



New Candidate Auditing Organization Participation in the Transitional Phase of the Medical Device Single Audit Program (MDSAP)

The MDSAP Regulatory Authority Council (RAC) is pleased to announce that additional candidate Auditing Organizations are invited to apply for participation in the Medical Device Single Audit Program (MDSAP) in 2017.

The MDSAP audit process was designed and developed to ensure and provide an efficient yet thorough coverage of the Quality Management System requirements implemented by medical devices manufacturers. These requirements are based on ISO 13485:2016 – Medical devices - Quality management systems, and the specific requirements from the medical device regulations of the Regulatory Authorities that are participating in the MDSAP.

The current pilot phase will finish on December 31st, 2016. From January 1st, 2017 the program will be open for applications from new candidate Auditing Organizations. Due to the program's operational limitations, a small number of successful applications from candidates already operating under a 3rd party medical device regulatory scheme will progress to further assessment stages in 2017.

The applications received will be considered primarily on the quality of the application. In cases where an Auditing Organization fails during the application review or stage 1 assessment, the submission will be declined providing an opportunity for other candidates. If there is an excess of eligible candidates, consideration will be given to the depth and breadth of competence and the order in which applications are received. Where applications are declined the Auditing Organization will be ineligible for a period of one year; from the day of the refusal notification.

The procedure for submitting the application can be found at the following link:

<http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377581.htm>

A handwritten signature in black ink, appearing to read "Fábio", is positioned above the printed name of the Chairperson.

Fábio Pereira Quintino
Chairperson, MDSAP Regulatory Authority Council

Date: 11/29/2016