

 Responsible Office/Division	Document No.: MDSAP QMS P0002.005	Page: 1 of 14
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Title: MDSAP QMS Document Control and Approval Procedure		Project Manager: Hiromi Kumada, PMDA

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1. Purpose/Policy

This document describes the Medical Device Single Audit Program (MDSAP) procedures to develop, review, approve, and publish the MDSAP documents on the web site. Development and issuance (publication) of these documents requires collaboration among various participating regulatory authority representatives, including, in some cases, the MDSAP Regulatory Authority Council (RAC).

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The Document Control and Approval process is one of the primary tools for all work related to the development, management, maintenance, and expansion of the MDSAP. It is important to keep all operational documents current to reflect revisions to regulatory authority laws, regulations, procedures, and organizational structure.

The MDSAP QMS Management Representative is responsible for establishing and maintaining a uniform, controlled and centralized system for the creation, revision, approval, publication, retrieval, distribution, and disposal of all internally generated documents and reference documents affecting the MDSAP.

These documents may also be requested directly from the RAC Secretariat, MDSAP QMS Site Representative(s), and/or MDSAP@fda.hhs.gov.

These documents may be edited and updated frequently, to accurately reflect current policies and procedures, and to assure that the quality system documents used by regulatory authorities and MDSAP staff are properly developed, approved, active and located where needed.

2. Scope

This procedure applies to the creation and control of documented information which calls for quality requirements used by regulatory authorities to specify requirements or prescribe activities affecting the MDSAP. This procedure outlines the process for adding, modifying, or deleting documents within or related to the MDSAP Quality Management System (QMS). This procedure is revised as needed and reviewed every two years. Training will be provided (as necessary) when a document is revised or a new document is implemented.

3. Definitions/Acronyms

Appendix: An appendix is a section added at the end of a document to provide additional information.

Controlled Copy: A formal copy of the latest, approved version of a document. A controlled copy must be systematically tracked, updated and stored for use.

Documented Information: information required to be controlled and maintained by an organization and the medium on which it is contained. (ISO 9000:2015(E))

Document Control: Ensuring that documents are reviewed for adequacy, approved for release, distributed to and used at the location where the prescribed activity is performed. Obsolete documents are to be retained.

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Document History Record: The Document History Record contains version and publication dates, document and version numbers, approval signatures, and revision records.

Document Number: A unique identifier to differentiate documents (Procedure, Form or Guidance) and their versions. All document numbers will include a standard prefix “MDSAP” and a unique alpha-numeric identifier for a type of document and its version. For example:

Procedure: MDSAP P0002.001 (Initial release of procedure .001)
 Form: MDSAP F0002.1.002 (Second version of form 1.002)
 Guidance: MDSAP G0001.003 (Third version of guidance .003)

To distinguish the two (2) programs “Audit” and “Assessment” listed within MDSAP, all documents specific to the audit program will have the prefix “MDSAP AU”, and all documents specific to the assessment program will have the prefix “MDSAP AS”. For example:

Audit Program:

Procedure: MDSAP AU P0002.001 (Initial release of procedure .001)
 Form: MDSAP AU F0002.1.002 (Second version of form 1.002)
 Guidance: MDSAP AU G0001.003 (Third version of guidance .003)

Assessment Program

Procedure: MDSAP AS P0002.001 (Initial release of procedure .001)
 Form: MDSAP AS F0002.1.002 (Second version of form 1.002)
 Guidance: MDSAP AS G0001.003 (Third version of guidance .001)

All document numbers related to the internal Quality Management System (QMS) within MDSAP will include a standard prefix (MDSAP QMS) and a unique alpha-numeric identifier for a type of document and its version. For example:

Procedure: MDSAP QMS P0002.001 (Initial release of procedure .001)
 Form: MDSAP QMS F0002.1.002 (Second version of form 1.002)
 Guidance: MDSAP QMS G0001.003 (Third version of guidance .0001)

Effectiveness: Extent to which planned activities are realized and planned results achieved. (ISO 9000:2015 (E))

Effective Date: Date the documents are signed by the Chair person and it officially begins to be used.

Electronic Document Title: A unique identifier for electronic storage of documents assigned by the MDSAP QMS Management Representative to differentiate electronic draft documents and their revisions, or assigned by the

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RAS to differentiate electronic released document versions and their revisions. Includes the Document Number and the Revision Date. For example:

MDSAP P0002.001 (yyyy/mm/dd) – Document Title.docx
MDSAP AU P0002.001 (yyyy/mm/dd) – Document Title.docx
MDSAP AS P0002.001 (yyyy/mm/dd) – Document Title.docx, or
MDSAP QMS P0002.001 (yyyy/mm/dd) – Document Title.docx.

Form: A document used to facilitate procedural implementation or document procedural objectives

Form Number: A unique alpha-numeric identifier assigned by the RAS used to differentiate forms and their versions. The Form Number consists of a prefix “F” (Form) followed by five digits. The first four digits designate the procedure the form is associated with. The next digit indicates the sequential number of the form. For example, the first form associated with the procedure MDSAP P0002 would be:

MDSAP F0002.001
MDSAP AU F0002.1.001
MDSAP AS F0002.1.001, or
MDSAP QMS F0002.1.001

Implementation Date: Date that staff has received training and documents are posted to the MDSAP web page.

Guidance: Guidance documents are developed as necessary to supplement, direct the implementation of, or clarify approved regulatory, statutory, or MDSAP policy. Guidance documents may also include work instructions that support the implementation of a procedure.

Guidance Number: A unique alpha-number identifier assigned by the RAS used to differentiate guidance documents and their versions. The Guidance Number consists of a prefix “G” and a sequentially assigned four-digit number. For example:

MDSAP G0001.001
MDSAP AU G0001.001
MDSAP AS G0001.001, or
MDSAP QMS G0001.001

Master Document List: A list of released documents maintained by the RCS and including the Document Number, Version date, Revision Date and Publication Date.

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Master file: This file includes all signed original documents and all electronic files.

New Document Proposal/Change Request (NDP/CR) Form: A document that defines the basis for a proposed revision or a new document proposal to a published document, including the originator identification, rationale, description of proposed revisions and impact evaluation. The form can also be used to initiate the development of procedural documents and form may be created by anyone representing a participating regulatory authority.

New Document Proposal (NDP) Template: A pre-developed page layout used to make new documents with a similar design, pattern. This template includes work instructions and is used to propose a new document as an attachment to a New Document Proposal Form. The form may be initiated by anyone representing a participating regulatory authority.

Non-significant Impact New Document or Revision: New documents or revisions to existing versions that have minimal or no impact on the accomplishment or maintenance of MDSAP objectives defined in the MDSAP P0001 Functional Statement.

Originator: Any representative of a participating regulatory authority who requests that a new document be created, or that a revision to an existing document be made.

Procedure Number: A unique alpha-numeric identifier assigned by the MDSAP QMS Management Representative to differentiate procedures and their versions. The Procedure Number consists of a prefix "P" and a sequentially assigned four-digit number. For example:

MDSAP P0002.001
MDSAP AU P0002.001
MDSAP AS P0002.001, or
MDSAP QMS P0002.001

Publication Date: Date that documents are published to the MDSAP website (yyyy/mm/dd.) The publication date is recorded in the Master Document List.

Revision of Drafts: An iteration of document development that has not been approved for release by the RAC Chair. Revisions of Drafts are distinguished by a Revision Date and are not publically available on the MDSAP website.

Revision of Versions: An iteration of a released version that is the result of a non-significant impact revision. Revisions of Versions are distinguished by a Revision Date and are publically available on the MDSAP website.

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Revision Date: A date assigned by the MDSAP QMS Management Representative, when amendments were made to a draft document, or by the RAS, when a non-significant impact revision was made to a released version (yyyy/mm/dd.)

Subject Matter Experts: Subject Matter Experts assist in the creation or revision of documents. Subject Matter Experts may also review proposed new documents or proposed document revisions for accuracy and appropriate content.

Uncontrolled Copy: An informal copy of a document for which no attempt is made to update it after distribution. Copies of documents made by users (in paper or electronic form) are considered “uncontrolled copies”. The responsibility of making sure a document is the most current approved document is with the user of the document.

Version: A document that is publically available from the MDSAP website.

Version Date: Date the documents are signed by the Chair of the RAC or MDSAP QMS Management Representative as applicable (yyyy/mm/dd.) The version date is recorded in the Master Document List.

Version History: A summary of the cumulative history of the versions of a document.

Version Number: A sequentially assigned number appearing at the end of a Document Number. The version number is assigned by the MDSAP QMS Management Representative or MDSAP QMS Site Representative after each approval of a document by the RAC Chair. For example:

- .001 (initial release)
- .002 (second version)

4. Authorities/Responsibilities

4.1 MDSAP Regulatory Authority Council Chair:

- Maintains final document approval authority for all MDSAP documents

Note: Final document approval authority may be delegated to the MDSAP QMS Management Representative or his or her designee for non-significant impact new documents or revisions.

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- Ensures resources are available to accomplish requirements specified within the documents

4.2 MDSAP Regulatory Authority Council (RAC):

- Reviews and recommends final document approval, disapproval or approval with revision to the RAC Chair
- Works with the MDSAP QMS Management Representative, MDSAP QMS Site Representative and document originator (as necessary) to resolve questions and conflicts
- Provides a rationale for document disapproval or revision to the MDSAP QMS Management Representative, MDSAP QMS Site Representative and document originator as appropriate

4.3 MDSAP Regulatory Authority Secretariat (RAS):

RAC Secretariat will assist the RAC Chairperson for issues relating to the RAC Board only. Those issues could be:

- Preparation of official communications – including application rejection letters as applicable – to the candidate Auditing Organization
- Coordination and collection of the information for management review as needed and maintains related management review records
- Assembling summary report and documents action items and plans
- Coordination of reviews and versions of MDSAP documents, including assuring all proposed new and revised documents are available for review and comment by the RAC
- Maintaining and controlling superseded or obsolete documents as related to the RAC
- Maintaining a copy (electronic) of approved versions of documents as related to the RAC
- Coordinating the clearance of MDSAP related documents
- Serving as a Liaison between the RAC and the MDSAP QMS Management Representative, MDSAP QMS Site Representative or other regulatory authority

Note: In the event of a vacancy in the MDSAP Secretariat position, the aforementioned duties will be performed by the MDSAP QMS Management Representative, with assistance from MDSAP QMS Site Representatives.

4.4 MDSAP QMS Management Representative:

- Coordinates with the Regulatory Authority Council Secretariat to assure all proposed new or revised documents are available for review and comment by the RAC

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- Reviews proposed new documents or proposed revisions to existing documents to determine if they represent a non-significant impact new document or revision

Note: The MDSAP QMS Management Representative should confer with his or her regulatory authority's representative(s) to the RAC; or other subject matter experts to assist in this determination where necessary.

- Maintains final document approval authority for non-significant impact new documents or revisions to existing documents
- Reviews and recommends approval of proposed new or revised documents
- Works with the MDSAP QMS Site Representative and document originator (as necessary) to resolve questions and conflicts
- Ensures training related to new or revised documents is provided as necessary

4.5 MDSAP QMS Site Representative:

- Reviews, revises (as necessary) proposed new documents and the revision of existing documents in their area of responsibility
- Verifies the necessity and technical accuracy of the documents
- Identifies training needs resulting from new or revised documents
- Works with the document originator to resolve questions and conflicts
- Assists the MDSAP QMS Management Representative in training affected entities in new or revised documents as necessary
- Ensures biennial reviews of all documents used in his or her area of responsibility are conducted

4.6 All MDSAP Regulatory Authority Representatives:

- Ensures implementation of document control system
- Ensures documents used within their area of responsibility are the most current approved documents
- Performs biennial review of documents used within his or her area of responsibility
- Identifies the need for new documents or the modification of existing approved versions of documents
- Discusses proposed original document or document revision with MDSAP QMS Site Representative and/or MDSAP QMS Management Representative as applicable
- Authors and reviews for accuracy proposed original documents or document revisions

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- Originates document creation or revision by completing an Original Document Proposal Template or revising an existing document

5. Procedures

This procedure should be used for the generation of new documents and the review and revision of existing documents.

5.1 General Document Format

The font for a proposed new or revised document (including procedures, forms and guidance) should be **Arial**; font size 12 for narrative and font size 14 for main titles. The word “DRAFT” should appear as a watermark on each page of each proposed new or revised document. To allow for editing a draft document should:

- Not have the security function activated;
- Not be read-only;
- Not be password protected, and
- Employ limited use of hypertext or cross-referencing.

If published documents are provided in a PDF format, they must be electronically searchable.

All required signatures and dates may be electronic or written.

5.2. Biennial Reviews

Every twenty-four months, a biennial document review will be initiated based on the latest date of review/version. The most current approved MDSAP documents will be reviewed to ensure they continue to meet their defined purpose and scope. The MDSAP QMS Management Representative and MDSAP QMS Site Representatives are responsible to assure the biennial review is conducted and revisions to documents are proposed as necessary. This review includes verification of the consistency with other existing policies/procedures.

Minor document revisions such as typographical errors, page numbering sequence errors, grammatical errors, spelling errors, etc. proposed between biennial reviews that do not impact the utility of the document can be saved by the Secretariat and addressed cumulatively at the biennial document review; or approved as a non-significant impact revision.

5.3. New Document Development and Approval

The need for a new document can be recognized in many ways (e.g. group discussion, a single originator’s initiative, external events, etc.).

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The originator should complete the New Document Proposal/Change Request (NDP/CR) Form to identify the rationale and to evaluate the impact of the proposal. The MDSAP QMS Site Representative and/or MDSAP QMS Management Representative should agree with the concept of and necessity for the proposed new document prior to the originator initiating the new document development and approval process. Once agreed, the originator of the new document requests a document number from the RAC Secretariat or MDSAP QMS Site Representative.

In case of approval, the originator will use the New Document Proposal/Change Request (NDP/CR) Form and the New Document Proposal (NDP) Template to initiate the creation of a new document. The NDP/CR Form and template are located on the MDSAP website and are to be completed and forwarded electronically. The forms can also be obtained electronically from the RAC Secretariat.

The originator should solicit input from various entities (e.g. subject matter experts, colleagues who will use or be affected by the proposed new document, MDSAP QMS Site Representatives, etc.) during the development of the proposed new document and completion of the NDP/CR documents.

The originator will provide an electronic copy of the completed NDP/CR Form and template to the MDSAP QMS Site Representative, MDSAP QMS Management Representative, or MDSAP RAC Secretariat in the event there is no MDSAP QMS Site Representative or MDSAP QMS Management Representative assigned.

The MDSAP QMS Site Representative (if applicable) will forward the completed NDP/CR Form and template with a statement indicating review and concurrence (as well as any other comments), to the MDSAP QMS Management Representative.

When the proposed new document does not have a significant impact on the MDSAP as stated by the MDSAP QMS Management Representative (i.e. not a new version), MDSAP QMS Management Representative or MDSAP QMS Site Representative will revise the proposed new document as specified, assign a revision date, revise the Master List of Documents, and provide the final document to the MDSAP QMS Management Representative for final approval and signature.

The MDSAP QMS Management Representative will sign and date the proposed new document (that does not have a significant impact on the MDSAP) authorizing its approval and return it to the MDSAP RAC Secretariat or MDSAP

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QMS Site Representative who will publish the approved new document to the MDSAP website.

When the proposed new document may have a significant impact on the MDSAP, the MDSAP QMS Management Representative will provide the completed NDP/CR template along with the MDSAP QMS Site Representative and/or MDSAP QMS Management Representative's statement(s) of review and concurrence (as well as any other comments) to the MDSAP RAC Chair.

The MDSAP RAC Chair will collaborate as necessary with the MDSAP RAC and reject, approve, or approve with revisions the proposed new document.

When a proposed new document is rejected, the MDSAP RAC Chair will provide a documented rationale for rejection (in writing or electronically) and return the completed NDP/CR template and rationale to the MDSAP RAC Secretariat for dissemination to the MDSAP QMS Management Representative, MDSAP QMS Site Representative, originator, and RAC members, as applicable.

When a proposed new document is approved or approved with revisions, the MDSAP RAC Chair will forward the completed NDP/CR template with a statement of approval or, a statement of approval with revisions to the MDSAP RAC Secretariat and RAC members.

The MDSAP RAC Chair will sign and date the new document, or new version, authorizing final approval and return it to the MDSAP QMS Management Representative who will assign a revision date, publish the approved new document to the MDSAP website, and notify the RAC members that the new document has been published.

The MDSAP QMS Management Representative or MDSAP QMS Site Representative will ensure training is provided on the new document as necessary.

Note: If the new document proposal is not approved, the MDSAP QMS Site Representative and/or MDSAP QMS Management Representative will provide a documented rationale for rejection, sign and date the NDP/CR Form and file for record retention purposes.

Note: The review of a new proposed document includes verification of the consistency with other existing policies/procedures.

5.4. Revised Document Development and Approval

The need for a revision to a published document can be recognized in many ways (e.g. group discussion, a single originator's initiative, external events, etc.).

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The originator should discuss the concept of and necessity for the revision to a published document with the MDSAP QMS Site Representative and/or MDSAP QMS Management Representative, as applicable. The MDSAP QMS Site Representative and/or MDSAP QMS Management Representative should agree with the concept of and necessity for the proposed revision to the published document prior to the originator initiating the process for the revision and approval of a published document.

The originator should prepare a new draft of an existing document as an MS Word file with the "Track Change" feature activated. A Microsoft Word copy of the document to be revised may be obtained from a non-public area of the MDSAP website, the MDSAP RAC Secretariat, or MDSAP QMS Site Representatives.

The Originator will provide an electronic copy of the draft document to the MDSAP QMS Site Representative or MDSAP QMS Management Representative.

The MDSAP QMS Site Representative (if applicable) will forward the draft document with a statement indicating review and concurrence (as well as any other comments), to the MDSAP QMS Management Representative.

When the proposed revisions to a published document do not have a significant impact on the MDSAP as stated by the MDSAP QMS Management Representative, the MDSAP QMS Management Representative or MDSAP QMS Site Representative will revise the existing document, and assign a Revision Date, revise the Master List of Documents and provide the revised document to the MDSAP QMS Management Representative for final approval and signature.

The MDSAP QMS Management Representative will sign and date the revised document (when the proposed document revisions do not have a significant impact on the MDSAP) authorizing its approval and return it to the MDSAP RAC Secretariat or MDSAP QMS Site Representative who will remove the previous revision of the document from the MDSAP website and publish the approved revised document.

When the proposed revisions to a published document may have a significant impact on the MDSAP, the MDSAP QMS Management Representative will provide the draft document (as well as any other comments) to the MDSAP RAC Chair through the MDSAP Secretariat.

The MDSAP RAC Chair will collaborate as necessary with the MDSAP RAC and

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reject, approve, or approve with revisions the draft document.

When a draft document revision is rejected, the MDSAP RAC Chair will provide a documented rationale for rejection (in writing or electronically) and return the document and rationale to the MDSAP QMS Management Representative, MDSAP QMS Site Representative, originator, and RAC members, as applicable.

When a draft document revision is approved or approved with revisions, the MDSAP RAC Chair will forward the approved draft revised document with a statement of approval or, a statement of approval with revisions to the MDSAP QMS Management Representative and RAC members.

The MDSAP QMS Management Representative will revise the existing document, revise the Master List of Documents and provide the final document to the MDSAP Chair for final approval and signature.

The MDSAP RAC Chair will sign and date the revised document authorizing final approval and return it to the MDSAP RAC Secretariat or MDSAP QMS Management Representative who will assign a revision date, remove and archive the previous version of the document from the MDSAP website, and publish the newly approved version of the document.

The MDSAP QMS Management Representative or MDSAP QMS Site Representative will ensure training is provided on the new document as necessary.

Note: The review of the proposed document revisions includes verification of the consistency with other existing policies/procedures.

5.5. External Documents

Document from external sources are controlled using a log to track the use of versions as part of the quality system. The title, date, version and, if applicable, page numbers are to appear on these lists. Lists are maintained for the reference documents.

5.6. Document Retention and Archiving

Documents are retained and archived according to the MDSAP QMS P0007, Control of Quality Records Procedure.

5.7. Forms

Forms may be created as necessary to assist in the implementation or documentation of procedural requirements. New forms are to be developed in conjunction with new procedures. New forms will be forwarded with the associated new procedure for review and approval.

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New versions of forms are to be identified in the form's associated procedure.

Revised forms are to be forwarded with the related procedure when submitted for approval.

Instructions for completing forms should be embedded within the form or form template.

Any optional section that does not apply will be annotated with "Not applicable" or "None".

6. Forms

MDSAP QMS F0002.1 – New Document Proposal and Change Request (NDP/CR) Form

MDSAP QMS F0002.2 - New Document Proposal (NDP) Template

7. Reference Documents

MDSAP P0001- MDSAP Functional Statement

MDSAP QMS P0007- Control of Quality Records Procedure

8. Document History

VERSION No.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown, USFDA
002	2015-12-30	Changes were made throughout the document to reflect the QMS role and responsibilities for RAC, Secretariat, and QMS Rep and according to the MDSAP QMS structure.	Liliane Brown, USFDA
003	2016-10-11	Changes were made throughout the document based on the revision on ISO 9001:2015	Liliane Brown, USFDA
004	2018-06-21	Changes were made throughout the document to reflect current practice and clarify roles. Biennial document review. Notes were added on section 5.3 and 5.4.	Kimberly Lewandowski-Walker/ Hiromi Kumada
005	2019-01-11	Note made to section 4.3 to allow for the MDSAP QMS Management Representative to assume duties of MDSAP Secretariat, if position of Secretariat is vacant Adjusted formatting	Hiromi Kumada, PMDA/ Kimberly Lewandowski-Walker, US FDA

Version 005
Approval

Approved: ON FILE^{b1} Date: 2019-01-11
CHAIR, MDSAP RAC