POLICY ON VENDOR MANAGEMENT

INTRODUCTION:

The purpose of this Policy is to provide requirements to approve manufacturers and suppliers (referred as 'Vendor' hereafter) supplying all the input materials such as Raw Material, Excipients, Chemicals and packaging materials used in …….. products.

This policy emphasizes the importance of establishing defined and mutually agreed requirements in accordance with current Good Manufacturing Practices (cGMP).

SCOPE:

This policy is applicable to all the vendors who supplies any input material that are used in manufacturing of Drug Substance (API) or Drug Product or Primary Packing Material, Medical device/ Component of combination product, critical consumable and material which are being qualified for other than pharmaceuticals directly or indirectly to …….

POLICY DETAILS:

- All the vendors (of API, PM, Excipient and Primary Packing Material, Medical device/ Component of combination product, API Starting material, Intermediate, other raw material, Critical consumable), shall be approved by evaluation of their quality systems and compliance status of applicable cGMP standards.

- Supply Chain / Sourcing Department shall identify potential vendors in concurrence with Quality.

- For new materials, IPD shall define the specification(s) whereas for existing material, as a part of alternate vendor development existing specification shall be applicable.

- **The Approval process shall be predefined and include but not limited to:**
  - ✓ Pre assessment of GMP System
  - ✓ Evaluation of samples
  - ✓ Certification of TSE/BSE, OVI, Metal Catalysts etc.
  - ✓ cGMP status (Regulatory Accreditations of site)

After satisfactory evaluation of Documents and samples, physical audit shall be triggered includes element of six systems.

Audit shall be mandatory for following categories:

- Active Pharmaceuticals Ingredients (API)
- Key starting material, Intermediate for Active Pharmaceuticals Ingredients
- Primary Packing materials
- Sterile Packing materials
- Medical Device/ Component of Combination product
- For categories other than above, a risk assessment shall be performed and based on assessment the need for audit shall be identified.
- A formal approval of vendor shall be in place after satisfactory evaluation.
- Any Conditional approval shall be processed through change control procedure. Desktop audit shall be performed as applicable.
- Approval shall be completed before commercial launch of the product, with quality agreement in place. All the vendors from which materials is sourced, shall be appropriately approved.
- Vendor shall be evaluated periodically for consistent Quality, timely supplies and response to audit queries by applicable unit and re-evaluation of status of vendor(s) shall be in place.
- Reaudit shall be carried out in case of any critical observation during audit and vendor shall be blocked till resolution of observation/ satisfactory CAPA is received.
- Written procedure (SOP) describing Qualification, Evaluation and approval of an API starting material, intermediate, Other raw material, API's, Excipients, Packaging material, Medical device/ Component of combination product, Critical consumable manufacturer/ supplier shall be established.

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 Pharmaceuticals Ingredient
BSE	:	Bovine Spongiform Encalopathy CAPA: Corrective Action Preventive Action
COA	:	Certificate of Analysis
GMP	:	Good Manufacturing Practices
ICH	:	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IPD	:	Integrated Product Development
ISO	:	International Organization for Standardization OVI: Organic Volatile Impurities
PM	:	Packaging Material
SOP	:	Standard Operating Procedure
TSE	:	Trans Spongiform Encalopathy

REFERENCES:

ISO 9001: Quality Management Systems – Requirements

ICH Q7A: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
ICH8: Pharmaceutical Development

ICH9: Quality Risk Management

ICH10: Pharmaceutical Quality Systems Handbook

EudraLex – Volume 1: Pharmaceutical Legislation Medicinal Products for Human Use
EudraLex – Volume: Pharmaceutical Legislation Notice to applicants and regulatory

guidelines medicinal products for human use

EudraLex –Volume 4: Good Manufacturing Practice (GMP) Guidelines

Schedule M: Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.

Parts 210 & 211: cGMP in Manufacturing, Processing, Packaging, or Holding of Drugs and Finished Pharmaceuticals

Part 820: Quality System Regulation for Medical Devices

IPEC-PQC GMP: The Joint IPEC-PQC Good Manufacturing Practices Guide for Pharmaceutical Excipients