HKTDC
Hong Kong International Medical Devices and Supplies Fair
香港國際醫療器材及用品展
7 – 9 / 5 / 2018

Organiser 主辦機構: HKTDC 香港貿發局

Co-organiser 協辦機構: Hong Kong MHDIA 香港醫療及保健器材行業協會 Hong Kong Medical and Healthcare Device Industries Association

Info as at 23 / 4 / 2018

Seminar on "Regulatory Intelligence: Updates on Procurement Guidelines and Medical Device Regulations"

「法規新知: 最新採購政策及醫療器材法規」研討會

Lucky Draw will be held after the Seminar.
研討會後將舉行抽獎環節。

Date 日期 : 9 / 5 / 2018 (Wednesday 星期三)
Time 時間 : 11:15am – 12:45pm
Venue 地點 : Seminar Room, Hall 3F, HKCEC
香港會議展覽中心 3F 展館 研討室
Language 語言 : English 英語 (恕不設即時傳譯服務)
(Simultaneous interpretation service will not be provided)
Admission 入場 : Free of charge, pre-registration required 免費參加, 需預先登記

Time 時間	Programme 程序表
11am – 11:15am	**Registration 登記**
11:15am – 11:35am	**Updates on Harmonization of Medical Device Regulations from AHWP** **亞洲醫療器材法規協調最新發展** Speaker: Ms Carol Liu, Secretariat, Asian Harmonization Working Party 講者: 亞洲醫療器械法規協調組織 秘書處 劉音博女士
11:35am – 11:55pm	**Medical Device Regulatory Update for EU 歐盟醫療器材法規要求更新** Speaker: Mr Jonathan Tang, Study Director, STC 講者: 香港標準及檢定中心 研發總監 唐嘯華先生
11:55pm – 12:15pm	**Medical Device Regulatory Update for US 美國醫療器材法規要求更新** Speaker: Ir Prof Albert Poon, Associate Specialist, Medical Device Program of SGS 講者: 資深醫療器械及生物醫學工程師 潘家發教授
12:15pm – 12:35pm	**Tapping into China's Medical Device Industry: Policies and Procedures of Hospital Procurement** **中國醫療設備採購法律法規與流程解讀** Speaker: Ms Xiaoyu Wang, Director of Industry Data Research, China Medical Devices 講者: 《中國醫療設備》雜誌社 行業數據研究部主任 王曉宇女士
12:35pm – 12:45pm	**Q&A 問答環節**

Remarks:
(1) Free admission. Seats are limited and granted on a first-come-first-served basis. 免費入場。座位有限，先到先得。
(2) Pre-registered attendees have priority admission until 15 minutes before the event commences. Thereafter unoccupied seats may be made available to walk-in attendees. 已登記人士將獲安排優先入座，請各已登記人士於活動開始前 15 分鐘到達活動場地，此後主辦機構有權因應現場情況安排未登記人士入座。
(3) Trade only and persons under 18 will not be admitted. 只接待 18 歲或以上之業內人士進場。
(4) The Organiser reserves the right to make any changes without prior notice. 主辦機構保留任何更改之權利而不作另行通告。

About the Speakers and Sharing

Updates on Harmonization of Medical Device Regulations from AHWP
亞洲醫療器材法規協調最新發展

Ms Carol Liu, Secretariat, Asian Harmonization Working Party
亞洲醫療器械法規協調組織 秘書處 劉音博女士

Ms Carol LIU is the Consultant of Smart Healthcare, MedTech, & Optics Unit of the Hong Kong Productivity Council (HKPC), with solid experiences in technology development on biomedical applied research and medical device regulatory affairs. Carol is the project manager for the biomedical technology development and government funded projects on biomedical R&D and industry good practices, covering projects on R&D on Bio-Optics for Dermatology, Laparoscopic Surgery, Artificial Finger Joint and Ankle Joint for Prosthetics, Driver Physiological Status Monitoring for Enhancing Road Safety, Smart Healthcare Solutions; Regulatory Control of Use on Medical Devices for Cosmetic Procedures; ISO13485 Quality Management System for Medical Devices; Professional upgrade on Biomedical Engineering, Paediatric Dermatology; Promotion of Patent Commercialization for Innovation and Invention, etc.; Since 2011, Carol has served as the Secretariat of Asian Harmonization Working Party (AHWP) on harmonization of medical device regulatory. She also serves as Committee Member of the Biomedical Division of HKIE, Executive Committee of IEEE EMBS HK Macau Joint Chapter, and Guest Lecturer for The Medical Engineering Programme, The University of Hong Kong and for The Department of Electronic Engineering, City University of Hong Kong.

Medical Device Regulatory Update for EU
歐盟醫療器材法規要求更新

Mr Jonathan Tang, Study Director, STC
香港標準及檢定中心 研發總監 唐嘯華先生

Expert in Medical Device Biological Risk Assessment
Head of Medical Device Biocompatibility Testing Lab Team

Mr Jonathan Tang is currently the Study Director at STC where he established and operates STC's first medical device biocompatibility testing lab. This lab provides full scope of medical device biocompatibility testing services with CNAS, CMA accreditation and GLP compliance. In the past, Mr Tang has worked in NAMSA China as a Technical Specialist who was responsible for managing medical device testing and consulting projects. Before NAMSA, Mr Tang worked at TUV SUD as a Biologist where he managed more than 100 GLP safety and efficacy studies, including protocol development, study execution, and final report. Mr Tang obtained his Master degree of Science from the National University of Singapore and Undergraduate degree in Veterinary Medicine from Northwest A&F University, China.

Abstract of Sharing:

The final text of the new European Medical Devices Regulation (MDR) has been published in the Official Journal of the European Union. Effective May 25th, 2017, the new regulation affects the selling of medical devices in Europe. The following speech will cover topics such as Europe's changing regulatory environments and how these changes are impacting manufactures.

Medical Device Regulatory Update for US
美國醫療器材法規要求更新

Ir Prof Albert Poon, Associate Specialist, Medical Device Program of SGS
資深醫療器械及生物醫學工程師 潘家發教授

Ir Prof Albert Poon has more than 30 years of experience in Medical Device and Biomedical Engineering aspects for HKSAR Government with specialization in regulation and technology development. He contributed to Regulatory Affairs and regulatory framework of MD in Hong Kong and established the foundations for Medical Device Control Office. He is technical expert on MD to Diagnostics and Imaging MD Unit of WHO and in MD nomenclature; actively participating in MD regulation and biomedical technical advice in projects of NGOs such as World Health Organization, London School, EAC (Africa) and GIZ (Germany). Ir Prof Poon is a Certified Medical Laser Safety Officer and Certified Clinical Engineer and he has major contributions in education and training for development of biomedical engineers in Hong Kong.

About the Speakers and Sharing

Tapping into China's Medical Device Industry: Policies and Procedures of Hospital Procurement
中國醫療設備採購法律法規與流程解讀

Ms Xiaoyu Wang, Director of Industry Data Research,
China Medical Devices Magazine
《中國醫療設備》雜誌社 行業數據研究部主任 王曉宇女士

- Director of data department of China medical industry development research institute.
- Book planning and organizer of China medical devices procurement directory.
- Members of four national science and technology department projects.
- Planning and organizer of The 2nd Chinese PLA General Hospital-MIT Health Data Conference and Workshop

Responsible for China's medical equipment industry data report, the China medical medical devices procurement directory planning, editing. Preface analysis report of the clinical engineering industry association, Clinical medical engineering yearbook analysis and production. Members of four national science and technology department projects. Organize and planning of The Chinese PLA General Hospital-MIT Health Data Conference and Workshop.

Abstract of Sharing:

Part I: The procurement risk management of medical equipment, medical equipment purchasing common legal risk, way of medical equipment procurement related policy laws, equipment every link of bidding and tendering law risk, measures for the management of large medical equipment configuration.

Part II: the management of medical equipment procurement process, the medical equipment procurement feasibility evaluation method and case analysis, bidding procedure management and case interpretation, medical equipment acceptance practices, large medical equipment configuration review process.