MDSAP – Three Important Documents

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The Medical Device Single Audit Program, MDSAP, developed by the International Medical Device Regulators Forum, IMDRF, provides a global approach to auditing and monitoring medical Device manufacturers on an international scale.

MDSAP would recognized Auditing Organizations (AOs) to conduct a single audit of a medical device manufacturer to satisfy the requirements of the participating medical device regulatory authorities in the pilot program.

The MDSAP participants are:

- Therapeutic Goods Administration of Australia
- Brazil's Agência Nacional de Vigilância Sanitária
- Health Canada
- Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency

The Official Observers are:

- World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme
- European Union (EU)

Documents of Importance to Medical Device Manufacturers

IMDRF has published a suite of documents to implement MFSAP. Many of the documents relate to the Auditing Organizations, program administration, *etc*. However, four documents are of particular importance to device manufacturers. The MDSAP related documents are available from the FDA website, UCM377578. The headings below use the identification from the website.

<u>MDSAP AU P0002.003 Audit Model</u>

The Audit Model has specific instructions for performing MDSAP audits. It includes both an audit sequence and instructions for auditing each process.

The MDSAP audit sequence allows for an audit conducted in a logical, focused, and efficient manner. Utilizing four primary processes, one supporting process, and one foundational process.

The four primary processes are:

- Management
- Measurement, Analysis, and Improvement
- Design and Development
- Production and Service Controls

The supporting and foundational processes are, respectively:

- Purchasing
- Risk Management

The processes comprise the requirements of a quality management system for medical device manufacturers based on:

ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes
RDC ANVISA 16/2013, Brazilian Good Manufacturing Practices
MHLW Ministerial Ordinance No. 169 Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents
21 CFR Part 820 Quality System Regulation

MDSAP audits are process based and built on a foundation of requirements for risk management. The document does not explicitly provide the risk management requirements, nor does it refer to ISO 14971:2007.

Each of the primary and supporting processes has a chapter with Audit Tasks, links to other processes, and citations of specific regulations and clauses.

For the foundational process, risk management, embedded references in the other processes use blue italics.

MDSAP AU G0002.1.003 Companion Document

The MDSAP Audit Process Companion document is a reference and includes additional detail regarding each audited process as well as guidance for assessing the conformity of each process.

GHTF/SG3/N19:2012 – Nonconformity Grading System for Regulatory Purposes and Information Exchange

In addition to the MDSAP documents cited above, audit nonconformity grading uses a GHTF developed document. Instead of subjective audit grades such as major, minor, or critical, each audit nonconformance receive a numerical grade based on the effect on product realization, the frequency of occurrence, and some additional factors.

This approach allows unambiguous grading useful for exchanging information between the Auditing Organization (AO) and the regulators.