

 <b>Responsible Office/Division</b>	<b>Document No.:</b> MDSAP QMS P0002.001	<b>Page:</b> 1 of 14
	<b>Version Date:</b> 2013-07-15	<b>Effective Date:</b> 2013-07-15
<b>Title:</b> MDSAP QMS Document Control and Approval Procedure		<b>Project Manager:</b> Liliane Brown, USFDA

## Table of Contents

1. Purpose/Policy .....	1
2. Scope .....	2
3. Definitions/Acronyms .....	2
4. Authorities/Responsibilities .....	6
4.1. MDSAP Regulatory Authority Council Chair: .....	6
4.2. MDSAP Regulatory Authority Council (RAC): .....	6
4.3. MDSAP Regulatory Authority Council Secretariat (RAS): .....	7
4.4. Lead Project Manager: .....	7
4.5. Project Manager: .....	8
4.6. All MDSAP Regulatory Authority Representatives: .....	8
5. Procedures .....	8
5.1. General Document Format .....	8
5.2. Biennial Reviews .....	9
5.3. New Document Development and Approval .....	9
5.4. Revised Document Development and Approval .....	11
5.5. External Documents .....	13
5.6. Document Retention and Archiving .....	13
5.7. Forms .....	13
6. Forms .....	14
7. Reference Documents .....	14
8. Document History .....	14

### 1. Purpose/Policy

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

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.

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 2 of 14
---	--------------------------------------	--------------

The MDSAP Regulatory Authority Council Secretariat (RAS) 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.

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 all documents which call 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.

Document: For the purpose of this procedure, the word document is defined as in ISO 9000:2005. A document may be a record, specification, procedure, drawing, report, standard, etc. Documents include forms and guidance.

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.

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 assigned by the RAS 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:

Uncontrolled when printed:  
For the most current copy, contact MDSAP Secretariat

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 3 of 14
---	--------------------------------------	--------------

Procedure: MDSAP P0002.001 (Initial release of procedure 0002)  
 Form: MDSAP F0002.1.002 (Second version of form 0002.1)  
 Guidance: MDSAP G0001.003 (Third version of guidance 0001)

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 0002)  
 Form: MDSAP AU F0002.1.002 (Second version of form 0002.1)  
 Guidance: MDSAP AU G0001.003 (Third version of guidance 0001)

Assessment Program

Procedure: MDSAP AS P0002.001 (Initial release of procedure 0002)  
 Form: MDSAP AS F0002.1.002 (Second version of form 0002.1)  
 Guidance: MDSAP AS G0001.003 (Third version of guidance 0001)

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

Procedure: MDSAP QMS P0002.001 (Initial release of procedure 0002)  
 Form: MDSAP QMS F0002.1.002 (Second version of form 0002.1)  
 Guidance: MDSAP QMS G0001.003 (Third version of guidance 0001)

Effectiveness: Extent to which planned activities are realized and planned results achieved. (ISO 9000:2005)

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 Lead Project Manager to differentiate electronic draft documents and their revisions, or assigned by the 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.

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 4 of 14
---	--------------------------------------	--------------

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 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.

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

Minor Changes (Revisions): Changes to documents including typographical errors, style, and other revisions that do not affect the process, which is the subject of the document. These changes may be performed by the Project Manager.

Major Changes (Revisions): Changes which affect the content or quality of the action being prescribed in the document, such as updated technology resulting in

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 5 of 14
---	--------------------------------------	--------------

change of procedure or multiple changes within the document.

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 RAS 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.

Revision Date: A date assigned by the Lead Project Manager, when amendments

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 6 of 14
---	--------------------------------------	--------------

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 Lead Project Manager 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 RAS 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 Lead Project Manager or his or her designee for non-significant impact new documents or revisions.

- 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

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 7 of 14
---	--------------------------------------	--------------

- Works with the Lead Project Manager, Project Manager and document originator (as necessary) to resolve questions and conflicts
- Provides a rationale for document disapproval or revision to the Lead Project Manager, Project Manager and document originator as appropriate

#### **4.3. MDSAP Regulatory Authority Secretariat (RAS):**

- Implements and maintains the document control system
- Coordinates reviews and versions of MDSAP documents, including assuring all proposed new and revised documents are available for review and comment by the RAC
- Maintains a Master Document List to ensure current and/or revised documents are available to regulatory authority representatives
- Assures approved documents are identified in the Master Document List with a document and version number, version date and revision date.
- Publishes the latest version of documents on the MDSAP website for access by all users
- Retrieves and archives superseded or obsolete documents published on the MDSAP website
- Maintains and controls superseded or obsolete documents
- Provides guidance and serves as facilitator during development and implementation of MDSAP documents
- Coordinates the clearance of MDSAP documents
- Reviews MDSAP documents to ensure accuracy, consistency, and format as applicable
- Maintains a master copy (electronic) of approved versions of documents
- Coordinates the evaluation and follow up of proposed original or revised document submissions
- Serves as a Liaison between the RAC and the Lead Project Manager, Project Manager or other regulatory authority
- Provides guidance and serves as facilitator during development and implementation of documents

#### **4.4. Lead Project Manager:**

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

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 8 of 14
---	--------------------------------------	--------------

- 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 Project Manager and document originator (as necessary) to resolve questions and conflicts
- Ensures training related to new or revised documents is provided as necessary

#### **4.5. QMS Project Manager:**

- 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 Lead Project Manager 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 Project Manager and/or Lead Project Manager as applicable
- Authors and reviews for accuracy proposed original documents or document revisions
- 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



MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 9 of 14
---	--------------------------------------	--------------

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 RAC Secretariat will notify the Lead Project Manager and Project Managers at least three months prior to the twenty-four month date that the biennial document review is required. The Lead Project Manager and Project Managers are responsible to assure the biennial review is conducted and revisions to documents are proposed as necessary.

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.).

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 Project Manager and/or Lead Project Manager 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 has to request a document number from the RAC Secretariat or QMS Project Manager.

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

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 10 of 14
---	--------------------------------------	---------------

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, Project Managers, 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 Project Manager, Lead Project Manager, or MDSAP RAC Secretariat in the event there is no Project Manager or Lead Project Manager assigned.

The Project Manager (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 Lead Project Manager.

The Lead Project Manager will forward the completed NDP/CR Form and template with a statement indicating review and concurrence (as well as any other comments); or a statement authorizing final approval or, a statement authorizing final approval with revisions (for proposed documents that do not have a significant impact on the MDSAP) to the MDSAP RAC Secretariat.

When the proposed new document does not have a significant impact on the MDSAP as stated by the Lead Project Manager (i.e not a new version), the MDSAP RAC Secretariat 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 Lead Project Manager for final approval and signature.

The Lead Project Manager 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 who will publish the approved new document to the MDSAP website.

The MDSAP RAC Secretariat will notify the Lead Project Manager, Project Manager (if applicable), and RAC members that the new document has been published.

When the proposed new document may have a significant impact on the MDSAP, the MDSAP RAC Secretariat will provide the completed NDP/CR template along with the Project Manager and/or Lead Project Manager'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.

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 11 of 14
---	--------------------------------------	---------------

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 Lead Project Manager, Project Manager, 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 RAC Secretariat who will assign a revision date, publish the approved new document to the MDSAP website, and notify the Lead Project Manager, Project Manager (if applicable), and RAC members that the new document has been published.

The Lead Project Manager or Project Manager will ensure training is provided on the new document as necessary.

Note: If the new document proposal is not approved, the Project Manager and/or Lead Project Manager will provide a documented rationale for rejection, sign and date the NDP/CR Form and return it to the MDSAP RAC Secretariat for recording and dissemination proposes.

#### **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.).

The originator should discuss the concept of and necessity for the revision to a published document with the Project Manager and/or Lead Project Manager, as applicable. The Project Manager and/or Lead Project Manager 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 or the MDSAP RAC Secretariat.

The Originator will provide an electronic copy of the draft document to the Project Manager, Lead Project Manager, or MDSAP RAC Secretariat in the event there is no Project Manager or Lead Project Manager assigned.

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 12 of 14
---	--------------------------------------	---------------

The Project Manager (if applicable) will forward the draft document with a statement indicating review and concurrence (as well as any other comments), to the Lead Project Manager.

The Lead Project Manager will forward the draft document with a statement indicating review and concurrence (as well as any other comments); or a statement authorizing final approval or, a statement of authorizing final approval with revisions (when the proposed document revisions do not have a significant impact on the MDSAP) to the MDSAP RAC Secretariat.

When the proposed revisions to a published document do not have a significant impact on the MDSAP as stated by the Lead Project Manager, the MDSAP RAC Secretariat will revise the existing document, and assign a Revision Date, revise the Master List of Documents and provide the revised document to the Lead Project Manager for final approval and signature.

The Lead Project Manager 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 who will remove the previous revision of the document from the MDSAP website and publish the approved revised document.

The MDSAP RAC Secretariat will notify the Lead Project Manager, Project Manager (if applicable), and RAC members that the newly approved version has been published.

When the proposed revisions to a published document may have a significant impact on the MDSAP, the MDSAP RAC Secretariat will provide the draft document along with the Project Manager and/or Lead Project Manager'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 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 RAC Secretariat for dissemination to the Lead Project Manager, Project Manager, 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 RAC Secretariat, and RAC members.

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 13 of 14
---	--------------------------------------	---------------

The MDSAP RAC Secretariat 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 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 RAC Secretariat will notify the Lead Project Manager, Project Manager (if applicable), and RAC members that the newly approved version has been published.

The Lead Project Manager or Project Manager will ensure training is provided on the new document as necessary.

#### **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.

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".

MDSAP QMS Document Control and Approval Procedure	Document No.: MDSAP QMS P0002.002	Page 14 of 14
---	--------------------------------------	---------------

## 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

Version  
Approval

Approved: Chair, MDSAP RAC - Signature on file      Date: 2013/07/16