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"*

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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 Documents

Two Proposed Documents produced in Dublin, Ireland February 2-5, 2015:

- **IMDRF/MDSAP WG (PD1)/N8R2** – "Medical Device Single Audit Program (MDSAP): Guidance on Regulatory Authority Assessment Methods of Auditing Organization's Processes"
- **IMDRF/MDSAP WG (PD1)/N24R2** – "Medical Device Single Audit Program (MDSAP): Medical Device Regulatory Audit Reports"

IMDRF/MDSAP WG (PD1)/N8R2

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 (PD1)/N8R2

- 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 (PD1)/N24R2

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 (PD1)/N24R2

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.

Thank you

- Acknowledgment of the very hard work performed and the outstanding results by the MDSAP Working Group members.