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	Version Date: 2019-01-11	Effective Date: 2019-01-15
Title: MDSAP QMS Training Procedure		Project Manager: Kimberly Lewandowski-Walker, USFDA

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1. Purpose/Policy

The purpose of this document is to define the Medical Device Single Audit Program (MDSAP) Team training requirements. This procedure will assist to assure that MDSAP Team members have the knowledge, skills and abilities to perform their respective roles successfully by developing proficiency through various methods of training. This document is separate from the IMDRF/MDSAP WG/N4:2013 Competency and Training Requirements for Auditing Organizations which may not apply to all MDSAP Team Members.

2. Scope

This procedure applies to all MDSAP Team members of each participating Regulatory Authority (RA).

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3. Definitions/Acronyms

Training: Act of developing a particular skill or type of behavior through demonstration, instruction and practice.

Competence: Ability to apply knowledge, and skills to achieve intended results. (ISO 9000:2015)

Regulatory Authority (RA): A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (GHTF/SG1/N78:2012)

4. Authorities/Responsibilities

MDSAP QMS Management Representative: Responsible for notifying the MDSAP Team, through the participating RA Training Representative, when new or revised procedures and policies are released.

MDSAP Team Member: All MDSAP Team Members are responsible for assessing their individual training needs. Team Members should document their training and coordinate with their RA Training Representative, to ensure that training records are current.

Regulatory Authority (RA) Training Representative: Responsible for overseeing the MDSAP Training Program within their Regulatory Authority; coordinating with the RA's MDSAP Team members to satisfy training requirements; and compiling, storing and maintaining training records from each MDSAP Team Member.

Note: Each RA is responsible for assigning a RA Training Representative.

5. Procedures

Training Requirements

MDSAP Team Members shall be initially qualified to perform their assigned tasks and responsibilities on the basis of education, training and/or prior experience. Team Members must be appropriately trained in, and have knowledge of, the applicable regulations, standards and policies associated with a specific job function before independently performing MDSAP specific roles. It is essential that MDSAP Team Members are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives of the MDSAP.

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5.1. Types of Training Required

All MDSAP Team Members shall become proficient with the MDSAP Standard Operating Procedures (SOPs) which pertain to the Team Member's role. A Team Member's proficiency with an SOP may be demonstrated through self-certification, classroom work, other documented learning experiences (e.g. On-The-Job Training) or through a combination of these. Additionally, for training not available through an MDSAP course, a Team Member must participate in an internal RA course and/or recognized external coursework relating to their role. The Team Member's supervisor will evaluate their proficiency and, if a deficiency in performance is observed, provide constructive feedback, and / or arrange specific additional training for the Team Member.

The Training Document Review Checklist available as an attachment outlines the internal SOPs, Standards and Guidance Documents in which Team Members may need to develop proficiency, or where appropriate, familiarity. The MDSAP Team Member's Supervisor shall determine which of these are necessary for the Team Member to perform their role.

Refer to the MDSAP QMS F0014.1 Training Document Review Checklist.

The following external courses are recommended for MDSAP Personnel conducting Audits and Assessments:

- American Society for Quality (ASQ) Certified Biomedical Auditor Exam Preparation
- ISO 9001 Lead Auditor Course (with emphasis on ISO 13485 if possible)
- Other courses that comply with the requirements of the RABQSA Qualification based approach to training for Quality Management System Auditors – (<http://www.rabqsa.com/docs/downloads/TCD32.pdf>)

5.2. Training Methods

5.2.1. Self-Training (i.e. Required Reading)

MDSAP Team Members will undertake the majority of their MDSAP training via a supervised or personal review of SOPs, Standards, Regulations, Policy, Manuals, Guidance Documents and others, and then applying the learned material to their daily work processes. This involves the MDSAP Team Member taking the time to review and ensure understanding of the applicable material. If the Team Member has questions regarding the material, it is incumbent on the Team Member to seek clarification.

The MDSAP Team Member's supervisor and the RA Training Representative,

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in consultation with the employee, will evaluate the success of self-training methods on an annual basis. The MDSAP Team Member's supervisor will share the results of this evaluation with the Team Member.

5.2.2. Instructor Led Training

- 5.2.2.1. Classroom Training - Includes internal and external training courses in a classroom setting and used to impart knowledge regarding MDSAP associated programs, procedures and policies. This type of training generally includes a defined schedule of subject material instruction and may include written examinations to determine the level of understanding and the effectiveness of the course. The RA Training Representatives may conduct classroom training internally or arrange an accredited external course.
- 5.2.2.2. "On the Job" Training (OJT) – MDSAP Team Member training at the place of work while performing MDSAP assigned roles under the close supervision of a supervisor or delegate (e.g., a mentor). This type of training must ensure that it provides the Team Member the knowledge or skills essential to the full and adequate performance of the assigned role.
- 5.2.2.3. Webinars (Web-based Seminar) and other Virtual Courses – May be interactive or one-way presentation, lecture, workshop or seminar conducted over the internet using web conferencing technologies.

5.3. eLearning Modules

Generally considered to be any instruction (either instructor-led or self-led) delivered over the internet, a local network, CD/DVD-ROM, computer, satellite broadcast, etc. Currently, the U.S. Food & Drug Administration's Center for Devices and Radiological Health maintains a website where many eLearning Modules in English, Spanish and Chinese may be accessed for free at: <http://www.fda.gov/training/cdrhlearn/default.htm>

5.4. Identification of Training Needs

Unless otherwise specified, MDSAP supervisors and Team Members shall assess training needs on an annual basis (once per calendar year). An MDSAP supervisor may perform the assessment as part of the Team Members annual performance review.

Training needs may also be identified more frequently (e.g. when a new or

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revised procedure or policy affecting the MDSAP Team Member's role is released; or when the evaluation of training effectiveness demonstrates a need for further training).

5.5. Evaluation of Training Effectiveness

The RA Training Representative is to perform an annual evaluation of the MDSAP Training Program. The Representative may presume that MDSAP Team Members who have participated in all required MDSAP training are competent unless a Supervisor observes substandard performance. The methods to be used by the RA Training Representative for reviewing the effectiveness of training may include:

- Monitoring MDSAP Team Member performance
- Interviews with MDSAP Team Members
- Observations made by the RA Training Representative or other members of the MDSAP Team
- Group discussions
- Input from subject matter experts

The RA Training Representative shall document the evaluation of the annual MDSAP Training Program using the form MDSAP QMS F0014.2 Training Program Evaluation. The RA Training Representative must record any observed gaps in the MDSAP Training Program and document a plan on the form to correct the deficiency. The RA Training Representative must relay any gaps in the competency of an MDSAP Team Member to the relevant MDSAP supervisor who is to ensure that a remediation plan is developed and implemented for the affected Team Member.

5.6. Maintenance and Retention of Training Records

Once an MDSAP Team Member completes the required training, evidence of completion of the training must be provided to the RA Training Representative who will; verify completion of the training and record completion in the RA's personnel files. The RA Training Representative may record the evidence of completion in the form of a completed Training Document review checklist, self-certification, course transcript, certificates, travel records, instructor emails/notes, results letters, etc. The RA shall retain training records for not less than 2 calendar years.

5.7. Training Documentation

The MDSAP Team Member and RA Training Representative are responsible for maintaining appropriate records of education, training, skills and experience. The MDSAP Team Member has the ultimate

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responsibility for ensuring individual training records are current.

6. Forms

MDSAP QMS F0014.1 - Training Review Checklist Form

MDSAP QMS F0014.2 - Training Evaluation Form

7. Reference Documents

ISO 10015:1999(E). Quality Management - Guidelines for Training. (1999, December 15).

International Organization for Standardization (ISO).

IMDRF/MDSAP WG/N6FINAL:2013 – Regulatory Authority Assessor
Competence and Training Requirement

8. Document History

VERSION No.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown USFDA
002	2013-08-01	<p>Page 1 and 2; Section 3 Definitions /Acronyms: Definition –Training: revised to reflect correct definition according to ISO 9001:2008.</p> <p>Definition – Competence: revised to reflect correct definition according to ISO 9000:2006 clause 3.9.14 and as suggested by IMDRF “Competency and Training Requirements for AOs, July 11, 2013.</p> <p>Definition - Regulatory Authority (RA) was added to the list as defined in GHTF/SG1/N78:2012.</p> <p>Page 9; Section 7 Reference Documents: added the info on IMDRF “Competency and Training Requirements for AOs” dated July 11, 2013 document.</p>	Liliane Brown USFDA
003	2016-10-11	Revisions were made mostly in section 3 Definition/Acronyms to reflect the ISO 9001;2015/ISO 9000:2015 revisions	Liliane Brown/ Patricia Serpa
004	2019-01-11	<p>Updated project manager</p> <p>Changed the responsibilities/authorities for the RAC Secretariat to the MDSAP QMS Management Representative in section 4.0</p> <p>Changed the responsibilities for the MDSAP Secretariat to the Training Representative in section 5.2.2.1.</p> <p>Adjusted formatting</p>	Kimberly Lewandowski-Walker, USFDA/Hiromi Kumada, PMDA

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Approval

Approved: ON FILE Date: 2019-01-11
CHAIR, MDSAP RAC