IMDRF International Medical Device Regulators Forum

Medical Device Single Audit Program (MDSAP) Working Group

Kimberly A. Trautman
Associate Director, International Affairs
Office of the Center Director
Center for Devices and Radiological Health

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

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"
  - Proposed document for 2 month public comment period to May 31, 2014.
  - 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.