

 Responsible Office/Division	Document No.: MDSAP QMS F0002.2.003	Page: 1 of 3
	Version Date: 2019-01-11	Effective Date: 2019-01-15
Title: MDSAP QMS New Document Proposal (NDP) Template Preparation Guidelines	Project Manager: Hiromi Kumada, PMDA	

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[Mandatory]

1. Purpose/Policy

State the objective or reason for the procedure. The purpose of this procedure is to ... (define, describe, identify, provide, outline, establish) (guidance, guidelines, and requirements) for:
[Purpose is mandatory/Policy is optional]

2. Scope

Specify area, function or personnel involved. This procedure... (encompasses or applies to) (all, any, each):
[Mandatory]

3. Definitions/Acronyms

Add definitions that are procedure specific or assist in clarifying the procedure.
[Mandatory]

4. Authorities/Responsibilities

List authorities and responsibilities for all personnel who will use the procedure.
[Mandatory]

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5. Procedures

Describe who, what, when, and how. List actions. Any optional section that does not have content will be annotated with “Not Applicable” or “None”.

Note: this SOP serves as a guideline for SOP formatting. Uncontrolled copy headers and footers are required to be in compliance with this format.

[Mandatory]

6. Forms

List any forms by title and Form Number. Use of hypertext to the most current approved form is encouraged.

[Optional]

7. Reference Documents

List other documents by title and Document Number that relate to the procedure. Use of hypertext to the most current approved document is encouraged.

[Optional]

8. Document History

Revise document history as described in the table and key below.

[Mandatory]

Other requirements: The font for a proposed new or revised document 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 document. The proposed revised document should be used change track options.

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.

(Reference to following document: MDSAP QMS P0002 Document Control and Approval Procedure)

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VERSION No.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2012/12/12	Initial Release	Keith Smith
002	2013/04/02	Header: revised "revision" to "effective". #6 section procedure added "Note" info. Added info as "other requirements".	Liliane Brown
003	2019-01-11	Changed project manager Changed point of contact in the footer Adjusted formatting Reflected current practices in "other requirements" section	Hiromi Kumada

Version 003
Approval

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