


MD-SOP-0031 R- 01

BATCH ID: 5500

SITE: 12

reason1001

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|   |  |                              |  |
|---|--|------------------------------|--|
|  |  | 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<br><input type="checkbox"/> CMC<br><input type="checkbox"/> LO<br><input type="checkbox"/> PATH<br><input type="checkbox"/> SA GOS | <input type="checkbox"/> GBT<br><input type="checkbox"/> NCFS<br><input type="checkbox"/> QA | <input type="checkbox"/> GxP Supt Dept.<br><input type="checkbox"/> Non-GxP Supt<br><input type="checkbox"/> SA | <input type="checkbox"/> Global<br><input type="checkbox"/> ALN<br><input type="checkbox"/> GRN<br><input type="checkbox"/> MSN<br><input type="checkbox"/> SHA | <input type="checkbox"/> CHA<br><input type="checkbox"/> HAR<br><input type="checkbox"/> MUE | <input type="checkbox"/> DEN<br><input type="checkbox"/> IND<br><input type="checkbox"/> PCV | <input type="checkbox"/> GCP<br><input type="checkbox"/> GMP | <input type="checkbox"/> GLP<br><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><br>• <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><br>• <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 NUMBER:   |  | VERSION:                     |  |

| 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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