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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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
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”
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

– 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.
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

– 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.