**IMDRF / DITTA**
Joint Virtual Workshop

# CYBERSECURITY

## WHERE ARE WE TODAY?

## WORKSHOP PROGRAMME
## & 
## SPEAKERS OVERVIEW

**MONDAY 21 SEPTEMBER 2020**

13:00 to 16:00 CEST  /  19:00 to 22:00 SGT  /  7:00 to 10:00 EST

Cybersecurity is a high priority for physicians, hospitals, and manufacturers of all internet-connected devices, and even more so when patient safety and health information are at stake. DITTA continues to be pro-active and lead efforts to strengthen cybersecurity for medical technologies. Cybersecurity is a shared responsibility. Collaboration between regulators, healthcare providers and industry are thus essential to safeguard the patients' health information and their physical safety. As IMDRF has recently adopted its guidance on cybersecurity of medical devices, the workshop takes place at the right time to discuss its implementation in the different jurisdictions.

## Workshop Objectives

- Follow-up on the publication of the IMDRF cybersecurity guidance
- Better understand how regulatory frameworks are evolving and provide an overview of requirements in various jurisdictions
- Understand current developments of cybersecurity international standards in healthcare
- Learn from healthcare providers on steps towards ensuring their facility is secure
- Understand ways to avoid cyber-attacks utilizing advanced risk frameworks
- Learn what the medical device industry is doing to make devices more secure and prevent cyber attacks

## 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

Monday, 21 September 2020, 19:00 Singapore Time

| Australia | AEST | 21:00 |
|---|---|---|
| Brazil | BRT | 8:00 |
| Canada | EST | 7:00 |
| China | CST | 19:00 |
| Belgium, France, Germany | CEST | 13:00 |
| Ireland | GMT | 11:00 |
| Japan | JST | 20:00 |
| Russia | MSK | 14:00 |
| Singapore | SGT | 19:00 |
| South Korea | KST | 20:00 |
| Switzerland | CEST | 13:00 |
| USA | EST | 7:00 |

# Agenda

| TIME ZONES | | | |
|---|---|---|---|
| CEST | SGT | EST | |
| **13:00** | **19:00** | **7:00** | Welcome from DITTA Chair<br>**Nicole Denjoy**, *DITTA Chair and COCIR Secretary General* |
| **13:05** | **19:05** | **7:05** | Opening Remarks<br>**Dr Choong May Ling**, *Mimi, Chief Executive Officer, Health Sciences Authority, Singapore* |
| **13:10** | **19:10** | **7:10** | Introduction by IMDRF Cybersecurity WG Convenor<br>**Aftin Ross**, *U.S. FDA* |
| **13:20** | **19:20** | **7:20** | Part 1 **Regulations – status in IMDRF jurisdictions** |
| | | | Overview of regulatory developments in cybersecurity in various IMDRF jurisdictions<br>1. Canada: **Marc Lamoureux**, *Health Canada*<br>2. EU: **Nada Alkhayat**, *European Commission*<br>3. Japan: **Kanako Sasaki**, *MHLW*<br>4. Singapore: **Zhuang Guangyi**, *HSA*<br>5. U.S.A: **Suzanne Schwartz**, *US FDA* |
| **14:00** | **20:00** | **8:00** | Part 2 **What healthcare providers are doing on cybersecurity** |
| | | | 1. Singapore: **Leon Chang**, *Head, Cyber Defence Group, Integrated Health Information Systems Pte Ltd, Singapore*<br>2. Europe: **Philippe Costard**, *Cybersecurity Advisor, Santhea, Belgium* |
| 14:20 | 20:20 | 8:20 | VIRTUAL BREAK |
| **14:25** | **20:25** | **8:25** | Part 3 **International standards on cybersecurity** |
| | | | Latest developments in international standardization activities on cybersecurity in healthcare and medical devices.<br>IEC/ISO: **Ben Kokx**, *Philips* |
| **14:50** | **20:50** | **8:50** | Part 4 **What Industry is doing to prevent cyber-attacks** |
| | | | Industry will provide an overview of security best practices and challenges in the medical device industry is facing.<br>How to deal with legacy products?<br>1. **Keiichiro Ozawa**, *Fujifilm*<br>2. **Ken Zalevsky**, *Bayer*<br>3. **Paul Chua**, *Becton Dickinson* |
| **15:35** | **21:35** | **9:35** | Part 5 **Multi-stakeholder panel discussions** |
| | | | Discussion between regulators, industry, standardisation bodies and healthcare providers on how to maximize collaboration and ensure cybersecurity in healthcare.<br>Panel including 2 regulators, 1 DITTA rep., 1 rep for standardization, 1 rep. for hospital provider<br>1. EU: **Matthias Neumann**, *Federal Ministry of Health, Germany*<br>2. South Korea: **Dr Se-il Park**, *Ministry of Food and Drug Safety (MFDS)*<br>3. **Ken Zalevsky**, *Bayer*<br>4. **Ben Kokx**, *Philips*<br>5. **Leon Chang,** *Head, Cyber Defence Group, Integrated Health Information Systems Pte Ltd, Singapore* |
| **15:55** | **21:55** | **9:55** | **Concluding Remarks & Next Steps** |
| | | | Conclusions by IMDRF Cybersecurity WG Chairs and DITTA Chair<br>• IMDRF Cybersecurity WG Chairs: **Marc Lamoureux**, *Health Canada* and **Suzanne Schwartz**, *US FDA*<br>• DITTA, **Nicole Denjoy**, *Chair* |
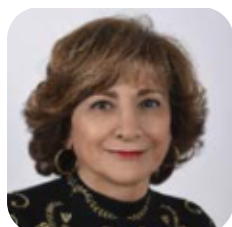
**WELCOME FROM DITTA CHAIR**

# NICOLE DENJOY

*DITTA Chair and COCIR Secretary General*

Nicole Denjoy is the COCIR Secretary General since 2005 and is based in Brussels.
Nicole has gathered more than 35 years of experience in the medical technology industry, working for companies including L'air Liquide, Ohmeda, Boston Scientific and Baxter. Nicole has a Masters in Organisation and Change Management.

Nicole represents COCIR in a variety of influential fora at European Level as well as at international level. Nicole is also Chair of DITTA, the Global Trade Association representing Medical Imaging, Radiation Therapy and Healthcare IT Industry (www.globalditta.org) and leads the DITTA Industry voice in official relationships with WHO since DITTA was granted a NGO status in 2015 and leads the partnership between DITTA and the World Bank since 2016.
In addition, Nicole is Vice-Chair of the Business at OECD Health Committee representing the private business sector in front of the OECD Health Committee

**OPENING REMARKS**

# DR CHOONG MAY LING, MIMI

*Chief Executive Officer, Health Sciences Authority, Singapore*

Dr Choong May Ling, Mimi was appointed as Chief Executive Officer on 1 July 2014. She oversees HSA's wide-ranging public health responsibilities, comprising health products regulation, the national blood service, and the national analytical and forensic sciences and forensic medicine services.

Dr Choong began her civil service career as a doctor in the Ministry of Health, and has worked in Singapore General Hospital, Kandang Kerbau Hospital, and Ministry of Health Headquarters. She has also served in various capacities in the Ministry of Education, the Ministry of Finance, the Ministry of Health, the former Ministry of Communications and Information Technology, the Ministry of Information, Communications and the Arts, and the Ministry of Home Affairs.

**Latest Update from IMDRF Cybersecurity Working Group Presented in conjunction with Health Canada**

## AFTIN ROSS

*Senior Project Manager/Senior Science Health Advisor Center for Devices and Radiological Health, U.S. FDA*

Aftin Ross is a senior project manager and senior science health advisor in the All-Hazards Readiness Response and Cybersecurity program at the FDA's Center for Devices and Radiological Health (CDRH). In this role, she leads cross-disciplinary projects related to preparedness including medical device cybersecurity, respiratory protective devices, personal protective equipment, and incident response. Aftin has had leadership roles in CDRH incident response to COVID-19, device-related infections, and natural disasters such as the 2017 Atlantic hurricanes.

Regarding cybersecurity, she has been a lead in CDRH's medical device cybersecurity efforts spearheading the execution of three FDA public workshops, serving on various interagency cybersecurity work groups, supporting numerous cross-stakeholder efforts (e.g. the 2017 healthcare cybersecurity task force), managing CDRH's MITRE cybersecurity contract, supporting the development of international cybersecurity policy as a member of the International Medical Device Regulators Forum (IMDRF), and engaging in policy development as a member of the CDRH cybersecurity workgroup.

Aftin earned a B.S. in mechanical engineering from the University of Maryland Baltimore County where she was a Meyerhoff Scholar. She completed her graduate work at the University of Michigan earning a master's and PhD in biomedical engineering. After her graduate work, she completed a post-doctoral fellowship as a Whitaker International Fellow at the Karlsruhe Institute of Technology in Karlsruhe, Germany. In 2016, she completed the National Preparedness Leadership Initiative, an executive education program in the Harvard School of Public Health and Kennedy School of Government and in 2019 she became a certified Six Sigma Green Belt.

# Part 1
## Regulations – status in IMDRF jurisdictions

**MODERATOR**

## LIN ANLE

*Senior Regulatory Specialist, Medical Devices Cluster, Health Products Regulation Group, Health Sciences Authority, Singapore*

Mr Lin Anle is a Senior Regulatory Specialist with the Medical Devices Cluster, Health Sciences Authority (HSA). In addition to the review of medical device pre-market and post-market submission, he also involved in formalising the regulatory requirements for medical devices manufactured by additive manufacturing and medical devices incorporating artificial intelligence (AIMDs). He is currently involved in the International Medical Device Regulatory Forum (IMDRF)-AIMDs working group and WHO AI4H working group on Regulatory Considerations (WG-RC).

Anle was previously the Chairman for the Industry Chapter Advisory Board under the Biomedical Engineering Society Singapore (BES) and remains an executive committee member of BES, whose overall aim is to promote the field of Biomedical Engineering in Singapore.

Anle holds a M.Sc. Management of Technology from National University of Singapore and B.Eng. Bioengineering from Nanyang Technological University, Singapore.

**REGULATION STATUS IN CANADA**

## MARC LAMOUREUX

*Manager, Digital Health Division, Health Canada*

Marc obtained his B.Sc. in Biophysics from the University of Guelph and his M.Sc. in Medical Physics from Carleton University. Before joining Health Canada, Marc spent two years as a Medical Health Physicist with The Ottawa Hospital where he worked closely with federal and provincial regulatory bodies to improve the quality and safety of diagnostic and therapeutic radiation programs.

Since 2011, Marc has worked in medical devices at Health Canada specializing in the technical assessment of medical software, diagnostic imaging devices, and radiotherapy equipment. He is vice-chair of Canada's Subcommittees for IEC TC62B (Diagnostic Imaging) and TC62C (Radiotherapy) and is a co-chair of the International Medical Device Regulators Forum's Cybersecurity Working Group. He is currently the lead for Health Canada's Building Better Access to Digital Health Technologies initiative and is the manager of the Digital Health Division at Health Canada.
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### REGULATION STATUS IN EUROPE

# NADA ALKHAYAT

*Policy Officer – B6 Medical Devices and HTA*
*European Commission*

Nada Alkhayat is a Policy Officer at the European Commission responsible for horizontal aspects related to the implementation of the new Medical Devices and In vitro diagnostic Medical Devices Regulations. She currently chairs the Medical Device Coordination Subgroups on Nomenclature and  New Technologies, the latter being the group responsible for elaborating the EU MDR/IVDR guidance on cybersecurity, medical device software qualification and classification and clinical evaluation/performance evaluation of medical device software. Nada also supports implementation work on the IVDR, UDI and Expert Panels.

A Pharmacist by education, she also holds a Diploma and Masters in Advanced European Studies.

### REGULATION STATUS IN JAPAN

# KANAKO SASAKI (MS.)

*Deputy Director (International), Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)*

Kanako Sasaki is the Deputy Director at the Ministry of Health, Labour and Welfare (MHLW). She is in charge of regulation of medical device and IVD. She holds a Master Degree in Health Science (the University of Tokyo). She has over 10 years of experience in public health and health policy.
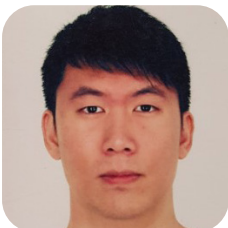
### REGULATION STATUS IN SINGAPORE

# ZHUANG GUANGYI

*Senior Regulatory Specialist, Medical Devices Cluster, Health Products Regulation Group, Health Sciences Authority, Singapore*

He is currently the team lead in the Diagnostic Unit which is responsible for the evaluation of Premarket applications for diagnostic medical devices including IVDs. Having 9 years' experience in HSA, he was instrumental in developing the Medical Device Software and Telehealth regulatory frameworks in Singapore. He was also a member of the Health Informatics Technical Committee Workgroup on Medical Device Security convened by the Ministry of Health, Singapore, to develop the Technical Reference (TR-67) for Connected Medical Device Security. As for international collaboration efforts, he was recently part of the IMDRF Medical Device Cybersecurity Working Group that drafted the IMDRF guidance "Principles and Practices for Medical Device Cybersecurity" to provide general principles and best practices to facilitate international regulatory convergence in cybersecurity.

**REGULATION STATUS IN U.S**.

# SUZANNE SCHWARTZ

*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation, Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST),  U.S. FDA*

Suzanne B. Schwartz, MD, MBA is the Director of the Office of Strategic Partnerships and Technology Innovation (OST) at FDA's Center for Devices & Radiological Health (CDRH).

Suzanne's work in medical device cybersecurity includes raising awareness, educating, outreach, partnering and coalition-building within the Healthcare and Public Health Sector (HPH) as well as fostering collaborations across other government agencies and the private sector. Suzanne has been recognized for Excellence in Innovation at FDA's Women's History Month for her work in Medical Device Cybersecurity.

Together with Health Canada, Suzanne has represented FDA in co-chairing the International Medical Device Regulators Forum (IMDRF) Work Group on Medical Device Cybersecurity leading to its first international guidance publication in March 2020. She chairs CDRH's Cybersecurity Working Group, tasked with formulating FDA's medical device cybersecurity policy and has additionally served as co-chair of the Government Coordinating Council (GCC) for the HPH Critical Infrastructure Sector, focusing on the sector's healthcare cybersecurity initiatives.

Suzanne earned an MD from Albert Einstein College of Medicine; an executive MBA from NYU Stern School of Business, completed Cohort X of the National Preparedness Leadership Initiative – Harvard School of Public Health & Harvard Kennedy School of Government executive education, and earned in September 2018 a certificate of mastery for completion of requirements at the Federal Executive Institute – Leadership for a Democratic Society.

# Part 2
## What healthcare providers are doing on cybersecurity

**MODERATOR**

## LIN ANLE

*Senior Regulatory Specialist, Medical Devices Cluster, Health Products Regulation Group, Health Sciences Authority, Singapore*

**HEALTHCARE SERVICE PROVIDER IN SINGAPORE**

## LEON CHANG

*Head, Cyber Defence Group, Integrated Health Information Systems Pte Ltd, Singapore*

Leon Chang is the Head of Cyber Defence Group for Integrated Health Information Systems (IHiS), the technology agency for Singapore's public healthcare sector. IHiS aims to improve the Singapore population's health and health administration by integrating intelligent, highly resilient, and cost effective technologies with process and people.

Leon works closely with the Ministry of Health and Public Healthcare Institutions to uplift cyber defences across the sector. Specifically, he oversees the public healthcare's cyber defence strategy, policy, governance, risk management and policy compliance, as well as the operation of public healthcare's cyber defence capabilities in identifying, preventing, detecting, responding to and recovering from threats and incidents.

**HEALTHCARE SERVICE PROVIDER IN EUROPE**

## PHILIPPE COSTARD

*Cybersecurity Advisor, Santhea, Belgium*

Philippe has been working for over 20 years in the IT and telecom industry. He specialized 10 years ago in ICT Audit and Security (he holds an Executive Master in ICT Audit and Security from the Solvay Brussels School).
For the last 3 years, he has been working as an Expert in Cybersecurity and Data Protection Officer (DPO) at Santhea, the first association of health institutions and services in Brussels and Wallonia.

# Part 3
## International standards on cybersecurity

**MODERATOR**

## NICOLE DENJOY
***DITTA Chair and COCIR Secretary General***

**IEC/ISO:**

## BEN KOKX
***Security expert in several ISO/IEC committees, Director Product Security at Philips***

Ben leads the cybersecurity tiger team within JWG7 of ISO TC 215 and IEC SC62A. He is the nominated IEC TC62 expert within IEC ACSEC (Advisory Committee on Information security & privacy), and an expert within several ISO/IEC JTC 1/ SC 27 workgroups. Within Europe he is the convener of CEN/CENELEC JTC 13/WG 6 (product security) and an ENISA eHealth expert.

Ben joined Philips Healthcare in 2001 as a software designer for the interventional X-Ray business unit, and soon became responsible for the security features of these products. Ben is a member of the Philips Healthcare global product security team since the start of the program in 2003. Over the years, he worked as a product security and privacy officer in both business and market positions. Since 2012, Ben works in the central Product & Services Security Office where he, as Director of Product Security, is currently responsible for the product security standards and regulations.

He chairs the COCIR Data Protection & Cybersecurity Focus Group.

# Part 4
## What Industry is doing to prevent cyber-attacks

**MODERATOR**

## NICOLE DENJOY
*DITTA Chair and COCIR Secretary General*

## KEIICHIRO OZAWA

*Regulatory Specialist, FUJIFILM Corporation*

In 2005 he joined JIRA, Japanese trade association, and he has been dedicating to the medical device industry on the framework of the regulatory affairs with over fifteen years of experience as a regulatory specialist in FUJIFILM Corporation.
Medical device software and network systems are the significant theme for his career. Currently he works as a vice-chair of Cybersecurity Working Group of DITTA, global trade association, to contribute to the worldwide regulatory convergence of medical device.
IMDRF activities such as IMDRF Medical Device Cybersecurity Guide Working Group and IMDRF Medical Device Clinical Evaluation Working Group are important work items to realize the global regulatory harmonization which he is working on. But the fundamental concept and paradigm to control the medical device software have been established in the activity of IMDRF SaMD Working Group which he also contributed to in the past. Meanwhile a wide range of activities on regulatory harmonization has been accomplished in AHWP in which he works at TC WG1. Working in the medical device regulatory field it is unavoidable to employ and study the international standards. And he has been joining IEC TC62/SC62A JWG7 working as a member of the Task Force Team of IEC 62304 Ed.2 for the development of IEC 62304. Keiichiro is also the Vice-Chair of the DITTA Cybersecurity Working Group.

## KEN ZALEVSKY

Ken is a certified CyberSecurity Leader with over eighteen years of experience in the medical device industry and a trusted cybersecurity consultant to national and international healthcare industry stakeholders. Ken's employment experience includes leading the Medical Device CyberSecurity function during his seventeen years at Bayer, and his role as Chief Executive Officer at Vigilant Ops. Ken has collaborated with the United States Food and Drug Administration (US FDA) and US Department of Homeland Security on various cybersecurity initiatives, including cyber simulation exercises and industry guidance documents.

Ken is an active participant and member of the cybersecurity teams of several industry trade associations including MITA (Medical Imaging Technology Alliance) and AdvaMed (Advanced Medical Technology Association). In addition, Ken is the chair of the Cybersecurity Working Group at the global association DITTA (Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association). Ken is a lead contributor to the cybersecurity task forces of these associations and has been an author of numerous cybersecurity whitepapers including CSP 1-2015 CyberSecurity in Medical Imaging, and Cyber Hygiene of Medical Imaging Equipment. Ken's work has also been featured in Healthcare Business News, where he has advised medical device manufacturers on cybersecurity best practices.

Ken earned certification in CyberSecurity Leadership from the School of Computer Science at Carnegie Mellon University, an undergraduate degree in Applied Math from Carnegie Mellon University and a graduate degree in Business Management from Carnegie Mellon University. Ken also attended the Executive Education program at Harvard Business School. In addition, Ken holds a Property/Casualty insurance license with a certification in Managing Cyber Risk. Ken is also Chair of the DITTA Cybersecurity Working Group.

# PAUL CHUA

*Product Security Officer, Greater Asia, Becton Dickinson*

Paul is responsible for the adoption of the BD corporate product security framework across the BD product portfolio within Greater Asia region and various other aspects of the overarching product security program that build products which are secured by design, in use and through partnership with transparency and control in mind. He leads product security risk assessment, architecture reviews, awareness/training, incident response, strategic cyber initiatives, and external engagements, in enhancing BD's broader efforts to comply with local law and regulations within the APAC region.

Paul is a seasoned professional with more than 24 years of experience managing product development, sales/marketing and operations at APAC level for IT, Telecommunications, Cybersecurity, and Homeland Security across established multinational companies, startups and government agencies. Prior to joining BD, Paul was the Chief Product Officer of a Singapore data analytics startup, where he was responsible for developing multiple suites of Cybersecurity Data Analytics-as-a-Service and Data Fusion-as-a-Service products for the Healthcare, BFSI, Maritime and Government enterprises.

Paul holds a Bachelor of Applied Science (Computer Engineering) from Nanyang Technological University of Singapore and a Masters of Business Administration from Northwestern University, Kellogg School of Management. Paul is a Certified Information Systems Security Professional (CISSP) and a CREST Registered Threat Intelligence Analyst (CRTIA).

# Part 5
## Multi-stakeholder panel discussions
Panel including 2 regulators, 1 DITTA rep., 1 rep for standardization, 1 rep. for hospital provider

**MODERATOR**

## ZHUANG GUANGYI

*Senior Regulatory Specialist, Medical Devices Cluster, Health Products Regulation Group, Health Sciences Authority, Singapore*

**REGULATOR EU**

## MATTHIAS NEUMANN

*Deputy Head of Division, Medical Devices Safety – Federal Ministry of Health, Germany*

Matthias Neumann studied Physics and made his PhD on Biophysics and Health Physics at University-Hospital Charité of the Humboldt-University Berlin.

He joined the Federal Ministry in 2002 and his career in the Division for Medical Devices spans over 17 years.

He was previously about 5 years with the Federal Institute for Drugs and Medical Devices. There he was responsible for the risk assessment of all kinds of Active Medical Devices including Active Implantable Medical Devices.

In his current position as Deputy Head of the Division "Medical Devices Safety" he has to contribute to the national, European and international regulation of Medical Devices. He is and was involved in international and European initiatives in particular on software, UDI, new technologies, standardisation etc.

**REGULATOR SOUTH KOREA**

## DR SEIL PARK

*Assistant Director, Ministry of Food and Drug Safety (MFDS)*
*National Institute of Food and Drug Safety Evaluation (NIFDS) Cardiovascular and imaging devices Division*

Ph.D. degree in Electrical engineering, specializing in plasma-bio display and earned his master's in electric engineering and bachelor's degree(BS) in electronic communication engineering.

He served AHWP as an AHWP Executive Deputy Secretary General for 3 years(2015-2017), and now has a role for Chair on AHWP WG1 which is General Medical Device(pre-market approval) for three years(2018-2020). He is an experienced engineer for 18 years. He has an advanced knowledge and also participated in standardization as a project leader for 4 years. Prior to working in Korea MFDS, he worked in one of testing laboratories in Korea as a senior researcher, in charge of various assignments related to international standards.

Publications:
Various Guidelines related to Medical Device technical documents

**INDUSTRY**

## KEN ZALEVSKY

**SDO**

## BEN KOKX

*Security expert in several ISO/IEC committees, Director Product Security at Philips*

**HOSPITAL PROVIDER**

## LEON CHANG

*Head, Cyber Defence Group, Integrated Health Information Systems (IHiS) Pte Ltd, Singapore*

# Concluding Remarks & Next Steps
## Conclusions by IMDRF Cybersecurity WG Chairs and DITTA Chair

## IMDRF Cybersecurity WG Chairs:

### MARC LAMOUREUX

*Manager, Digital Health Division, Health Canada*

### SUZANNE SCHWARTZ

*Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation, Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST), U.S. FDA*

## DITTA:

### NICOLE DENJOY

*Chair*

# 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/*



# 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 ten 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/*