CIMDR

China International Medical Device Regulatory Forum

3rd China International Medical Device Regulatory Forum Notice

Sep.4–Sep.7, 2012

Beijing

Organizer: China Center for Pharmaceutical International Exchange (CCPIE)

Support Unit: Center for Medical Device Evaluation, SFDA (CMDE)

Co-organizers: Advanced Medical Technology Association (AdvaMed);

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR);

China Association for Medical Devices Industry (CAMDI)

European Medical Technology Industry Association (Eucomed)

Japan Radiation Imaging Medical System Industry Association（JIRA）

European Diagnostic Devices Manufacturers Association (EDMA)

Notice on Holding the Third China International Medical Device Regulatory Forum (CIMDR)

In order to spread the publicity of China medical device administration regulations and policies, strengthen exchange and cooperation of international medical device administration, promote experience exchange and learn from each other among international medical device evaluation authorities, 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, and, with SFDA’s approval, China Center for Pharmaceutical International Exchange (CCPIE) will hold the third CIMDR from Sep 4, 2012 to Sep 7, 2012.

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.

Moreover, 2012 is a very important year in the revision process of theChinese medical device regulations as the newly revised “Regulations for the Supervision and Administration of Medical Devices” and renewed supporting provisions will very much likely be promulgated. CIMDR will arrange key speakers in accordance with the promulgation situation of the new regulations.

We look forward to your participation!

China Center for Pharmaceutical International Exchange (CCPIE)

April 6, 2012

Preliminary Scheme

Ⅰ **Time and Venue of the third CIMDR:**

Time: September 4, 2012-September 7, 2012
(September 4: all day registration, September 5, 6, 7: Forum)
Venue: Beijing Jiuhua Spa & Resort

Sep.4: All Day Registration

Ⅱ **Forum:**

Sep.5: Plenary Meeting

Opening Ceremony --- Introduction of Chinese Medical Device Regulations (“Regulations for the Supervision and Administration of Medical Devices” has been placed in the priority list of 2012 by the State Council, and the supporting provisions will also be issued then.)
--- Presentations by high level officials from SFDA and its related departments and bureaus

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; Chinese technical institutions for medical device supervision.

Full Day of Sep.6, Morning of Sep.7: Sub-forums

1.In-vitro Diagnostic Devices Forum
Newly developed Chinese regulations and technical evaluation repuirements, and global new technical developments, evaluation practices, clinical trial requirements, standards and testing, quality system, risk management, and adverse event monitoring and handling of in-vitro diagnostic reagent, equipment, home-use testing devices, etc.

2.Drug-device Combination Products Forum
Newly developed Chinese regulations and technical evaluation repuirements, and global new technical developments, evaluation practices, clinical trial requirements, standards and testing, quality system, risk management, and adverse event monitoring and handling of drug-device combination products.

3.Ophthalmic and Optometry Devices Forum
Newly developed Chinese regulations and technical evaluation repuirements, and global new technical developments, evaluation practices, clinical trial requirements, standards and testing, quality system, risk management, and adverse event monitoring and handling of contact lens, intraocular lens, eye care products, ophthalmic surgical devices, optometry products and materials, etc.

4.Orthopaedics and Surgical Instruments Forum
Newly developed Chinese regulations and technical evaluation repuirements, and global new technical developments, evaluation practices, clinical trial requirements, standards and testing, quality system, risk management, and adverse event monitoring and handling of spine, joint, trauma and surgical device products, etc.

5.Medical Imaging Devices Forum
Newly developed Chinese regulations and technical evaluation repuirements, and global new technical developments, evaluation practices, clinical trial requirements, standards and testing, quality system, risk management, and adverse event monitoring and handling of CT, X-ray device, ultrasonic and magnetic resonance products, etc.

6.Medical High Molecule Products and Consumables Forum
Newly developed Chinese regulations and technical evaluation repuirements, and global new technical developments, evaluation practices, clinical trial requirements, standards and testing, quality system, risk management, and adverse event monitoring and handling of transfusion sets, syringes, blood bags, blood collectors, dialyzers, dressings, medical packaging materials, medical consumables, etc.

7.Cardiovascular and Cerebrovascular System Devices Forum
Newly developed Chinese regulations and technical evaluation repuirements, and global new technical developments, evaluation practices, clinical trial requirements, standards and testing, quality system, risk management, and adverse event monitoring and handling of pacemakers, defibrillators, artificial heart valves, cardiovascular stents, catheters, closure devices and related biological materials, etc.

8.Odontological Device Forum
Newly developed Chinese regulations and technical evaluation repuirements, and global new technical developments, evaluation practices, clinical trial requirements, standards and testing, quality system, risk management, and adverse event monitoring and handling of dental chairs, dental surgical devices, dentures, dental implants and materials, etc.

Registration Information

Location of the Forum

District16, JiuHua Hotel
Xiaotangshan, Changping, Beijing, China
Zip Code: 100211
Tel：010-61782288
Web: http://www.jiuhua.com.cn

Conference Language

English and Chinese Mainly; all venues are in foreign language simultaneous interpretation.

Registration Fee

RMB4000 Yuan before August 5
RMB5000 Yuan after August 5

Registration Procedures

1. Login China International Medical Device Regulatory Forum
   web site:http://www.cimdr.com and click the online registration button；or login http://www.ccpie.org web site and open China International Medical Device Regulatory Forum page , enter the English interface and click the online registration button —— complete and upload the registration information form, handle remittance and fax remittance voucher to the Forum Secretariat: 010-82212857 (please indicate in the postscript CIMDR2011 and the registrant name).
2. The Secretariat will, after receipt of your remittance and registration information, send you a short message within 7 working days to confirm your registration. After receiving the confirmation message, you can go to the website to print the registration confirmation letter. If you do not receive the short confirmation message, please contact the Secretariat.
3. Field registration time: 9:00-20:00, Sep.4, 2012
   (In order to guarantee hotel rooms, facilitate registration and avoid field congestion on the registration day (Sep.4), it is strongly recommended that you register beforehand.)
4. Please hold your registration confirmation letter to check in at the registration desk at Zone 16, Jiuhua Hotel, Beijing, receive forum materials, and handle accommodation procedures.

Registration Fees Delivery

Bank transfer to:
BANK OF COMMUNICATIONS HAIDIAN BRANCH
Account Name:
Asia-Med (Beijing) Exhibition&Conference Services Co.,Ltd
Account：110060576018150017317
ADD：NO.16 SUZHOU ST.,HAIDIAN DISTRICT,BEIJING
Swift No.:commcnshbjg

Cancellation

When a registered representative desires cancellation, please inform the secretariat in written form before August 14, 2012 for refund. The paid registration fee will be returned after deducting a handling charge of 200 yuan. Application for refund submitted after August 15, 2012 will not be accepted.

Traffic

Take subway from downtown area and get off at Tiantongyuan station, and then take a taxi to Jiuhua Hotel (about 10km), or take a taxi from downtown area to Jiuhua Hotel directly (the whole distance is over 20km, depending on the place you start with). The Organizing Committee will arrange shuttle bus service on September 4. Details of shuttle bus arrangements will be announced on the website before the Forum.

Return air ticket booking

Return tickets can be purchased at Jiuhua business center.

Volunteer Supporting

Please contact the Forum Secretariat for volunteer supporting arrangement.
Contact: Ms. Natalie Yu：0086-10-82212866 ext 6016
Mr. Ma Zheng：0086-10-82212871
Ms. Shi Hui: 0086-10-82212866 ext 6015
Fax: 010-82212857
e-Mail: yuyue@ccpie.org
mazheng@ccpie.org
shihui@ccpie.org

Registration Form
The Third China International Medical Device Regulatory Forum (CIMDR)

Please login http://www.cimdr.com or http://www.ccpie.org to make online registration. In case of internet inconvenience, please complete this form and fax to the Secretariat: 010-82212857.

Name:_____ Gender：_____

Organization：_____ Title：_____

Address：_____ Zip：_____

Tel：_____ Fax：_____

Mobile：_____ E-mail：_____

Registration Fee

☐4000 Yuan before August 5	☐5000 Yuan from August 5

(Meals and forum materials are included)

Accommodation: (enjoy the forum discount price, at your own expense)

Room type	Forum Discount Price	Published Price
Standard room,JiuHua Hotel, 3 star level (District 9)	☐280	420
Standard room, JiuHua Hotel, 4 star level (District 15)	☐420	700
Single room, JiuHua Hotel, 4 star level (District 15)	☐420	700
Executive suite, JiuHua Hotel, 4 star level (District 15)	☐960	1320
Standard room, JiuHua Hotel, 5 star level (District 16)	☐480	840
King-size-bed room, JiuHua Hotel, 5 star level (District 16)	☐480	840
Business suite, Jiuhua Hotel, 5 star level (District 16)	☐1080	1440

Arrival Date: _____ Departure Date : _____

The Organizing Committee will arrange rooms according to booking order and room availabilities, but does not guarantee the type of rooms. The Organizing Committee will not accept earnest money. When you wish to make a change on your reservation, be sure to notify the Secretariat in writing.

Please return this form by fax or e-mail, or mail to:
China Center for Pharmaceutical International Exchange,
1106 Office Building B, Maples International Center, 32 Xizhimen North Street, Beijing, China
Zip Code: 100082
Tel: 0086-10-82212866 ext 6010
E-mail:yuyue@ccpie.org
Fax: 010-82212857
Web: http://www.cimdr.com
http:// www.ccpie.org

Conference Secretariat

Add: 1106 Office Building B, Maples International Center, 32 Xizhimen North Street, Beijing, China

Contact: Ms. Natalie Yu: 0086-10-82212866 ext 6016

Mr. Ma Zheng: 0086-10-82212871

Ms. Shi Hui: 0086-10-82212866 ext 6015

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