



AdvaMed
Advanced Medical Technology Association



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DIAGNOSTICS FOR HEALTH

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Medical Technology



MITA
MEDICAL IMAGING
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A DIVISION OF **NSMA**

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Medical Technology Industry Calls for Regulatory Convergence In U.S.-E.U. Trade Deal

Washington, D.C. – The medical technology industry represented by AdvaMed, COCIR, Eucomed, EDMA and MITA met yesterday with senior U.S. and E.U. government officials as part of the U.S.-E.U. High Level Regulatory Cooperation Forum urging them to consider regulatory convergence for medical technology in upcoming negotiations on the Transatlantic Trade and Investment Partnership (TTIP).

At the meeting, our joint delegation outlined the importance of our technologies and the opportunities they bring to advance a sustainable healthcare system in the U.S. and E.U. Our industry is focused on making TTIP a matter of high importance that will bring measureable results in the short and mid-term such as 1) mutual recognition of ISO 13485, 2) a single audit process, 3) harmonized format for product registration submission and 4) a common way to trace products through a single unique device identification (UDI) process with interoperable databases.

“As the single largest free trade agreement in history, TTIP will promote E.U. and U.S. international competitiveness, create jobs and grow our respective economies,” said Stephen Ubl, President of AdvaMed. “Trade in goods and services between the E.U. and U.S. accounts for nearly one trillion U.S. dollars and supports millions of jobs. This agreement will create new jobs that will improve access to the life-saving medical technologies that E.U. and U.S. companies manufacture,” noted Serge Bernasconi, Chief Executive Officer of Eucomed and EDMA. The economic relationship between the U.S.-E.U. is the largest in the world, accounting for half of all global economic output, and the medical technology industry looks forward to continued engagement as negotiations move forward.

“Success here will set the scene and encourage other economies to join in the effort to increase patient access to high-quality healthcare to billions of citizens that many Americans and Europeans enjoy,” said Gail Rodriguez, Executive Director of MITA. “Greater regulatory harmonization will bring life-saving medical technologies to the world market more efficiently by reducing the time and cost it takes products to reach patients that need them most, especially as our industry is already working on a global scale,” added Nicole Denjoy, Secretary General of COCIR.

The medical technology industry enthusiastically supports this opportunity, and looks forward to concrete developments of this highly regarded initiative.

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AdvaMed is the Advanced Medical Technology Association that represents medical device and diagnostics manufacturers in the United States.

COCIR is the voice of the European Radiological, Electromedical and Healthcare IT Industry.

EDMA is the industry association that represents the interests of the In Vitro Diagnostic (IVD) industry throughout Europe.

Eucomed represents the medical technology industry in Europe.

MITA is the collective voice of medical imaging equipment, radiation therapy and radiopharmaceutical manufacturers in the United States.