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|  Responsible Office/Division | Document No.: MDSAP QMS F0002.1.001 | Page: 1 of 2 |
| | Version Date: 2013-07-15 | Effective Date: 2013-07-15 |
| Title: New Document Proposal /Change Request Form Instruction (NDP/CR) | | Project Manager: Liliane Brown, USFDA |

These instructions are based on MDSAP QMS P0002, Document Control and Approval Procedure. Please consult this procedure for additional information on the document control process.

Note: Minor changes (i.e. grammatical) may be made, reviewed and approved by the process owner or/and the QMS project manager. A New Document Proposal/Change Request (NDP/CR) will be generated and submitted to QMS project manager for final review.

1. Obtain a NDP/CR form through the RAC Secretariat or on the MDSAP webpage.
2. Complete the "Requestor" section on the form.
3. Forward the form to QMS project manager or project team leader that a request has been initiated. The QMS project manager ensures that appropriate management is notified.
4. The QMS project manager reviews the request and performs one of the following:
 - a. If more information is needed or the form needs changes, the requestor is contacted.
 - b. If the request is approved, the appropriate box is marked, with an electronic signature and date.
 - c. If the request is not approved, mark that no changes are required and identify the reason.
5. The QMS project manager is notified that the management review has been completed, either by a submission of the form or via email.
 - a. If the management review determines that the document(s) should be removed, the QMS project manager removes the document(s), archives them and updates the Master List.
 - b. If the management review determines new or revised documents are needed, the QMS project manager identifies and assigns author(s), reviewer(s), and approver(s).
 - c. The QMS project manager notifies the requestor by email or verbally if a NDP/CR is not approved.
6. Upon notification of approval of the request, the assigned author(s) will either retrieve the MDSAP QMS F0002.2 New Document Proposal (NDP) Template for compiling a new document(s) or select the appropriate existing document(s) to be revised.
7. After the document(s) are written or revised, the assigned authors(s) will summarize the new document(s) or changes to a revised document(s). Training, resources and impacts should be recommended. The new or revised document(s) are to be submitted to the assigned reviewer(s).

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8. The reviewer(s) evaluate the document(s) and concerns/changes are noted and discussed with the author(s) for further revisions.
 - a. If the reviewer(s) approve the document(s), they enter electronic signature(s) and date. It is then forwarded to the assigned approver(s).
 - b. If, after discussions with the author(s), the document(s) are not approved, the reasons are identified and QMS project manager is notified. Author(s) and QMS project manager should work together to try and resolve any conflicts.
9. The approver(s) reviews the document. Changes and concerns are noted and discussed with the reviewer and/or the author(s). The approver(s) determine final action.
 - a. If the document(s) are approved, enter electronic signature(s) and date, forward to QMS project manager and reviewer(s).
 - b. If the document(s) is not approved, reason has to be identified and author(s), reviewers(s) and QMS project manager is notified. All parties will try to work together and resolve any conflicts until approved.
10. The QMS project manager performs a final review of the process and the document(s). Of clarifications are needed, the document(s) are sent back to the approvers(s). After final approval the QMS project manager updates the Master List, posts the approved document and notifies the MDSAP participants via email.