Medtec China 2018 onsite: MDiT Forum and Regulation Summit 2018

Regulation Track A: Chinese Regulatory Updates and Compliance

Morning of Sep 26 | Conference Room 3, B2 of SWEECC

09:00-09:50	Registration & Networking Breakfast Meeting
09:50-10:00	Moderator Remarks
10:00-10:40	Development prospect of Chinese medical device industry
10:40-11:20	Understanding of medical device review and approval system by CFDA
11:20-12:00	The contents and requirements of database in UDI **Liang Yan, President, Shanghai Pudong Medical Device Trade Association**
12:00-13:30	Lunch & show visit
13:40-14:20	The interpretation and implementation of the medical device registration system
14:20-15:00	Key points for the implementation of clinical trial quality management of medical device in China
15:00-15:40	Supervision of post-markting Medical Devices after changes of Regulation **Haihong Jiang, Medical Device Regulation Expert**
15:40-16:20	Clinical trial design of medical device complying with the updated regulation
16:20-16:25	Track Close

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Regulation Track B: US & EU Regulatory Updates and Market Access and Overseas Market Access Strategy

Afternoon of Sep 27 | Conference Room 4, B2 of SWEECC

13:20-13:30	Registration & Networking
13:30-13:40	Moderator Remarks
13:40-14:20	Perspective of FDA: Medical Device Registration and Listing: Reminders about R&L **William M. Sutton, FDA Assistant Country Director, China**
14:20-15:00	How to support product registration with foreign clinical data, from China to US and from US to China **Thomas Jaw, Medical Research Manager, NAMSA**
15:00-15:10	Tea Break & Networking
15:10-15:50	How to get access to Japan Medical Market
15:50-16:30	How to get access to Ireland Medical Market
16:30-16:35	Track Close

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Quality Track A: Outsourcing and Supplier Management

Afternoon of Sep 26 | Conference Room 4, B2 of SWEECC

13:20-13:30	Registration & Networking
13:30-13:40	Moderator Remarks
13:40-14:20	Current situation and trend analysis of medical device outsourcing market
14:20-15:00	From the view of medical device manufactures, how to do the supplier development and management control
15:00-15:10	Tea Break & Networking
15:10-15:50	Brief probe into Supplier classification and auditing according to the Supplier Audit Guide for Medical Device Manufacturers **David Wei, Senior Registered Engineer, ASQ**
15:50-16:30	How to collaborate with CRO/CMO to accelerate product listing and improve product quality **Yvonne Leonard，Director of Marketing, WuXi AppTec Laboratory Division**
16:30-16:40	Track Close

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Quality Track B: MDSAP updates and FDA Inspection

Morning of Sep 27 | Conference Room3, B2 of SWEECC

09:00-09:05	Registration & Networking
09:05-09:10	Moderator Remarks
09:10-10:00	**MDSAP Regulatory Introduction** FDA Update MDSAP program, Critical information from FDA ■ Overview of MDSAP ■ Current MDSAP Auditing Organizations (AOs) ■ MDSAP audit vs FDA inspection ■ Number of MDSAP Audits Conducted ■ 2017/2018 MDSAP Performance Metrics **William M. Sutton,FDA Assistant Country Director, China; Translation: Scott Yu**
10:00-10:30	**Industrial Practice :How to integrate the MDSAP in your own quality system** ■ MDSAP Common data update ■ How to evaluate the whether you need MDSAP? ■ How to integrate the MDSAP in your quality system with ISO13485 **YUZELI MEDTEC CONSULTANT Inc. RAC , Global**
10:30-10:50	Q&A
10:50-11:00	Tea Break & Networking
11:00-12:00	**FDA Industry practice :Experience sharing of FDA inspection during 2017 and 2018** ■ FDA inspection experience ■ How to response 483 ■ Design Control readiness for FDA inspection 1) How FDA get evidence that the design control system compliance? 2) What is the 510(K) role during the inspection? 3) What kind of evidence that the inspector interested? **YUZELI MEDTEC CONSULTANT Inc. RAC , Global**
12:00-12:20	**Q&A**
12:20-12:40	Experience sharing of CFDI oversea inspection **YUZELI MEDTEC CONSULTANT Inc. RAC , Global**

12:40-12:50	Track Close

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Technology Track A: Perspective of end user Design & New Technology

Afternoon of Sep 26 | Conference Room 5, B2 of SWEECC

13:20-13:25	Moderator Remarks
13:25-14:05	From the view of clinician: Medical device safety by design and the application of Human-Centered Approach **Xiaoli Yu, Doctor, Second Affiliated Hospital of Guangzhou Medical University**
14:05-14:45	From concept to practice: innovation design and case study of implant products **Eken Elkem**
14:45-14:55	Tea Break & Networking
14:55-15:35	Application of 3D printing in Medical Devices innovation **Chengtao Wang, Professor, Shanghai Jiaotong University**
15:35-16:15	New developments of surgery robotic and innovation of sensor technology
16:15-16:20	Track Close

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Technology Track B: Next-Gen Design & New Technology

Morning of Sep 26 | Conference Room A, SWEECC

09:20-09:25	Registration & Networking
09:25-09:30	Moderator Remarks
09:30-10:00	Design for demand, case study of demand deliver innovative products
10:00-10:30	How to make the medical device design manufacturability **INTEGRATED TECHONOGIES LIMITED**
10:30-11:00	Innovation elements in electronic medical products design **Joymed Technology (Shanghai) Co., Ltd**
11:00-11:30	Innovation and challenges of bio material design and R&D
11:30-11:40	Track Close

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Technology Track C: Pack & Ster Hub

Morning of Sep 27 | Conference Room A, Hall 2 of SWEECC

09:30-09:40	Moderator Remarks
09:40-10:10	Regulatory standard system and compliance of sterilization medical device packaging in China
10:10-10:40	Packaging and quality: the requirements for packaging from manufacturers
10:40-11:10	The sterile barrier of packaging and validation process
11:10-11:40	Microbiological test related to sterilization and validation process
11:40-11:45	Track Close

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Technology Track D: Processing Techniques of Medical Plastics and Product Innovation

Afternoon of Sep 27 | Conference Room A, Hall 2 of SWEECC

13:30-13:40	Moderator Remarks
13:40-14:10	Development status and market trend of medical plastic products
14:10-14:40	Requirements on plastics and high polymer material from medical device manufacturers **Hua Jiang, Director of Biology Department, State Food and Drug Administration Tianjin Medical Device Quality Supervision and Inspection Center**
14:40-15:10	Medical silicone tube: how to realize product innovation through material, processing and collaboration
15:10-15:40	Application and hotspots of mechanical engineering in medical plastic products

15:40-15:50	Track Close

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Technology Track E: Dressing Material and Technology Forum

Afternoon of Sep 26 | Conference Room A, Hall 2 of SWEECC

13:30-13:40	Moderator Remarks
13:40-14:10	Import and export situation analysis and the new trend of medical dressings
14:10-14:40	R&D and design sharing of new type medical dressings
14:40-15:10	Application of medical non-woven fabric in surgical infection and control products
15:10-15:40	Processing equipment and technology in medical dressing manufacturing
15:40-15:50	Conference Close

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The 4rd Market Report Track of Medical Device Industry

Morning of Sep 28 | Conference Room A, Hall 2 of SWEECC

09:50-10:00	Moderator Remarks
10:00-10:30	Market report of medical device industry or the whole medical industry **Fred Mao, Consulting Director, Frost Sullivan Consulting**
10:30-11:00	Investment and M&A trend analysis of medical device industry
11:00-11:30	New growth point and the changes in medical device market **Stephen Sunderland，CEO，L.E.K.**
11:30-11:40	Conference Close

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Regulatory Lecture

Sep 27 | Conference Room B, Hall 2 of SWEECC

09:30-09:50	会议主持人致辞
09:50-10:20	Osmunda
10:20-10:50	Challenges and consequences for industry based on revisions of ISO 10993 standards **Dr. Albrecht Poth，Knoell**
10:50-11:20	Implementation of the European Medical Device Regulation (EU) 2017/745 and its impact on manufacturers **Dr. Baixue Zhou,Knoell**
11:20-11:50	Preparing for the US market – What to expect from US-FDA **Lacey Chessor，Knoell**
11:50-14:00	Lunch+ Exhibition Visiting
14:00-14:20	ASCA of medical device to FDA and CFDA standards **PhD, Bill Harrison, VP, Safety assessment center, Wuxi AppTec**
14:20-14:45	Biological Evaluations of Medical Devices **Mark A. Cabonce, M.S., DABT，Director of Technical & Regulatory, Wuxi AppTec**
14:45-15:05	Designing Materials Characterization Studies for MedicalDevices, following ISO 10993-18 **Sandi Schaible，Director, Analytical Chemistry, Wuxi AppTec**
15:05-15:30	Radiation Verification Dose Survivors **Sean Colwell, B.A. Technical Director, Wuxi AppTec**
15:30-15:40	会议结束语

**Conference agenda updates according to speaker confirming.*

*Conference Inquiry:

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