



International Medical Device Regulators Forum (IMDRF) and Medical Device Single Audit Program (MDSAP) Working Group

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IMDRF Work Items

Medical Device Single Audit Program (MDSAP)

- The Work Group will develop a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems. The documents will be applicable to competent authority auditing groups/inspectorates, as well as third party organizations that conduct such audits. This is an initial critical step in establishing a single audit program.

MDSAP WG Update

- At the end of October, the “Recognition Criteria for Medical Device Auditing Organizations” was published on the IMDRF website for public comment until December 14th.
- 406 comments were received on the document.

MDSAP WG Update

- January 28-31, 2013, the Working Group meet in Brasilia to review and reconcile the comments and in addition, draft text on the extra sections assigned by the Management Committee in Sydney to include requirements for the Code of Conduct, Unannounced Audits and Auditor Competency.

MDSAP WG Update

- As a result of the Brasilia meeting, the Working Group submitted the Recognition Criteria Document PD(2) N3R5 for review and approval as a second proposed document for public comment due to the addition of the new requirements for the Code of Conduct and the Unannounced Audits, as well as revised text due to revisions in accepting comments.

MDSAP WG Update

- Working Group will be requesting approval by the Management Committee of PD(2) for publication on the IMDRF website by the end of March 2013 for a 2 month comment period to end May 31, 2013.

MDSAP WG Update

- Also, as a result of the Brasilia meeting, the Working Group submitted the IMDRF Competency and Training Requirements document PD(1) N4R2. The text for the competency requirements was too large to be subsumed into the base document, so a separate document was drafted.

MDSAP WG Update

- Reference to the PD(1) N4R2 IMDRF Competency and Training Requirements document was placed in the base Recognition Criteria document PD(2) N3R5.

MDSAP WG Update

- If both PD documents are approved, the Working Group plans to consolidate the comments from both of these document in June 2013.
- Meet in Tokyo, Japan in July to review the comments and finalize these two document for submission to the Management Committee for final approval by November 2013.

MDSAP WG Update

- Working Group has also submitted New Work Item Extensions for consideration here in Nice:
 - Assessor Competency and Training Requirements for Regulatory Authorities undertaking Assessments of Auditing Organizations
 - Assessment Program and Auditing Strategy of Medical Device Recognized Auditing Organization

MDSAP WG Update

- Assessor Competency and Training Requirements for Regulatory Authorities undertaking Assessments of Auditing Organizations
 - Complimentary guidance document that parallels IMDRF WG (PD1)/N4R2 - Auditor Competency and Training Requirements for Organizations undertaking Audits of Medical Device Manufacturers but is directed towards the Recognizing Regulatory Assessors.

MDSAP WG Update

- Assessment Program and Auditing Strategy of Medical Device Recognized Auditing Organization
 - Complimentary guidance document to IMDRF WG (PD2)/N3R5 - Recognition for Organizations undertaking Audits of Medical Device Manufacturers. The proposed document would explain how Regulatory Authorities shall assess the Auditing Organization to the criteria laid out in the IMDRF Recognition document.

MDSAP WG Update

- Work Plan for the New Work Item Extensions:
 - Drafts have already been produced
 - Work via email exchanges to produce a Proposed Document for the June IMDRF MC Teleconference end of June
 - Public Comment Period July – August 2013

MDSAP WG Update

- Additional Face to Face meeting to resolve comments Silver Spring, MD September 2013
- Submit to IMDRF MC as Final Document October 2013
- Completion by November 2013

MDSAP WG Update

If successful IMDRF could produce a suite of four (4) documents on the Medical Device Single Audit Program by the end of calendar year 2013.

Future

- **Single Audit by Regulators would:**
 - benefit patient health and patient access
 - leverage regulatory resources
 - minimize medical device manufacturing disruptions due to multiple regulatory audits
 - provide global benefit both on short term goals and longer term goals by IMDRF regulators