Medical Device Single Audit Program (MDSAP)

The Medical Device Single Audit Program (MDSAP) Regulatory Authority Council (RAC) invites medical device manufacturers to participate in our innovative regulatory single audit program.

The MDSAP Pilot, which started on 01 January, 2014, is the implementation of the International Medical Device Regulators Forum (IMDRF) MDSAP initiative. The transition to full implementation of the program is expected to begin 01 January 2017.

The international partners fully participating in the Medical Device Single Audit Program are:

- Australia's Therapeutic Goods Administration (TGA),
- Brazil's National Health Surveillance Agency (ANVISA),
- Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)
- Health Canada, and
- the United States Food and Drug Administration (FDA)

The European Commission and the World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme are observers and active participants in the Pilot Program's Regulatory Authority Council and subject matter expert groups.

MDSAP enables medical device manufacturers to contract with an MDSAP authorized Auditing Organization to conduct a single audit against the relevant medical device regulatory requirements of all fully participating regulatory authorities.

The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the requirements for a quality management system for medical devices derived from: ISO 13485:2003 – Medical devices - Quality management systems – Requirements for regulatory purposes (and ISO 13485:2016); the Brazilian Good Manufacturing Practices (ANVISA RDC 16/2013); the Quality System Regulation (21 CFR Part 820), and other specific requirements of fully participating regulatory authorities including registration, licensing, advisory notices or recalls, adverse event reporting, etc.

MDSAP audit reports may be used by fully participating regulatory authorities in lieu of their own inspection reports. Please refer to the MDSAP webpage for specific information regarding the program. A comprehensive FAQ appears on the webpage. Q34 specifically relates to how each regulatory jurisdiction intends to use the findings of MDSAP Pilot reports; and any inspection exclusions. I encourage you to study the webpage thoroughly; and hope you will find the program attractive.

Fábio Pereira Quintino
Chairperson, MDSAP Regulatory Authority Council

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