

11th China International Medical Device Regulatory Forum

First Round Notice

Fuzhou Strait International Conference & Exhibition Center
Fuzhou · China
November 17–20, 2020

Host: China Center for Food and Drug International Exchange (CCFDIE)

Co-Host: Center for Medical Device Evaluation (CMDE), NMPA

Support: Advanced Medical Technology Association (AdvaMed)

European Medical Imaging, Electromedical and Healthcare IT Industry Association (COCIR)

China Association for Medical Devices Industry (CAMDI)

Japan Radiation Imaging Medical System Industry Association (JIRA)

MedTech Europe

Korea Medical Devices Industrial Coop. Association (KMDICA)

Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)

Medical Imaging and Technology Alliance (MITA)

Asia Pacific Medical Technology Association (APACMed)

Chinese Society for Biomaterials (CSBM)

Notice on Holding 11th China International Medical Device Regulatory Forum (CIMDR)

In order to publicize the Chinese medical device regulations and policies, strengthen the exchange of international medical device regulations and technical norms, promote the experience exchange and interactive learning among medical device evaluation bodies of different countries, improve scientific and technical level of the evaluation, enhance enterprises' consciousness to obey the regulations, boost communications between enterprises and governments as well as among enterprises themselves, push forward application of new technical standards and technological achievements, further improve safety and effectiveness of medical devices, China Center for Food and Drug International Exchange (CCFDIE) will hold the 11th CIMDR from November 17 to 20, 2020.

The theme of 11th CIMDR is Perfection, Innovation, Contributing China's Wisdom to Global Supervision. Representatives of Chinese and foreign medical device regulatory authorities, medical device technical review institutions, international organizations for regulatory harmonization activities of medical devices and standardization institutions, as well as specialists from medical device application areas and representatives of medical device enterprises will give speeches and interact on the CIMDR, and will discuss measures and experiences in the filed of medical devices to address the challenges of fighting against COVID-19 globally.

Because of impact of COVID-19 pandemic, the previously scheduled time and location of the Forum (September 8 to 11, 2020 in Wuhan, Hubei Province) have been adjusted. After communicating with related departments, it is planned to postpone CIMDR to November 17–20, 2020, at Fuzhou Strait International Conference & Exhibition Center in Fujian Province. In order to protect the health of representatives and to ensure the good effectiveness of the Forum, according to the requirements of the Notice on Further Improve Related Epidemic Prevention-and-Control Work in Key Areas and Key Units as well as Key Groups issued by Joint Prevention and Control Mechanism of the State Council, we will continue to pay close attention to the development and changes of the epidemic, to hold this Forum in strict accordance with the relevant epidemic-prevention requirements. CIMDR will still be held on spot in the main venue at Fuzhou, combined with online and live broadcast if necessary to ensure the participation effects.

We Look Forward to Your Participation!

Time and Scheme

Full Day of November 17: Registration

Full Day of November 18,
Afternoon of November 20: Plenary Meeting

Opening Ceremony

Introduction of New China Medical Devices Supervision Regulations, Implement the associated administrative regulations-Presented by related leaders from Medical device regulatory authorities.

Introduction of International Medical Device Supervision Regulations, Technical Methods and Medical Device Standards—By medical device regulatory authorities of various countries; technical organizations; medical device standardization organizations and experts from pharmaceutical industry.

Full Day of November 19, Morning of November 20: Sub-forums

- 1. Medical Device Innovative Forum
- 2. Medical Device Clinical Trial and RWE Forum
- 3. Medical Device Regulatory Science Forum
- 4. Medical Device Standards and UDI Implementation Forum
- 5. Medical Device Biologic Evaluation Forum
- Medical Device Post-marketing Inspection and Risk Management Forum
- 7. Medical Device Cybersecurity Forum
- 8. Al Forum
- Orthopedics, Odontological and Surgical Devices
 Forum (Including 3D printing and customized
 products)
- 10. IVD (Including CDx) Forum
- 11. Drug-device Combination Products Forum
- 12. Medical Imaging Devices Forum
- Medical High Molecule Products and Consumables Forum
- Cardiovascular and Cerebrovascular System
 Devices Forum
- 15. Optics and Ophthalmic Devices Forum
- 16.Emergency Management and Epidemic Prevention and Protective Products Forum (Including Topics on Temperature Management)

In order to continue actively promoting the development of innovative medical devices, improving the quality of development, intensifying the risk control and consolidating implementation of responsibility, also to encourage the growth of small and micro enterprises, forums on R&D and Application on Household Medical Devices, Medical Device Managers 50 (MD50) and Development of Regulatory Affairs Professionals will be held in the same period of the 11th CIMDR, to discuss the scientization and legalization of medical device supervision as well as new technologies of innovative medical device, representatives from the field of medical devices and related industries are warmly welcome.

Forum Information

Location of the Forum

Fuzhou Strait International Conference & Exhibition Center Address: No.198 on South Binjiang Road at Chengmen Town, Cangshan district, Fuzhou city,

Fujian province, China

Tel: +86(591)8803 9800

Website: http://www.fsicec.com/en/about.asp

Forum Language

English and Chinese Mainly. Simultaneous interpretation in Chinese and English is provided.

Registration Fee

Early bird registration (By October 18, 2020)	Online registration and on–site registration (Since October 19, 2020)
RMB 4800 / person	RMB 5800 / person

*Only those representatives who complete the payment before (including) October 18, 2020 can be qualified for the early bird registration price. The price will be automatically become RMB 5800 online since October 19, 2020.

Registration Procedures

1. Online Registration

1) Fill in Registration Information Form: Login in China International Medical Device Regulatory Forum website: www.cimdr.com and click the "online registration"; Please complete and upload the registration information form, and handle remittance on time.

2) Check Registration Confirmation Letter: After receipt of your remittance and registration information, the Secretariat will send you an email within 7 working days to confirm your registration. If you do not receive the confirmation email, please contact the Secretariat:

Zhang Dongyue: 86-18710251585 Wu Jianhua: 8610-82212866-6017

3) Check-in for the forum: Please take with you the "Registration Confirmation Letter" or your ID card to receive your badge, forum materials and check-in at the registration desk.

2. On-site Registration

If one has not yet registered online in advance, please fill in the registration information at the self-help registration desk and follow the registration procedure form to finish the registration on-site.

Date of on-site registration and payment:

9:00-20:00, November 17, 2020.

In order to avoid congestion on the registration day, online registration beforehand is highly recommended.

3. Cancellation and Refund

When a registered representative desires cancellation, please send a refund statement with the stamp of your company by email to inform the secretariat by October 23, 2020 (Friday). The Secretariat will finish the refund in 30 work days after forum ends. 30% of the registration fee will be charged as service charge. Any fee arises during cancellation and refund will be borne by the one who asks for refund. Refund submission will not be accepted after October 23, 2020.

Registration Fee Payment

New-Creation (Beijing) Exhibition & Conference Services Co.,Ltd is entrusted to undertake the service of this forum.

Please remit the registration fee to:

New-Creation (Beijing) Exhibition & Conference Services Co.,Ltd.

Bank Name: Huaxia Bank Beijing Shijicheng Sub-

BranchBank

Account No.: 1028 1000 0003 42509

Address: No.2, Landianchang East Road, Haidian District, Please indicate "CIMDR2020", your name and company in the postscript when remitting.

Team registration for more than 20 people can remit to:

China Center for Food and Drug International Exchange

Bank Name: Industrial and Commercial Bank of

China, Beijing Xueyuanlu Branch Account No.: 0200025509006763272

Address: No.34 Xueyuan South Road, Haidian

District, Beijing

Please indicate "CIMDR2020", your name and

company in the postscript when remitting.

Traffic Information

About 40 minute-drive from Fuzhou Changle International Airport to the FSICEC.

About 25 minute-drive from the Fuzhou railway station to the FSICEC.

About 15 minute-drive from the Fuzhou South railway station to the FSICEC.

About 15 minute-drive from the Fuzhou new South bus station to the FSICEC.

**The organizer will provide shuttle bus service on November 17. More details of the pick-up service will be released on the website before the Forum.

Accommodation Information

For those who need room reservation, please select the type of the room you prefer after filing in personal information of online registration.

**Since the rooms to be provided are limited, please make reservations as early as possible. Should you have any questions, please contact the person in charge of Accommodation:

Leng Li: 86-13011011085.

Others

For details about the cooperation of the forum, please contact Forum Secretariat.

Forum Secretariat

Address: Room 1106, 11th Floor, Office Building B, Maple International Center, No. 32, Xizhimen North Street, Haidian District, Beijing, 100082, P.R.C

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