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1. Purpose/Policy

The purpose of this procedure is to provide guidelines for MDSAP-recognized auditing organizations and their auditors as to required training for conducting MDSAP audits. Training has been created regarding the MDSAP Audit Approach. This training is required of each auditor who will be performing MDSAP audits.

2. Scope

The training described in this procedure supplements the competency requirements as detailed in IMDRF/MDSAP WG/N4 - Competence and Training Requirements for Auditing Organizations; and ISO 17021-1:2015 - Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements. It is required that Auditing Organizations that participate in MDSAP are in conformity with the requirements detailed in IMDRF/MDSAP WG/N4 and ISO 17021-1:2015 in addition to the requirements detailed in this procedure.

3. Definitions/Acronyms

Authorized Auditing Organization: An Auditing Organization who underwent a successful Stage 1 and Stage 2 assessment and provided an appropriate response to any identified nonconformities is “authorized” to perform MDSAP audits, until after 3 witnessed audits are completed and any new

nonconformity resolved.

Recognized Auditing Organization: Auditing Organization that has successfully satisfied applicable recognition criteria and are therefore "recognized" to conduct MDSAP audits.

Medical Device Single Audit Program Regulatory Authority Council (RAC): The RAC consists of representatives from all participating regulatory authorities (Australia, Brazil, Canada, Japan, United States) and provides direction, oversight, and resources to support the MDSAP development, implementation, maintenance, and expansion. MDSAP P0003.

MDSAP Observer: A member of the World Health Organization (WHO) or a nonparticipating regulatory authority who observes and/or contributes to RAC activities. MDSAP P0030.

MDSAP Affiliate Member: A non-participating MDSAP Observer or non-participating MDSAP RAC regulatory authority that wants to engage in MDSAP, demonstrates understanding of MDSAP and utilize MDSAP audit reports and/or MDSAP certificates for evaluating a medical device manufacturer's quality management system.

4. Authorities/Responsibilities

Auditing Organizations: Auditing Organizations that are authorized or recognized under MDSAP are responsible for following this procedure and ensuring that all personnel involved in MDSAP activities are appropriately trained in MDSAP policies and procedures as applicable to their position. Auditing Organizations are required to develop processes to record and maintain records of training and competency for personnel involved in MDSAP activities.

Regulatory Authorities: Regulatory Authorities participating in MDSAP are responsible for developing and maintaining training on the MDSAP Audit Approach and assessing the Auditing Organization's conformity with this procedure, IMDRF/MDSAP WG/N4, and ISO 17021-1:2015.

5. Procedures

Auditing Organizations

In addition to the requirements detailed in IMDRF/MDSAP WG/N4 and ISO 17021-1:2015 regarding competency requirements for personnel involved in auditing and certification activities, auditors that conduct MDSAP audits are

required to complete the following training modules:

The required MDSAP training on the MDSAP Audit Approach is intended to be performed in the following order:

(1) Introduction to MDSAP
(2) MDSAP Management
(3) MDSAP Device Marketing Authorization and Facility Registration
(4) MDSAP Measurement, Analysis and Improvement
(5) MDSAP Medical Device Adverse Events and Advisory Notices Reporting
(6) MDSAP Design and Development
(7) MDSAP Production and Service Controls, part 1
(8) MDSAP Production and Service Controls, part 2
(9) MDSAP Production and Service Controls, part 3
(10) MDSAP Purchasing

Learners must score 80% or better on each of the Final Quizzes for successful completion of the training.

In addition to the required training on the MDSAP Audit Approach, there are additional training modules regarding topics such as the regulatory framework of the various regulatory authorities participating in the MDSAP, and country-specific pre-market and post-market information. These training modules are recommended, but not mandatory. These optional modules can count as a maximum of ten (10) of the 32 hours of training in device regulations as described in IMDRF WG N4, clause 7.1 – Mandatory Initial Training.

MDSAP-authorized Auditing Organizations, MDSAP-recognized Auditing Organizations, Auditing Organizations whose applications to become MDSAP Auditing Organization have been accepted by MDSAP, MDSAP Affiliates, and MDSAP Observers can send inquiries regarding training to MDSAP.training@fda.hhs.gov.

Other stakeholders (including industry)

Publicly-available training on the MDSAP Audit Approach for other stakeholders is available at CDRH Learn, https://www.fda.gov/training-and-continuing-education/cdrh-learn, under the heading “Postmarket Activities - Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization”.

6. Forms

N/A

7. Reference Documents

IMDRF/MDSAP WG/N4 - Competence and Training Requirements for Auditing Organizations
ISO 17021-1:2015 - Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements.
MDSAP AS P0005 - Assessment Program Procedure
MDSAP AS P0016 - On-Site Assessment Procedure (Stage 2, Surveillance, Re-recognition, Critical Locations)
MDSAP AS P0014 - Special Remote Assessment Procedure
MDSAP AS P0020 - Special On-Site Assessment Procedure
IMDRF/MDSAP WG/N11 – MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2021-10-01	Replaces MDSAP AU WI0006.1.003 – Auditor Training Work Instruction Procedure was re-written throughout due to the discontinuation of Articulate Online LMS for MDSAP training; clarifications are included in this revision as to definitions, scope, authorities, and responsibilities.	CAPT Kimberly Lewandowski-Walker, US FDA

Version Approval 001

Approved: _____ Date: _____
CHAIR, MDSAP RAC