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Aus, Brazil, Canada, US setup joint audit program

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Singapore: The medical device regulators of Australia, Brazil, Canada and the US have all signed on to a statement of cooperation to develop a single audit program for medical devices to be used by all four market authorities.

The US FDA, Australian Therapeutic Foods Administration (TGA), Brazil's ANVISA and Health Canada have signed on a statement-of-cooperation to develop a single audit program for medical devices so that they can be used by all four market authorities.

The statement-of-cooperation intends to make the quality management system auditing processes of the respective countries more efficient and less burdensome by establishing the Medical Device Single Audit Program (MDSAP). Following the execution of the MDSAP program, the audit of a medical device manufacturer's quality system in any one-of-the-four countries will meet regulatory requirements of all four countries. This is a significant move , which will substantially ease medical device company's paths-to-market in these regions.

MSDAP's stated objectives include promoting work-sharing arrangements and mutual acceptance among participating regulators in order to allow more efficient and flexible use of resources among the FDA, Health Canada, ANVISA and TGA regarding medical device quality system audits, leveraging existing conformity assessment structures when appropriate and standardizing participants' market oversight practices regarding third-party auditing entities.

The statement of cooperation included no information on possible implementation time frames for MDSAP, but it's fair to assume participating regulators will need a fair amount of time to align their resources and technologies to begin developing

the program. Emergo Group will provide further details as we learn them.