HLL Lifecare Limited
(A Govt. of India Enterprise)
KANAGALA – 591 225, Belagavi Dist.

No. HL /BG/HR/GMP SERVICES/2026-27 **Date: 04.11.2026**

TENDER NOTIFICATION

Tenders are invited from eligible and experienced Consultancy firms / agencies for providing GMP services to HLL Lifecare Limited, Kanagala – 591225, for its Pharmaceutical / Medical Device Manufacturing Plants for a period of **one (01) year**.

The scope of work, eligibility criteria, terms & conditions, and other requirements are detailed in this Tender Document and Annexure-A.

1. Eligible firms / agencies shall participate in the tender through CPPP along with all relevant documents on or before **16.11.2026 (Monday) 17:00** Hrs.
2. The tender will be opened on 17.11.2026 (Tuesday) or if the tender will not open on said date, the convenient date will be communicated to the tenderer.
3. The selection of the firm / agency shall be based on evaluation of technical qualifications, relevant experience, competency, suitability for the assignment and the financial quotation. HLL Lifecare Limited reserves the right to accept or reject any or all tenders, wholly or partly, without assigning any reason whatsoever, and its decision shall be final and binding on all bidders.

DGM (HR)

Minimum Technical Eligibility Criteria:

1. **Experience of the Firm**: The firm / agency should have a minimum of five (05) years' experience in providing GMP services to pharmaceutical manufacturing facilities/companies/firms. Documentary evidence in the form of work orders and completion certificates shall be submitted.

2. **Experience in Regulatory Compliance:** The bidder should have experience in providing GMP services for pharmaceutical manufacturing facilities complying with one or more of the following regulatory requirements:

    a) WHO-GMP
    b) US FDA
    c) EU GMP
    d) MHRA
    e) PIC/S
    f) CDSCO
    g) ICH Guidelines

    Documentary evidence in support of the above experience shall be submitted.

3. **Availability of Qualified Professionals:** The firm/agency should have qualified and experienced professional(s) in the field of pharmaceuticals, including formulation, quality assurance, research and development (R&D), clinical research, bioequivalence (BE) studies, regulatory affairs including international product registration, Greenfield Pharmaceutical Projects, etc.

    Brief profiles of the proposed key personnel, indicating his/their qualifications and relevant experience, shall be enclosed.

4. **Registration:** The firm/agency should have valid firm registration, copy of the registration certification need to be submit along with the bid.

Note: Preference will be given to firm/agency having experience in handling WHO inspections, regulatory audits, CTD/eCTD dossier preparation, and international regulatory submissions.

Scope of Work:

i. The Firm / agency shall provide services in the areas specified below by deputing its competent and experienced shortlisted personnel to HLL site/plant/division for a minimum of four (4) working days in a month. The services for the remaining days shall be provided through online mode.

ii. HLL shall nominate one or two officers as the contact persons for coordinating the assignments and for making the necessary arrangements in connection with the services.

iii. The services shall encompass the following areas, including but not limited to:

1. WHO Prequalification (PQ) services

Provide end-to-end consultation or services for WHO Prequalification of pharmaceutical products, particularly hormonal formulations.

Services include, but not limited to:

- Product selection and development
- Formulation development support
- Bioequivalence (BE) study planning and coordination
- Preparation and review of Common Technical Document (CTD) dossiers
- Regulatory documentation
- Inspection readiness and technical support during WHO assessments
- Response to regulatory observations and deficiency letters

2. Product Portfolio Development and Business Strategy

Provide strategic consultation for business growth through:

- Selection of new products
- Product portfolio development
- Market and technical feasibility assessment
- Product life-cycle planning
- Regulatory pathway evaluation
- Business development support for domestic and international markets

3. Greenfield Pharmaceutical Manufacturing Projects

Provide complete technical consultation for establishing new pharmaceutical manufacturing facilities from concept to commercial production.

Services include:

- Project feasibility studies
- Facility planning and layout design
- Equipment selection and qualification
- Utility planning
- Cleanroom design
- Qualification and validation
- Documentation systems
- Standard Operating Procedure (SOP) development
- Regulatory compliance planning
- Commissioning support
- Inspection readiness

4. Quality Management System (QMS) Audits

- Conduct comprehensive quality audits of pharmaceutical manufacturing facilities to evaluate compliance with Current Good Manufacturing Practices (cGMP).
- Assess compliance with the **Revised Schedule M** requirements, WHO GMP guidelines, and **WHO Technical Report Series (TRS) 968**.
- Audit functional departments including:
  - Production
  - Quality Control (QC)
  - Quality Assurance (QA)
  - Warehouse and Materials Management
  - Engineering and Utility Systems
  - Environmental Monitoring
  - Environment, Health & Safety (EHS)
  - Documentation and Data Integrity
- Perform gap analysis and recommend Corrective and Preventive Actions (CAPA) to achieve regulatory compliance and operational excellence.

5. Qualification and Validation Services

Provide technical support for qualification and validation of critical pharmaceutical systems, including:

- Heating, Ventilation and Air Conditioning (HVAC) systems
- Purified Water and Water for Injection (WFI) systems
- Compressed Air Systems
- Cleanroom qualification and environmental monitoring

Services include preparation and execution of:

- User Requirement Specifications (URS)
- Design Qualification (DQ)
- Equipment qualification (IQ,OQ,PQ)
- Validation Master Plans (VMP)
- Validation protocols and reports

6. Contract Manufacturing and Third-Party Quality Audits

Conduct technical and quality audits of contract manufacturing facilities producing:

- Oral Rehydration Salts (ORS)
- Anti-Tuberculosis (Anti-TB) medicines
- AYUSH products
- Nutraceuticals
- Export-oriented pharmaceutical products
- Medical Device products
- Personal Hygiene Products

The audits focus on manufacturing capability, quality systems, documentation, regulatory compliance, and supply chain reliability.

7. BDU REVAMPING AND GMP COMPLIANCE

The Firm shall undertake assessment, engineering, design and consultancy services for revamping and modernization of the existing Bulk Drug Unit (BDU), including the Effluent Treatment Plant (ETP), to meet applicable GMP, environmental and statutory requirements. The scope shall include preparation of designs, drawings, technical specifications, BOQs, tender documents and technical support during execution and commissioning of the works.

The scope of services shall include, but not be limited to, the following:

a) Assessment and Gap Analysis: Assess the existing manufacturing facilities, civil infrastructure, process equipment, utilities, QC laboratory and ETP. Identify deficiencies with reference to Revised Schedule M, WHO-GMP guidelines, applicable ICH requirements and environmental regulations. Submit a gap assessment report with recommendations and an action plan.

b) Civil and Infrastructure Upgradation: Assess and prepare designs and drawings for renovation and modification of buildings, production areas, flooring, walls, ceilings, drainage and other infrastructure required for GMP compliance.

c) Electrical, HVAC and Utilities: Assess and prepare upgradation plans, engineering drawings and specifications for electrical systems, HVAC, air handling units, water systems, power distribution and other required utilities.

d) Plant Layout and Equipment: Review and optimize the manufacturing layout, process flow, material and personnel movement and equipment positioning. Assess existing equipment and recommend repair, refurbishment, replacement or procurement of additional equipment. Prepare equipment specifications and URS, wherever required.

e) QC Laboratory Upgradation: Assess the existing QC laboratory and recommend improvements in infrastructure, instruments, equipment and utilities. Prepare necessary layouts, specifications and BOQs.

f) ETP Revamping: Assess the existing ETP with reference to effluent characteristics, treatment capacity, process design, equipment and applicable KSPCB requirements. Recommend necessary modifications, capacity enhancement or replacement of equipment. Prepare process flow diagrams, engineering designs, technical specifications and BOQs for civil, mechanical, electrical and instrumentation works to ensure compliance with applicable environmental standards.

g) GMP and Quality Systems: Review the existing Quality Management System, SOPs, GMP documentation, CAPA, deviation management, change control and data

integrity practices. Provide support for necessary improvements, equipment and utility qualification, process validation and other applicable validation activities.

h) Engineering Designs, BOQs and Tender Documents: Prepare detailed engineering drawings, designs, technical specifications and item-wise BOQs covering civil, electrical, HVAC, utilities, process equipment, QC laboratory and ETP works. Prepare tender-ready scope of work, technical qualification criteria, specifications, inspection and testing requirements, installation and commissioning requirements and acceptance criteria.

i) Tender and Procurement Support: Assist HLL in technical scrutiny and evaluation of bids, preparation of comparative statements, review of technical deviations, clarification of bidders' queries and evaluation of contractor and vendor proposals.

j) Project Implementation and Monitoring: Prepare the project implementation schedule and provide technical support during execution of the works. Review contractor drawings, specifications and submissions; conduct periodic site inspections; monitor quality and progress; identify deviations and recommend corrective measures. Provide technical support during installation, testing and commissioning of equipment, utilities and ETP systems.

k) Regulatory Compliance and Project Handover: Provide support for GMP compliance assessments and regulatory audit preparedness. On completion of the works, review the completed installations, as-built drawings, commissioning and qualification records, and submit a final project completion and compliance report.

8. Regulatory Affairs and International Product Registration

Provide comprehensive regulatory support for domestic and international product registrations.

Services include:

- Preparation of CTD/eCTD dossiers
- Compilation and review of technical documentation
- Country-specific regulatory submissions
- Regulatory gap analysis
- Preparation of responses to regulatory queries
- Product life-cycle management

9. Technical Training and Capacity Building

Design and deliver customized training programmes for pharmaceutical professionals on:

- Current Good Manufacturing Practices (cGMP)
- Revised Schedule M requirements

- WHO GMP guidelines
- Quality Management Systems (QMS)
- Quality Risk Management (QRM)
- Validation principles
- Data Integrity
- Good Documentation Practices (GDP)
- Regulatory inspection preparedness

Deliverables: The firm / agency will provide:

- Technical audit reports
- Gap assessment reports
- CAPA recommendations
- Validation protocols and reports
- Regulatory dossiers (CTD/eCTD)
- Standard Operating Procedures (SOPs)
- Training to staff
- Project implementation plans
- Regulatory compliance and inspection readiness support

DECLARATION

I / we confirm having read and understood all the specifications, instruction, forms, terms and conditions and all relevant information regarding the concerned Tender Notification and agreed to abide by all without any deviation from what are stated above.

Signature
Name & Address

Date:
Place:

No. HL /BG/HR/GMP SERVICES/2026-27 **Date: 04.11.2026**

PRICE BID

Service Charges / Fee Schedule

1. Name & Address of the Tenderer**:**

2. Monthly Service Charges:

Sl. No.	**Service Particulars**	**Charges** (Inclusive of All)
1	Monthly Service Charges	

*Note: *The Tenderer should enclose self-attested copies of all the relevant documents as mentioned above.*

Seal & Signature of Tenderer

Place:

Date:

Annexure – A

General Terms and Conditions:

1. Section 135 (Exemption of Owner, Agent or Manager from Liability in Certain Cases) of Chapter XIII of the Occupational Safety, Health and Working Conditions Code, 2020 (Act No. 37 of 2020), as amended from time to time, shall be applicable.
2. The above Tender / Subsequent Work order is liable to be suspended or cancelled at any time at the discretion of the General Manager (Operations) & Unit Chief, HLL Lifecare Ltd, Kanagala - 591225 with or without assigning any reason and his decision will be final and binding on all concerned parties.
3. Work is to be carried out strictly as per the schedule and any change in the mode of work if desired by us is to be implemented and the tenderer shall supervise the work.
4. Personnel engaged by firm for aforesaid contract shall be employee of the firm/ agency only and not of HLL Lifecare Ltd, Kanagala.
5. There will not be any Employee Employer relationship between HLL Lifecare Ltd and the persons employed for aforesaid work.
6. HLL Lifecare Ltd will not be liable for any accident happened while on work during the contract period.
7. The personnel deployed by the successful bidder for execution of the work shall be covered under the Employees' State Insurance (ESI) Scheme or the Employees' Compensation provisions, as applicable, under the Code on Social Security, 2020 and the rules made thereunder.
8. The service provider or the personnel engaged by the firm/agency will not have any lien or right of employment as regular employees of HLL Lifecare Ltd.
9. In case of any damages caused to our property while executing the job, the cost of the same shall be recovered from the monthly bill.
10. The tenderer should have GST registration / PAN number and other statutory relevant documents, if applicable. All statutory deductions will be applicable.

11. Company reserves the right to incorporate any left out clause subsequently that will be binding on the firm / agency. The firm / agency should follow the suggestion / instruction given by HLL Lifecare Ltd Representative time to time for the same.

12. Sub contract is not allowed. On award of contract the firm / agency should execute an **agreement** with HLL Lifecare Ltd., in the prescribed manner.

13. The tender should be complete in all respects. Incomplete tenders are liable to be rejected.

14. Tenders shall submit their bid through CPP Portal only, tenders submitted other than CPP portal are liable to be rejected and this will be at the sole risk of the tenderer.

15. In case more than one tenderer quote the same rate in the price bid, the decision of HLL Lifecare Ltd will be final and binding on all the bidders.

16. The Management (HLL Lifecare Ltd) also reserves the right to allot the work to the L-2 or L-3 parties at the L-1 rates respectively, if required.

17. The tenderer should comply with the Safety, Quality policy and other applicable rules from time to time, of the Company.

18. In case of back out from the commitment, monthly payment will be forfeited followed by blacklisting, if applicable.

19. Issue of Tender Form is solely at the discretion of the Management.