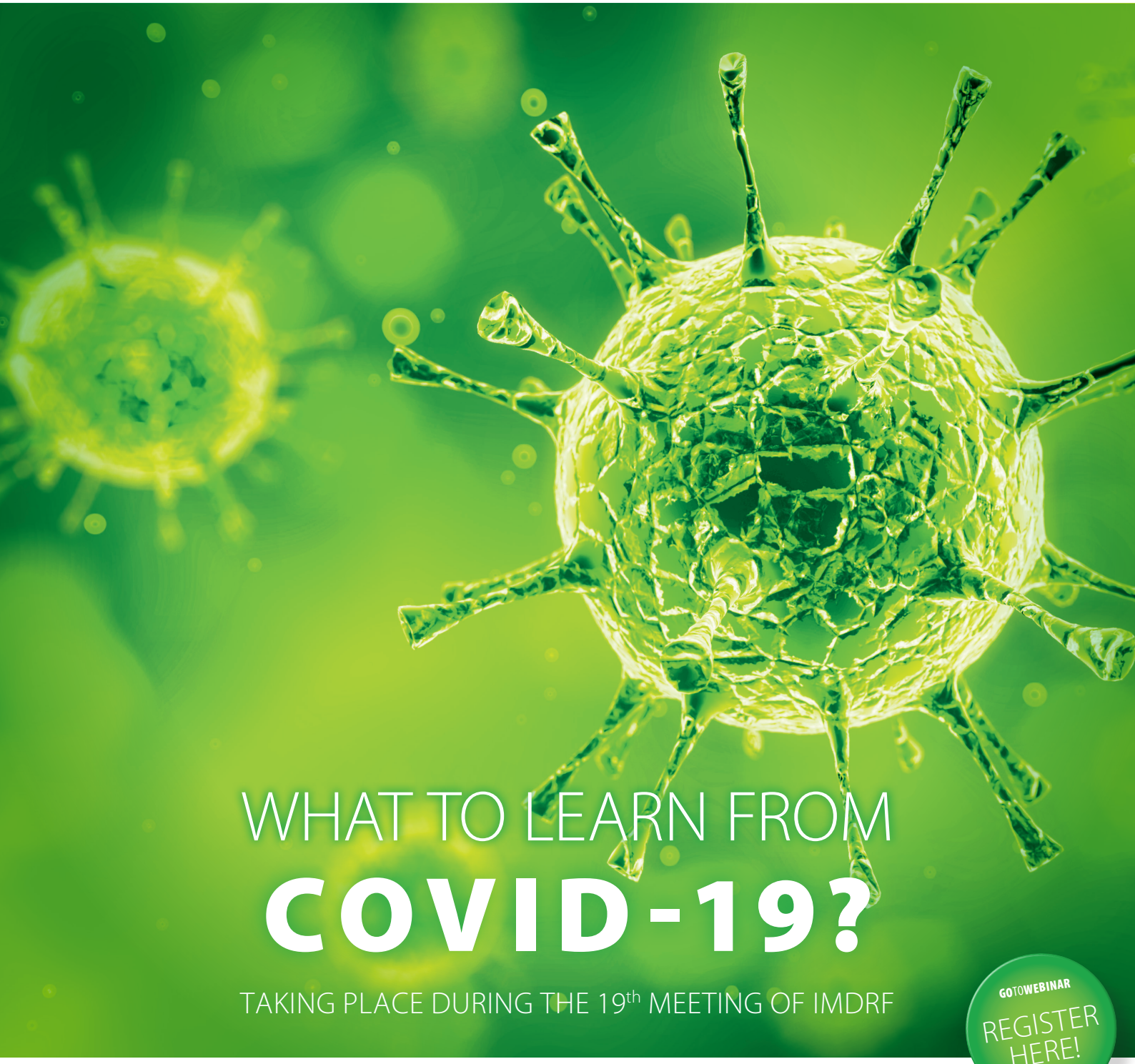
DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

IMDRF / DITTA

Joint Virtual Workshop



WHAT TO LEARN FROM COVID-19?

TAKING PLACE DURING THE 19th MEETING OF IMDRF

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WORKSHOP PROGRAMME & SPEAKERS OVERVIEW

TUESDAY 16 MARCH 2021

12:00 to 14:30 CET / 20:00 to 22:30 KST (Korea Standard Time) / 7:00 to 09:30 EST

Preamble

The first cluster of COVID-19 cases was reported in December 2019. Since then, the disease has spread across the globe. Medical devices have been essential in the fight against COVID-19 – from early detection over treatment, management to aftercare.

To respond to major challenges caused by the pandemic, medical device regulators and industry have employed all the necessary efforts to ensure the continuous supply of critical and priority medical devices.

Now, more than a year after the crisis has started, it is time to take stock of these activities and evaluate what lessons to draw to ensure the future resilience of healthcare systems and regulatory frameworks.

Workshop Objectives

- Learn how regulators have responded to the challenges posed by COVID-19, including the use of emergency authorisations or other measures
- Better understand how the medical device industry has contributed to the fight against COVID-19
- Learn how COVID-19 has impacted the supply of medical devices at global level & the difficulties industry has faced in delivering medical devices
- Exchange views on the lessons learned from COVID-19 to improve regulatory frameworks for medical devices and make them resilient for future crises

Time zone table

Tuesday 16 March 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	CET	12:00
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			
KST	CET	EST	
20:00	**12:00**	**7:00**	Welcome & Introduction by **Masaaki Ohtsuka**, *DITTA Chair*
20:05	**12:05**	**7:05**	Keynote Opening by **Jeong Lim Lee**, *IMDRF Chair*
20:10	**12:10**	**7:10**	Keynote by **Michael Griffin**, *World Health Organisation*
20:20	**12:20**	**7:20**	Part 1 **Response to COVID-19 in different IMDRF jurisdictions**

This session will provide updates on how different jurisdictions have responded to the challenges posed by the COVID-19 crisis.

Moderator: **Min-Jung Kim**, *MFDS*

1. South Korea: **Choong-Man Hong**, *MFDS*
2. United States: **Dr. Jeff Shuren**, *US FDA*
3. EU: **Erik Hansson**, *European Commission*
4. Australia: **Tracey Duffy**, *TGA*
5. Japan: **Kanako Sasaki**, *MHLW*

21:10	**13:10**	**8:10**	Part 2 **Industry opportunities and challenges to fight COVID-19**

This session will contribute to a better understanding of the various initiatives and actions taken by industry.

Moderator: **Nicole Denjoy**, *DITTA*

1. **John Schaeffler**, *GE Healthcare*
2. **Danelle Miller**, *Roche*
3. **Dr. Jung-Eun Joanna Lee**, *Sugentech*
4. **Jan-Willem Scheijgrond**, *Philips*

21:50	**13:50**	**8:50**	Part 3 **Multi-stakeholder interactive session**

In this session, panelists from Part 1 and Part 2 will exchange views on the lessons learned from COVID-19 crisis between regulators, healthcare providers and industry.

Moderator: **Sunny Woo**, *KMDIA*

1. Regulator representatives from part 1
2. **Dr. Hyuk Min Lee**, *Severance Hospital of Yonsei University*
3. **Dr. William Morice**, *Mayo Clinic*
4. Industry representatives from part 2

22:20	**14:20**	**9:20**	Conclusions

Conclusions by **Patrick Hope**, *DITTA*

WELCOME & INTRODUCTION

MASAAKI OHTSUKA

DITTA Chair

He 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.

KEYNOTE OPENING

DR. JEONG RIM LEE

IMDRF Chair

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.

KEYNOTE

MICHAEL GRIFFIN

World Health Organisation

Michael Griffin is the Strategy and Partnerships Technical Officer for the Operations Support & Logistics unit within the Health Emergency Programme at the WHO. He is the focal point of the Pandemic Supply Chain Network, a public-private collaboration to develop a supply chain network that can scale with the appropriate assets, resources, and expertise to respond to pandemics. Additionally, as part of the WHO COVID-19 emergency response, Mr. Griffin leads the market development initiatives for biomedical equipment.

With a background in strategic development and project management of new ventures and innovative initiatives, Mr. Griffin has worked in the private, developmental, and humanitarian sectors building new operational models, investing in new technology companies, and developing public private partnerships in various international settings including Eastern Africa, Europe and North America. He has undergraduate degrees in Liberal Arts and Civil Engineering from Columbia University as well as a MBA from the Graduate School of Business at Columbia University.

Part 1

Response to COVID-19 in different IMDRF jurisdictions

MODERATOR

MIN-JUNG KIM

Deputy Director, Medical Device Policy Division, Medical Device Safety Bureau, Ministry of Food and Drug Safety, South Korea

Min-Jung Kim is in charge of Medical Device international affairs including the IMDRF 2021 Secretariat, APEC, WTO TBT and CPTPP, etc.

She is also responsible for the laws and regulations on managing clinical trial sites for medical devices to oversee safety of the medical devices in Korea, and regulations for supplying orphan medical devices and devices in need of being introduced to the applicable patients which is directly driven by the MFDS.

SOUTH KOREA

DR. CHOONG-MAN HONG

MFDS

Dr. Choong-Man Hong earned his Ph.D in Toxicology from Seoul National University in 1996. He served as a postdoctoral fellow at the Center of Biologics Evaluation and Research(CBER) in FDA from 2005 to 2007.

He has been working for the MFDS since 1991. His career with the Medical Device Evaluation Department started in 2015. For 4 years from 2015, he served as director of Orthopedic & Restorative Devices Division.

He has hold a position of director of High-tech Medical Devices Division since 2020, in charge of the review of high-risk medical devices as well as international affairs.

UNITED STATES

DR. JEFF SHUREN

Director of the Center for Devices and Radiological Health, US FDA

Jeffrey Shuren, MD, JD is the Director of the Center for Devices and Radiological Health (CDRH) at FDA. He previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati.

In 1998, Dr. Shuren joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. From 1998 to 2003, he served as a Staff Volunteer in the National Institutes of Health's National Institute of Neurological Disorders and Stroke Cognitive Neuroscience Section supervising and designing clinical studies on human reasoning. Dr. Shuren returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009.

EUROPEAN UNION

ERIK HANSSON

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 is responsible for several EU working groups (such as MDCG), heads the EU delegation to the multilateral regulatory cooperation in IMDRF, deals with bilateral trade related issues in the sector and is coordinating the cooperation with national Competent Authorities in the CAMD framework.

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.

AUSTRALIA

TRACEY DUFFY

Therapeutic Goods Administration, Australia

Tracey Duffy is the First Assistant Secretary of the Medical Devices and Product Quality Division in the Therapeutic Goods Administration (TGA). The TGA is part of the Federal Department of Health.

Her current responsibilities include medical device regulation, Good Manufacturing Practice medicine inspections and Laboratory testing. Tracey has held several leadership roles within the Department of Health and private sector experience in health and aged care related roles.

JAPAN

KANAKO SASAKI,

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 2

Industry opportunities and challenges to fight COVID-19

MODERATOR

NICOLE DENJOY

DITTA Vice-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 Vice-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

JOHN SCHAEFFLER

Executive Global Government Affairs Leader, GE Healthcare

John Schaeffler is the Executive Global Government Affairs Leader for GE Healthcare. John re-joined GE Healthcare in March 2010. Prior to that time, he served as Senior Leader of Government Relations from 2004 to 2009. In between his time at GE Healthcare, John was the Senior Vice President of Federal Affairs of DaVita – a dialysis provider. Prior to coming to GE Healthcare the first time, John spent nine years at the American Health Care Association (AHCA) ending his time there as Senior Vice President for Policy and Government Relations. John began his career as a legislative aide to two Members of Congress from Minnesota from 1987 through 1995. He is a graduate of American University's School of Public Affairs with a degree in political science.

DANELLE MILLER

Vice President, Global Regulatory Policy and Intelligence, Roche Diagnostics

Danelle R. Miller is Vice President, Global Regulatory Policy and Intelligence for Roche Diagnostics. In that role, she is responsible for guiding Roche Diagnostics' global regulatory policy efforts. Ms. Miller joined Roche Diagnostics in 2005, and served as Regulatory Counsel for Roche Diagnostics' Indianapolis-based affiliates, and later as Global Regulatory Counsel, where she counseled Roche Diagnostics worldwide on quality and regulatory issues. Prior to joining Roche Diagnostics, she worked for the law firm of Baker & Daniels, where she was responsible for representing food, drug and medical device companies on regulatory and related issues involving the Food and Drug Administration and other federal and state agencies. Ms. Miller also has served as Regulatory Counsel for a major pharmaceutical firm. Ms. Miller holds a B.S. from the University of Tulsa, M.A. from Ball State University, and a J.D. with high honors from the University of North Carolina School of Law.

DR. JUNG-EUN JOANNA LEE

Vice president, CSO & CMO

Sugentech is the major In-Vitro Diagnostics (IVD) and KOSDAQ-listed company in Korea, while its subsidiary named Modori-C is mobile healthcare App development company. JuneEun Lee has been working as CSO and CMO for Sugentech and CEO for Modori-C. Sugentech is IVD company with robust and exhaustive Bio-IT convergence technologies, offering home-use to Lab test kits, operational system and equipment.

Dr. JungEun Joanna Lee, after getting PhD in Cell biology from Seoul National University, started her professional career in Accenture, Strategy Group and has played executive roles in various industry such as Yahoo, Doosan, Samyang Corp., General Motors (US and Korea) and Samsung for Operational group, Strategy, New Business Development, Program management, Sales and Marketing. The experience of various industry and different functions is of great help to configure the strategy and to lead the execution of the Bio-IT converging IVD company with a good acumen and agility. Her detailed profile could be found at : https://www.linkedin.com/in/jungeun-lee-10891341/

JAN-WILLEM SCHEIJGROND

Vice President, Global Government & Public Affairs, Philips,

Mr. Scheijgrond currently serves as Vice President Global Government and Public Affairs at Royal Philips, where he heads up the global network within Philips that is responsible for the relations with governments and related stakeholders to address societal challenges in particular in the area of large scale health care transformations.

He is also responsible for partnerships with international partners such as the United Nations and International donors. In that role Mr. Scheijgrond is focusing on partnerships that strengthen health systems in support of achieving Universal Health Coverage.

Mr. Scheijgrond is a Board Member of the Partnership for Maternal and Newborn Child Health (PMNCH), member of the Global Finance Facility Investors Group and Chairman of the UN Global Compact Netherlands.

Mr. Scheijgrond joined Philips in 2009 as Senior Director as part of the Corporate Sustainability Office with responsibility for risk and reputation management.

He started his career at the United Nations Environment Program, where he developed best practices guides related to cleaner production for emerging markets. Subsequently, he held a number of sustainability and government affairs related functions at the BLC Leather Confederation, Epson, and Hewlett-Packard.

Mr. Scheijgrond holds a Masters degree in Environmental Technology from Wageningen University, the Netherlands, he is married and has two children.

Part 3
Multi-stakeholder interactive session

MODERATOR

SUNNY WOO

Korea Medical Devices Industry Association, 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.

PROF. HYUKMIN LEE

M.D., Ph.D., Department of Laboratory Medicine and Research Institute of Bacterial Resistance, Yonsei University College of Medicine

Dr. Hyukmin Lee is a professor at the Department of Laboratory Medicine and Research Institute of Bacterial Resistance of Yonsei University College of Medicine. He is one of the nation's most renowned experts in the field of the diagnosis of infectious diseases. Currently, he is the Director at Infection Control of Korean Society for Laboratory Medicine, and he has also served as the Team leader at COVID-19 Response TFT of Korean Society for Laboratory Medicine. He contributed to establishing 'Korean Diagnosis System' by bridging Korea Disease Control and Prevention Agency and medical institutions for COVID-19 diagnosis.

He holds Ph.D., degree in Laboratory Medicine from Graduate School, Yonsei University, Seoul, S. Korea.

DR. WILLIAM MORICE

Chair of the Department of Laboratory Medicine and Pathology at Mayo Clinic

William G. Morice, II, M.D., Ph.D., is the Chair of the Department of Laboratory Medicine and Pathology at Mayo Clinic in Rochester, MN and the President of Mayo Clinic Laboratories (aka Mayo Medical Laboratories MML). Dr. Morice is also a Consultant in the Division of Hematopathology and served as the Chair of this Division from 2009 to 2015. He holds the academic rank of Professor of Laboratory Medicine and Pathology.

As an expert in diagnostic hematopathology, flow cytometry, and T and NK cell biology, among other topics, Dr. Morice is sought after as a national and international lecturer and visiting professor. Additionally, as an active educator and mentor, Dr. Morice teaches residents, fellows, and allied health staff the analytic approach to the diagnosis of benign and malignant hematolymphoid disorders.

Dr. Morice has written more than 160 peer-reviewed articles, book chapters, and abstracts. He received his Bachelor of Science degree in Biochemistry from Indiana University and earned his M.D./Ph.D. (Immunology) degrees from the Mayo Clinic Graduate School. Dr. Morice completed a preliminary residency year in internal medicine a combined residency program in anatomic pathology and clinical pathology, and fellowships in surgical pathology and hematopathology; all at Mayo Graduate School of Medicine.

Outside of work he enjoys time with his family, competitive cycling, and seeking to live life to the fullest.

Conclusions

Conclusions by Patrick Hope, DITTA

PATRICK HOPE

DITTA Vice Chair and MITA Executive Director

Patrick Hope has been MITA's Executive Director since 2015. He has over 20 years of advocacy experience representing provider and medical imaging interests. The Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is the leading organization and collective voice of medical imaging equipment, radiopharmaceutical manufacturers, innovators and product developers in the United States. MITA represents companies whose sales make up more than 90 percent of the global market for advanced imaging technologies. Patrick also serves as a Vice Chair of DITTA.

Patrick holds a law degree from Catholic University Columbus School of Law, a master of arts in congressional studies from Catholic University and a bachelor of arts and science in history and political science from St. Mary's University, San Antonio, Texas.

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 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/***