IMDRF International Medical Device Regulators Forum

Medical Device Single Audit Program (MDSAP) Working Group

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MDSAP Working Group Final Documents from November 2013

IMDRF MDSAP WG N3 – *"Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"*

IMDRF MDSAP WG N4 – *"Competency and Training Requirements for Auditing Organizations"*

IMDRF MDSAP WG N5 – *"Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations"*

IMDRF MDSAP WG N6 - *"Regulatory Authority Assessor Competency and Training Requirements"*

MDSAP Working Group
Final Documents from November 2014

IMDRF/MDSAP WG/N11 - MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

IMDRF/MDSAP WG/N22 - MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes

MDSAP Proposed Final Documents

Two Proposed Final Documents produced in Silver Spring, MD June 2015:

- **IMDRF/MDSAP WG (PF)/N8R3** – "Medical Device Single Audit Program (MDSAP): Guidance on Regulatory Authority Assessment Methods of Auditing Organization's Processes"
- **IMDRF/MDSAP WG (PF)/N24R3** – "Medical Device Single Audit Program (MDSAP): Medical Device Regulatory Audit Reports"

MDSAP Information Document

Information Document produced in Silver Spring, MD June 2015:

“Clarification of the Term “Legal Entity” for MDSAP Recognition Purposes”

IMDRF/MDSAP WG (PF)/N8R3

The purpose of this document is to provide guidance to the Regulatory Authority assessors when conducting the assessment of an Auditing Organization according to the method presented in IMDRF/MDSAP WG/N5, chapter 6.

IMDRF/MDSAP WG (PF)/N8R3

- Work Item Extension off the work on N5 after receiving more than 700 comments on N5 PD1.

- The Working Group received many comments to reduce the size and scope of N5 PD1 into two separate documents.

- MDSAP N8 was approved as a separate document in Brussels in 2013.

MDSAP N8 Timeline

- Proposed document for 2 month public comment period to May 31, 2015.
- Face to Face meeting June 22 – 26, 2015 in Silver Spring MD to review comments and revise document.
- Submit to Management Committee as Proposed Final Document by end of July for September IMDRF Management Committee meeting in Kyoto.

IMDRF/MDSAP WG (PF)/N24R3

This document IMDRF/MDSAP WG/N24 describes the format and content of MDSAP medical device regulatory audit reports submitted to regulatory authorities. The audit report serves as a written record of the audit team's determination of the extent of fulfillment of specified requirements.

IMDRF/MDSAP WG (PF)/N24R3

It enables the Auditing Organization to capture in a consistent manner the evidence of a manufacturer's conformity with the audit criteria for the MDSAP, and will facilitate the exchange of information between Regulatory Authorities.

MDSAP N24 Timeline

- Proposed document for 2 month public comment period to May 31, 2015.
- Face to Face meeting June 22 – 26, 2015 in Silver Spring MD to review comments and revise document.
- Submit to Management Committee as Proposed Final Document by end of July for September IMDRF Management Committee meeting in Kyoto.

Information Document

Clarification of the Term “Legal Entity” for MDSAP Recognition Purposes”

- For purposes of MDSAP recognition in accordance with IMDRF/MDSAP WG/N11, the applicant for recognition as an Auditing Organization is deemed to be the legal entity.

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- The applicant must clearly delineate the perimeter of the legal entity, and establish a specific address, where the management responsible for the MDSAP recognition program is employed by that legal entity.

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The management responsible for the MDSAP program must comply with N3 section 7.1.3. where, “The management of the Auditing Organization shall have appropriate knowledge and processes to: set up and operate a system for the selection of the auditing personnel, the verification of their competence, the assignment of their tasks, their initial and ongoing training, and, their instruction and monitoring to ensure that personnel who administer and perform the audits are competent to fulfill the tasks required of them.”

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The management for the MDSAP program is directly responsible for, manages, and retains authority for the following:

- Establishment of the contract with the medical device manufacturer (including the requirements of N3 – 5.1.4, 5.1.5);
- Identification of competence requirements for any internal or external auditor or technical expert to perform specific activities (N3 – 7.5.1); and,
- Final review and decision-making on conformity to regulatory requirements (N3 – 7.5.1).

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These listed activities cannot be delegated outside of the applicant's legal entity, even to a related organization or a subsidiary.

Under the MDSAP recognition program, these related organizations or subsidiaries are regarded as separate legal entities.

CONCLUSION of MDSAP Work Group

- IMDRF Website will be updated to note the conclusion of the IMDRF MDSAP Work Group.
- Website will refer and link to the MDSAP Pilot Consortium for information on implementation of the IMDRF MDSAP concepts and requirements.

Thank you

Acknowledgment of the very hard work performed and the outstanding results by the MDSAP Working Group members over the past 4 years.

4 years and 9 documents – excellent accomplishments!