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”
IMDRF MDSAP WG N11 - Per the request of the Management Committee (MC) during the Nice, France meeting in addition to MDSAP N3, N4, N5 and N6 - The purpose of this document is to specify the objective and consistent grading of any nonconformities found by Regulatory Authorities (RA) during the assessment of AOs under MDSAP; and, the process for recognition, when necessary remediation steps for any assessment nonconformities, as well as the steps for de-recognition if appropriate.
MDSAP N11 Timeline

- IMDRF/MDSAP WG (PD1)/N11R2 – “MDSAP Assessment Outcomes and Recognition/Re-recognition Decision by Regulatory Authorities”
  - Face to Face meeting July 7-10, 2014 in London to review comments and revise document.
  - Submit to Management Committee as Proposed Final Document by end of July for September IMDRF meeting.
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.

- This diagram is being presented to the IMDRF Management Committee to determine if this should be posted on the website with the four approved MDSAP documents.
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
Thank you

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