Guidance & Alerts

CFDA releases new medical device testing guidance
CFDA 7/19/13
The new guidance from the CFDA lays out in detail a new paradigm for the CFDA's own device testing requirements, including timelines for completion, standards to be used, and requirements for samples. This will apply to both national and industry standards that are commonly used during medical device testing. It calls on CFDA testing laboratories to improve their current approaches to testing of medical devices, in addition to mandating the timely return of samples to manufacturers seeking CFDA approval, something that is a frequent complaint from foreign firms. This is a welcome change and certain to help resolve intellectual property issues due to samples not being returned.

CFDA medical device division issues open call for feedback
CFDA 7/16/13
With the recent CFDA restructuring, the regulatory authority’s medical device division has issued an open call for feedback. The scope is not limited to any particular area and can be found here: http://www.sfda.gov.cn/WS01/CL0779/82400.html

CFDA updates adverse event reporting system guidance
CFDA 7/17/13
This guidance update from the CFDA concerns the progress of the medical device adverse event (AE) reporting system currently underway. The goal of AE reporting system is to protect the public health via coordination of medical device AE reporting at a national level, something that is currently being done

“The new guidance from the CFDA lays out in detail a new paradigm for the CFDA's own device testing requirements, including timelines for completion, standards to be used, and requirements for samples.”
only at the provincial level. There will be several “monitoring institutions” throughout China responsible for making this plan a reality by standardizing monitoring work and expanding monitoring coverage, as well as creating an AE early warning system and an overall network to support a national medical device AE monitoring system. The goals are to have a functional system in place by the end of 2014, with one year of review and testing prior to final release in 2015.

What’s new at the CFDA
For other CFDA news, see http://eng.sfda.gov.cn/WS03/CL0757 (English) or http://www.sfda.gov.cn/WS01/CL0001 (Chinese).

Healthcare Updates

Mayo Clinic signs deal with Chinese firm
Mayo Clinic 7/13/13
The Mayo Clinic announced it has signed a deal with Valurise Health Solutions Inc., known as Haorensheng in China, to integrate components of Mayo Clinic's suite of Healthy Living services into its product line for employers and insurers in greater China, including the People's Republic of China, Hong Kong, Macau, and Taiwan. “We are excited to provide Mayo Clinic knowledge to the people of China, where the demand for high-quality health and wellness offerings is growing rapidly. We welcome this opportunity to inform, inspire, and partner with the people of China in their quest for better health,” said Dr. Paul Limburg, medical director of the Mayo Clinic Office of Wellness. As part of the deal, the Mayo Clinic will provide its “Ask Mayo Clinic” triage algorithms; EmbodyHealth programs, tools, and newsletters; health information content; Mayo Clinic Health Letter; and condition management content and materials.

Mental health care falls short in China
China Daily 7/29/13
According to experts on aging as well as industry insiders, more effort is needed to improve training for mental health caregivers for the elderly in China, where it has been estimated that only 4%-5% of nursing home caregivers have accredited professional mental health care training. Guo Ping, a researcher at the China Research Center on Aging, said many extreme events resulting in injury and death, including suicide, have occurred in Chinese nursing homes in recent years. “They mainly happen because of management loopholes at institutions and poor nursing services, such as a lack of timely mental health care,” Mr. Guo noted. Some elderly people “act irrationally and emotionally partly because of normal brain decline,” he added, “and their behavior can be dangerous.” Mr. Guo warned that conflicts can occur easily among such people if caregivers fail to notice problems early.

NHFPC to carry out medical care facilities survey
MOH 7/29/13
The State Council’s National Health and Family Planning Commission (NHFPC) announced it will survey medical service facilities in September. The survey, the fifth of its kind to be conducted since 1993, is intended to help the government learn about local medical service conditions, about demand in the medical sector, and about the distribution of available medical service resources. As part of the survey, medical workers will fill out questionnaires in order to collect information on their working conditions and their feelings toward their jobs. The survey will be conducted from September 1-25 of this year, covering 300,000 people nationwide, according to the NHFPC.

China continues medical reforms
MOH 7/25/13
According to a recent outline issued by the State Council, China will aim at 26 tasks for long-term healthcare reform, including accelerating the building of a national healthcare system, consolidating the basic drug system, improving the operation of grassroots medical...
institutions, and promoting reform of public hospitals. More efforts will also be made to guarantee subsidies for rural doctors and accelerate the establishment of public-funded medical institutions in China. The reforms will create a mechanism to assess and monitor progress while solving emerging problems in a timely manner, said an NHFPC spokesperson. According to the commission, the 26 tasks will be jointly carried out by the NHFPC, the National Development and Reform Commission, the Ministry of Finance, the Ministry of Human Resources and Social Security, and the State Commission Office for Public Sector Reform, in addition to 8 other contributing departments.

“The more efforts will also be made to guarantee subsidies for rural doctors and accelerate the establishment of public-funded medical institutions in China.”

Device Updates

ExAblate Receives CFDA Approval

InSightec 7/30/13

InSightec Ltd, a developer of MR-guided Focused Ultrasound Therapy, announced that its ExAblate system has received approval from the CFDA for non-invasive treatment of uterine fibroids. Uterine fibroids are benign tumors that grow in the uterus. About 20%-50% of women of childbearing age suffer from uterine fibroids. Hysterectomy (surgical removal of the uterus) is the most common form of treatment. ExAblate combines high-intensity focused ultrasound waves and continuous MRI guidance and monitoring. The focused ultrasound energy is used to ablate or destroy the fibroids while the MRI images are used to plan and guide the therapy and monitor treatment outcome. Benefits of ExAblate are that it is incisionless, requires no hospitalization, has a high safety profile with low risk of infection and complications, and results in rapid recovery. ExAblate received approval from the US FDA in 2004.

Mindray Medical completes acquisition of ZONARE Medical Systems

Mindray 7/17/13

Mindray Medical International, a developer, manufacturer, and marketer of medical devices worldwide, announced that it has completed the acquisition of ZONARE Medical Systems, an ultrasound technology developer in the high-end radiology segment, for $102 million USD. Mindray expects that the combined business will benefit from ZONARE’s strong innovative R&D capability and direct sales and service network in the high-end ultrasound market, together with Mindray’s efficient engineering, extensive distribution channels, and broad production platforms. “This transaction brings us superior technology that will ultimately accelerate the launch of our next-generation high-end ultrasound product. It also gives us immediate access to the high-end ultrasound market in the US, Canada, Scandinavia, and Germany. We are optimistic about the transaction and believe we will be better positioned to serve the healthcare market on a worldwide basis for the long term,” said Mr. Minghe Cheng, Mindray’s co-CEO.

Misonix receives clearance in China for the BoneScalpel

Misonix 7/16/13

Misonix, Inc., an international surgical device company that designs, manufactures, and markets ultrasonic products for spine surgery, skull-based surgery, neurosurgery, wound debridement, cosmetic surgery, laparoscopic surgery, and other surgical applications, announced that it has received a registration certificate from the CFDA to market its ultrasonic bone cutting product, BoneScalpel, in China. The BoneScalpel is a novel ultrasonic osteotome (bone cutting and compression device) that facilitates en bloc bone removal and refined osteotomies while sparing elastic soft tissue structures. Most users report that the surgical field is relatively bloodless and clean and that loss of viable bone is minimal and controllable. The BoneScalpel has been used extensively around the world for bone removal in cervical, thoracic, and lumbar spine surgeries.

Drug Updates

Smithfield’s China deal spurs heparin supply and safety concerns

Reuters 7/25/13

US lawmakers are concerned that a Chinese company’s planned $4.7 billion acquisition of pork producer Smithfield Foods could affect the safety and availability of heparin, a blood thinner derived from pig intestines that is widely used in heart surgery and kidney dialysis. Smithfield, the world’s largest pork producer with more than 46,000 employees in 25 states and four countries, is also a major supplier of crude heparin. Smithfield and the Chinese company, Shuanghui Group, submitted their proposal in June to CFIUS (Committee on Foreign Investment in the US), an executive branch panel of the US government that examines foreign investment. According to Smithfield, CFIUS has said that they will need an additional 45 days to review the planned deal.
Sihuan gets CFDA nod for ulcer drug
Sihuan 7/18/13
China-based Sihuan Pharmaceutical has received CFDA approval to conduct clinical trials in China of its ulcer drug anaprazole sodium. This is Sihuan’s fifth Category I innovative drug that has received approval for clinical trials. Applications for patents have already been made in China, the US, Japan, and Europe. Anaprazole sodium is a new generation of proton pump inhibitors (PPIs) that treats ulcers by inhibiting gastric acid secretion and eradicating Helicobacter pylori. Preclinical studies have shown that the new drug covalently binds to the “proton pump,” thus providing substantially stronger and longer inhibitory effects when compared to other PPI drugs, traditional H2-receptor antagonists, and antacids currently available in the market.

Foreign investment in China continues to rise
Reuters 7/17/13
Foreign direct investment in China in June jumped 20.1% from the same period a year earlier, the Commerce Ministry announced this month, the biggest year-on-year monthly gain since March 2011. China drew $14.4 billion in foreign direct investment in June, the Ministry said, while in the first half that investment totaled $62 billion, up 4.9% from the same period of 2012. Foreign direct investment, or FDI, is an important gauge of the health of the external economy, toward which China’s vast factory sector is oriented, but it is a small contributor to overall capital flows compared with exports, which were worth about $2 trillion in 2012. The June investment data show that “overseas investors are still optimistic on the outlook of China’s economy in the medium and long term thanks to China’s recent efforts to move the economy up the value chain and its strong domestic consumption,” said Li Wei, China economist at Standard Chartered Bank in Shanghai. “We expect stronger FDI in the second half compared to the first, as we believe China can achieve a 7.5% target for gross domestic product growth for 2013” based on recent messages from policy makers.

Public Conferences
International Conference on Oncology and Therapy (COT 2013)
July 16-18, 2013, Beijing, China
http://www.emgii.org/workshop/cot2013july

Flow AppComponent in China continues to rise
Reuters 7/17/13
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Industry Insights
Chinese pharma firms continue to raise funds
Humanwell 7/11/13
Chinese pharmaceutical company Humanwell Healthcare will issue up to 60 million type A shares in a private placement to raise approximately 1.03 billion RMB ($166 million USD), the company reported. The shares represent 10.8% of the company’s enlarged share capital, based on its share capital (493,443,636) as of March 31, 2013. The investors’ largest shareholder, Wuhan Dangdai Technology Industry Group Holding Co, agreed to subscribe to at least 16.8% of the additional shares issued. Proceeds from the placement will be used to acquire an 80% stake in Beijing Baron Medical Equipment Co Ltd and fund its subsidiary Wuhan Zhong Yuan Rui De Biological Products Co’s relocation and GMP renovation projects. Humanwell Healthcare (Group) Co Ltd, formerly known as Wuhan Humanwell Healthcare (Group) Co Ltd, engages in the development, production, and sale of pharmaceutical products, including blood products and traditional Chinese medicines, among others.

“China-based Sihuan Pharmaceutical has received CFDA approval to conduct clinical trials in China of its ulcer drug anaprazole sodium. This is Sihuan’s fifth Category I innovative drug that has received approval for clinical trials.”
5th Annual BioProcess International China
August 20-21, 2013, Shanghai, China
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- Accelerated IND filings in China
- Overcome downstream processing and purification bottlenecks
- Viral safety for biologics to protect your operations
- Compare data from mAbs, vaccines, biosimilars, fusions and more

2013 PharmaSUG China Conference
Sept 6-7, 2013, Shanghai, China

The Pharmaceutical Industry SAS Users Group (PharmaSUG) is a non-profit organization consisting of professionals worldwide who use SAS software in their work. Its primary purpose is to provide a forum for the exchange of information and the promotion of new ideas concerning the use of SAS software as it relates to quantitative health sciences, including epidemiology, health economics, health management, outcomes research, biostatistics, clinical research, and the pharmaceutical industry.

PharmaSUG presents a wide range of information helpful to health sciences and healthcare professionals, including business intelligence and business strategy for the pharmaceutical, biotechnology and health research industries in China; topics and issues facing managers in China such as recruiting and retention, performance management, and staff career development; and the use of SAS in healthcare research focusing on patient-reported outcomes, registries, risk evaluation and mitigation strategies and other post-submission activities.

2013 conference sections include:

- Applications Development
- Beyond the Basics
- CDISC, Submission Preparation, Data Standards, and Regulatory Review
- Coders Corner
- Data Management
- Health Outcomes, Epidemiology, and Postmarketing
- Industry Basics
- Management and Career Development
- Programming Technique
- Statistics and Pharmacokinetics