

*Registration is required.

Regulation Summit: Chinese Regulatory Updates and Compliance

Sep 25, 2019 | Conference Room 4 B2 of SWEECC

09:00-09:50	Registration & Networking Breakfast Meeting
09:50-10:00	Moderator Remarks
10:00-10:20	Updates of Regulations of Supervision and Administration of Medical Devices Medical Device Registry of Shanghai Food and Drug Administration (Pending)
10:20-10:40	Establishment and implementation of medical device registrant system Haihong Jiang, Director; Associate professor; Lawyer, Shanghai University of Medicine&Health Sciences
10:40-11:00	Practice process of Listing Permit Holder System in China <ul style="list-style-type: none"> • Updated case study sharing in Shanghai Medical Device Supervision and Management office of Shanghai Food and Drug Administration (Pending)
11:00-11:20	Opportunities for Medical Devices R&D Enterprises and Developers Under Registration System Gemmy Song Expert Team, Jiushun Group
11:20-13:30	Lunch & Exhibition Visit
13:30-14:10	Interpretation of Clinical Trial Management System Reform of Medical Device Jincheng Zhan, Marketing Manager, OSMUNDA Medical Device Service Group
14:10-14:50	Application of Innovative Medical Devices – Interpretation of Expert Xiaoming Feng, Researcher & Deputy Director, Department of Biomaterials and Tissue Engineering, China Food and Drug Testing Institute
14:50-15:20	Tea Break & Networking
15:20-16:00	Supervisory management plan for imported medical device and its influence Christine Jiang, Regulatory Affairs Director; Co-Founder, RAMED (Beijing) Medical Technology Co., LTD.
16:00-16:30	Medical Device Administration Events (MDAE) management and re-evaluation Yunzhang Cheng, Professor; Doctoral Supervisor, Director of Shanghai Interventional Medical Device Engineering Technology Research Center; Deputy Dean of School of Medical Instrument and Food Engineering of USST; Executive Director of National continuing education base for professional and technical personnel
16:30-16:40	Track Close

Quality Track A: Risk Management of Medical Product Life Cycle

Morning of Sep 26, 2019 | Conference Room 4, B2 of SWEECC

09:00-09:20	Registration & Networking
09:20-09:30	Moderator Remarks
09:30-10:10	Updates and orientation of ISO 14971 Carrie Wu, Quality Director; M.R., Conod Medical Co., Limited
10:10-10:50	Biological evaluation and testing of medical device based on risk management
10:50-11:10	Tea Break & Networking
11:10-11:50	From the Perspective of Device Manufacturer: How to Conduct Reliability-Centered Medical Device Quality Management Lingyun Shao, Deputy Director, Central R&D Management Department (Reliability & Product Safety & Public Platform), Mindray Bio-Medical Electronics Co., LTD
11:50-12:30	Development Status and Analysis of Medical Device Reliability Chunxia Li, Director, Laboratory of Medical Equipment Reliability, Institute of Integrated economy and Technology of Mechanical Industry Instrument
12:30-12:40	Track Close

Quality Track B: MDSAP Update and FDA Inspection

Morning of Sep 26, 2019 | Conference Room 6, B2 of SWEECC

9:00-9:10	Registration & Networking
9:10-9:15	Moderator Remarks
9:15-9:45	<p>MDSAP Update</p> <ul style="list-style-type: none"> • MDSAP latest update • FDA' S plans to adopt ISO 13485 <p>William M. Sutton, Assistant Country Director, FDA China</p>
9:45-10:25	<p>MDSAP factory experience sharing</p> <ul style="list-style-type: none"> • The challenges that factory and NB will meet when supervisory and certification audit • The influence of MDR on Quality system MDSAP audit <p>ZELI YU, RAC, Global</p>
10:25-10:35	Tea Break & Networking
10:35-11:15	<p>FDA inspection, what' s new in 2019?</p> <ul style="list-style-type: none"> • Change of organization chart • Change of 510 k • FDA adopt ISO13485 • Key working points of 2018-2020 <p>ZELI YU, RAC, Global</p>
11:15-11:55	<p>Key points of FDA inspection for device manufacturers in 2018-2019</p> <ul style="list-style-type: none"> • Review of FDA inspection of 2018 and summary of recall • Key points for FDA inspection • How to prepare your inspection • Notification of replying 483s <p>ZELI YU, RAC, Global</p>
11:55-12:05	Q&A
12:05-12:10	Track Close

Technology Track A: The 7th IIMD China Summit (Implantable and Interventional Medical Device)

Sep 25, 2019 | Conference Room 7, B2 of SWEECC

09:20-09:50	Registration & Networking
09:50-10:00	Moderator Remarks
10:00-10:40	New trends in the interventional medical device industry - the latest sharing of cardiovascular system regulations and technologies Tingfei Xi, Director, Researcher, National Institutes for Food and Drug Control
10:40-11:20	Research and development of drug - carrying balloon and clinical application case sharing Heyan Dong, Chairman, President, Chairman, National Technical Committee on Cardiovascular Implants, Dalian Medical Device Industry Association, Liaoning Biomedical Materials R&D Center Co., Ltd.
11:20-12:00	To Intervene in the Research and Development of Artificial Heart Valve and Its Clinical Application Xiaoli Yu, Doctor, Second Affiliated Hospital of Guangzhou Medical University
12:00-13:30	Lunch
13:30-14:10	Innovative R&D of orthopedic implants based on transformation of clinical demands Xiaojun Chen, Engineer of Sanshui Laboratory, GDMDT; Guangzhou medical device quality supervision and inspection center, state food and drug administration; Guangdong medical equipment quality supervision and inspection institute packaging material container inspection center
14:10-14:50	Design and R&D sharing of orthopaedic implants Zion Xu , APAC R&D Director, Zimmerbiomet
14:50-15:10	Tea Break & Networking
15:10-15:50	Understanding Chinses regulation on Supervision and Administration of Customized Medical Devices and the influence
15:50-16:30	Application of 3D printing technology in IIMD products Weimin Zhou, Director; Research Fellow, Technology Innovation Center for 3D Printing of Shanghai Industrial Technology Institute
16:30-16:40	Conference Close

*Free.

Technology Track B: Technology Development of New Type Medical Dressings

Morning of Sep 25, 2019 | Conference Room A, Hall 2 of SWEECC

9:50-10:00	Moderator Remarks
10:10-10:30	Category and market requirement analysis of high-end new type medical dressings Jiamian Zhu, General Manager, Roosin Medical Co., Ltd.
10:30-11:00	Research and development of antimicrobial dressings and technology sharing Fang Hu, Chairman, Bestlife Regenerative
11:00-11:30	Performance and application of medical dressings containing silver Yimin Qin, Director, State Key Laboratory of Bioactive Seaweed Substances
11:30-12:00	Application of biological dressing products in clinical treatment
12:00-12:10	Track Close

Technology Track C: Plastic Molding Technology in Medical Device Manufacturing

Afternoon of Sep 25, 2019 | Conference Room A, Hall 2 of SWEECC

FANUC

13:50-14:00	Moderator Remarks
14:00-14:30	Analysis injection molding technology of medical device from quality standard, cleanliness and efficiency requirement Dongqian Wang, Sales Manager, FANUC
14:30-15:00	Improve mould design and manufacturing technology to meet the new requirements of medical equipment development Mancang Song, Deputy director , Mold Research Institute, Dalian University of Technology
15:00-15:30	The practical application of flat hot runner technology in medical device manufacturing
15:30-16:00	How can medical device manufacturers cooperate with injection molding companies to produce products that meet the requirements
16:00-16:10	Track Close

Technology Track D: The 3rd Session of Pack & Ster Hub

Afternoon of Sep 26, 2019 | Conference Room A, Hall 2 of SWEECC

13:50-14:00	Moderator Remarks
14:00-14:30	Regulatory standard system and compliance of sterilization medical device packaging in China Selena Qin, Secretary General, CMPC
14:30-15:00	New Medical Device Packaging Material – Tyvek® 40L Introduction and Application Sharing Helen Zhang, Healthcare Global Market Development Leader, S&C
15:00-15:30	Medical Films---Full Compliance with the requirements of ISO11607-1 Luc Vander Broeck, Application Manager, Pharmaceutical & Medical Device Films, Klöckner Pentaplast Europe Pharmaceutical Films Division
15:30-16:00	Packaging scheme and seal verification Jimmy Song, Deputy Chairman, CMPC
16:00-16:30	The method of accurately controlling the sealing effect of the package by monitoring the sealing pressure and other parameters online Shi Rui, Technology Specialist, CMPC
16:30-16:40	Track Close

Technology Track E: The 4th Conference of Medical Device Design

Morning of Sep 26, 2019 | Conference Room A, Hall 2 of SWECC

09:50-10:00	Moderator Remarks
10:00-10:30	Basic principles of medical device product design
10:30-11:00	How to get design ideas from end users Maolin He, Senior Application Consultant of Minitab, Techmax
11:00-11:30	Case study: how to improve the design sense of medical device products Enjoyjob Design
11:30-12:00	Case Study: Tailored Draw Tower Gratings in MultiCore Fiber enabling unobtrusive and passive curvature, shape and force sensing solutions Dr. Bram Van Hoe, Director of Sales and Marketing, FBGS Technologies
12:00-12:30	The importance of human factors engineering in the design of medical devices and innovative medical robots
12:30-12:40	Track Close

Technology Track F: Core Components and Technologies of Medical Electronic Products

Morning of Sep 25, 2019 | Conference Room B, Hall 2 of SWEECC

9:50-10:00	Moderator Remarks
10:00-10:30	Market demand and development trend of medical electronic devices
10:30-11:00	The latest R&D of pacemakers and the demand for its core components
11:00-11:30	Research and application of flexible wearable ion humidity sensor
11:30-12:00	Application of high integration single chip solution in medical instrument Nano and Advanced Materials Institute Ltd.
12:00-12:30	Case study: design of medical switch and power supply C&K Switches
12:30-12:40	Conference Close

Technology Track G: Seminar on Medical Bonding and Welding Technology

Afternoon of Sep 25, 2019 | Conference Room 8, B2 of SWEECC

13:20-13:30	Moderator Remarks
13:30-14:10	Application, regulation standard and development trend of medial bonding and welding technology Ke Chen, Associate Professor, Doctoral Supervisor, School of Materials Science and Engineering, Shanghai Jiao Tong University
14:10-14:50	Common problems in medical plastic welding David Fang, Medical Industry Manager, Branson Ultrasonics(Shanghai) Co., Ltd.
14:50-15:30	Comparison and Selection of Leak Detection Methods in Medical Device Production Process. Bruce Li, Medical Industry Manager, ATEQ CHINA CO.,LTD
15:30-16:00	Innovative adhesive solution for medical products Dr. -Ing. Jian-Yi Shao , Managing Director, Hoenle UV Technology (Shanghai) Trading Co.,Ltd
16:00-16:30	Selection and application of medical adhesive
16:30-16:40	Conference Close

The 2nd Edition of Regulatory Lecture: Best Practice for Product Compliance and Market Launch

Sep 26, 2019 | Conference Room B, Hall 2 of SWEECC

10:20-10:30	Moderator Remarks	
10:30-10:50	Updates from U.S. FDA/CDRH 2018/2019	
10:50-11:20	MDR transition period is coming to an end, how should medical device enterprises deal with it Hongtao Fu, Shenzhen Joyantech Consulting Co., Ltd.	
11:20-11:50	The relationship among manufacturers, suppliers and Notified Body in the new EU regulations	
11:50-14:00	Lunch & Exhibition Visit	
14:00-14:10	WuXi AppTec	Opening Speech
14:10- 14:30		Impact of MDR on Pre-clinical Testing Nan Zuo, Director, Regulation Registration Division of WuXi AppTec
14:30- 14:50		Chemical characterization of medical device- case studies for extractables assessment of orthopedic products Xiaolong Rong, Technical Director, Chemistry Laboratory of WuXi AppTec
14:50- 15:10		Animal Surgical Experiments on Medical Instruments—Animal Surgical Experiments of Implants and Interventional Instruments Yuzhu Sun, Surgeon, Surgical Services of WuXi AppTec
15:10-15:30		Similarities and Differences between Medical Devices and Drug Clinical Trials Xiaoying Gao, Senior Project Manager; Strategic Management Manager, WuXi Clinical

The 5th Market Report Track of Medical Device Industry

Morning of Sep 27, 2019 | Conference Room A, Hall 2 of SWECC

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	Investment and M&A trend analysis of medical device industry Maggie Zhao, Partner, Medical & Health Division, Youchoose Capital
11:00-11:30	Analysis new growth points and changes of medical device market from product, region and terminal use demand Stephen Sunderland, Managing Director, L.E.K. Consulting
11:30-12:00	From the point of view of the whole industrial chain, what is worth paying attention to the new hot spot?
12:00-12:10	Q&A