Fact Sheet

TUV USA Inc. (Member of TÜV NORD Group)

215 Main Street
Salem, NH 03079, USA
Tel.: 001 603 870 8023
Fax: 001 603 870 8026

Medical Device Single Audit Program (MDSAP)
One audit for five markets – Australia, Brazil, Canada, Japan and USA
MDSAP have two new Affiliate Members – Argentina and Republic of Korea

General

In the past, medical device manufacturers who wished to license their products in Australia, Brazil, Canada, Japan and USA had to demonstrate fulfilment of the national regulatory requirements of each country within different approval processes. This naturally involved a great deal of time and expense. The MDSAP program was developed by the IMDRF (International Medical Devices Regulators Forum) to help international organizations bridge the requirements of the international market.

About IMDRF

The International Medical Device Regulators Forum (IMDRF) was established in February 2011 in order to discuss the future direction of regulatory harmonization in the area of medical technology. The Forum consists of voluntary groups from medical device supervisory bodies from the global community, with the goal to accelerate regulatory harmonization and convergence.

Members of the MDSAP

There are five member jurisdictions to the MDSAP:

- Australia, Therapeutic Goods Administration (TGA)
- Brazil, National Health Surveillance Agency (ANVISA)
- Canada, Health Canada (HC)
- Japan, Pharmaceuticals and Medical Devices Agency (PMDA)
- USA, Food and Drug Administration (FDA)

Argentina's National Administration of Drugs, Food and Medical Devices (ANMAT) and the Republic of Korea's Ministry of Food and Drug Safety (MFDS) have signed on as Affiliate Members to MDSAP. The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are the official MDSAP observers.

Objective of the MDSAP

The objective of the MDSAP is to achieve a common audit standard, which takes the different regulatory requirements of national approval bodies into consideration. The manufacturer must have their quality management system monitored / audited in a surveillance audit once a year by a third party auditing organization recognized or authorized to perform MDSAP audits.

Recognition within the MDSAP Program

Australia TGA recognizes the audit report from the MDSAP audit. However, certain conformity assessments have to be presented within the framework of the market approval.

Brazil ANVISA recognizes MDSAP in place of the initial audit. Brazil requires a GMP certificate from ANVISA for the registration of medical devices for Class III and IV devices. The GMP certificate can be issued based on an ANVISA audit or the audit report of a recognized MDSAP auditing organization.

Health Canada recognizes the MDSAP certificate to grant product licenses. The MDSAP program has fully replaced the CMDCAS program.

Japan PMDA and their Health Ministry have fully accepted the MDSAP audit report in lieu of its inspection.

The US FDA recognizes MDSAP audits in place of routine inspections. FDA will continue to inspect manufacturers with activities related to the Electronic Product Radiation Control (EPRC) provisions of the Act.