



DITTA Workshop on Cybersecurity *Better understanding on where we are today*

In conjunction with the 13th meeting of the IMDRF in Shanghai, China

Monday 19 March 2018

***Location:** Hyatt on the Bund, 199 Huangpu Rd, Hongkou Qu, Shanghai Shi, China
Grand Ballroom I*

This workshop will benefit from simultaneous translation in Chinese and English.

AGENDA

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 is at stake. DITTA continues to be pro-active and lead efforts to strengthen cybersecurity for medical technologies. Because cybersecurity is not only the responsibility of industry but goes beyond, collaboration between regulators, healthcare providers and industry is required to safeguard the patients' protected health information and their physical safety.

08:30 – 09:00 Coffee and Registration

09:00 – 09:05 Welcome and Introduction *(Patrick Hope, DITTA Chair)*

09:05 – 09:15 Key Note Address *(Lin Yuan, IMDRF Chair, and Director General, Department of International Cooperation, CFDA)*

Session 1 – Status of regulations in IMDRF jurisdictions

Several IMDRF member jurisdictions are currently developing or extending their cybersecurity regulations. The goal of this session is to better understand how regulatory frameworks are evolving and provide an overview on evolution in various jurisdictions. Are there possibilities to move towards global convergence?

09:15 – 10:15 Panel discussion *(60 minutes)*

- Moderator *(Diane Wurzburger, GE Healthcare)*
- Overview of the regulatory landscape in China *(Peng Yuan, Director, Department of Medical Device Registration, CFDA)*
- Update on regulations in the United States *(Jeff Shuren, Director Center for Devices and Radiological Health, US FDA)*
- European regulatory views on cybersecurity *(Matthias Neumann, Senior Executive Medical Device Safety Unit, German Federal Ministry of Health)*
- The Japanese view on cybersecurity regulation *(Yumiko Aoyagi, Deputy Director Medical Device Evaluation Division, MHLW)*
- Update on regulatory developments in Canada *(David Boudreau, Director Medical Devices Bureau, Therapeutic Products Directorate, Health Canada)*
- Interactive discussion



Session 2 – International standards on cybersecurity

The international standardisation landscape is constantly evolving. The aim of this session is to better understand current developments of cybersecurity international standards in healthcare. Participants and audience will discuss how those standards are complementing and provide support to the regulatory framework.

10:15 – 11:00 Panel discussion (45 minutes)

- Moderator (*Keiichiro Ozawa, DITTA Cybersecurity WG Vice-Chair*)
- IEC (*Toshiaki Nakazato, Canon Medical Systems*)
- ISO (*Peter Linders, Philips Healthcare*)
- Interactive discussion

11:00 – 11:15 Coffee Break

Session 3 – What is Industry doing to prevent cyber-attacks?

The goal of this session is to share initiatives, best practices and actions taken by manufacturers in the field of cybersecurity. Panellists and audience will discuss how to avoid cyber-attacks utilising advanced risk frameworks.

11:15 – 12:15 Panel discussion (60 minutes)

- Moderator (*Nicole Denjoy, DITTA Vice-chair*)
- DITTA member (*Keiichiro Ozawa, DITTA Cybersecurity WG Vice-Chair*)
- DITTA member (*Jim Jacobson, Siemens Healthineers*)
- DITTA member (*James He, Philips Healthcare*)
- DITTA member (*Weiping Zhong, GE Healthcare*)
- GMTA member (*Zach Rothstein, Associate Vice President, AdvaMed*)
- Interactive discussion

What are healthcare providers' views on cybersecurity?

This session will address the health care providers' perspectives. The aim is to learn from them on the steps they are taking towards ensuring their facility is cyber secure and discuss collaboration between key actors in the eco-system.

12:15 – 12:30 (15 minutes)

Cybersecurity considerations in constructing a network system (*Eric de Roodenbeke, CEO of International Hospital Federation*)

12:30 – 12:35 Conclusion & Wrap-Up (Patrick Hope, DITTA Chair)