Polfa Warszawa S.A.

Warsaw, 28 June 2022

REQUEST FOR QUOTATION No. 5
being conducted as a market assessment study –
extension of the deadline for submitting quotations

In connection with the project titled: "*Development of a universal fast-response platform, based on RNA technology, ensuring the national drug and epidemiological safety*", funded from the state budget by the Medical Research Agency, Polfa Warszawa S.A., you are kindly requested to submit a bid for specialist consulting services relating to the evaluation, coordination of modifications and approval of completeness of developed and received design specifications, including design quality specifications, i.e. URS, VMP, CS, HAZOP, etc., at the baseline design stage.

I. NAME AND ADDRESS OF THE CUSTOMER

Warszawskie Zakłady Farmaceutyczne Polfa S.A.
ul. Karolkowa 22/24
01-207 Warszawa

II. CONTRACT AWARD PROCEDURE

1. This contract is not subject to the Public Procurement Law of 11 September 2019 (consolidated text: Dz. U. [Journal of Laws] of 2019, item 2019).
2. The procedure is being conducted as an intentional and cost-efficient market assessment study while respecting the following rules:
1) to achieve the best possible outcomes using the allocated resources;
2) to choose the best possible means and methods to meet the pre-defined objectives;
3) to ensure transparency, fair competition and equal treatment of contractors.

III. DESCRIPTION OF THE REQUEST FOR QUOTATION

III.1. This Request For Quotation (RFQ) refers to *the provision of specialist consulting services relating to the evaluation, coordination of modifications and approval of completeness of developed and received design specifications, including design quality specifications, i.e. URS, VMP, CS, HAZOP, etc., at the baseline design stage*.

III.2. Description of the project:

Design and release for use of a new research and manufacturing site to be located at ul. Osmańska in Warsaw, which will be comprised of the following areas:

- non-GMP areas: R&D (technological and physical/chemical) laboratories, non-GMP storage space, technical areas plus rest and refreshment facilities;
- GMP areas (physical/chemical laboratory (KJ), microbiological laboratory (KJB), GMP storage space plus a receiving bay and sample collection area, sample retention area, records archive, stability testing site, manufacturing site plus weighing, packing and sterilization rooms).

Given the need to design and release for use of the above areas, the scope of works will include as follows:

- relocate the existing R&D Laboratory of the sponsor (Fluid Technology Laboratory and Analysis Laboratory);
- relocate the PW Microbiological Laboratory;
- prepare and release for use of the GMP Analysis Laboratory;
- design and release for use of the GMP manufacturing site, including the preparation of detailed design specifications for the individual operations in the course of manufacturing of clinical trial batches and small commercial batches, taking into account product characteristics as well as all process-related activities (Pilot Plant, dosage forms: sterile solutions for injections in vials, sterile solutions for injections in pre-filled syringes (PFS) made from cyclo-olefin polymer (COP), PFS, cartridge – PFS).

The objective of the project is to obtain a manufacturing authorization and a GMP certificate for medicinal products and manufacturing of small commercial batches.

The necessary supply utilities available in the area: electric power, sewer water, water for injections (WFI), purified water (PW), clean steam (steam generating unit on site), clean/process gases e.g. nitrogen, compressed air, hot water, hot water – HVAC, cooling water – HVAC, condensate, gas.

The project covers the following systems: HVAC, (AHU, chillers, LAF, ventilation ducts), CIP and SIP systems, vacuum system, toxic waste removal system, waste water discharge system, central dust extraction system, RMS, BMS, PMS, AC, CCTV, UPS, PLC, supporting corporate computer systems, i.e. TW, ORACLE, CMMS, etc.

The process and auxiliary equipment included in the project, without limitation: weighing rooms, solution preparation system, filtration system, vial/PFS filling line, parts washing system, weighing balances, autoclave, VHP area, isolator + isolated transport system, safety shower (MS), serialization machine.

Toxic substances classified as OEB2 – OEB5 will be handled in laboratories and manufacturing areas. It may be required that APIs/finished products be kept under reduced temperature (for detailed specifications, see AR/ER/001/2022).

The manufacturing site should comply with EU-GMP, US-FDA, CA and EAU requirements, including in particular the requirements of Annex 1: Manufacture of Sterile Medicinal Products.

Non-GMP areas

- R&D (Physical/Chemical) Analysis Laboratory
- Fluid Technology Laboratory
- Non-GMP storage space
- Technical areas

GMP areas

- Manufacture of sterile dosage forms such as solutions for injections (in vials/PFS/cartridges).
- In-process tests (IPC Lab).
- Quality control tests (physical/chemical analysis) of starting and packaging materials and finished products as specified.
- Microbiological tests (testing of finished products, environmental parameters, staff, utilities, starting and packaging materials).

- Packing and serialization processes.

III.3. Scope of the RFQ:

- Punctual (as per agreed schedule) assessment of submitted design specifications, including in particular the critical aspects in terms of GMP (CDEs, CAs), which might be relevant to the critical quality attributes of the finished product (CQA) or critical process parameters (CPP), e.g. general layout, HVAC layouts, P&ID HVAC, classification layouts, materials/staff/product/waste flow layouts, process flow, process description, equipment layout, utilities layouts, detailed design criteria – HVAC, etc.;

- Providing assessments and active participation in the development of qualification and quality documents, i.e. GMP Review, DQ, Containment Strategy, SIA, Validation Master Plan, Risk Analysis, etc.;

- Participation in regular project meetings on site / TC (as necessary and as agreed) organized as part of meetings with designer, general contractor, subcontractors and members of the Design Team or PQC;

- Punctual (as per agreed schedule) assessment of the following items prepared under URS: building (main URS), critical auxiliary systems (e.g. HVAC, water systems), process and auxiliary equipment (e.g. equipment sterilizer, VHP area, product distribution line, process tanks, isolator for sample collection/weighing processes, lyophilizer, automatic dishwasher for the process equipment), computerized systems (e.g. RMS, BMS) – listing as per the project scope;

- Punctual (as per agreed schedule) assessment of completeness and quality of the design specifications submitted to the Customer at the end of a project stage prior to the official submission for approval;

- Development / assessment of risk analysis, qualification/validation plans, including project qualification in terms of compliance with EU, FDA, CA, EAU requirements;

- Ongoing communication with and reporting on the progress and results of works to Project Quality Coordinator.

III.4. Requirements

a) Experience in similar green-field projects in the pharmaceutical / biotechnological industry or similar high capex projects;
b) English speaking and writing skills;
c) Knowledge of general EU-GMP, FDA, CA, EAU requirements and those relating to Good Manufacturing Practices as specified in the respective Regulation of Minister of Health, knowledge of the qualification and validation procedures as per Annex 11 and Annex 15 of EU-GMP, CFR requirements and the guidelines applicable in the USA, CA, knowledge of other relevant guidelines, i.e. ISPE (PDA or WHO) GAMP, ISO, ASTM;
d) Knowledge of EU GMP Annex 1 Revision: Manufacture of Sterile Medicinal Products (Draft) will be an advantage;
e) Hands-on experience in recording and resolving problems related to designing and qualification of areas, GMP-critical systems (e.g. HVAC, water and clean steam systems, clean gases), computer-based systems and equipment;

f) Knowledge in the area of designing areas and preventing cross-contamination as per GMP and EMA's guidelines;
g) Knowledge of specific security requirements for facilities and management standards for high-toxic waste, up to and including the rating of OEB5;
h) General knowledge of control systems, such as RMS/BMS, PMS, which are used for sterile manufacturing processes;
i) General knowledge of computerized systems and data integrity standards;
j) Knowledge in the area of microbiology, supervision of manufacturing processes and sterile areas;
k) Knowledge of manufacturing issues related to industrial operations involved in the manufacture of sterile products using aseptic processes;
l) Knowledge in the field of manufacturing process which is carried out using the RNA technology will be an asset.

A declaration of compliance with the above requirements should be included in the Comments section in Appendix 2 hereto, under your analysis of your compliance with the "Requirements for contractors" in section V or as a separate appendix to your response to the RFQ.

III.5. Partial bids or variants will not be accepted.

IV. CONTRACT DELIVERY SITE AND DATE

IV.1. The date of delivery for the contract contemplated hereunder: from the date when a contract is signed until 31 October 2022, taking into account an additional period of two weeks for the project qualification (DQ) following formal approval of the design specifications. The qualification process will be considered to have been completed as soon as a report is submitted for approval.
IV.2. The services will be deemed to have been successfully completed when *the design and quality specifications are accepted by the Customer by means of written approval of the documentation, followed by approval of the DQ project qualification report for the BASIC stage*.
IV.3. Place of contract delivery: ul. Barska 31 in Warsaw plus online meetings.

V. REQUIREMENTS FOR CONTRACTORS

V.1. The procedure is open to any Contractors who meet all of the following requirements:

1) Participation in the coordination of two similar green-field projects (design and release for use of GMP manufacturing areas for parenteral dosage forms, including auxiliary laboratories, i.e. Quality Control Laboratory or Biological Laboratory) during the last 4 years, which were successfully completed (implementation and approval following a GMP inspection).

2) Participation in at least 5 projects relating to the validation/qualification of a manufacturing site carrying out aseptic processes.

Assessment procedure:

The submitted bids will be evaluated based on:

a) The bidder's declaration and list of completed services as per Appendix 2 – dates of completion of services and names of customers.

b) CVs of persons who will be involved in the project.

c) Additional declaration provided in the Comments section in Appendix 2 or as a separate appendix containing a declaration describing the bidder's compliance with the requirements of section III.4 (you are welcome to include a summary of specific projects you have carried

out, including their brief description, to demonstrate that you do have the required specific experience and knowledge).

V.2. Bids submitted by Contractors who demonstrate that they meet the specified requirements will be taken forward to the bid examination and assessment stage. The compliance with the above requirements will be assessed based on a 'meet – does not meet' basis. Bids submitted by Contractors who fail to meet any of the above requirements will be rejected.

VI. CONTRACT AWARD CRITERIA

VI.1. The following criteria will be used by the Customer for the assessment of bids:
– total net price – 100%

VI.2. The score (P_C) for the Total Net Price will be calculated as follows:

$$P_C = \frac{C_N}{C_B} * 100\ points$$

where:

- P_C - score for the Total Net Price
- C_N - the lowest total net price based on non-rejected bids
- C_B - total net price of the bid under assessment
-

Bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland on the end date of the bid submission period.

VI.3. The maximum score that can be awarded to Bidder is 100 points. Results will be calculated to two decimal places.

VII. PLACE AND DEADLINE FOR SUBMISSION OF BIDS

VII.1. The final deadline for submitting bids is 05 July 2022 by 11:59 p.m.
– bids can be sent in electronic format (a photocopy of signed document) to the following email address: bogdan.oleksiak@polpharma.com.

VII.2. A bid will be considered to have been properly submitted if a complete bid is delivered to the above email address within the time limit stipulated in this section.

VII.3. No bids submitted past the submission deadline will be considered.

VIII. PREPARATION OF BIDS

VIII.1. The Bidder should draw up one bid using the bid form attached as Appendix 1 hereto.

VIII.2. Bids may be modified or withdrawn prior to the end of the time limit for the submission of bids.

VIII.3. Bidders are required to carefully read the information contained in the RFQ.

VIII.4. The costs of preparing and delivering bids will be borne by the respective Bidder.

VIII.5. For any matters related to this RFQ, please contact the Customer through Bogdan Oleksiak, e-mail: bogdan.oleksiak@polpharma.com.

IX. AMENDMENTS TO THE CONTRACT

IX.1. The Customer reserves the right to make material amendments to the contract, as compared to the bid based on which Contractor was awarded the contract, to the following extent and in the following situations:

IX.1.1. To reflect changes in law that affect the delivery of the services covered by the Contract (in particular changes in VAT rates);

IX.1.2. To improve technical parameters of the services covered by the contract in line with new solutions brought about by technological advancements, without any effects on the gross flat rate;

IX.1.3. To extend the deadline for the delivery of the services covered by the Contract due to additional works which need to be carried out to ensure proper delivery of the services covered by the Contract and which the Customer, while exercising due diligence, could not have foreseen beforehand, subject to section IX.1.6 below;

IX.1.4. To extend the deadline for the delivery of the services covered by the Contract due to force majeure event(s), with any consequences of such an extension;

IX.1.5. To change the parameters of the services covered by the Contract without altering the nature of the Contract – technology-related changes, in particular: the need to deliver the services covered by the Contract using other solutions – in terms of technology or materials – than those specified in the Request for Quotation in the event that the use of the original solutions could lead to non-delivery or improper delivery of the services covered by the Contract, subject to section IX.1.7. below;

IX.1.6. To make changes with respect to additional deliveries or services to be provided by Contractor, which are not covered by the Contract, as long as they are necessary and when all of the following requirements are met:

– Contractor cannot be replaced due to economic or technical reasons, in particular relating to the interchangeability or interoperability of equipment, services or systems contracted under the original Contract,

– Contractor replacement could cause significant inconvenience or a material increase in costs for the Customer,

– each subsequent change does not exceed 50% of the original Contract net amount;

IX.1.7. To make changes without altering the nature of the Contract, when all of the following requirements are met:

– the Contract needs to be changed due to circumstances which could not have been foreseen by the Customer while exercising due diligence,

– the change does not exceed 50% of the original Contract net amount;

IX.1.8. To replace Contractor with a new contractor:

– as a result of merger, division, transformation, bankruptcy, restructuring or purchase of Contractor or its enterprise as long as the new contractor meets the conditions for participation in the procedure, there are no grounds for its exclusion and the change does not result in other material amendments to the Contract,
– as a result of the Customer taking over Contractor's obligations towards its subcontractors;

IX.1.9. To amend the Contract without altering the nature of the Contract, when the total value of the amendments is less than EUR 215,000 and at the same time it is less than 10% of the original Contract net amount.

IX.2. The Customer can also make non-material amendments to the Contract, as compared to the bid based on which Contractor was awarded the Contract.

IX.3. Any amendments to the Contract will be made in the form of an annex signed by both parties and will require approval from the Customer.

IX. ADDITIONAL INFORMATION

IX.1. Any costs and expenses incurred in connection with the preparation and submission of bids are to be paid by the respective Bidders.

IX.2. Until the end of the time limit for the submission of bids, the Customer reserves the right to amend or add new information to this RFQ.

IX.3. The submitted bids will remain valid and binding for 30 days from the final date of the time limit for submitting bids.

X. LIST OF APPENDICES

The following appendices are attached to this RFQ:

Appendix number	Appendix
Appendix 1	Bid form
Appendix 2	Declaration of compliance with the eligibility criteria for the participation in the procedure

Appendix 1 to the Request for Quotation No. 5

BID FORM

Bidder:

Name / Company	
Registered office/place of residence/address of the principal place of business	
E-mail address for the Customer to send correspondence related to the RFQ	
NIP [Taxpayer ID Number]	
REGON [Business ID Number]	
Phone number	
Contact person for the Customer	

We offer to deliver the contract for ***the provision of specialist consulting services relating to the development, evaluation and implementation of an integrated quality system in a new area for the manufacture of investigational medicinal products*** as per requirements of the Request for Quotation for **the total price of:**

net amount: PLN/EUR* ……

applicable VAT at ……%: PLN/EUR* ……

gross amount: PLN/EUR* ……

(say: ……...……..)

We also declare as follows:

a. We have read the Request for Quotation and appendices thereto, we raise no objections and we have obtained the information necessary to prepare our bid.

b. Our bid price includes a lump sum remuneration that covers all the obligations of the future Contractor as necessary to deliver the contract referred to hereunder.

c. Our bid will remain valid and binding for 30 days from the final date of the time limit for submitting bids.

d. We are/We are not a related party within the meaning of Commission Regulation (EC) No. 1126/2008.

……	……
(place and date)	(signature(s) of person(s) authorized to submit statements of will on behalf of the Bidder)

Appendix 2 to the Request for Quotation No. 5

Customer:
Warszawskie Zakłady Farmaceutyczne
Polfa S.A.

ul. Karolkowa 22/24

01-207 Warszawa

Contractor's Declaration

OF COMPLIANCE WITH THE ELIGIBILITY CRITERIA FOR THE PARTICIPATION IN THE PROCEDURE

By submitting a bid for **the provision of specialist consulting services relating to the development, evaluation and implementation of an integrated quality system in a new area for the manufacture of investigational medicinal products**, I declare as follows:

INFORMATION ON THE CONTRACTOR:

I declare that we meet the conditions for participation in the procedure as specified by the Customer in section V of this Request for Quotation:

- participation in the coordination of two similar green-field projects during the last 4 years, which were successfully completed (implementation and approval following a GMP inspection);
- participation in at least 5 projects relating to the validation/qualification of a manufacturing site carrying out aseptic processes.

SUMMARY OF PROJECTS

No.	**Scope of green-field project**	**Implementation period** **(from – to)** (day – month – year)	**Customer** (name, address)	**GMP inspection result**
1.				
2.				

3.				
4.				

No.	**Scope of the project relating to the validation/qualification of a manufacturing site carrying out aseptic processes**	**Implementation period (from – to)** (day – month – year)	**Customer** (name, address)
1.			
2.			
3.			
4.			

COMMENTS

....., date: .....

.....

(signature of Contractor's representative/agent)