in cybersecurity	MFDS Digital Health Device TF **Hyunsoo Kim** Assistant Director
		(4) Healthcare providers - Root causes and threats in the healthcare providers - Responses to current and potential threats - The roles healthcare providers play in cybersecurity	KMDIA: Seoul National University Bundang Hospital **Yeonsoo Hwang** CISO (Chief Information Security Officer)

		2. **Who is responsible to secure cybersecurity of medical devices throughout the life cycle and how do we collaborate?**	All speakers of Part 2
Part3: Q&A			
14:30~14:35	5‘	Q&A	
14:35~14:40	5‘	Closing Remarks	KMDIA Vice Chair **Myung-jung Kim**

* If a speaker is not available for the live presentation due to the time difference, the presentation will be recorded beforehand to play the recording at the time of the webinar.

[Note]

IMDRF WGs vs. Korea IMDRF WGs vs. DITTA WGs

IMDRF WG	Korea IMDRF WG	DITTA WG
RPS	RPS	Regulated product submission
PMD	PMD	-
IVDD	IVDD	-
GRRP	GRRP	-
Standards	Standard	Regulations & Standards / Standardisation
SaMD	SaMD	Medical Software & Artificial Intelligence
AIMD	AIMD	
AET	AET & NCAR	-
NCAR		
MDSAP	MDSAP	Medical device single audit program
CS	CS	Cybersecurity / Digital health & cybersecurity
MDCE	PR &CE	Clinical Evaluation
PR		
UDI	UDI	Unique device identification
		Good refurbishment practice
		Global health
		Environmental policy