

**8th GHTF Conference
Meeting Session Brief**

Title: China Regulatory Procedures Meeting
Date/Time: Monday, September 18, 2:30 - 4:30 p.m.

Topic: Top officials from the Medical Device Department of China's State Drug Administration (SDA) will provide an outline and update on the new medical device regulatory framework implemented in April 2000. The session offers industry representatives and regulatory officials a chance to hear firsthand about how the new Chinese regulatory system is working in practice, to learn about the SDA's plans for future regulatory developments, and to raise questions on topics of interest or concern regarding registration of medical devices for China's rapidly-growing market.

Proposed Agenda:

Co-Moderators' Introductory Remarks: Mr. Jeffrey Gren & Mr. Michael Baker
Outline of China's Medical Device Regulatory Requirements: SDA officials
Frequently-Asked Questions about the New Regulatory System: SDA officials
State Drug Administration's Plans for Future Refinement of Regulations: SDA officials
Audience Questions/Answers

Speakers:

Hao Heping, Director-General, Department of Medical Device Administration
State Drug Administration of China
38A Bei Lishi Road, 100810, Beijing, People's Republic of China
Tel: (86) 106-831-3344 / Fax: (86) 106-831-5648/5649

Chang Yonghen, Dir., Foreign Product Registration Div., Dept. of Medical Device Admin.
State Drug Administration of China
38A Bei Lishi Road, 100810, Beijing, People's Republic of China
Tel: 86-106-831-3344 / Fax: 86-106-831-5648/5649

Co-Moderators:

Jeffrey L. Gren, Dir., Office of Microelectronics, Medical Equipment & Instrumentation
U.S. Department of Commerce
ITA-Room 1015, 14th Street at Constitution Avenue, NW
Washington, D.C. 20230 U.S.A.
Tel: 1-202-482-2470 / Fax: 1-202-482-0975 / e-mail: Jeffrey_Gren@ita.doc.gov

Michael Baker, Director-General
EUCOMED
Place St.Lambert, 14
B-1200 Brussels, Belgium
Tel: 32-2-772-2212 or 32-2-775-9221 / Fax: 32-2-771-3909
e-mail: Michael.Baker@eucomed.be

Attachments:

- Order #276 of the State Council of the People's Republic of China:
"The Regulation and Supervision of Medical Devices (effective April 1, 2000)
- "Administrative [Management] Provisions on Registration of Medical Devices"
- "Categorized Rules on Medical Device Clinical Trial Reports"
- "Regulations for Medical Device Classification"