POLICY ON QUALIFICATION

INTRODUCTION:

The objective of this policy is to ensure that the facilities, infrastructure for computerized system, instruments, equipment, systems and utilities used for manufacturing, testing, release, storage and distribution are maintained in a qualified state.

SCOPE:

Applicable to the facilities, instruments, equipment, systems and utilities used in manufacturing testing, storage and distribution in …….. and associated units.

POLICY DETAILS:

- A Validation master plan and written procedures shall be available for providing the approach towards qualification.
- All facilities, infrastructure for computerized system, instruments, equipment, systems and utilities whose consistent performance may have an impact on quality of the product shall be qualified, prior to use.
- Risk based approach shall be used to determine the scope and extent of qualification. Staff involved in qualification and validation activities shall have adequate training.
- In case the third party or supplier is engaged in any qualification or validation activity, agreements clearly segregating the roles and responsibilities shall be available.
- Qualification shall be done in accordance with predetermined and approved qualification protocols which mention the objective, scope, responsibility, ancillary systems/equipment/ instruments with its qualification status, critical process parameters, critical quality attributes, sampling plan and acceptance criteria, at the minimum.
- Qualification and validation shall provide documented evidence that the facilities, infrastructure for computerized system, instruments, equipment, systems and utilities meet the following criteria.
- Designed in accordance to GMP (Design Qualification)
- Built and installed in compliance to design specification (Installation Qualification) Operate in accordance to design specification (Operational Qualification)
- Support a specific process in a way that consistent output is produced meeting its predetermined specification and quality attributes. (Performance Qualification)
- The test plan during qualifications shall include tests, preferably based on worst case conditions and challenges and that prove that the required outcome is achieved.
- The results of the qualification should be recorded in qualification reports.
- Frequency and need for requalification shall be periodically assessed or defined based on class of equipment, for example AHU, LAF etc.

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- ✧ Periodic requalification, in accordance to a predefined schedule, and requalification after changes shall be carried out.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION:

Qualification: Qualification is the act of planning, carrying out and recording of tests on facilities, infrastructure for computerized system, instruments, equipment, systems and utilities, which form part of the validated process, to demonstrate that it will perform consistently and as intended.

ABBREVIATIONS:

AHU : Air handling unit
EU : European union
GMP : Good manufacturing practices
ICH : International conference on harmonization LAF : Laminar air flow
WHO TRS : World health organization technical report series

REFERENCES:

ICH Q7 Good manufacturing practice guide for active pharmaceutical ingredients. Annex 15 to EU Guide to good manufacturing practice: Qualification and validation
WHO TRS 961 Annex 5 Supplementary guidelines on good manufacturing practices for heating, ventilation and air- conditioning systems for non-sterile pharmaceutical dosage forms
WHO TRS 961 Annex 3 WHO good manufacturing practices for pharmaceutical products: main principles.