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

No. HL /BG/HR/Pharma Consultancy/2026-27 **Date: 24.07.2026**

TENDER NOTIFICATION

Tenders are invited from eligible and experienced Pharmaceutical Consultancy firms / agencies for providing consultancy services to HLL Lifecare Limited, Kanagala – 591225, for its Pharmaceutical Manufacturing Plant, on a monthly consultancy basis 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. The completed tenders should reach us via email **(to unitchiefkfb@lifecarehll.com)** along with all relevant documents on or before **07.08.2026 (Friday) 17:00** Hrs.
2. The tender will be opened on 08.08.2026 (Friday) at 11:00 AM. Or if the tender will not open on said date the convenient date will be communicated to the tenderer.
3. The selection of the Consultancy 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 Consultancy Firm**: The consultancy firm/agency should have a minimum of ten (10) years' experience in providing consultancy services to pharmaceutical manufacturing facilities/companies. Documentary evidence in the form of work orders and completion certificates shall be submitted.

2. **Experience in Similar Assignments:** The consultancy firm/agency should have successfully completed, or be currently carrying out, at least five (5) consultancy assignments of a similar nature during the last five (5) years for pharmaceutical manufacturing facilities. Documentary evidence in the form of work orders and completion certificates shall be submitted.

3. **Experience in Regulatory Compliance:** The bidder should have experience in providing consultancy 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.

4. **Availability of Qualified Professionals:** The consultancy firm/agency should have at least 2 qualified and experienced professionals 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 their qualifications and relevant experience, shall be enclosed.

5. **Client References:** The bidder should submit performance certificates or satisfactory completion certificates issued by previous clients for similar consultancy assignments.

6. The firm should have valid firm registration, copy of the registration certification need to be submit along with the bid.

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

Scope of Work:

i. The Consultancy Firm shall provide services in the areas specified below by deputing its competent and experienced shortlisted personnel for a minimum of seven (7) 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 consultancy services encompass the following areas:

1. WHO Prequalification (PQ) Consultancy

Provide end-to-end consultancy for WHO Prequalification of pharmaceutical products, particularly hormonal formulations.

Services include:

- 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 consultancy 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. Clinical Study Protocol Development

Desirable support for clinical study protocols in accordance with internationally accepted scientific and regulatory standards. Services include:

- Clinical study design
- Protocol preparation
- Statistical planning
- Ethical and regulatory compliance
- Clinical documentation
- Study monitoring guidance

4. Greenfield Pharmaceutical Manufacturing Projects

Provide complete technical consultancy 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

5. 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.

6. 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

7. 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

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

8. Bulk Drug (API) Manufacturing Audits

Carry out comprehensive audits of Active Pharmaceutical Ingredient (API) manufacturing facilities in accordance with:

- Revised Schedule M
- WHO GMP guidelines
- Applicable ICH requirements

Audit coverage includes:

- Manufacturing operations
- Quality Management Systems
- Laboratory controls
- Process validation
- Cleaning validation
- Documentation practices
- Data integrity
- Regulatory preparedness

9. 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

10. 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 consultant will provide:

- Technical audit reports
- Gap assessment reports
- CAPA recommendations
- Validation protocols and reports
- Regulatory dossiers (CTD/eCTD)
- Standard Operating Procedures (SOPs)
- Training materials and technical workshops
- 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.

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KANAGALA – 591 225, Belagavi Dist.

No. HL /BG/HR/Pharma Consultancy/2026-27 **Date: 24.07.2026**

Signature
Name & Address

Date:
Place:

PRICE BID

Pharmaceutical Consultancy Fee Schedule

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

2. Consultancy Fee (per month):

Sl. No.	**Service Particulars**	**Charges** (Inclusive of All)
1	Consultancy Charges per month (for 7 physical visit and online services for the rest of the days)	
2	Consultancy Charges for physical visits over and above 7 days	

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

Seal & Signature of Tenderer

Place:

Date:

No. HL /BG/HR/Pharma Consultancy/2026-27 **Date: 24.07.2026**

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. Pharmaceutical Consultancy firm engaged by you for aforesaid contract shall be Consultant 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 Pharmaceutical Consultant 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 Pharmaceutical Consultancy firm / agency. The Pharmaceutical Consultancy 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 Pharmaceutical Consultancy firm 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 be sent through email only, tenders submitted other than email 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.