Warsaw, 27.04.2026

PRICE INQUIRY No. NUSI 139/PR144016/2026
conducted in the market research mode

In connection with the implementation of the project entitled "Development of a universal fast-response platform, based on RNA technology, ensuring the national drug and epidemiological safety" financed from the state budget by the Medical Research Agency, Zakłady Farmaceutyczne Polpharma S.A. asks for the submission of offers for **the provision of services in the field of assessing the documentation of the R&D Department, described in detail in point III.**

I. NAME AND ADDRESS OF THE CONTRACTING AUTHORITY

Pharmaceutical Plants Polpharma S.A.
ul. Pelplińska 19
83-200 Starogard Gdański

II. PROCEDURE OF AWARDING THE CONTRACT

II.1. This order is not subject to the provisions of the Act of 11 September 2019. Procurement Law public (t.j. Dz.U. z 2019 r. poz. 2019)

II.2. Conduct conducted in the market research mode, in a deliberate and economical manner while maintaining principles:
1) obtaining the best results from given expenditures;
2) optimal selection of methods and means to achieve the assumed goals;
3) transparency, fair competition and equal treatment of contractors.

III. DESCRIPTION OF THE SUBJECT OF THE INQUIRY

III.1. The subject of the price inquiry is: a service related to the evaluation of documentation created in the Research Department and Development (R&D) in the context of verifying compliance with the requirements of the FDA (*Food and Drug Administration*) and ICH (*The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use*) guidelines, i.e. Quality Guidelines with particular emphasis on Q1, Q2, Q6, Q8 to Q11 and Q14, and preparing a report for each evaluated document. The documentation for evaluation, in the planned amount of fifty (50), includes both the analytical and technological parts:

- Technology Transfer Protocol to the external manufacturing site;
- Technology Development Report to the external manufacturing site;
- Technology Transfer Report to the external manufacturing site;
- Technology Transfer Protocol to the production plant in Polpharma;
- Technology Development Report to the production plant at Polpharma;
- Technology Transfer Report to the production plant in Polpharma;
- Risk Analysis (2 pcs.);
- Feasibility Study Report;
- Report - Product Information Sheet;
- Report - Preformulation plan;
- Report - Preformulation report;
- Report – Pharmaceutical Form Development Plan;
- Report - Pharmaceutical Form Development Report;
- Proposed Manufacturing Recipe;
- Nitrosamine Risk analysis (2 pcs.);
- Elemental Impurities Risk Assessment;
- Analytical Methods Development Reports (5 pcs.);
- Analytical Method Validation Protocols (11 pcs.);
- Analytical Method Validation Rreports (11 pcs.);
- Stability Study Plans (3 pcs.);

- Sameness Study Protocol;
- Sameness Study Report.

III.2. CPV CODE: 73100000-9 Research and experimental development services

III.3. The scope of the price enquiry includes:

I. PREPARATION OF REPORTS	
Lp.	**Scope**
1.	Preparation and submission of the assessment for each document submitted for review in the form of a detailed REPORT including: • analysis of the submitted document in terms of compliance with FDA requirements and ICH with particular emphasis on Q1, Q2, Q6, Q8 to Q11 and Q14, • identification and indication of deficiencies in the submitted documentation that may hinder a successful FDA inspection or PAI inspection, along with references to the specific sections in FDA and ICH guidelines and requirements (and others, if required) that define the identified deficiencies, • identification and indication of errors in the submitted documentation that may hinder a successful FDA inspection or PAI inspection, along with references to specific sections in FDA and ICH guidelines and requirements (and other, if required) that define the indicated errors, • preparation and submission of a detailed list of required and recommended changes/corrections/additions to the evaluated documents.
1A.	Evaluation of the document after correction: The Bidder shall re-evaluate the document corrected and submitted by the Contracting Authority and shall submit a report on the re-evaluation
1B.	Written consultation: The Bidder shall provide a written response, with references to FDA, ICH and other applicable regulations and requirements, if required, to the questions regarding the report submitted by the Contracting Authority
1C.	Online consultation: The Bidder shall organize a consultation with the expert responsible for preparing the document evaluation report, in the form of an online meeting, to discuss the comments submitted
II. PREPARING A LIST OF DEFICIENCIES	
Lp.	**Scope**
2.	Analysis and identification of missing documents required to successfully pass an FDA inspection and PAI inspection, including: preparation and submission of a detailed list of missing documents and data, along with specifying the required content and indicating references to FDA and ICH guidelines and requirements (and others, if required)
2A.	Document Assessment: The Bidder shall perform an assessment of the document prepared by the Contracting Authority as part of the completion of the indicated, missing documents

III.4. The Contracting Authority does not allow the submission of partial or variant bids.

IV. PLACE AND DATE OF EXECUTION OF THE PRICE INQUIRY

IV.1 Planned date of signing the contract / order: **May/June 2026.**

IV.2 Planned period of execution of the subject of the price inquiry:

- Date of commencement of the contract: after signing the contract;
- the entire order should be completed within a maximum period of 12 months from the signing of the Contracts;
- The Contracting Authority may submit documents for opinion throughout the term of the contract;

- The Bidder is obliged to submit reports on the opinions on documents sent by the Ordering Party within a period not longer than 10 working days (Mon – Fri) from the date of submission of each document, also in the event that the documents are submitted within the final term of the contract;
- Dates of consultation with the expert evaluator in the form of an online meeting: no longer than 7 working days (Mon - Fri) from the submission of the inquiry.

IV.3 Communication between entities and arrangements will take place via e-mail.

IV.4 Documents for evaluation and opinion reports will be sent by e-mail or will be placed in a network location indicated by the Contracting Authority.

IV.5 The Contracting Authority allows partial payments for the performance of individual parts of the service.

V. REQUIREMENTS FROM CONTRACTORS

V.1. Contractors who meet the following conditions may apply for the contract:

V.1.1. The Bidder is not personal or capital-related with the Contracting Authority. A capital or personal relationship shall be understood as mutual links between the Contracting Authority and the Bidder or persons authorised to incur obligations on behalf of the Contracting Authority or persons performing on behalf of the Contracting Authority activities related to the preparation and conduct of the procedure for selecting the Bidder (Contractor).

In order to meet this condition, the Bidder is obliged to send together with the offer **a DECLARATION OF LACK OF CONNECTION BETWEEN THE BIDDER - ATTACHMENT NO. 2** to this Request for Proposal.

V.1.2. The Bidder has personnel possessing appropriate competencies and experience, in particular:

V.1.2.1. experience in similar tasks in the pharmaceutical industry, consisting of the preparation and review of documentation development at the research and development stage, in accordance with the requirements of FDA (*Food and Drug Administration*) and ICH (*The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use*),

V.1.2.2. practical knowledge of the currently applicable FDA regulations and currently applicable ICH guidelines,

V.1.2.3. practical knowledge in the preparation and assessment of pharmaceutical development documentation for medicinal products, in accordance with the Quality by Design (QbD) approach,

V.1.2.4. knowledge and experience in the field of synthetic oligonucleotides,

V.1.2.5. proficiency in the Polish or English language (spoken and written to a communicative degree).

In order to meet this condition, the Bidder shall submit a signed **STATEMENT OF COMPETENCE – ATTACHMENT NO. 3** to this Request for Proposal together with the offer.

V.1.3. The Bidder shall demonstrate that in the period of the last three (3) years prior to the expiry of the deadline for submission of bids, and if the period of operation is shorter – in this period, it has duly performed at least two (2) contracts involving the performance of tasks analogous to the subject of the contract. To confirm the fulfilment of the condition, the Bidder shall submit a list of completed contracts, in accordance with **ATTACHMENT NO. 3** together with references confirming that they have been duly performed.

V.1.4. The Bidder shall demonstrate that it has a team of persons assigned to the performance of the subject of the Agreement, possessing the qualifications and experience necessary for the proper performance of the contract. To confirm the fulfilment of the condition, the Bidder shall attach to the offer information on the proposed composition of the team indicated for the implementation of the subject of the Agreement, together with the CVs of the persons forming this team, confirming their competence and experience, in accordance with the information provided in **ATTACHMENT NO. 4**. Together, the proposed team must meet the requirements: at least two (2) individuals with a minimum of fifteen (15) years of experience in the pharmaceutical industry, including experience in the preparation and/or evaluation of research and development documentation, in accordance with FDA requirements and ICH guidelines. At

least one (1) of the indicated persons must have documented, practical experience including participation in the preparation or conduct of Pre-Approval Inspection (PAI), evaluation of CMC documentation, and identification of deficiencies and non-conformities in documentation in the context of FDA requirements and ICH guidelines (experience in question may be gained in particular as part of work at FDA or during audits, regulatory advisory services or preparation of entities for PAI inspections).

V.1.5. The Contracting Authority stipulates that the implementation of the subject of the contract may not be based on indirect consultations or orders to external entities / experts.

In order to meet this condition, the Bidder shall confirm that the proposed list of persons is made up of persons directly cooperating with the Bidder – **ATTACHMENT NO. 4** to this Request for Proposal.

V.2. Method of assessment of requirements for Bidders:

V.2.1. The evaluation of the bids in terms of meeting the requirements will be made according to the formula: "meets – does not meet". A bidder who fails to meet any of the conditions specified in point V.1. will be dismissed from the present proceedings

V.2.2. Verification of compliance with the requirements for Bidders will take place on the basis of:

V.2.2.1. verification of the data, values and rates provided in ***the Offer Form*** and the validity of signatures submitted by persons representing the Bidder,

V.2.2.2. verification of the ***Bidder's Declaration of Lack of Connections*** - the correctness of filling in and validity of signatures submitted by persons representing the Bidder,

V.2.2.3. verification ***of the Statement of Competence*** together with the submitted copies of references,

V.2.2.4. verification of the ***List of Persons Forming the Team*** for the implementation of the subject of the Request for Proposal together with the attached CVs of these persons.

VI. PLACE AND DATE OF SUBMISSION OF BIDS

VI.1. Bids must be submitted by **12.05.2026** in the form of electronically signed documents or scans of documents to the address: **proces.ofertowy@polpharma.com** with the RFP number in the title: **NUSI 139/PR144016/2026**

VI.2. The offer should be signed by persons authorized to represent the Bidder on the basis of entries in the relevant registers or on the basis of a power of attorney. The power of attorney should be attached to the offer.

VI.3. The submission of an offer will be considered effective if the complete offer is received by the e-mail box with the address specified above within the time specified in point VI.1.

VI.4. Bids submitted after the deadline will not be considered.

VI.5. The Contracting Authority does not envisage a public opening of bids.

VI.6. The tenderer may amend or withdraw its tender before the deadline for submission of tenders.

VII. DESCRIPTION OF HOW PRICES ARE CALCULATED

VII.1. Method of calculating the value of the offer: the net and gross value should be calculated and place in **the offer in the Offer Form** constituting **ATTACHMENT NO. 1**.

VII.2. Bids submitted in a currency other than PLN will be converted into PLN at the average exchange rate of the National Bank of Poland (https://www.nbp.pl/) from the end of the deadline for submission of tenders.

VII.3. The price should include all costs related to the preparation and execution of the subject of the inquiry.

VII.4. The price submitted in the offer may not be changed during the performance of the contract.

VIII. DESCRIPTION OF THE CRITERIA THAT THE CONTRACTING AUTHORITY WILL FOLLOW WHEN SELECTING THE TENDER

VIII.1. When evaluating the bids, the Contracting Authority will be guided by the following criterion:

TOTAL NET OFFER COST – 100%

The total cost of the tender is understood by the Contracting Authority as the total cost calculated as the sum of the basic net cost and the additional net cost in accordance with the rules and formula given below:

$$C_C = C_P + C_D$$

where:

- C_C - Total net offer cost
- C_P - BASE COST OF THE OFFER according to ATTACHMENT no. 1
- C_D - ADDITIONAL COST OF THE OFFER according to ATTACHMENT no. 1

The Contracting Authority shall understand the total cost of additional services as the net cost of the offer, calculated as the sum of the unit costs presented by the Bidder in ATTACHMENT 1, assuming, for the purposes of this calculation, one (1) unit of each service.

VIII.2. The number of points (P_C) awarded to the audited Offer in the criterion "Total net cost of the offer" will be calculated according to the formula:

$$P_C = \frac{Cc_{min}}{Cc_B} * 100\ pkt$$

where:

- P_C - number of points for the criterion "Total net cost of the offer"
- Cc_{min} - the lowest net cost of the offer among the unrejected offers,
- Cc_B - total net cost of the investigated offer

For the evaluation of the offer, the offers submitted in a currency other than PLN will be converted into PLN at the average exchange rate of the National Bank of Poland as of the closing date of the deadline for submission of bids.

VIII.3. The most advantageous offer will be considered the offer from among the unrejected offers, which will receive the highest number of points in total. A maximum of 100 points can be obtained by the Bidder. The calculations will be made to two decimal places.

IX. DESCRIPTION OF HOW TO PREPARE THE OFFER

IX.1. The bidder should prepare one price offer in accordance with the template form constituting ATTACHMENT No. 1 to the Request for Proposal.

IX.2. The offer should be made in Polish or English.

IX.3. **The offer should be signed by persons authorized to represent the Bidder on the basis of entries in the relevant registers or on the basis of a power of attorney. The power of attorney should be attached to the offer.**

IX.4. The deadline for binding the bid is 90 days from the deadline for submitting bids.

IX.5. The tenderer may amend or withdraw its tender before the deadline for submission of tenders.

IX.6. Bidders are obliged to carefully read the information contained in the Price Enquiry.

IX.7. The costs of preparing and delivering the offer are borne by the Contractor.

IX.8. In matters related to this inquiry, please contact the Contracting Authority, e-mail: proces.ofertowy@polpharma.com with the price inquiry number in the subject of the e-mail: NUSI 139/PR144016/2026

IX.9. The minimum invoice payment deadline is 30 days from the date of invoice issuance.

X. THE MANNER OF COMMUNICATION BETWEEN THE BUYER AND THE SELLERS, PERSONS AUTHORIZED TO CONTACT

X.1. In the procedure, the Contracting Authority and the Contractor shall submit statements, applications, notices and information in Polish or English

X.2. All notices, statements, requests and information provided in electronic form require immediate confirmation of the fact of receipt of such receipt by each of the parties at the request of each party.

X.3. In the absence of confirmation of receipt of correspondence by the Contractor, the Ordering Party assumes that the correspondence sent by the Ordering Party to the e-mail address provided by the Contractor has been delivered to the Contractor in a way that allows them to familiarize themselves with its content.

X.4. Correspondence related to this inquiry should be sent to the e-mail address: proces.ofertowy@polpharma.com

X.5. In correspondence related to this inquiry, the Contractor should use the number of the procedure: **NUSI 139/PR144016/2026**

X.6. The person authorized to communicate with the Contractor is **Mr. Paweł Pięta.**

X.7. No verbal or telephone information, explanations or answers to inquiries addressed to the Ordering Party are provided.

X.8. Any questions regarding this inquiry should be submitted by e-mail to the address indicated above no later than 3 days before the deadline for submitting bids.

X.9. Answers to questions and further details Inquiries resulting from questions from potential Contractors will be sent to the entity that sent the question.

XI. MODE OF EVALUATION OF BIDS AND ANNOUNCEMENT OF RESULTS

XI.1. In the course of the examination and evaluation of bids, the Contracting Authority may request from the Contractor supplements (if this does not affect competitiveness) and explanations regarding the content of the submitted bids. It may also ask for obvious accounting errors and errors to be corrected.

XI.2. The Contracting Authority reserves the right to check the credibility of the documents, statements, lists, data and information presented by the Contractor in the course of the evaluation of the bid.

XI.3. If two or more Contractors obtain the same number of points, the most advantageous offer in terms of environmental and climate impact will be selected. For this purpose, the Contracting Authority has the right to call on the Bidders whose bids have received the highest final number of points to supplement the bid by providing the information indicated by the Buyer regarding the environmental impact of the subject of the bid.

XI.4. **The Contracting Authority reserves the right to negotiate offers** with all Bidders whose bid meets the specification, in particular in the event that the price offered by the Bidders exceeds the budget allocated by the Contracting Authority for the execution of the contract.

XI.5. Until the deadline for submission of bids, the Ordering Party reserves the right to change or supplement the content of this price inquiry.

XI.6. The Contracting Authority reserves the right to terminate the procedure without selecting the Contractor, without giving a reason. Bidders are not entitled to claim reimbursement of costs incurred in connection with the preparation of the bid.

XI.7. If the supplier's income generated in connection with the execution of the project is subject to withholding tax in Poland, then ZF Polpharma S.A. is obliged by law to deduct withholding tax from the supplier's remuneration and pay it to the Polish tax authorities **(the remuneration includes withholding tax).**

XI.8. Transfer to the Ordering Party (within the agreed remuneration) of all exclusive rights and any transferable other rights to intangible assets that arise in connection with the performance of the subject of the contract (hereinafter referred to as "Intellectual Property Rights"). Thus, all Intellectual Property Rights arising in connection with the execution of the order will be the exclusive property of the Ordering Party. Intellectual property rights include both "work", "inventive design" and "know-how", which will be defined in detail in the content of the contract.

XI.9. Withdrawal by the Contracting Authority from concluding the contract in the event of notification of the contractor about the selection of its bid may not be the basis for claims for the costs of participation in the procedure.

XII. CHANGE IN THE CONTENT OF THE AGREEMENT

XII.1. The Contracting Authority reserves the **right to make significant changes to the provisions of the Agreement** for the services offered in relation to the content of the offer on the basis of which the Contractor was selected, to the following extent and situations:

XII.1.1. amendments to the provisions of law, to the extent affecting the performance of the Agreement (in particular changes in VAT rates);

XII.1.2. improvement of the technical parameters of the subject of the Agreement, resulting from the update of solutions due to technological progress, without affecting the gross lump sum price

XII.1.3. extension of the deadline for the performance of the Agreement as a result of the need to perform additional works, the performance of which is necessary for the proper performance of the Agreement, and the performance of which the Contracting Authority, acting with due diligence, could not have foreseen in advance, subject to point 1. XII.1.7 below;

XII.1.4. extension of the deadline for the performance of the Agreement as a result of force majeure along with all the consequences arising in connection with the extension of this deadline

XII.1.5. changes in the parameters of the subject of the Agreement, not leading to a change in the nature of the Agreement - technological changes, in particular: the need to perform the Agreement with the use of technical/technological and material solutions other than those indicated in the Request for Proposal, in a situation where the application of the envisaged solutions would threaten non-performance or defective performance of the Agreement, subject to point 1 of the Agreement. XII.1.7. below;

XII.1.6. the changes concern the performance of additional supplies or services of the Contractor, not covered by the Agreement, insofar as they have become necessary and the following conditions have been met in total:

- the change of the Contractor may not be made for economic or technical reasons, in particular concerning the interchangeability or interoperability of equipment, services or installations ordered under the basic subject matter of the Agreement,
- a change of the Contractor would cause a significant inconvenience or a significant increase in costs for the Contracting Authority,
- the value of each subsequent change does not exceed 50% of the net value of the original subject of the Agreement,;

XII.1.7. the change does not lead to a change in the nature of the Agreement and the following conditions have been met in total:

- the necessity to amend the Agreement is caused by circumstances that the Ordering Party, acting with due diligence, could not have foreseen,
- the value of the change does not exceed 50% of the value of the original net subject of the Agreement;

XII.2. The contractor is to be replaced by a new contractor:

- as a result of a merger, division, transformation, bankruptcy, restructuring or acquisition of the Contractor or its enterprise, provided that the new Contractor meets the conditions for participation in the procedure, there are no grounds for exclusion against it and it does not entail other material changes to the Agreement,
- as a result of the Contracting Authority's assumption of the Contractor's obligations towards its subcontractors.

XII.3. The Contracting Authority also provides for the **possibility of making insignificant changes to the provisions of the concluded Agreement** in relation to the content of the offer on the basis of which the Contractor was selected.

XII.4. Amendments to the Agreement will be introduced in the form of annexes signed by both Parties, and the possibility of their introduction depends on the acceptance by the Ordering Party.

XIII. OTHER INFORMATION

XIII.1. The Contractor bears all costs related to the preparation and submission of the offer.

XIII.2. Until the deadline for submission of bids, the Ordering Party reserves the right to change or supplement the content of this price inquiry.

XIII.3. PROTECTION OF PERSONAL DATA.

With regard to the personal data contained in the offers, the Ordering Party will become the administrator of such data within the meaning of Article 4(7) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ("GDPR"). The Contracting Authority will process this data for the purpose of evaluating the bids, concluding a contract with the selected contractor and for the purposes of performing the concluded contract, i.e. on the basis of Article 6 Period 1 bed. b) RODO.

The Contracting Authority will transfer the personal data contained in the submitted bids, on the basis of the relevant provisions of law, to the authorized authorities and institutions authorized to audit projects co-financed from the funds from the budget of the Medical Research Agency. Information on the scope of data processing by the competent institutions can be found on the website: https://abm.gov.pl/pl/wolnytekst/198,Polityka-dotyczaca-cookies.html

The Contracting Authority will process personal data for the period in which it is obliged under the relevant provisions of law to store all documentation related to the project co-financed from the budget of the Medical Research Agency.

XIV. LIST OF ATTACHMENTS

The following documents are attached to this Price Inquiry:

Designation of the attachment	Attachment Name
ATTACHMENT No. 1	Template of the offer form
ATTACHMENT No. 2	DECLARATION OF LACK OF CONNECTION BETWEEN THE BIDDER
ATTACHMENT No. 3	STATEMENT OF COMPETENCE
ATTACHMENT No. 4	Form template - a list of people forming a team to carry out the subject of the contract

ATTACHMENT NO. 1
to the PRICE INQUIRY No.: NUSI 139/PR144016/2026

MANDATORY ATTACHMENT TO THE OFFER
REGARDING COMPLIANCE WITH THE CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

OFFER FORM

Bidder:

Full name of the Bidder (company name) or name and surname in the case of running a business	
Bidder's registered office (registered office of the company or company, in accordance with the registration documents)	
E-mail address to which the Ordering Party should send correspondence related to the Request for Proposal	
Provider's Tax Identification Number	
REGON Offer	
Phone No. Offer	
Contact person with the Ordering Party	

We offer the execution of the subject of the Request for Proposal **for the service of conducting the evaluation of the documentation of the R&D Department in accordance with the requirements of the FDA and ICH guidelines**, in accordance with the requirements of this Request for Proposal. The value of the service offered is specified in Table No. 1 of this ATTACHMENT.

continued: ATTACHMENT NO. 1
to the PRICE INQUIRY No.: NUSI 139/PR144016/2026

Table No 1: Detailed statement of planned costs in currency[*1)]:

No	Subject of the request for quotation	Quantity	Unit Net Value	Total Net value	Total Gross value
REPORTS					
1.	Preparation and submission of the assessment for each document submitted for review in the form of a detailed REPORT including: • analysis of the submitted document in terms of compliance with FDA requirements and ICH with particular emphasis on Q1, Q2, Q6, Q8 to Q11 and Q14, • identification and indication of deficiencies in the submitted documentation that may hinder a successful FDA inspection or PAI inspection, along with references to the specific sections in FDA and ICH guidelines and requirements (and others, if required) that define the identified deficiencies, • identification and indication of errors in the submitted documentation that may hinder a successful FDA inspection or PAI inspection, along with references to specific sections in FDA and ICH guidelines and requirements (and other, if required) that define the indicated errors, • preparation and submission of a detailed list of required and recommended changes/corrections/additions to the evaluated documents	50			
	POINT 1 VALUE				
1A.	Evaluation of the document after proofreading: The Bidder shall re-evaluate the document corrected and submitted by the Contracting Authority and shall submit a report on the re-evaluation	*as required by the Contracting Authority*	***2)**	N/A	N/A
1B.	Written consultation: The Bidder shall provide a written response, with references to FDA, ICH and other applicable regulations and requirements, if required, to the questions regarding the report submitted by the Contracting Authority	*as required by the Contracting Authority*	***3)**	N/A	N/A
1C.	Online consultation: The Bidder shall organize a consultation with the expert responsible for preparing the document evaluation report, in the form of an online meeting, to discuss the comments submitted	*as required by the Contracting Authority*	***4)**	N/A	N/A
	VALUE = SUM OF POINTS 1A+1B+1C				

continued: ATTACHMENT NO. 1
to the PRICE INQUIRY No.: NUSI 139/PR144016/2026

cont. Table No.1: Detailed statement of planned costs in currency[*1)]:

No	Subject of the request for quotation	Quantity	Unit Net Value	Total Net value	Total Gross value
LIST OF DEFICIENCIES					
2.	Analysis and identification of missing documents required to successfully pass an FDA inspection and PAI inspection, including: preparation and submission of a detailed list of missing documents and data, along with specifying the required content and indicating references to FDA and ICH guidelines and requirements (and others, if required)	1			
	POINT 2 VALUE				
2A.	Document Assessment: The Bidder shall perform an assessment of the document prepared by the Contracting Authority as part of the completion of the indicated, missing documents	*as required by the Contracting Authority*	**[*2)]**	N/A	N/A
	POINT 2A VALUE				
	BASE COST OF THE OFFER = TOTAL POINTS: 1+2				
	ADDITIONAL COST OF THE OFFER = SUM OF POINTS 1A+1B+1C+2A				

[*1)] the valuation currency shall be provided;

[*2)] A unit cost for each document must be provided;

[*3)] A unit cost for each written consultation should be provided;

[*4)] A unit cost for each online consultation must be provided.

continued: ATTACHMENT NO. 1
to the PRICE INQUIRY no.: NUSI 139/PR144016/2026

At the same time, we declare that we meet the conditions for participation in the procedure specified by the Contracting Authority in the PRICE INQUIRY No. NUSI 139/PR144016/2026 and:

a. we have read this Request for Proposal with attachments and do not raise any objections and have obtained the necessary information to prepare this offer,

b. the value includes a lump sum remuneration for all duties as a potential future Contractor, necessary to complete the subject of the Request for Proposal,

c. We consider ourselves bound by this offer for a period of **90 calendar days** from the deadline for submission of offers,

d. I am/am not* a related entity within the meaning of Commission Regulation (EC) No 1126/2008

e. There are no circumstances in relation to us :

- described in Article 7(1) of the Act of 13 April 2022 on special arrangements for counteracting support for aggression against Ukraine and for the protection of national security;
- as described in Article 5k of Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine.

.....
(City and date)

.....
(signature of the person(s) authorized to make a declaration of intent on behalf of the Bidder)

ATTACHMENT NO. 2
to the PRICE INQUIRY no.: NUSI 139/PR144016/2026

MANDATORY ATTACHMENT TO THE OFFER
REGARDING COMPLIANCE WITH THE CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

DECLARATION OF LACK OF CONNECTION BETWEEN THE BIDDER

By submitting an offer **for the service consisting in the assessment of R&D documentation in accordance with FDA requirements and ICH guidelines**, I declare the following:

We, the undersigned, hereby declare on behalf of the:

..... *(name, address of the company's registered office)* .....

that our company/company is not a related entity to the Ordering Party in terms of person or capital and we meet the conditions for participation in the procedure specified by the Ordering Party in **part V.1.1** Request for Proposal No. **NUSI 139/PR144016/2026**.

By capital or personal relationship, we mean mutual links between the Ordering Party and the Bidder or persons authorised to incur liabilities on behalf of the Ordering Party or persons performing on behalf of the Ordering Party activities related to the preparation and conduct of the selection procedure of the Bidder (Contractor), consisting in particular in:

a) participation in the company as a partner in a civil partnership or a partnership,
b) holding **at least 10%** of shares or stocks,
c) performing the function of a member of a supervisory or management body, proxy,,
d) being married, in a relationship of direct consanguinity or affinity, second-degree consanguinity or second-degree affinity in the collateral line, or in a relationship of adoption, guardianship or guardianship.

Signatures and stamps ....

Data: ....

ATTACHMENT NO. 3
to the PRICE INQUIRY no.: NUSI 139/PR144016/2026

MANDATORY ATTACHMENT TO THE OFFER

REGARDING COMPLIANCE WITH THE CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

STATEMENT OF COMPETENCE

By submitting an offer **for the service consisting in the assessment of R&D documentation in accordance with FDA requirements and ICH guidelines**, I declare the following:

I hereby declare that we meet the conditions for participation in the procedure specified by the Contracting Authority in **Part V.1 of** the Request for Proposal No**. NUSI 139/PR144016/2026**.
A list of completed tasks, confirming our competence and experience, specified in point V.1.2 ÷ V.1.5, contains **Table No. 1**.

LIST OF COMPLETED PROJECTS/TASKS
CONFIRMING COMPETENCIES AND EXPERIENCE

Table No. 1

No.	**Name of the completed task / project**	**Task/project implementation period (from – to)** (MONTH/YEAR)	**Entity for which the task/project was performed** (name, address)	**References Attached** (YES / NO)
1.				
2.				
3.				

COMMENTS

At this point, the Bidder may enter comments regarding the completed tasks/projects given in Table No. 1 above.

Signatures and stamps ……. …….

Data: ……. …….

ATTACHMENT NO. 4
to the PRICE INQUIRY no.: NUSI 139/PR144016/2026

MANDATORY ATTACHMENT TO THE OFFER
REGARDING COMPLIANCE WITH THE CONDITIONS FOR PARTICIPATION IN THE PROCEDURE

PROPOSED LIST OF PEOPLE FORMING A TEAM TO PERFORM THE SUBJECT OF THE CONTRACT

By submitting an offer **for the service consisting in the assessment of R&D documentation in accordance with FDA requirements and ICH guidelines**, we propose a team of people to perform the subject of the Agreement, in accordance with the terms of participation in the procedure specified by the Ordering Party in **part V.1** Request for Proposal No. **NUSI 139/PR144016/2026**.

No.	Name and surname	Position	Number of years worked in the pharmaceutical industry	Documented experience in PAI, CMC documentation and FDA and ICH requirements* (YES / NO)	CV copy attached* (YES / NO)
1					
2					
3					
4					
5					

* A detailed description of experience in PAI, CMC documentation, as well as FDA and ICH requirements shall be provided in the attached CV.

Signatures and stamps: ……. …….

Date: ……. …….