BINH DINH PHARMACEUTICAL & EQUIPMENT JOINT STOCK COMPANY
BIDIPHAR NHONHOI BRANCH
Add: 498 Nguyen Thai Hoc Street, Quy Nhon Nam Ward, Gia Lai Province, Viet Nam
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INVITATION LETTER

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Invitation to Participate in the Consultant Selection Process

Bidiphar Sterile Biotechnology Drug Manufacturing Line WHO GMP & PIC/S GMP Consultancy Project

Date: 13 August 2026

Dear Sir/Madam,

On behalf of Binh Dinh Pharmaceutical and Medical Equipment Joint Stock Company (Bidiphar), we are pleased to invite your esteemed organization to participate in the Consultant Selection Process for the Bidiphar Sterile Biotechnology Drug Manufacturing Line WHO GMP & PIC/S GMP Consultancy Project.

Bidiphar seeks to establish a long-term strategic partnership with an experienced international consulting firm capable of providing end-to-end consulting services for WHO GMP and PIC/S GMP compliance, facility design advisory, technology transfer, regulatory registration, MAH establishment and management, pharmacovigilance interface, product commercialization and PIC/S GMP compliance assessment.

1. About Bidiphar

Bidiphar is one of Vietnam's leading pharmaceutical manufacturers with more than four decades of experience in the research, development, manufacturing and commercialization of pharmaceutical products.

As part of its long-term strategic development, Bidiphar is investing in a Sterile Biotechnology Drug Manufacturing Line to strengthen its sterile biotechnology manufacturing capability and support future WHO GMP and PIC/S GMP compliance and regulatory objectives.

The facility is intended for sterile liquid injections and lyophilized injections packaged in vials, pre-filled syringes and cartridges, together with the associated supporting systems.

This project represents an important strategic investment in Bidiphar's long-term development and is intended to support the Company in preparing for, implementing, achieving and maintaining WHO GMP and PIC/S GMP compliance for sterile biotechnology drug manufacturing.

Recognizing the strategic importance and technical complexity of this project, Bidiphar intends to appoint a highly qualified consulting partner with proven experience in sterile biotechnology drug facilities, WHO GMP and PIC/S GMP certification, facility design, qualification and validation, technology transfer, regulatory registration, MAH/AP services, pharmacovigilance and product commercialization.

2. Project Scope: The project includes the provision of end-to-end consulting services to support Bidiphar in preparing for, implementing, achieving and maintaining WHO GMP and PIC/S GMP compliance for the Sterile Biotechnology Drug Manufacturing Line and its associated supporting systems.

The expected scope of services shall cover, but not be limited to:

- GMP design advisory for the Sterile Biotechnology Drug Manufacturing Facility from the early facility design stage, including Concept Design, Basic Design, Detailed Design and Design Qualification consulting;

- Preliminary audit and readiness assessment for the sterile biotechnology drug facility, systems, personnel, QMS/PQS, QC Laboratory and selected product SKUs;
- Quality Management System / Pharmaceutical Quality System (QMS/PQS) development;
- Sterile pharmaceutical manufacturing operations and associated production systems in compliance with WHO GMP and PIC/S GMP requirements;
- Quality Control (QC) Laboratory, warehousing, materials management and finished goods storage;
- Utilities systems including HVAC, Water Systems, Gas systems and related infrastructure;
- Qualification, validation, continued process verification and Quality Risk Management (QRM) activities;
- Training on WHO GMP and PIC/S GMP requirements, qualification and validation, regulatory registration, inspection readiness and other disciplines within the project scope;
- Technology Transfer and WHO & PIC/S Regulatory Registration;
- Marketing Authorisation Holder (MAH), Authorised Person (AP), Pharmacovigilance and WHO & PIC/S Batch Certification / Release systems;
- Product commercialization, maintenance of Marketing Authorisations within PIC/S member countries, WHO GMP and PIC/S GMP certification support, and post-certification periodic assessments.

Bidiphar expects the selected Consultant to become a long-term strategic partner throughout the project lifecycle, including facility design advisory, WHO GMP and PIC/S GMP compliance, technology transfer, regulatory registration, commercialization and continued compliance improvement.

In addition to supporting Bidiphar in obtaining WHO GMP and PIC/S GMP certification, the Consultant is expected to perform post-certification periodic assessments to maintain WHO GMP and PIC/S GMP compliance and ensure continued inspection readiness.

3. Project Objective

The selected Consultant is expected to provide comprehensive professional consulting services throughout the implementation of the Sterile Biotechnology Drug Manufacturing Line Project, including but not limited to:

- End-to-End WHO GMP & PIC/S GMP consulting;
- Facility design advisory, including Concept Design, Basic Design, Detailed Design and Design Qualification (DQ);
- Preliminary audit and readiness assessment;
- Quality Management System / Pharmaceutical Quality System (QMS/PQS) development;
- Consultancy on sterile pharmaceutical manufacturing operations and associated production systems;
- Consultancy on Quality Control (QC) Laboratory;
- Consultancy on warehousing, materials management and finished goods storage;

- Consultancy on utilities systems including HVAC, Water Systems, Gas systems and related infrastructure;
- Qualification, validation and continued process verification activities;
- Implementation of the Quality Risk Management (QRM) Plan;
- Training on WHO GMP and PIC/S GMP, qualification and validation, regulatory registration and inspection readiness;
- WHO GMP certification support for the sterile biotechnology drug manufacturing facility;
- Technology Transfer;
- WHO & PIC/S Regulatory Registration;
- MAH, Authorised Person (AP), Pharmacovigilance and WHO & PIC/S Batch Certification / Release systems;
- Product commercialization and maintenance of Marketing Authorisations within PIC/S member countries;
- Training, coaching and knowledge transfer related to Technology Transfer and other project disciplines;
- PIC/S GMP certification support for the sterile biotechnology drug manufacturing facility;
- Post-certification periodic assessments to maintain WHO GMP & PIC/S GMP compliance and continued inspection readiness.

Knowledge transfer to Bidiphar personnel is considered one of the key objectives of this consultancy. The Consultant is expected to help develop Bidiphar's internal capabilities to maintain the relevant quality systems and WHO GMP / PIC/S GMP compliance after completion of the consultancy services.

The selected Consultant is expected to provide structured project deliverables in accordance with the applicable User Requirement Specifications (URS) and the forthcoming Request for Proposal (RFP).

The detailed scope of services will be provided in the Request for Proposal (RFP) and the applicable User Requirement Specifications (URS).

4. Consultant Selection Philosophy

Bidiphar is committed to conducting this consultant selection process in a **transparent, fair, professional and collaborative** manner.

The evaluation will not be based solely on commercial considerations. Bidiphar intends to select the Consultant offering the optimum overall value to the Project rather than solely the lowest commercial proposal.

Consulting firms will be assessed comprehensively based on:

- Technical competence;
- Relevant experience in sterile biotechnology drug facilities and WHO GMP / PIC/S GMP projects;
- Project implementation methodology;

- Qualifications and experience of the proposed project team;
- Capability to support Bidiphar throughout the WHO GMP and PIC/S GMP compliance and certification journey;
- Capability to support facility design advisory, technology transfer, regulatory registration, MAH/AP interface, pharmacovigilance and product commercialization;
- Capability to support WHO GMP / PIC/S GMP certification and post-certification compliance maintenance;
- Knowledge transfer approach and ability to build Bidiphar's internal capability;
- Long-term value and sustainable contribution to the successful delivery, certification, commercialization and operation of the Sterile Biotechnology Drug Manufacturing Line Project.

5. Consultant Selection Process

This invitation represents the **Pre-Qualification Stage** of Bidiphar's consultant selection process.

Following the review of the submitted qualification documents, Bidiphar will issue the complete **Request for Proposal (RFP)** package to consulting firms that satisfy the required qualification criteria and demonstrate suitable experience relevant to the project scope.

6. Documents Enclosed

The following documents are enclosed with this invitation:

1. Invitation Letter;
2. Confirmation of Participation Form;
3. Mutual Non-Disclosure Agreement (NDA);
4. Annexes – Expert Qualification Form, WHO GMP & PIC/S GMP Experience and Capability Form, Presentation Registration Form, and Tentative Consultant Selection Schedule.

7. Requested Submission

Interested consulting firms are kindly requested to submit the following information.

A. Confirmation of Participation

- Confirmation of participation in the consultant selection process;
- Nomination of one primary contact person for all communications with Bidiphar throughout the consultant selection process.

B. Confidentiality

- A duly executed Mutual Non-Disclosure Agreement (NDA).

Consulting firms that have previously executed a Mutual Non-Disclosure Agreement (NDA) with Bidiphar and where such agreement remains valid and in effect, are not required to execute a new NDA. In such cases, the consulting firm is kindly requested to confirm the validity of the existing NDA in its Confirmation of Participation.

C. Preliminary Qualification Documents

The preliminary qualification package should include, but not be limited to:

- Company overview and organizational structure;
- Experience in sterile biotechnology drug facilities and WHO GMP / PIC/S GMP certification projects;
- At least three (03) similar completed reference projects within the most recent five (05) years, including at least one (01) project related to a sterile biotechnology drug facility that has obtained PIC/S GMP or EU GMP certification from a competent regulatory authority, or for which the product has obtained Marketing Authorisation approval;
- Reference project information including client name, country, project name, project type, scope of services, technical information, project duration, project status, project outcomes and relevant regulatory authority, where applicable;
- Experience in facility design advisory, QMS/PQS, QC Laboratory, warehousing, utilities, qualification and validation, WHO GMP / PIC/S GMP certification, Technology Transfer, Regulatory Registration, MAH/AP services, Pharmacovigilance and commercialization;
- Proposed project organization;
- Qualifications and experience of key experts proposed for the project;
- Relevant capabilities in:
    - Facility Concept Engineering Design and construction quality management;
    - Commissioning, Qualification, Validation and Facility Assessment;
    - Quality Management System establishment and Quality Risk Management;
    - WHO GMP and PIC/S GMP certification support;
    - Technology Transfer and supporting studies;
    - WHO & PIC/S Regulatory Registration strategy;
    - MAH, Authorised Person (AP), Pharmacovigilance and batch certification / release systems;
    - Product commercialization and Marketing Authorisation maintenance within PIC/S member countries;
    - Post-certification periodic assessment and continued inspection readiness.

D. Presentation Registration, Comments and Recommendations

The Consultant is requested to register its proposed project presentation and may provide comments or recommendations regarding the consultant selection schedule, implementation timeline or approach that may contribute to improving the efficiency and quality of the overall project implementation.

8. Annex 1 – Tentative Consultant Selection Schedule

Phase	No.	Activity	Responsible Party	Deliverable / Outcome	Tentative Timeline	Consultant's Proposed Revision (if any)
Phase 1 Invitation	1	Invitation Letter Issued and Published on Bidiphar Website	Bidiphar	Stage 1 Invitation Package	**13-Aug-26**	

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Phase	No.	Activity	Responsible Party	Deliverable / Outcome	Tentative Timeline	Consultant's Proposed Revision (if any)
	2	Confirmation of Participation, signed Mutual NDA, Presentation Registration, Company Capability, Expert Qualifications, WHO GMP / PIC/S GMP Experience and Similar Reference Projects	Consulting Firm	Stage 1 Registration Package	By 17-Aug-26	
Phase 2 Pre-Qualification	3	Preliminary Qualification Review and Official URS / RFP Issuance	Bidiphar	Qualified Consultant List & Official URS / RFP	**18-Aug-26**	
Phase 3 Technical Dialogue	4	Review of Official URS / RFP Documents	Consulting Firm	Initial Review	18–25 Aug 2026	
	5	Site Visit (if required)	Both Parties	Site Understanding	18–25 Aug 2026	
	6	Technical Discussions and Clarification Meetings	Both Parties	Clarification Records	18–25 Aug 2026	
	7	Project Presentation / Preliminary Solution Presentation	Consulting Firm	Initial Technical Approach	18–25 Aug 2026	
Phase 4 Proposal Preparation	8	Bidiphar issues clarification responses	Bidiphar	Clarification Response	18–25 Aug 2026	
	9	Finalization of Technical & Commercial Proposal	Consulting Firm	Final Proposal	26–28 Aug 2026	
Phase 5 Proposal Submission	10	Submission Deadline for Technical and Commercial Proposal / **Bid Opening**	Consulting Firm	Technical & Commercial Proposal / Bid Opening	**28-Aug-26 15:30 / 29-Aug-26 09:00**	

Notes:

- The above schedule is a tentative timeline prepared by Bidiphar for planning and coordinating the Consultant Selection Process. All dates and times specified in this schedule are based on Vietnam Time (GMT+7).
- The Stage 1 registration package, including Confirmation of Participation, signed Mutual NDA, Presentation Registration, company capability information, expert qualification **information,**

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WHO GMP / PIC/S GMP experience and evidence of similar contracts/reference projects, shall be submitted no later than 17 August 2026.
Bidiphar will issue the official URS and complete Request for Proposal (RFP) package to eligible **consulting firms on 18 August 2026.** Technical discussions and **clarifications will be conducted from 18 to 25 August 2026.** The final Technical and Commercial Proposal shall be **submitted no later than 15:30 on 28 August 2026**, Vietnam Time (GMT+7), and the bid opening is scheduled for 09:00 on 29 August 2026.

9. Confidentiality

All technical, commercial and project-related information exchanged during this consultant selection process shall be treated as strictly confidential and used solely for the purpose of preparing the proposal.

Detailed project information, including the official URS and complete tender package, will be shared with eligible consulting firms after the Mutual Non-Disclosure Agreement (NDA) has become effective.

10. Reservation of Rights

Bidiphar reserves the right, at its sole discretion, to:

- request additional information or clarification;
- amend the consultant selection schedule where necessary;
- establish a shortlist of consulting firms;
- modify, suspend or cancel the consultant selection process at any stage without incurring any liability.

Participation in this consultant selection process does not constitute any commitment by Bidiphar to award a contract.

11. Contact Information

For any clarification regarding this invitation, please contact:

Mr. Tran Dinh Khai
Project Management Department
Binh Dinh Pharmaceutical and Medical Equipment Joint Stock Company (Bidiphar)

Email: **khaitd@bidiphar.com**
Mobile: **+84 979 791 299**
WhatsApp | Viber | Zalo | WeChat

Closing Statement

Bidiphar sincerely appreciates your interest in this strategic project and welcomes your participation in this consultant selection process.

We believe that the successful delivery of this Project will require close collaboration, mutual trust, knowledge sharing and a long-term commitment between Bidiphar and the selected Consultant.

We also believe that your expertise and international experience can make a significant contribution to the successful WHO GMP and PIC/S GMP compliance and certification of the Bidiphar Sterile Biotechnology Drug Manufacturing Line, as well as to technology transfer,

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regulatory registration, product commercialization and sustainable compliance during the post-certification period.

We look forward to receiving your Confirmation of Participation and to exploring the opportunity of building a long-term strategic partnership with your organization.

Yours faithfully,

FOR AND ON BEHALF OF BIDIPHAR

M.S.D.N: 4100259564 CÔNG TY CỔ PHẦN DƯỢC-TRANG THIẾT BỊ Y TẾ BÌNH ĐỊNH (BIDIPHAR) GIA LAI

Tran Quang Hoa
Project Management Department Manager
Authorized by the General Director