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1. Purpose/Policy

This procedure describes the process for planning and conducting *self*-assessments also called Internal Audit as part of the Quality Management System (QMS) for MDSAP activities. To avoid confusion, MDSAP QMS will apply the word “self-assessment” versus “audit” throughout the document.

2. Scope

This procedure addresses *self*-assessments intended for evaluating adherence or conformity to established quality system requirements, determining the effectiveness of the quality system, and identifying opportunities for continual improvements.

3. Definitions/Acronyms

Audit: Systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. (ISO 9000:2015)

- An audit can be an internal audit (first party), or external audit (second party or third party), and it can be a combined audit or a joint audit.

Combined Audit: audit carried out together at a single auditee on two or more management systems. (ISO 9000:2015).

- The parts of a management system that can be involved in a combined audit can be identified by the relevant management system standards, product standards, service standards or process standards being applied by the organization.

Joint Audit: Audit carried out at a single auditee by two or more auditing organizations. (ISO 9000:2015)

Audit Scope: Extent and boundaries of an audit. (ISO 9000:2015)

Audit Plan: Description of the activities and arrangements for an audit. (ISO 9000:2015)

Audit Criteria: Set of policies, procedures or requirements used as a reference against which objective evidence is compared. (ISO 9000:2015)

Audit Evidence: Records, statements of fact or other information, which are relevant to the audit criteria and verifiable. (ISO 9000:2015)

Audit Findings: Results of the evaluation of the collected audit evidence against audit criteria. (ISO 9000:2015)

- Audit findings indicate conformity or nonconformity. Audit findings can also lead to the identification of opportunities for improvement or recording good practices

Audit Conclusion: outcome of an audit, after consideration of the audit objectives and all audit findings. (ISO 9000:2015)

Audit Client: Organization or person requesting an audit. (ISO 9000:2015)

Auditee: Organization being audited. (ISO 9000:2015)

Audit Team: one or more persons conducting an audit, supported as needed by the technical experts. (ISO 9000:2015)

- One auditor of the audit team is appointed as the audit team leader. The audit team can include auditors-in-training.

Auditor: Person who conducts an audit (ISO 9000:2015)

Quality assessment: the assessment of the overall precision and accuracy of the data, after the analysis is run.

Quality Control and Assessment Measures: Internal Checks are performed by the project field volunteers, staff, and lab.

Observer: person who accompanies the audit team but does not act as an auditor. (ISO 9000:2015)

Technical Expert: person who provides specific knowledge or expertise to the

audit team. (ISO 9000:2015)
Specific knowledge or expertise relates to the organization, the process, or activity to be audited

4. Authorities/Responsibilities

Each site should use the below outlined procedure in addition to their "in-house" Audit and/or Assessment Procedure for individual responsibilities and for additional information as needed. MDSAP internal assessments may be conducted in-person or by using technology.

5. Procedures

Preparation / Pre-Assessment

- The designated "lead" assessor (if more than one person is conducting the self-assessment) requests procedures and other internal working documents at least fifteen (15) calendar days in advance of the assessment. Most documents and procedures will be available on the MDSAP website and/or MDSAP Sharepoint.
- The QMS Site Representative provides the requested documents in a reasonable time and manner, but not later than five (5) calendar days prior to the commencement date of the assessment. As needed the assessor(s) and QMS Site Representative engage in pre-assessment meeting(s) or dialogue in preparation for the assessment.

Initial Interview/Opening Meeting

The assessor(s) initiates the assessment by meeting with the QMS Site Representative and any members of the staff as needed. At that time the "lead" assessor if more than one person:

- Outlines the objectives of the assessment;
- Requests any additional source documents needed for the review;
- Arranges the work space
- Sets times and places for interviews as necessary
- Resolves any logistical problems.

Interviews and Document Review

- Assessor(s) conduct interviews as well as review and evaluate relevant documents as describes in the QMS Assessment Checklist. If the assessor(s) find nonconformity(ies), the assessor(s) will ascertain the reasons and whether they are valid and documented.
- Some degree of discretion can be exercised by the assessor(s) in conducting the assessment. If review indicates that a problem exists, or procedures appear deficient, additional efforts may be necessary in pursuing assessment findings or to clarify the situation.

Exit Interview

- Assessor(s) and QMS Site Representative meet as necessary periodically throughout the assessment to discuss the findings.
- At the completion of the assessment, the assessor(s) conduct a closeout interview with QMS Site Representative. Other staff members at the site may participate in the discussion. This closeout interview may be in person or may be conducted using technology.
- The assessor or if more than one the "lead" assessor discuss the findings and recommendation including any opportunities for improvement and any best practices observed. Any effort should be made during the exit interview to resolve any difference of opinion regarding identified non-conformity noted by the assessor(s).

Assessment Report

Follow the appropriate MDSAP QMS F0008.1 Assessment Report Form and submit the draft report with a copy of the MDSAP QMS F0008.2 Assessment Checklist and relevant attachments (if any) to the QMS Site Representative within ten (10) calendar days after the assessment visit. Any non-resolved nonconformity (ies) should be reported using the MDSAP QMS F0013.1. – Concern Resolution Report Form.

Assessment Report Review

The QMS Site Representative and the site management review the draft report within ten (10) calendar days after receiving it from the lead assessor, notifying the assessor(s) of clearance or clarifications needed. If clarifications are needed, then the assessor resubmits the redrafted report within five (5) calendar days. The QMS Site Representative will submit the final signed report to QMS Management Representative by the due date. A completed assessment does not indicate that all findings have been resolved. An assessment is closed when all findings have been addressed.

6. Forms

- MDSAP QMS F0008.1 - Assessment Summary Report Form
- MDSAP QMS F0008.2 - Assessment Checklist
- MDSAP QMS F0008.3 - Assessor's Qualification Form *(optional)*
- MDSAP QMS F0008.4 - Assessment Schedule and Instructions *(optional)*
- MDSAP QMS F0013.1 – Concern Resolution Report Form

7. Reference Documents

- MDSAP QMS P0001 Quality Manual
- ANSI/ISO/ASQ QE 19011:2008, Guidelines for management systems auditing – U.S. Version with supplemental guidance added

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown
002	2013-09-25	Revision: assessment versus audit. Entire document was revised to make it easier and self-explanatory when using the assessment process with a checklist.	Liliane Brown
003	2016-10-11	Section 3: Definition and Acronyms were added including updates throughout the document to address ISO 9001:2015 revisions. Templates QMS F009.1 Corrective Action and Problem Report Form and QMS F0008.5 Assessment Resolution of Finding Form was replaced with QMS F0013.1 Concern Resolution Form	Liliane Brown
004	2019-01-11	QMS manager was replace with QMS Site Representative throughout the procedure. The title for QMS F0013.1 was corrected to Concern Resolution Report Form. Revised the timeframes in section 5. Adjusted formatting	Hiromi Kumada/Kimberly Lewandowski-Walker

Version 004
Approval

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