Medical Device Single Audit Program (MDSAP)

IMDRF MDSAP

International Medical Device Regulators Forum Medical Device Single Audit Program

IMDRF recognises that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale.

IMDRF International Medical Device Regulators Forum

- A voluntary group of medical device regulators: Australia, Brazil, Canada, China, Europe, Japan, Russia, and USA
- Superseded the Global Harmonization Task Force (GHTF) in 2012
- Mission is to strategically accelerate international medical device regulatory harmonization and convergence.
- WHO is an official observer. The Asian Harmonization Working Party and APEC's Life Sciences Innovation Forum's Regulatory Harmonization Steering Committee are affiliate organizations.

Definitions

Medical device: any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- investigation, replacement, modification, or support of the anatomy, or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

IMDRF developed MDSAP to encourage and support global convergence of regulatory systems, where possible.

It seeks to strike a balance between the responsibilities of Regulatory Authorities to safeguard the health of their citizens as well as their obligations to avoid placing unnecessary burdens upon Auditing Organizations or the regulated industry.

At its inaugural meeting in Singapore in 2012, the IMDRF identified a work group to develop specific documents for advancing a Medical Device Single Audit Program (MDSAP).

MDSAP Working Group to develop a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems

IMDRF MDSAP Working Group

A collection of documents intended to implement the concept of a Medical Device Single Audit Program

- Requirements for Medical Device Auditing Organizations
- for Regulatory Authority Recognition
- Competence and Training Requirements for Auditing Organizations,"
- Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations
- Regulatory Authority Assessor Competence and Training Requirements.

Forthcoming document on the decision process for recognizing an Auditing Organization or revoking recognition.

Definitions

Audit: A systematic, independent, and documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. (ISO 17000:2004)

Auditing Organization: An organization that audits a medical device manufacturer for conformity with quality management system requirements and other medical device regulatory requirements.

Medical Device Single Audit Program (MDSAP) Pilot

From January 2014, participating NRAs will accept the MDSAP audit reports as a substitute for routine Agency inspections.

The MDSAP Pilot is intended to allow MDSAP recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot program.

Participants:

- Therapeutic Goods Administration of Australia,
- Brazil's Agência Nacional de Vigilância Sanitária,
- Health Canada
- US FDA