# **1. PURPOSE:**

The purpose of this Standard Operating Procedure (SOP) is to ensure contractual obligations are established for procuring and provision of subcontracted activities.

**2. SCOPE:**

The scope of this SOP applies to subcontracted activities such as manufacturing, packaging, analysis, cleaning, sanitisation of premises, pest control, equipment and premises maintenance.

# **3. DEFINITIONS:**

NIL

# **4. REFERENCES:**

* ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices- Clause 12: Subcontracting
* Food Safety Management: Requirements for a Food Safety System based on Prerequisite Programmes and Hazard Analysis and Critical Control Point (HACCP) principles

# **5. AUTHORITY AND RESPONSIBILITY:**

Management ensures that contracts or agreements are in place for subcontracted activities such as manufacturing, packaging, analysis, cleaning, sanitization of premises, pest control, equipment and premises maintenance.

**Employees**

All employees are responsible to adhering to this SOP.

# **6. METHOD:**

**6.1 Types of subcontracting**

The following relate to some of the subcontracted activities;

a) manufacturing;

b) packaging;

c) analysis;

d) cleaning, sanitization of premises;

e) pest control;

f) equipment and premises maintenance.

**6.2 Contract giver**

The contract giver assess the contract acceptor's ability and capacity to carry out the contracted operations as per the (Approved List of Suppliers (GMP SOP05- Form 01) criteria.

The contract giver should ensure that the contract acceptor has all the means available to carry out the contract.

The contract giver should assess the contract acceptor’s ability to comply with these guidelines, as appropriate, and to ensure the operations can be performed as agreed.

The contract giver should provide the contract acceptor with all the information required to carry out

the operations correctly.

**6.3 Contract acceptor**

The contract acceptor should ensure that they have the means, experience and competent personnel

to meet the contract requirements.

The contract acceptor should not pass to a third party any of the work entrusted to them in the contract without the contractor giver’s prior approval and consent. Arrangements should be made between the third party and the contract acceptor to ensure that all information about operations is made available to the contract giver in the same way as in the original contract.

The contract acceptor should facilitate any checks and audits that the contract giver has defined in the contract. The contract acceptor should inform the contract giver of any changes that may affect the quality of the services or products provided prior to implementation unless otherwise specified in the contract.

**6.4 Contract**

A contract or agreement should be drawn up between the contract giver and the contract acceptor

which specifies their respective duties and responsibilities.

All data should be kept or made available to the contract giver.

# **7. RECORDS:**

The following records are maintained.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Record Title / ID** | **Format** | **Medium** | **Retention Period** | **Custodian(s)** |
| 1 | Approved List of Suppliers (GMP Form- SOP05-01) | English, Text | Electronic | 1 year | Production Controller |
| 2 | Written contracts and agreements | English, Text | Electronic | 1 year | Production Controller |

# **8. DOCUMENT AMENDMENT HISTORY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Summary of changes from previous version of the document** | **Changes Requested by** | **Remarks** |
| 0 | First version released for implementation. | N/A | Nil |
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