DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

IMDRF / DITTA

Joint Virtual Workshop

UDI GLOBAL HARMONIZATION

TAKING PLACE DURING THE 20th MEETING OF IMDRF

GOTOWEBINAR REGISTER HERE!

WORKSHOP PROGRAMME & SPEAKERS OVERVIEW

THURSDAY 9 SEPTEMBER 2021

12:00 to 14:30 CET / 20:00 to 22:30 KST (Korea Standard Time) / 7:00 to 9:30 US EST

IMDRF/DITTA Joint Workshop on UDI

UDI Global Harmonization

Unique Device Identifiers (UDIs) serve important regulatory and supply chain functions for medical devices. They allow for tracking of devices throughout the global supply chain to the patient and provide global visibility to device adverse event reporting and a better means to perform post-market surveillance, thereby enhancing patient safety.

Increasingly, UDI requirements such as Device Identifier triggers (rules requiring creation of a new Device Identifier) are not globally harmonized which is causing a proliferation of Device Identifiers to be created and registered globally. It is also noted that jurisdiction-specific concepts exist such as 'Basic UDI-DI' and other developing concepts such as 'Master UDI-DI'.

The COVID-19 Pandemic has shown the importance of quickly distributing medical devices and of removing barriers to such market access. Harmonization of UDI is an opportunity to facilitate this distribution.

Now, more than two years since IMDRF published its UDI Application Guide. This is a good moment to assess the implementation of UDI in the regulations of the IMDRF member jurisdictions and to draw attention to ensure its harmonization.

Workshop Objectives

- Provide an overview of IMDRF work on UDI
- Better understand how the IMDRF UDI guidance documents are implemented in various jurisdictions
- Evaluate the experience of industry and other stakeholders when applying UDI for medical devices, including how UDI is used by healthcare providers
- Exchange views on how UDI can be better implemented towards global convergence

Workshop Attendance

Each person having registered has received a specific/individual link to connect (Check your spam box, just in case!)

Registration is closed as we reached the limit of 500 registered participants

Time zone table

Thursday, 9 September 2021, 20:00 Korea Standard Time (KST)

Australia	AEST	21:00
Brazil	BRT	8:00
Canada	EST	7:00
China	CST	19:00
Belgium, France, Germany	CEST	13:00
Japan	JST	20:00
Russia	MSK	14:00
Singapore	SGT	19:00
South Korea	KST	20:00
Switzerland	CEST	13:00
UK	BST	12:00
USA	EST	7:00

Agenda

TIME ZONES			
CEST	KST	EST	
13:00	**20:00**	**7:00**	Welcome from DITTA Chair **Masaaki Ohtsuka**, *JIRA, DITTA Chair*
13:05	**20:05**	**7:05**	Opening Remarks **Oh-Sang Kwon**, *IMDRF Chair, Ministry of Food and Drug Safety, Korea*
13:10	**20:10**	**7:10**	Part 1 **Background and introduction to UDI and IMDRF guidance documents** Vision of a global UDI system, overview of elements/building blocks of UDI and IMDRF UDI guidance documents, N48 "UDI System Application Guide" and N53 "Use of UDI Data Elements across different jurisdictions". Moderator: **Chung-Keun Lee** Session 1 : Vision of a global UDI system 1. USA: **Erin Cutts**, *U.S. FDA* 2. EU: **Erik Hansson** Session 2 : IMDRF UDI Guidance Documents 1. USA: **Erin Cutts**, *U.S. FDA* 2. EU: **Nada Alkhayat** and **Orla Daly**, *European Commission* 3. Q&A
13:35	**20:35**	**7:35**	Part 2 **Implementation of UDI in different jurisdictions** How UDI is implemented or planned to implement in different jurisdictions, focused on regulatory systems to enable use of UDI and regional drivers of requirements and change triggers. Moderator: **Chung-Keun Lee** 1. Australia: **Michelle van Wijk**, *TGA* 2. Brazil: **Hélio Bomfim de Macêdo Filho**, *ANVISA* 3. Japan: **Kanako Sasaki**, *MHLW* 4. Q&A
14:10	**21:10**	**8:10**	Part 3 **UDI implementation and importance of harmonization for industry** Industry presentation on UDI implementation and importance of harmonization. What are issues with implementation and utilization of UDI for industry and hospitals? Moderator: **Sunny Woo**, *KMDIA, DITTA* 1. **Zita Yurko**, *Philips, DITTA* 2. **Tania Pearson**, *Medtronic, GMTA* 3. **Hee-kwon Son**, *Osstem Implant, KMDIA* 4. **Kevin Capatch**, *Geisinger Health System, USA* 5. Q&A
14:55	**21:55**	**8:55**	Part 4 **Panel discussion** Exchange views on how UDI can be better harmonized. Subtopics: 1) Harmonization of UDI Data element, 2) Harmonization of UDI DI trigger Moderator: **Annika Eberstein**, *COCIR, DITTA Vice Chair* 1. Panel discussion by the presenters of Part1, Part2 and Part3 2. Conclusion
15:20	**22:20**	**9:20**	Closing remarks • **Jeong-Rim Lee**, *Ministry of Food and Drug Safety, Korea* • **Annika Eberstein**, *COCIR, DITTA Vice Chair*

WELCOME & INTRODUCTION

Masaaki Ohtsuka

DITTA Chair and JIRA Secretary General

Masaaki Ohtsuka started his career as a software engineer of digital X-Ray systems in Japanese manufacturer. After that, He expanded his activities to project management and product planning.

From 2010 to 2014, he had worked as the division president of the global PACS development in the United States. In October 2020, He moved to Japan Medical Imaging and Radiological Systems Industries Association (JIRA), where he serves as Secretary General.

OPENING REMARKS

Oh-Sang Kwon

IMDRF Chair and Director General of the Medical Device Safety Bureau, MFDS

Oh-Sang Kwon joined the Ministry of Food and Drug Safety as of May 2013. He has been serving as the Director General of the Medical Device Safety Bureau, MFDS since this April. He now has been assuming the IMDRF 2021 Chairmanship since this June.
He received his master's degree in international development policy from the Sanford School of Public Policy at Duke University, USA and Bachelor's degree in philosophy from Korea University.

Part 1
Background and introduction to UDI and IMDRF guidance documents

Moderator

Chung-Keun Lee

Assistant Director, High-tech Medical Device Division, Medical Device Evaluation Department, National Institute of Food and Drug Safety, MFDS

Dr. Chungkeun Lee has served as a regulator (premarket reviewer) in the Ministry of Food and Drug Safety. He has a B.S in biomedical engineering and, a M.S and a Ph.D in Electric & Electronic Engineering from Yonsei University. As a post-doctoral scholar, he worked at cardiovascular division, Yonsei University Hospital. In November 2014, he joined the Medical Device Evaluation Department, MFDS. Since the he and has been reviewing medical electric device with high risk classification in premarket area. He has a keen interest about real world data and evidence, and regulatory science for medical devices.

United States

Erin Cutts

Center for Devices and Radiological Health (CDRH), U.S. FDA

Erin Cutts is an international policy analyst at FDA's Center for Devices and Radiological Health (CDRH). While at FDA, she has led various projects related to trade and international harmonization efforts including development of FDA's position on medical device nomenclature. She has also managed a variety of Center-wide programs including the Accreditation Scheme for Conformity Assessment (ASCA), which leverages internationally harmonized standards and conformity assessment practices. Erin's career began as a Research and Development Engineer at a medical device start-up company after which she joined FDA as scientific reviewer and then branch chief in the cardiovascular space. Erin holds a bachelor's degree in biomedical engineering from Georgia Tech.

EU

Erik Hansson

Former Deputy Head of the Medical devices and Health technology assessment unit of the DG for Health and Food safety (DG SANTE) of the European Commission

Erik joined the medical devices unit of the European Commission in 2012 to lead the implementation of the PIP Action plan, followed by the negotiations on the new Regulations. Erik has been responsible for several EU working groups (such as MDCG), has dealt with bilateral trade related issues in the sector and coordinated the cooperation with national Competent Authorities in the CAMD framework. He retired from the European Commission on 1 July 2021 and continues to head the EU delegation to the multilateral regulatory cooperation in IMDRF on behalf of the European Commission.

Erik received a Master degree in law from the University of Uppsala, Sweden, and held various positions in law courts and then in Swedish ministries and agencies coordinating preparations for EU-membership. Since joining the European Commission in 1997 Erik has mainly dealt with policies relating to the single market for goods as well as finance and strategic policy planning.

EU

Nada Alkhayat

European Commission

Nada Alkhayat is a pharmacist working as a Policy Officer at the European Commission's unit for Medical Devices and HTA. In her team, Nada holds a horizontal role in the implementation of the new medical devices regulations. She currently chairs the Medical Device Coordination Groups on New Technologies and Nomenclature and supports the work of the UDI and International groups. Her high interest areas include medical device software, Artificial intelligence and in vitro diagnostic medical devices. Prior to joining the Commission, Nada was a Regulations & Industrial Policy Officer at MedTech Europe and was interim VP at Junior Chambers International.

EU

Orla Daly ***European Commission***

Orla Daly has a legal and regulatory background, as a graduate of Law & French LL.B. (Trinity College Dublin) and MA graduate in Medical Ethics & Law (King's College London). She has previously worked on an independent government review in the UK and at London-based MedTech startups.

A Policy Assistant in the European Commission's unit responsible for Medical Devices and HTA, Orla is working on the implementation of the new Medical Devices and In vitro diagnostic Medical Devices Regulations. She currently chairs the Commission's Medical Device Working Groups on Market Surveillance and Unique Devices Identification and also works on international matters.

Part 2
Implementation of UDI in different jurisdictions

Moderator

Chung-Keun Lee

Assistant Director, High-tech Medical Device Division, Medical Device Evaluation Department, National Institute of Food and Drug Safety, MFDS

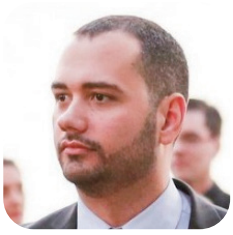
Dr. Chungkeun Lee has served as a regulator (premarket reviewer) in the Ministry of Food and Drug Safety. He has a B.S in biomedical engineering and, a M.S and a Ph.D in Electric & Electronic Engineering from Yonsei University. As a post-doctoral scholar, he worked at cardiovascular division, Yonsei University Hospital. In November 2014, he joined the Medical Device Evaluation Department, MFDS. Since the he and has been reviewing medical electric device with high risk classification in premarket area. He has a keen interest about real world data and evidence, and regulatory science for medical devices.

Australia

Michelle van Wijk

Therapeutic Goods Administration

Michelle van Wijk is the project manager for the UDI implementation in Australia. Michelle joined the TGA in 2019, having had previous roles in the private sector, including senior roles in management and IT consulting. Most recently, Michelle served as an executive partner with Gartner providing technical and strategic advice and insights to CIOs and other executives across the Asia Pacific Region.



Brazil

Hélio Bomfim de Macêdo Filho

ANVISA

Hélio Macêdo Filho is an Advisor at Anvisa's Medical Devices Office. He received his DSc. in Systems and Computer Engineering from the University of Rio de Janeiro in 2014. Systems Analyst (2008-2010), Researcher in Telecommunications (2010-2014), and Professor of Computer Science (2015-2017), Hélio joined Anvisa in 2015 and served as Business Analyst (2015-2016), Chief Information Security Officer (2016-2019), and Advisor (2019-Current). Author of published papers in refereed journals such as Theoretical Computer Science, Discrete Applied Mathematics, and Algorithmica.

Japan

Kanako Sasaki

Deputy Director, Medical Device Evaluation Division, Ministry of Health, Labour and Welfare (MHLW)

Kanako Sasaki is the Deputy Director at the Ministry of Health, Labour and Welfare (MHLW), and she is in charge of regulation of medical device and IVD. She is currently a management committee (MC) member in the International Medical Device Regulator Forum (IMDRF). She has over 10 years of experience in public health and health policy. She was dispatched to the European Medicines Agency (EMA) in 2017 and working on clinical data publication as an international expat. She earned a Master degree in Health Science from the University of Tokyo in 2009.

Part 3
UDI implementation and importance of harmonization for industry

Moderator

Sunny Woo

Korea Medical Device Industry Association(KMDIA), South Korea

Sunny Woo is the Manager of the IMDRF Supporting Team in the Korea Medical Devices Industry Association (KMDIA). She has contributed to international affairs in pharmaceuticals and medical devices over 10 years. She works closely with the Ministry of Food and Drug Safety (MFDS) to assist Korean medical device industry in actively participating in the global regulatory harmonization including AHWP and IMDRF.

Zita Yurko

Philips, Head of Regulatory Affairs & Standards, DITTA UDI Work Group Chair

Zita Yurko started her career as an electrical engineer specializing in the area of Regulatory Affairs. She is a United Stated Regulatory Affairs Certified professional who has over 23 years of medical device and over 13 years of commercial nuclear systems experience.

Zita was actively engaged with the FDA GUDID and the EUDAMED UDI module designs and release. She was part of the industry/regulator writing group for the UDI related guidance documents – N48, N53 and N54, currently in use today to guide the implementation of the jurisdictional UDI systems.

Tania Pearson

Medtronics, Senior Manager Regulatory Systems & Informatics, GMTA

Tania Pearson is a Senior Regulatory Affairs Manager, responsible for the global UDI strategy and implementation for Medtronic, Inc. She has been working in the medical device sector for 11 years. She worked in R&D for Pfizer for 12 years before joining Medtronic in 2010 under the Leadership Development Program. She has a BS in Chemistry from the University of Illinois at Urbana-Champaign and a MS in Regulatory Affairs from San Diego State University.

Tania is the owner of Medtronic's Global Standard Product Identification policy and the Global UDI policy. She is the Regulatory Process and Data SME for the UDI System for Medtronic. She has been a frequent speaker and panelist at the US UDI Conference, RAPS Convergence, Medical Device Labelling & Packaging Conference and the European UDI Forum. She was appointed to the GS1 Healthcare US Executive Leadership Committee (ELC) in 2020.

Hee-kwon Son

Osstem Implant

Hee-kwon Son has been working for Osstem Implant Co., Ltd. for 15 years since 2006. He has been involved in the regulatory affairs, leading to great achievements in regulatory submissions with various regulatory authorities including FDA, MHLW, MFDS, and etc. Recently, as the general manager, he is in charge of medical device licensing in 22 countries.

He is an expert member of ISO/TC 106(Dentistry). Also, he has served as a member of various consultation bodies organized by the Ministry of Food and Drug Safety.

Kevin Capatch

Director, Process Engineering, Geisinger Health

As a Director at Geisinger Health, Kevin utilizes Lean Thinking to focus on magnifying the value and eliminating the waste in the core value streams. Kevin's evangelistic leadership style and manufacturing-based operational expertise, combined with his information systems background, has allowed him to stimulate new thinking and promotion of process redesign in Geisinger's supply chain information and care support delivery systems. He is a foundational leader with the Healthcare Transformation Group (HTG), the Community Advisory Board (CAB) for GS1 U.S. Healthcare, and now serving on the Board of the newly formed Partnership for DSCSA Governance (PDG). He is active on multiple GS1, AHRMM, ASCx12, and C4SCS workgroups. He has completed AHRMM's Healthcare Supply Chain Leadership Institute and completed his master's degree in Project Management. In his spare time, he and his wife Diane, support their two son's passion for cooking, and auto and motorcycle restoration.

Part 4
Panel Discussion

Moderator

Annika Eberstein

DITTA Vice Chair and COCIR Interim Secretary General

Annika Eberstein is currently working as Interim Secretary General at COCIR. She is responsible for the coordination of all technical and regulatory activities at European and international level, as well as European research & innovation policies with a focus on public funding and public-private partnerships.

Before joining COCIR, Annika worked on product compliance, standards and R&D&I activities in the ICT and consumer electronics sector. She has degrees in European Studies, Political Science and Public Administration.

CLOSING REMARKS

Jeong-Rim Lee

Ministry of Food and Drug Safety, Korea

Dr. Jeong-Rim Lee is the director general of Medical Device Evaluation Department in the Ministry of Food & Drug Safety (MFDS) in South Korea. Under a special duties to pre-market approval and evaluation of medical devices, she has worked for the MFDS since 2001.

She has been actively participating in various international cooperative activities, such as AHWP, IEC/ISO, IMDRF, OECD, WHO, and so on.

She worked as a Visiting Scientist in the Department of Radiology at the University of Iowa in the U.S. in 1999 and as a Research Associate at the Mallinckrodt Institute of Radiology at Washington University in the U.S. from 2000 to 2001. She was seconded as a policy analyst to the Regulatory Policy Division in the OECD in France in 2018.

She got her B.S in Physics, M.Sc in Nuclear Physics, and Ph.D in Medical Physics in South Korea. She also earned her MBA from Conservatoire National des Arts et Métiers(CNAM) in France.

IMDRF International Medical Device Regulators Forum

About IMDRF

International Medical Device Regulators Forum

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization.

It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.

The IMDRF Management Committee, composed of regulatory officials, provides guidance on strategies, policies, directions, membership and activities of the Forum. Furthermore, the Management Committee oversees Working Groups, which draw upon expertise from various stakeholder groups such as industry, academia, healthcare professionals, consumer and patient groups.

The current members are:
Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea, and the United States of America.

The World Health Organization (WHO) is an Official Observer. The Asian Harmonization Working Party (AHWP), Pan American Health Organization (PAHO) and APEC LSIF Regulatory Harmonization Steering Committee are IMDRF Regional Harmonization Initiatives.

Further information about the work and operations of IMDRF is available on ***http://www.imdrf.org/***

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

About DITTA

DITTA is the global diagnostic imaging, healthcare ICT, and radiation therapy trade association

DITTA is the united global industry voice for diagnostic imaging, radiation therapy, healthcare ICT, electromedical and radiopharmaceuticals. Our members are national and regional industry associations representing more than 600 medical technology manufacturers, committed to improving health care and patient outcomes. DITTA was created in 2001 and incorporated in 2012 as a non-profit trade association. Since its inception, membership has grown significantly, and today counts eleven regional associations around the globe amongst its members. In 2015, DITTA granted the NGO status in official relations with the World Health Organization and signed a Memorandum of Understanding with the World Bank in 2016.

Through DITTA, the regional associations and their member companies are committed to working together more closely in order to promote sensible regulation, harmonized regulatory frameworks and the use of international standards around the globe.

DITTA's commitment includes and is not limited to promoting innovation, improve market access and enhance global competitiveness in the medical imaging, radiation therapy, healthcare ICT, electromedical and radiopharmaceutical industries.

DITTA's focus is to improve the global regulatory environment for manufacturers to ensure that they remain at the forefront of technological innovation and are successful in the global marketplace as they continue to develop more advanced, life-saving products that improve quality, safety and patient access around the globe while also promoting cost efficiency.

Further information about the work and operations of DITTA is available on ***http://www.globalditta.org/***