IMDRF International Medical Device Regulators Forum

MEDICAL DEVICE SINGLE AUDIT PROGRAM WORKING GROUP UPDATE

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TRANSMITTAL MEMO

- IMDRF/MDSAP WG/N3:FINAL(2016) *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition* was revised to remain consistent with ISO 17021: 2015 *Conformity Assessment -- Requirements for Bodies Providing Audit and Certification of Management Systems -- Part 1: Requirements*

SCOPE OF REVISION

- Changes are minor in nature and were made to ensure consistency between the IMDRF document and the ISO standard as well as maintain certain principles in the N3 document.
- No technical changes.
- A few items were reshuffled or sections merged because some information was already duplicative in the N3 document.

SCOPE OF REVISION

Changes in the standard are related to who can make decisions on the certification process.

- The new version of the standard mentions that outsourcing for the certification process can occur which is contrary to the content of N3 which does not allow for outsourcing of the certification process (principles outlined both in N3 and N29 (which have not and are not changing)).

ADDITIONAL CONSIDERATIONS

- Once the new version of N3 is approved, references throughout all of the other MDSAP documents will need to be updated.
  - This can be accomplished with the committee closed.

- The IMDRF website should be updated to move MDSAP to the "Closed work items." Under the MDSAP link that is relocated, please include the following: "The Medical Device Single Audit Program (MDSAP) Work Group has completed its work and has moved to the implementation phase. For current information on implementation see MDSAP [http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm]

ADDITIONAL CONSIDERATIONS

Transfer of the GHTF documents from the "GHTF Final Documents under Study Group 4 – Auditing" to the "GHTF Archived Documents" sections on auditing because several documents are obsolete. Specifically:

- GHTF/SG4/N28R4:2008 – "Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements" OBSOLETED by IMDRF/MDSAP WG/N3FINAL:2013 and Edition 2 2016
- GHTF/SG4/N30:2010 – "Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy" OBSOLETED by IMDRF/MDSAP WG/ N3FINAL:2013 and Edition 2 2016
- GHTF-SG4-N33 R16 – "Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports" OBSOLETED by IMDRF/MDSAP WG/N24FINAL:2015
- GHTF-SG4-(00)3 – "Training Requirements for Auditors" OBSOLETED by IMDRF/MDSAP WG/N4FINAL:2013

THANK YOU