Medical Device Single Audit Program (MDSAP) Working Group

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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.
• 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
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.