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	How to improve Quality through Unannounced inspection **Officer, CFDA**
10:40-11:20	Unique Device Identification (UDI) with Open Automatic Main Body Recognition being the Most Preferred Choice of Post-Market Supervision By the International Community **Liang Yan, Director, SIMSCA**
11:20-12:00	Perspective of final user: Medical Device Registration and Listing **Kui Cai, Commissioner, China Society For Drug Regulation Medical Device Supervision Committee**
12:00-13:30	Lunch & show visit
13:40-14:20	The interpretation and implementation of the medical device registration system **Feng Lin, Director, Division of Medical Devices Registration, SHFDA**
14:20-15:00	Key points for the implementation of clinical trial quality management of medical device in China **Vivian Li，Director of Medical Affairs and Clinical Research，Johnson & Johnson Medical China**
15:00-15:10	Tea Break & Networking
15:10-15:50	Regulatory Challenges and Risks with UDI Direct Marking Implementation **Bridge Ba，Medical Manager，FOBA China (a Danaher Company)**
15:50-16:30	Clinical trial design of medical device complying with the updated regulation **Luke Lu, NAMSA China Clinical Director**
16:30-16:35	Track Close

Medtec China 2018 onsite: MDiT Forum and Regulation Summit 2018

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 do Quality Control to apply 510 K easily **ZELI YU，RAC，Global**
15:50-16:30	EU MDR & IVDR implications for device manufacturers & supplier **Lane JI，Healthcare Director，BSI China**
16:30-16:35	Track Close

Medtec China 2018 onsite: MDiT Forum and Regulation Summit 2018

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 **Fred Mao, Executive Director, Frost Sullivan**
14:20-15:00	From the view of medical device manufactures, how to do the supplier development and management control **Alex Jiang, Quality Director of APAC & Emerging Markets, Smith & Nephew**
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

Medtec China 2018 onsite: MDiT Forum and Regulation Summit 2018

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 **ZELI YU, 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? **ZELI YU, RAC，Global**
12:00-12:20	**Q&A**
12:20-12:40	Experience sharing of CFDI oversea inspection **ZELI YU, RAC，Global**
12:40-12:50	Track Close

Medtec China 2018onsite: MDiT Forum and Regulation Summit 2018

Technology Track A: Concepts and Ways of Medical Device Design

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	New Solutions for innovation in Long Term Implantable Devices **Bertrand BORDES，Global Market Manager， Elkem**
14:45-14:55	Tea Break & Networking
14:55-15:35	The application of 3D printing technology in medical device innovation **Chengtao Wang, Institute of Biomedical Manufacturing and Life Quality of Engineering, Academic Leader, Shanghai Jiaotong University**
15:35-16:15	Quality Control based on reliability of medical device **Chunxia Li, Director, Instrumentation Technology and Economy Institutive**
	Track Close

Medtec China 2018 onsite: MDiT Forum and Regulation Summit 2018

Technology Track B: Next-Gen Design & New Technology

Morning of Sep 26 | Conference Room A, SWEECC

09:30-09:55	Registration & Networking
09:55-10:00	Moderator Remarks
10:00-10:30	Design for demand, case study of demand deliver innovative products **Jane Ye, Senior Scientist and Business development, INTEGRATED TECHONOGIES LIMITED**
10:30-11:00	How to shorten the development cycle of medical device **Aric Wang, R&D Director, Joymed Technology (Shanghai) Co., Ltd**
11:00-11:30	Innovation and challenges of bio material design and R&D **XiaoNong Zhang, Professor, Shanghai Jiaotong University**
11：30-12：00	Solution for Precision and Complex Metal Component in Medical Devices **Jason Tsai, Regional Manage，Indo-MIM Private Limited**
12:00-12:05	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 **Selena Qin,Secretary General，CMPC**
10:10-10:40	Cost Benefit Analysis When Purchasing HFFS Machinery **John P. Merritt,Business Development Director MCP MULTIVAC**
10:40-11:10	Particular requirements for validation of processes for sterilization and sterile barrier systems **Jimmy Song, Deputy Chairman,CMPC**
11:10-11:40	Microbiological Testing During Sterilization Validation **Haiying Xu, Vice-general manager of Tech, Moicroport**
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 **Yi Zeng, Doctor, The Ohio State University**
14:10-14:40	Requirements on plastics and high polymer material from medical device manufacturers **Hua Jiang, Director of Testing, Tianjin Medical Devices Quality Supervision and Testing Center, CFDA**
14:40-15:10	Safe and effective solution for elastomer materials bonding **Jenny Cheng， Technology Service Engineer ,Henkel**
15:10-15:40	Application and hotspots of mechanical engineering in medical plastic products
15:40-15:50	Track Close

Medtec China 2018onsite: MDiT Forum and Regulation Summit 2018

Technology Track E: Dressing Material and Technology Forum

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

14:00-14:10	Moderator Remarks
14:10-14:40	R&D and design sharing of new type medical dressings **Yimin Qin, Ph.D., Professor, MBA, Tai shan scholar**
14:40-15:10	Application of medical non-woven fabric in surgical infection and control products **Jun Luo, CEO, Beautiful Nonwoven**
15:10-15:40	Biocompatibility evaluation of new biological explanation materials **Gui zhang, Director of Shenzhen Advanced Medical Services co. LTD**
15:40-15:50	Track Close

Medtec China 2018onsite conference

The 4th Market Report Track of Medical Device Industry

Morning of Sep 28 |Conference 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, Executive Director, Frost Sullivan**
10:30-11:00	New growth point and the changes in medical device market **Stephen Sunderland，CEO，L.E.K.**
11:30-11:40	Track Close

Medtec China 2018 onsite conference

Regulatory Lecture

Sep 27 | Conference Room B, Hall 2 of SWEECC

10:00-10:20	Moderator Remarks **Liang Yan, Director, SIMSCA**
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
14:00-14:30	Wuxi AppTec –Medical Device Testing Business China Launch Event
14:30-14:50	ASCA of medical device to FDA and CFDA standards **PhD, Bill Harrison, VP, Safety assessment center, Wuxi AppTec**
14:50-15:15	Biological Evaluations of Medical Devices **Mark A. Cabonce, M.S., DABT，Director of Technical & Regulatory, Wuxi AppTec**
15:15-15:35	Designing Materials Characterization Studies for MedicalDevices, following ISO 10993-18 **Sandi Schaible，Director, Analytical Chemistry, Wuxi AppTec**
15:35-16:00	Radiation Verification Dose Survivors **Sean Colwell, B.A. Technical Director, Wuxi AppTec**
16:00-16:20	Tongji University Lecture
16:20-16:30	Track Close

Medtec China 2018 onsite conference

Grow in China, Grow with Moicroport

Sep 28 | Conference Room B, Hall 2 of SWEECC

09:50-10:00	Moderator Remarks
10:00-10:30	Grow in China, Grow with Moicroport **Raomin Wang, Purchasing Director, MicroPort**
10:30-11:15	Knowledge and risk introduction of Aorta products **Zhenyu Yuan, Doctor, Aorta R & D Director，MicroPort**
11：15-11：45	Knowledge and risk introduction of Surgical component products **Jian He，Supervisor of engineering department，Shanghai MicroPort Access Medtech Co.,Ltd.**
11:45-11:55	Track Close

**Conference agenda updates according to speaker confirming.*

*Conference Inquiry:

Speaker & Cooperation

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