POLICY ON TRAINING

INTRODUCTION:

…… is committed to providing continued training to ensure that employees remain proficient in their operational functions and in their understanding of cGMP requirements.

SCOPE:

Applicable to all personnel employed in units of ……. and its associated units.

POLICY DETAILS:

- All personnel employed to perform work / duties impacting quality of product shall have sufficient qualification and training to perform these activities.

- All new entrants shall be given induction training to familiarize them with history of company, organizational chart, facilities, company policies and company standard practices, basic GMP concepts and general safety training.

- Introduction to the department of work and work area specific training shall be given as part of On-the-Job training. Personnel shall be allowed to work under supervision / guidance of trained senior staff until the evaluation of the On-the-Job training is done and found to be successful.

- Certificate shall be issued for jobs that can be independently handled by the personnel.

- Re-training shall be considered if any deficiencies are noticed in working, any participant fails to meet acceptance criteria for evaluation of training or any employee resuming duties after long absence.

- Personnel employed in GMP environment shall have annual refresher training on GMP / Hygiene / Sanitization practices.

- Trainings shall be evaluated to ensure that the training process fulfills intended needs.

- Competency Matrix shall be prepared and training needs identified for refresher trainings and to develop competencies.

- All trainings shall be in English language. Training in local language shall be provided for personnel who do not comprehend English.

- Training shall be provided by qualified competent personnel.

- Visitors / Service providers entering GMP areas shall be qualified either by experience or training or both. Trainings shall be documented and records shall be maintained.

AMENDMENT AND WAIVER:

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

DEFINITION:

Not Applicable.

ABBREVIATIONS:

API : Active Pharmaceutical Ingredient.

CFR : Code of Federal Regulations.

cGMP: Current Good Manufacturing Practices.

ICH : The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

WHO : World Health Organization.

REFERENCES:

- ✓ 21 CFR part 211 Sub part B-Organization and personnel 211.25.
- ✓ A WHO guide to Good Manufacturing Practices requirement- Part 3.
- ✓ Training ICH Q7 Good Manufacturing Practices Guide for API's.