Table of Contents

[Expand Table of Contents as Necessary]

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

Version Approval 003

Approved: ON FILE ____________________________ Date: 2019-01-11

CHAIR, MDSAP RAC