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 N11

- Issued as a Proposed Document after the March IMDRF meetings for public consultation.
- Received over 200 comments
- Met in July in London
- Reviewed and revised the document into a Proposed Final submitted to the MC for their review and approval this meeting.

MDSAP N11

- This document defines:
  - The process and lifecycle for recognizing, maintaining, or ceasing recognition of an Auditing Organization.
  - The process of managing, grading, and closure of assessment nonconformities issued to an Auditing Organization; and,
  - The outcomes of an initial, surveillance, or re-recognition assessment process of an Auditing Organization.

MDSAP N11 Timeline

- IMDRF/MDSAP WG (PF1)/N11R3 – “MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization”
  - Submitted to Management Committee (MC) as Proposed Final Document mid-July
  - Received a few editorial comments to “clean up” the documents from MC members during review period.
  - Hope it will be approved as final and published shortly after Washington D.C meetings.

MDSAP Overview Diagram

- IMDRF MDSAP WG produced a one page flow diagram to respond to the request of an IMDRF delegation for an overview document/diagram.
- This diagram was presented to the IMDRF MC and Stakeholders in March but we requested that it not be finalized until we finalize N11, as it is a key figure in that document.
- We will publish the Diagram as an Information Document upon approval of N11.

MDSAP N8

- The purpose of this document is to provide Regulatory Authority Assessment Method Guidance that was extracted out of the PD1 version of IMDRF MDSAP N5.
- 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

- Redraft N8 in Fall 2014
- Face to Face meeting in late January/early February to produce a Proposed Document
- Submit to Management Committee for Spring 2015 IMDRF Meeting in Japan.
- Seek public comments in April and May
- Face to Face meeting June/July 2015 to produce Proposed Final document for Fall 2015 IMDRF Management Committee Meeting

MDSAP New Work Item Extension

- The Working Group has received comments requesting that IMDRF also draft a Audit Report guidance document such that Auditing Organization could draft and issue a harmonized single report to the medical device manufacturers under the MDSAP scheme.

MDSAP NWI Extension Suggested Timeline

- Draft in Fall 2014
- Face to Face meeting in late January/early February to produce a Proposed Document
- Submit to Management Committee for Spring 2015 IMDRF Meeting in Japan.
- Seek public comments in April and May
- Face to Face meeting June/July 2015 to produce Proposed Final document for Fall 2015 IMDRF Management Committee Meeting

MDSAP New Work Item Extension

- A draft document has already been prepared as part of the NWI Extension request
- If approved, the Working Group will work on this concurrently with N8
- Goal to wrap up the work of the MDSAP Working Group by the end of 2015.

Thank you

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