


MD-SOP-0031 R- 01

BATCH ID:

SITE: 2211

resone2211

This document has been electronically signed

| | | | |
|---|--|------------------------------|--|
|  | | STANDARD OPERATING PROCEDURE | |
| SOP NUMBER: | | VERSION: | |
| SOP TITLE: | | | |

PURPOSE OF THIS SOP AND WHAT IT IS APPLIED TO

<Describe the purpose of the SOP, what it should be applied to and when/under which circumstances. Include details of any specific limitations and/or exclusions>

WHO THIS SOP IS APPLICABLE TO

| FUNCTION(S) | | | SITE(S) | | | REGULATIONS | |
|--|--|---|---|--|--|--|---|
| <input type="checkbox"/> ED <input type="checkbox"/> CMC <input type="checkbox"/> LO <input type="checkbox"/> PATH <input type="checkbox"/> SA GOS | <input type="checkbox"/> GBT <input type="checkbox"/> NCFS <input type="checkbox"/> QA | <input type="checkbox"/> GxP Supt Dept. <input type="checkbox"/> Non-GxP Supt <input type="checkbox"/> SA | <input type="checkbox"/> Global <input type="checkbox"/> ALN <input type="checkbox"/> GRN <input type="checkbox"/> MSN <input type="checkbox"/> SHA | <input type="checkbox"/> CHA <input type="checkbox"/> HAR <input type="checkbox"/> MUE | <input type="checkbox"/> DEN <input type="checkbox"/> IND <input type="checkbox"/> PCV | <input type="checkbox"/> GCP <input type="checkbox"/> GMP | <input type="checkbox"/> GLP <input type="checkbox"/> None |

| | |
|------------------------|--|
| SPECIFIC APPLICABILITY | <If necessary, list sub-functions, groups or specific roles that the SOP applies to and any specific exclusions, otherwise "N/A" > |
|------------------------|--|

OTHER DOCUMENTS NEEDED TO EXECUTE THIS SOP

| DOC REFERENCE | TYPE | TITLE |
|---------------------|----------------|-----------------|
| <Add doc reference> | <Add doc type> | <Add doc title> |
| | | |

STEP-BY-STEP INSTRUCTIONS

<Add Heading 2; remove if no sub sections>

| ROLE | | ACTION |
|------------|---|--|
| <Add role> | 1 | <Add instructional text> • <Add decision option text> |
| | 2 | <Add instructional text> |
| | 3 | <Add instructional text> |
| | 4 | <Add instructional text> |


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| ROLE | | ACTION |
|------|---|--------------------------|
| | 5 | <Add instructional text> |

<Add Heading 2; remove if no sub sections>

| ROLE | | ACTION |
|------------|---|--|
| <Add role> | 1 | <Add instructional text> • <Add decision option text> |
| | 2 | <Add instructional text> |
| | 3 | <Add instructional text> |
| | 4 | <Add instructional text> |
| | 5 | <Add instructional text> |

SUPPLEMENTARY INFORMATION THAT IS NEEDED

<Add Heading 2; remove if no sub sections>

<Add Text>

<Add Heading 3; remove if no sub-sub headings>

<Add Text>

DEFINITIONS

| TERM | DEFINITION |
|------------|------------------------------|
| <Add term> | <Add non-obvious definition> |
| <Add term> | <Add non-obvious definition> |


CHANGES FROM THE PREVIOUS VERSION OF THIS SOP

| SOP SECTION | CHANGE |
|---------------|--------------------|
| <SOP section> | <Summarise Change> |

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| SOP SECTION | CHANGE |
|---------------|--------------------|
| <SOP section> | <Summarise Change> |

APPENDICES

<List Appendices>

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APPENDIX 1: <PROCESS OVERVIEW (RECOMMENDED)>

<Add Flowchart>

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APPENDIX 2: <ADD TITLE>

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