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1. Purpose/Policy

To control records generated by the Medical Device Single Audit Program and Quality Management System (QMS) processes.

2. Scope

This outlines the procedure for controlling records related to the MDSAP Quality Management System. This procedure addresses identification, access, filing, storage, retention, and disposal of records.

3. Definitions/Acronyms

Data: Facts about an object. (ISO 9000:2015).

Disposition: The action taken regarding records no longer needed for current Government business.

Record: Document stating results achieved or providing evidence of activities performed. (ISO 9000:2015)
Note: records can be used, for example, to formalize traceability and to provide evidence of verification, preventive action and corrective action. Generally records need not be under revision control.

4. Authorities/Responsibilities

The MDSAPQMS Site Representative ensures that records are maintained appropriately. (see MDSAP QMS P0002 Document Control and Approval Procedure for additional information).

Each MDSAP site is responsible for using the proper and approved forms and templates, and for following record control procedures.

> Note: The authority and responsibility for maintaining mandatory records are listed in the MDSAP QMS P0002 Document Control and Approval Procedure.

5. Procedures

Records are maintained to provide evidence of the conformity, implementation, and effective operation of the quality management system and other business activities of MDSAP. All records are required to be legible, accurate, readily identifiable and appropriately retrievable. Each MDSAP site is required to maintain records (electronically or if needed hardcopy) to ensure compliance with the local regulations and policies by promoting the management of records throughout their life cycle in an economical, efficient and effective manner.

Records and Maintenance

Each MDSAP site will complete records for all work activities performed and maintain records as well as assure information is documented and legible. MDSAP records (e.g. reports, correspondence, quality records), include but not limited to:

- Contract Audit Activity and records
- Emails for official business
- Electronic records such as Quality Management Information
- Memorandums

- Meeting minutes
- Records such as corrective and preventive actions, complaints & feedback, audit and assessment results, document changes requests, transmittal notices, master lists, and standard operating procedures.
- Training records
- Reports such as audit reports, and management review reports
- Work plans

Note: personal papers are not government/agency owned and are not considered MDSAP record. Personal papers are documentary materials belonging to an individual that are not used to conduct government business. Regulatory notes are not considered personal papers.

Record Identification

- Records are identifiable to the MDSAP entity, process/product, person or event to which they pertain, and
- Records are dated and identify the person who established the record.

Recording and Error Correction

- All work performed is recorded legibly
- Electronic records must have an audit trail to document the change(s), and
- Data or information is not discarded without explanation. To discard, the data or information is crossed out, initialed, dated and the reason for discarding indicated using the MS Word “Track Change” feature.

Maintenance and Storage of Electronic Records

- Electronic records and data files are backed up on a regular basis to safeguard against the loss of information due to equipment malfunctions or human error and should be performed in accordance with the requirement of MDSAP Box. Documents such as audit reports, archived procedures, reviews, corrective actions, etc., are filed and stored using MDSAP Regulatory Exchange Platform- secure (REPs) (audit and assessment reports) or MDSAP Box (other documents).
- External labels for example for storage media are labeled to facilitate accurate filing and retrieval of electronic records and should follow the process described in the MDSAP QMS P0002 Document Control and Approval Procedure.
- All electronic records (regardless of physical format or electronic/computer file format) shall be scheduled, managed and dispositioned in accordance with approved retention schedules. Each MDSAP site shall use system controls which ensure that its electronics records are authentic, not altered or tampered with, auditable and produced in systems which utilize security measures to ensure integrity. Security controls are in place to limit risk, magnitude of loss, misuse, or unauthorized release of information.

- Electronic records and data files must be backed up on a routine basis to preserve in case of equipment failure or catastrophe and to safeguard against the loss of information.

Access

- There is restricted access to all records to prevent unauthorized use and amending of information
- Records are secured at all times
- Electronic records should have password or file protection, or read-only capabilities as described in the MDSAP QMS P0002 Document Control and Approval Procedure.
- Each MDSAP site shall comply with all access control standards (which might be different per location), procedures, and requirements pertaining to the systems being used. Act ethically, take initiative, and accept responsibility for safeguarding information resources under their control. Keep alert to threats and vulnerabilities, stay abreast of security policies and issues, and report all know or suspected incident to the appropriate contact

Record Retention

- Each MDSAP site should regularly review the current records control schedules and, when required, propose updates to current record control schedules as the needs evolve, and draft records control schedules for new program's records. The retention period will not be less than five years or as governed by specific regulation and/or policy at that specific site.

Disposal of Records

- After the retention period is completed, records may be destroyed or if necessary transferred to an appropriate storage facility.

6. Forms

N/A

7. Reference Documents

MDSAP QMS P0002 – Document Control and Approval Procedure
ISO/IEC 17011 – Conformity Assessment –General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
ISO/IEC 17021 – Conformity Assessment – Requirements for Bodies providing Audit and Certification of Management Systems
IMDRF/MDSAP WG/N3:2016 – Requirements for Medical Devices Auditing

Organizations for Regulatory Authority Recognition

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown, FDA
002	2015-09-22	On page 3; Japan was added to the site which is applicable to this process.	Liliane Brown, FDA
003	2016-07-28	ON PAGE 4: Section Procedure, sub-section Record Maintenance; first paragraph 6th bullet – preventive actins was updated to preventive actions	Liliane Brown, FDA
004	2016-10-11	Changes were made throughout the document to reflect ISO 9001:2015 revisions	Liliane Brown, FDA
005	2019-01-11	Minor spelling corrections made Assigned new project manager for this document Changed responsibility from MDSAP Secretariat to MDSAP QMS Management Representative in section 4.0 Changed “MDSAP IT Portal” to MDSAP REPs and MDSAP Box in section 5.0 under the “Maintenance and Storage of Electronic Records” heading” Adjusted formatting	Kimberly Lewandowski-Walker, USFDA
006	2023-05-05	Changed to be the common procedure for each MDSAP site	Hiromi Kumada, PMDA

Version 006
Approval

Approved: Signature on file Date:2023-05-02
CHAIR, MDSAP RAC