Fact Sheet

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Medical Device Single Audit Program (MDSAP) Pilot Program

One audit for five markets – Australia, Brazil, Canada, Japan and USA

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. Now, IMDRF (International Medical Devices Regulators Forum) has developed a new unified program – the MDSAP (Medical Device Single Audit Program) – which covers different regulatory requirements. Conformity with these requirements can now be demonstrated by manufacturers within the framework of one single audit.

Objectives 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 national rules will retain their validity, which means that medical device manufacturers must have their quality management system monitored in a surveillance audit once a year by a third party auditing organization approved for MDSAP.

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 supervisory bodies from all over the world, and aims to accelerate regulatory harmonization and convergence in the international medical industry.

Regulatory Authorities participating in the MDSAP pilot program

The following Regulatory Authorities are participating in the MDSAP pilot program:

- 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)

Recognition within the MDSAP Program

The US-FDA recognizes MDSAP audits in place of routine inspections. Initial inspections are not included in the recognition.

ANVISA recognizes MDSAP audits for first audits. Basically, Brazil requires a GMP Certificate from ANVISA for registration of medical devices of Classes III and IV. The GMP Certificate can be issued based on an ANVISA audit or the audit report of a recognized MDSAP auditing organization.

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

Health Canada recognizes the MDSAP certificate to grant product licenses in order to sell products in Canada.

Japanese approval authority PMDA and also the Health Ministry have announced their commitment to officially join the MDSAP Program and will accept the MDSAP audit report.

Registration procedure for certification bodies

TUV USA Inc. (member of TÜV NORD Group) has already been registered as one of the first auditing organizations by the Regulatory Authorities and is authorized to perform audits within the framework of the MDSAP pilot program.

How to take part in the pilot program

All medical device manufacturers who need access to the relevant international markets can take part in the pilot program (2014-2016). TUV USA can perform the MDSAP audits during the MDSAP Pilot Program. In addition to the MDSAP audits, TUV USA also offers combined audits along with the European Medical Devices Directive or CMDCAS program. As per Health Canada's notification if you have a current CMDCAS certificate, you will need to transition it to the MDSAP Certificate latest by December 2018. To participate in the program, please contact us for more information. We are looking forward to hearing from you.