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| 1. Scope |

1.1 This procedure is applicable for all equipment used in the activities relating to XXXX in the context of all GxP related activities.

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| 2.0 Department/Site Affected |

2.1.  All personnel at XXXX involved in GxP related activities.

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| 1. Objective |

3.1 To ensure that all equipment used for GxP related activities are qualified and fit for purpose.

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| 4.0 Risks |

4.1. Risks associated with this Standard Operating Procedure include but are not restricted to the following:

4.1.1. Equipment is not qualified and increases the risk to patient safety.

4.1.2 Changes are implemented without the necessary testing and verification documentation being in place.

4.1.3 Equipment not delivering expected results due to lack of or non-qualification

4.2. Strict adherence to this Standard Operating Procedure should minimise all such risks.

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| 5.0 Terms and Definitions |

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| GxP | Good Pharmaceutical Practice |
| DQ | Design Qualification |
| IQ | Installation Qualification |
| OQ | Operational Qualification |
| PQ | Performance Qualification |
| URS | User Requirements Specification |
| Qualification | Action of proving that any equipment works correctly and actually leads to expected results. |
| RP | Responsible Person |

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| 6.0 Responsibilities |

6.1 Responsible Person

6.1.1. Responsible for ensuring that all equipment is qualified prior to use.

6.2 Change Requestors

6.2.1 Change Requestors must ensure, prior to change implementation, all the necessary qualification activities have been completed.

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| 7.0 Procedure |

7.1. All equipment qualification for GxP related activities will include:

7.1.1 Design Qualification

7.1.2 Installation Qualification

7.1.3 Operational Qualification

7.1.4 Performance Qualification

7.2 Design Qualification

7.2.1 DQ defines the functional and operational specifications of the equipment and details the evidence on supplier selection. DQ will ensure that any new equipment has all of the necessary functions and performance criteria to enable successful implementation for the intended use or application.

7.2.2 Design Qualification steps are:

7.2.2.1 Selection of the type of equipment

7.2.2.2 Description of intended environment

7.2.2.3 Description of the how the equipment will be used in the selected environment and within the process. If the equipment is being used for several applications different scenarios will be described.

7.2.2.4 Preliminary selection of the supplier

7.2.2.5 Final selection of the equipment and qualification of the supplier

7.2.2.6 Discuss with the supplier all required documentation of warranty, familiarization, training, consulting and other vendor services

7.2.2.7 Development and document final functional and operational specifications as per User Requirement Specifications Form Q036.

7.2.2.8 Review and approval of user requirement and functional specifications by users and the RP.

7.3. Installation Qualification

7.3.1 Installation Qualification establishes the documented evidence that the equipment is received as designed and specified, that is properly installed and configured in the selected environment and for the intended application.

7.3.2 Installation Qualification steps are:

7.3.2.1 Check if the environmental and safety conditions meet the criteria as specified for the equipment

7.3.2.2 Compare equipment, as received, with the purchase order (including software, accessories and spare parts)

7.3.2.3 Check the equipment for any damage

7.3.2.4 Install hardware

7.3.2.5 Switch on equipment and ensure all modules power up and perform electronic self-test, if required.

7.3.2.6 Install any software, if required.

7.3.2.7 Identify and make a list with a description of all hardware, including drawings where appropriate.

7.3.2.8 Document a list of software installed.

7.3.2.9 List equipment manuals and procedures.

7.4 Operational Qualification

7.4.1 Operational Qualification demonstrates that the equipment will function according to its operational specification in the selected environment. The equipment will be tested against critical performance specifications as specified in the design specifications.

7.4.2 The following steps will be completed as part of the OQ

7.4.2.1 Obtain functional and performance specifications from the equipment supplier

7.4.2.2 Identify functions that should be tested in the user environment

7.4.2.3 Complete Form Q003 User Acceptance Test Script

7.4.2.4 Link the test cases to the user requirements and functional specifications as defined

7.4.2.5 Define the frequency of the OQ as recommended by the supplier

7.4.2.6 Define re-qualification criteria and procedures.

7.5 Performance Qualification

7.5.1 Performance qualification demonstrates that the equipment consistently performs according to the specification appropriate for routine use.

7.5.2 The following steps will be completed as part of the PQ

7.5.2.1 Define test procedures and the performance criteria for the complete system selecting critical parameters:

7.5.2.2 For example for when qualifying a new temperature-controlled vehicle the parameters

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| 8.0 Related Documents |

8.1.SOP XX Change Control

8.2 Form Q003 User Acceptance Test Script

8.2 Form Q036 User Requirements Specification Template

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| 9.0 Appendices |

None

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| 10.0 Attachments |

10.1 Form Q036 User Requirements Specification Template

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| 11.0 Records and Retention |

11.1 All superseded controlled versions of this procedure must be retained safely and securely

11.2 Documents that are printed for reference purposes in hard copy will be valid for a 24hour period only.

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| 12.0 Document History |

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| Version Number | Version History |
| 1.0 | Original version of document |
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