Scope of Consultancy services
For
Various International GMP inspections including WHO- Geneva / PICS & EU-GMP

1. AIM

To assess and prepare KAPL manufacturing sites to meet PICS /WHO –Geneva /EU GMP standards leading to these GMP certifications

2. SCOPE

Evaluate and Assess four manufacturing blocks of KAPL to be prepared for the EU GMP Inspection

- **Cephalosporin Dry Powder Block**
- **New Non ParenteralBlock**
- **Liquid Injectable Block and**
- **Beta Lactum Dry Powder Block**

This document will detail the scope of work to be carried out as part of the assessment/ audits and beyond. It will also include the audit process employed by various international Drug authorities including EU competent authorities (CAs) in charge of GMP inspections, manufacturing authorizations, and quality defects of medicinal products.

1. Procedure

1.1 Objectives

The objectives of the consultancy agency / auditors will be to assess compliance of the site in line with various current GMP guidelines pertaining to the markets of ROW, PIC/S , WHO-Geneva , EU –GMP and prepare a report on gaps observed, estimate the approximate cost involved for any infrastructure requirement , prepare and guide the KAPL team for successful approvals.

From here on this document, aims to explain the work and methodology the consultant team shall employ in achieving this target.

1.2 Scope

The scope of the consultancy services covers all elements of defined objectives. The team of consultant shall periodically visit (frequency of visit could be 7 working days in a month or as per the need basis) inspect the facilities, review the documents, guide the KAPL team wherever required to meet the GMP requirements.

The consultants team s shall identify the Gaps, perform Gap-Analysis. They shall also propose Corrective action to bridge the gaps with potential time lines required to address the gaps. Resources in terms of infrastructure and manpower must be outlined along with approximate cost implications to ensure WHO – Geneva / PICS / EU-GMP compliance

1.3 Requirements

The requirements of the audit are those specified in the relevant audit documents.

1.4 Periodic audits of the plant and remedial measures to maintain the GMP

The Consultant team shall identify the overall resource necessary such as the team leader, the audit team members, and make provision for any other resources required for the authority inspection etc. and conduct regular inspections to monitor / maintain the system.

2. On-site auditingactivities

2.1. Audit plan

The consultant team shall prepare the audit plan, which shall be reviewed and accepted by the auditee [KAPL]. The audit plan includes:

- The audit objectives and scope
- The audit requirements
- The date and place where the audit is to be conducted
- The identification of functional units to be audited
- The identification of the individuals within the auditee having significant direct responsibilities for the units to be audited
- The expected time and duration for audit activities, including meetings with auditee's management, observed inspections and audit team meetings
- The working and reporting language of the audit
- The identification, roles and responsibilities of auditors and any accompanying persons (if any)
- The confidentialityrequirements
- The audit report topics, format and structure, expected date of issue and distribution
- The amount of details provided will differ between initial, re-assessment or follow-upaudits.
- The audit plan is adapted to suit the size and complexity of the auditee. The amount of details and depth of the audit will differ depending on the type of theaudit.

2.2. Audit teamwork assignments

If necessary, the consultant team shall assign to each member of the team responsibility for audit specific elements. Such assignments take into account the efficient use of the resources. Changes to the work assignments can be made to ensure the achievement of the audit objectives.
Reporting on theaudit

2.4 Report content

The Evaluation –Assessment audit report shall provide all interested parties with an accurate record of the audit findings and conclusions. These can include whether:

- The system conforms to the specified requirements
- The system is properly implemented and maintained
- The implemented quality system is effective in meeting stated policy and objectives
- Recommendations for improvement when agreed shall then be drafted by the Vendor Auditor Team and presented to KAPL team for review, approval and implementation.
- Corrective action to bridge the gaps with potential time lines required to address the gaps must be presented
- Resources in terms of infrastructure and manpower must be outlined along with approximate cost implications to ensure EU-GMP compliance

3: Training: Consultant shall carry out regular training to the related group of KAPL team members on GMP Related topics as per the guidelines of WHO –Geneva, PICS and EU-GMP.

4.0 ***Periodic Documents review****: consultant shall carry out regular review of technical documents and Close the gaps if any.*
Typical documents include
Failure investigation analysis
Risk management
Change control management
APQR
Quality Review management
CAPA
Deviations management
Equipment and facility Qualifications
Computer system validations
(Only indicative list)

5.0 Any clarifications regarding the scope of consultancy services, please contact

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