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PRESS CONTACTS:

Rachel Ryan (MITA)

rryan@powelltate.com

202.585.2055

Ashley McMaster (AdvaMed)

AMcmaster@AdvaMed.org

202.434.7245

MITA and AdvaMed Partner to Reduce Trade Barriers, Harmonize Medical Device Standards with China

Beijing, China –The Medical Imaging & Technology Alliance (MITA) and the Advanced Medical Technology Association (AdvaMed) yesterday concluded a series of successful activities aimed at reducing barriers to trade between China and the United States and harmonizing international standards for medical devices. The organizations participated in the U.S.-China Joint Commission on Commerce and Trade (JCCT) Pharmaceuticals and Medical Device Subgroup meeting and led a two-day standards workshop that provided China's State Food and Drug Administration (SFDA) and Chinese industry representatives with additional expertise on IEC 60601-1 third edition -- the internationally recognized standard for electrical medical equipment.

"MITA is pleased to be working closely with AdvaMed and its industry partners on efforts to help China transition to this comprehensive standard," said Gail Rodriguez, MITA executive director. "The enhanced certainties and efficiencies inherent in China's adoption of IEC 60601-1 third edition will yield significant benefits to patients and manufacturers."

"China's transition to the third edition will usher in a more collaborative era of medical standards, driven by safety and international progress in technology," said Ralph Ives, AdvaMed executive vice president for global strategy and analysis.

Working closely with the U.S. Department of Commerce and other industry partners, MITA and AdvaMed hosted a robust standards workshop on IEC 60601-1 third edition that featured industry experts and international consultants, including technical advisors, secretaries and leaders of related IEC and ISO technical committees and working groups. The purpose was to increase the Chinese government's familiarity with the standard and further expedite their transition process. To be fully representative of the global medical device industry, speakers came from North and South America, Europe and Asia.

Prior to the workshop, MITA and AdvaMed participated in the JCCT Pharmaceuticals and Medical Device Subgroup meeting, where AdvaMed led discussions on follow-up to its combination products workshop that took place in coordination with the April subgroup meeting in Shenzhen and the U.S. experience in regulating these cutting-edge therapies, which combine pharmaceutical and medical device components. At the meeting, SFDA officials expressed appreciation for the opportunity to exchange information on this challenging regulatory area and affirmed that the Chinese system has been modeled on international best practices.

During the meeting, MITA called on Chinese officials to include medical devices in the 2013 US – China remanufacturing dialogue, and it was announced that SFDA recently published a list of down classified X-ray products as part of their 2011 JCCT commitments.

In addition to emphasizing the importance of a joint review mechanism for combination products based on the primary mode of action, AdvaMed described the benefits of moving certain in-vitro diagnostic devices into lower-risk categories for regulatory purposes. “Currently, China classifies many in-vitro diagnostics as higher-risk devices than other major medical device markets, which slows patient access to the most advanced diagnostic technologies,” said Nancy Travis, AdvaMed vice president of global strategy and analysis.

AdvaMed also emphasized the importance of following Global Harmonization Task Force guidance that recommends acceptance of a broad range of clinical evidence in the registration process and to avoid mandating clinical trials for any group of medical devices. SFDA welcomed these suggestions as well as U.S. industry’s proposal to conduct an information exchange program on clinical evidence.

“We have made incredible progress over the past three days that will benefit members of both our associations, the larger global medical device manufacturing community and most importantly, patients who benefit from our technologies,” said Davey Han, MITA’s China representative.

For more information on MITA and AdvaMed’s international efforts, please visit: <http://medicalimaging.org> and <http://www.advamed.org>.

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The Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is the collective voice of medical imaging equipment manufacturers, innovators, and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.