MITA Announces Support of Medical Device Single Audit Program

MITA

Pilot Program Unveiled at IMDRF Stakeholder Meetings

The Medical Imaging & Technology Alliance (MITA) today announced its support of the pilot program for the Medical Device Single Audit Program (MDSAP), the details of which were unveiled this week at the November 2013 IMDRF Stakeholder Meetings. MITA member companies Siemens and Philips expressed their intent to participate, underscoring that is it necessary to be involved to fully understand the pilot and shape the final operational program.

“In an increasingly globalized world, the MDSAP represents an important step towards developing an internationally harmonized approach to the auditing of medical device manufacturers,” said Gail Rodriguez, executive director of MITA. “MITA members are excited by the opportunity to contribute to this process by participating in this pilot program.”

Currently, medical device manufacturers with operations and sales in several countries face duplicative audits from regulators. This can result in a single company facing multiple audits throughout the countries in which they operate, in some cases interrupting the normal flow of work and limiting resources for weeks.

Under the MDSAP pilot program, the auditing process will be similar to that of the Canadian Medical Devices Assessment System (CMDCAS) Program in Canada. Most routine auditing will be done by third party entities, whose competency and oversight will be assessed and monitored by regulators. Auditors will assess compliance for all the countries participating in the program in which a particular company does business, relieving manufacturers from duplicative and repetitive audits. The pilot will include the United States, Canada, Australia and Brazil. The program will start in January 2014, with initial audits under the new system anticipated to begin in June.

FDA’s Kim Trautman welcomed and encouraged industry participation in the pilot, explaining that “the Regulatory Authorities involved, including our Japanese colleagues who are observers at this time, are very interested in utilizing the Pilot program over the next three years to work with our stake holders both Auditing Organizations and industry in optimizing the single audit processes. We are looking to validate our new audit model and many processes in an effort to make them more efficient. The only way to do this is to trial the processes and receive feedback - for which we need industry's voluntary participation. We look forward to optimizing the program in order to serve the global community and international public health.”

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