



REQUEST FOR PROPOSAL

Date: 20 September 2021

Reference: **RFP-THPP-21-0004SVP**

1. The **Philippine Institute of Traditional and Alternative Health Care (PITAHC)** through its **Bids and Awards Committee (BAC)** invites interested bidders to submit a proposal with the Approved Budget for the Contract (ABC) in the amount **One Hundred Fifty Thousand Pesos Only (PhP150,000.00) inclusive of VAT** for the procurement of the item stated below:

PITAHC 2021 APP Reference	PR Number	Item Description
5021103002 / 5020702002 / 5020201002	THPP-21-08-0061	CONSULTANCY SERVICES FOR ASSISTANCE ON cGMP REQUIREMENTS IN COMPLIANCE FOR THE RENEWAL OF LICENSE TO OPERATE (LTO) BY SEPTEMBER 2022 <i>(As per attached Terms of Reference)</i>

2. Procurement shall be conducted through Small Value Procurement under Section 53.9 - Negotiated Procurement as prescribed under Rule XVI- Alternative Methods of Procurement of the 2016 Revised Implementing Rules and Regulations of Republic Act No. 9184, otherwise known as the “*Government Procurement Reform Act*”.
3. The proposal must be duly signed by the bidder and must be submitted to the PITAHC Building, Matapang St., East Avenue Medical Center Compound, Barangay Central, Quezon City or sent thru fax at (02) 8376-3067 or email at bacpitahc@gmail.com. The proposal shall be received until **27 September 2021**.
4. PITAHC reserves the right to waive any formality in the responses to the eligibility requirements and to this invitation. PITAHC further reserves the right to reject all proposals, or declare a failure of Small Value Procurement, or not award the contract, and makes no assurance that the contract shall be entered into as a result of this invitation without thereby incurring any liability to the affected bidder or bidders in accordance with R.A. No. 9184 and its IRR.
5. For any clarification, you may contact **Andy G. Matula** at telephone no. (02) 8282-5193 local 103.

(Sgd)

DR. FRANCIS VICENTE S. RAS

Chairperson, PITAHC BAC



TERMS AND CONDITIONS

1. Bidders shall provide the **correct and accurate information** required in this form.
2. Delivery Schedule: **Thirty days (30) days after receipt of Notice of Award.**
3. Delivery Site: **PITAHC Tacloban Herbal Processing Plant, Brgy. Bagacay, Tacloban City**
4. Payment Term: As provided in Item No. IX Deliverables Submission and Payment Schedule of the Terms of Reference.
5. Price proposal must be valid for a period of **thirty (30) calendar days** from the date of submission.
6. Price proposal to be denominated in **Philippine Peso**, include all taxes and duties and/or levies payable.
7. Proposals exceeding the ABC shall be automatically rejected.
8. The **award of contract** shall be made to the Lowest Calculated and Responsive Proposal which complied with the minimum technical specifications and other terms and conditions stated herein.
9. Any interlineations, erasures, or overwriting shall be valid only if they are signed or initialed by the bidder or any of his/her duly authorized representative/s.
10. Liquidated damages equivalent to one tenth of one percent (0.001%) of the value of the goods not delivered within the prescribed delivery period shall be imposed per day of delay. PITAHC shall rescind the contract once the cumulative amount of liquidated damages reaches ten percent (10%) of the amount of the contract, without prejudice to other courses of action and remedies open.
11. The bidder must **submit a copy** of the following documents, **together with the proposals**, to ensure that the said bidder is technically, legally and financially capable to undertake the proposed project:
 - Valid and current Mayor's/Business Permit
 - Business/Income Tax Return for CY 2019/2020
 - PHILGEPS Registration Number with PCAB license (*to be indicated in the Price Proposal Form*)
 - Duly Notarized Omnibus Sworn Statement by the prospective bidder in the new



TERMS OF REFERENCE

ENGAGEMENT OF CONSULTANCY SERVICES FOR THE ASSISTANCE ON CURRENT GOOD MANUFACTURING PRACTICES (cGMP) REQUIREMENTS IN COMPLIANCE FOR THE RENEWAL OF LICENSE TO OPERATE (LTO) BY SEPTEMBER 2022

I. BACKGROUND

PITAHC Tacloban is a government owned and controlled corporation established as the income generating arm of the institute. It is a manufacturing plant located in Brgy. Bagacay, Tacloban City. The plant manufactured herbal medicines namely: Lagundi tablet, Lagundi syrup, Sambong tablet, Ulasimang Bato tablet, Tsaang Gubat tablet, and Tsaang Gubat syrup. The plant was granted by the Food and Drug Administration (FDA) as initial License to Operate on September 11, 2020 and will be renewed by September 2022.

During the initial application in 2019, FDA issued Corrective Action Preventive Action (CAPA) for compliance. The plant was able to comply almost 90%; hence; it was granted with LTO with the commitment to comply the remaining 10% upon renewal. The 10% were mostly documentation requirements for both Solid Form Dosage and Liquid Line Facility.

Considering the critical requirement of documentation that is compliant to Current Good Manufacturing Practices (CGMP) guidelines and standards of FDA, THPPMP needs a technical consultant for assistance on CGMP requirements compliance for the renewal of License to Operate.

This Terms of Reference (TOR) calls for technical assistance from an individual consultant or firm to provide the needed works for THPPMP.

II. OBJECTIVE

To ensure that the documentation for both Solid Form and Liquid Line Facilities of THPPMP is complete and compliant to Current Good Manufacturing Practices (cGMP) for the renewal of License to Operate by September 2022.

III. METHODOLOGY

In order to meet the required documentation of both Solid and Liquid Line Facilities of the THPPMP in compliance to Current Good Manufacturing Practices (cGMP) for the renewal of License to Operate by September 2022, the Consultant may utilize any combination of strategies in order to attain the objectives of this project.

IV. DELIVERABLES

The Consultant is required to provide services for the following deliverables:

1. Review, prepare and submit proper and complete documentation in accordance to Current Good Manufacturing Practice – PICS;
2. Inspect and evaluate the THPP's facilities, and make recommendations for compliance of the CGMP-PICS for both Solid and Liquid facilities in preparation for audit by September 2022;
3. Conduct mock audit in preparation for audit by September 2022;
4. Represent as technical consultant during FDA inspection for THPPMP application of License to Operate (LTO) and cGMP certification.

V. RESPONSIBILITIES OF THE CONSULTANT

It shall be the responsibility of the Consultant to:

1. Ensure the accomplishment of the Item Nos. II and III;
2. Closely coordinate with PITAHC THPP regarding the progress of this project; and
3. Submit reports required for this project subject to the approval of the THPP Plant Manager.



VI. RESPONSIBILITIES OF PITAHC

PITAHC THPPMP shall be responsible through its plant manager to

1. Provide the Consultant of the following:
 - a. Comprehensive information to the consultant regarding the Scope of Work to be performed for compliance of Current Good Manufacturing Practice –PICS and FDA requirements;
 - b. Necessary assistance relevant to the achievement of the project objectives;
2. Timely payment in accordance with the terms of payment including the disbursement of the consultant fee and other incidental and administrative cost (i.e. accommodation and transportation including airfare tickets) shall follow the schedule of payment in Section VIII of this TOR;
3. Monitor the implementation of the project;
4. Review and evaluate all the reports submitted by the Consultant; and
5. Issue certificate of acceptance and recommendation for payment.

VII. DURATION OF ENGAGEMENT AND CONTRACT IMPLEMENTATION

The project shall be implemented within ninety (90) calendar days, inclusive of the technical assistance during the actual FDA audit schedule. All deliverables shall be submitted on or before the agreed deadline.

VIII. APPROVED BUDGET FOR THE CONTRACT (ABC) AND MODE OF PROCUREMENT

1. The ABC for the entire project is **One Hundred Fifty Thousand Pesos (PhP150,000.00)**, inclusive of all applicable government taxes, professional fees, and other incidental and administrative costs (*accommodation and transportation including airfare tickets*).
2. Of the above project budget, the engagement of the consultancy services shall be undertaken through Negotiated Procurement under Section 53.9 –Small Value Procurement considering that the ABC for this project falls under the threshold amount as provided in Item Letter D (8) (a) (ii) of the Annex “H” of the 2016 Revised Implementing Rules and Regulations of Republic Act 9184.

IX. DELIVERABLES SUBMISSION AND PAYMENT SCHEDULE

1. Below is the payment schedule for the expected output and deliverables of the consultant;

TRANCHE(S)	DELIVERABLE(S)	PAYMENT (in %)
1 st	Submission of proper and complete documentation to THPPMP in accordance to Current Good Manufacturing Practice – PICS after review of the existing documents, as stated in Section V, Number 1 under Responsibilities / Deliverables of the Consultant	40%
2 nd	Submission of recommendations for compliance of the cGMP-PICS for both Solid and Liquid facilities in preparation for audit by September 2022, after inspection and evaluation of facilities, as stated in Section V, Number 2 under Responsibilities / Deliverables of the Consultant	40%
3 rd	Conduct mock audit in preparation for the audit by September 2022, as stated in the Section V, Item Number 3 under Responsibilities / Deliverables of the Consultant	10%
4 th	Provide technical assistance during the conduct of actual FDA Audit	10%

2. THPPMP may allow advance payment to the winning Consultant in the amount, which not exceed fifteen percent (15%) of the total contract amount to cover the cost of mobilization, subject to the posting of irrevocable standby letter of credit to be issued by an entity acceptable to the agency and of an amount equal to the advance payment. The mobilization cost shall be repaid by the Consultant by deducting from the

progress payment.

X. QUALIFICATION OF THE CONSULTANT



The Consultant must possess the following qualifications:

CRITERIA	Rating (in %)
1. An individual with experience in preparation of Proper documentation in accordance to cGMP Guidelines/PICS	40
2. Has similar engagement in pharmaceutical production facility within the past 10 years and equivalent to 30% of the project cost	10
3. Highly knowledgeable in preparation of proper complete documentation in accordance to cGMP PICS Guidelines and Standards	40
4. Has Good technical writing skills in the documentation required	10
TOTAL	100

XI. CRITERIA FOR SELECTION

The PITAHC shall adopt the **Quality Cost Based Evaluation (QCBE)** in assessing the Consultant's competence using the following rating: **technical seventy percent (70%)** and **Financial (30%)**. Consultant must get a score of **eighty percent (80%)** to qualify.

XII. OTHER DOCUMENTARY REQUIREMENTS

Aside from the documentary requirements provided in Appendix A of Annex H of the 2016 Revised Implementing Rules and Regulations, the following documents shall be required in order to establish the qualifications of the Consultant:

1. List of previous contracts similar to this project;
2. Copies of certificate of Training relevant to this project; and
3. Submit accomplished report or written materials made by the consultant relative to this project.



PRICE PROPOSAL FORM

Date: _____

The Bids and Awards Committee
PITAHC Building, Matapang Street, East Avenue Medical Center Compound
Barangay Central Quezon City

Sir/Madam:

After having carefully read and accepted the Terms and Conditions, I/we submit our proposal for the item as follows:

Item No	Item Description	Qty.	Unit Price (in PhP)	Total Price (VAT inclusive) (in PhP)	Compliance to Technical Specifications	
					Yes	No
	CONSULTANCY SERVICES FOR ASSISTANCE ON cGMP REQUIREMENTS IN COMPLIANCE FOR THE RENEWAL OF LICENSE TO OPERATE (LTO) BY SEPTEMBER 2022 <i>(As per attached Terms of Reference)</i>	1	_____	_____		

Amount in Words: _____

The above-quoted price is inclusive of **all costs** and applicable taxes.

Very truly yours,

Signature : _____

Printed Name : _____

Date : _____

Company Name : _____

Contact Number : _____

PHILGEPS Registration Number: _____