REQUEST FOR PROPOSAL No. 04/2025

Poznań, 07.04.2025

Pharmaceutical and Chemical Company SYNTEZA Sp. z o.o.

ul. Św. Michała 67/71

61-005 Poznań

NIP 7821013533

KRS 0000124038

In connection with the implementation of the project titled "Development and advancement of a generic drug containing the active pharmaceutical ingredient dapagliflozin in a 10 mg dose, used in the treatment of type 2 diabetes and heart failure" as part of the Competition for the development and advancement of innovative solutions in the field of new pharmaceutical forms of authorized medicinal products, generic drugs and biosimilars; Pharmaceutical-Chemical Company SYNTEZA Sp. z o.o., acting in accordance with the principles of fair competition and equal treatment of contractors, announces a market research procedure for the commissioning of an audit of the production of the active pharmaceutical ingredient (API) - dapagliflozin at a manufacturer in India.

I. Public procurement procedure

The procedure for awarding this public contract is conducted without applying the provisions of the Public Procurement Law of January 29, 2004, in the form of a market research procedure. The contracting authority, in order to meet the requirements arising from the funding agreement, will select the service provider in this procedure in accordance with the General Terms of Project Implementation. Hence, this Request for Proposals has been sent directly to three potential contractors and posted on the contracting authority's website at www.synteza.com.pl. The bidder is not entitled to legal remedies specified under the Public Procurement Law..

II. Subject of the order

The subject of the order is to carry out an audit of the production of the active pharmaceutical substance API - Dapagliflozin propanediol monohydrate meeting the requirements of Good Manufacturing Practice.

1. The audit is to be conducted in accordance with the requirements of:
   - EU GMP part II (ICH Q7) for Actives Pharmaceutical Ingredients;
   - EU GDP for Actives Pharmaceutical Ingredients;
   - EU GMP Part II: Basic requirements for active substances used as starting materials - EU GMP for APIs.
2. The scope of the audit service will include, among others:
   - preparation of audit documentation (audit plan and/or list of audit questions);
   - audit at the manufacturer (manufacturing site) of the active pharmaceutical ingredient in the factory in India - checking documentation, premises, equipment / visit to areas;
   - assessment of the pharmaceutical quality system (e.g. DGM documentation, PQR, internal audits, contract agreements, risk management, changes and corrective actions CAPA, quality control, storage areas, transport and distribution, etc.);
   - preparation of the audit report together with an indication of non-conformities and their qualification;

- assessment of HDN and launch of the CAPA procedure; supervision over the implementation of CAPA.

3. The stationary audit is required (at the API manufacturing site).
4. The remote audit (online) is not permitted.
5. The joint audit is permitted.

III. Common Procurement Vocabulary (CPV):

CPV7921200-3

IV. Order completion date: until 15.09.2025

V. Conditions of participation in the procedure (access criteria):

Bidders meeting the following conditions will be admitted to the procedure:

1) the offer will be written in Polish or English and signed (handwritten or qualified signature) by a person authorized to represent the Bidder externally and to assume obligations in the amount corresponding to the offer price;
2) they have the authorizations to perform specific activities or actions, if the provisions of law impose the obligation to have them;
3) have an appropriate staff of auditors with:
   - knowledge of Good Manufacturing Practice (GMP);
   - skills in practical preparation for conducting audits;
4) have experience in
   - many years of practice as an auditor in a pharmaceutical plant, especially in the area of manufacturing active pharmaceutical ingredient (API);
   - conducting GMP audits of manufacturing active pharmeceutical ingredients substances, also in third countries (e.g. India, China, Taiwan).

5) In order to confirm the fulfillment of the above conditions, the Bidder is obliged to submit:

   a. An offer containing:
      - name, address and contact details of the bidder;
      - date of issue of the offer;
      - data enabling the evaluation of the offer in terms of the criteria;
      - offer validity period.

   b. Declarations of the following content:
      - The bidder declares that he/she is familiar with and accepts the terms and conditions of the order specified in the request for quotation and does not raise any reservations or comments in this respect;

   c. The bidder may submit only one offer covering the entire subject of the contract.
      - The Ordering Party does not allow for the submission of partial offers**;**
      - The Ordering Party does not allow for the submission of variant offers.

VI. Description of the method of preparing the offer:

a. A bidder who wishes to participate in the tender selection procedure must submit:
   - an offer on the form attached as Annex 1 to this request for quotation;
   - declaration constituting Annex No. 2 to this request for quotation;
   - confirmation of experience in conducting audits of API manufacturing sites, in the form of a list of audits carried out in the last two/three years (including those in third countries), containing at least 10 audits of API manufacturing in pharmaceutical plants.

b. the form and the declaration template must be completed in all places and signed by persons authorized to represent the Bidder.
c. offers should be delivered to the Ordering Party within the time specified in point VIII. Offers received after the deadline will be rejected.
d. offer validity minimum until 31.07.2025.
e. ways of submitting offers:
   - In person at the company's headquarters: Secretariat of Pharmaceutical-Chemical Company SYNTEZA Sp. z o.o., ul. Św. Michała 67/71, 61-005 Poznań; the envelope should be marked with the inscription: "04/2025" with the note: "do not open before 16.04.2025;
   - By mail, registered letter, or courier to the company address: Pharmaceutical-Chemical Company SYNTEZA Sp. z o.o., ul. Św. Michała 67/71, 61-005 Poznań; the envelope should be marked with the inscription: "04/2025" with the note: "do not open before 16.04.2025;
   - by e-mail to the e-mail address: cbr@synteza.com.pl.

VII. Clarification of the content of the offer and correction of errors

During the examination and evaluation of the offers, the contracting authority may request explanations from the bidders regarding the content of the submitted offers. It is not permissible for the contracting authority and the bidder to negotiate the submitted offer or make any changes to its content.
The contracting authority may correct in the offer:

- obvious typographical errors;
- obvious calculation errors, taking into account the calculation consequences of the corrections made;
- other errors consisting in the inconsistency of the offer with the specification of essential terms of the order, not causing significant changes in the content of the offer - immediately notifying the bidder whose offer was corrected.

VIII. The deadline for submitting offers is: 15.04.2025, hrs. 23:59 (polish time).

- Offers submitted to the contracting authority after the submission deadline will not be accepted and will be returned to the bidders. A successful submission of an offer means that the contracting authority receives the offer before the submission deadline. Changes to or withdrawal of an offer by the bidder before the submission deadline are permitted.
- The opening of the offers will take place at the Ordering Party's registered office on 16.04.2025. The Ordering Party will prepare the Offer Opening Protocol from the offer opening activities..
- After opening the offers, the Ordering Party will evaluate them. During the evaluation of the offers, the Ordering Party may call on the bidders to provide explanations regarding the offers they have submitted.
- At the end of the offer evaluation procedure, the Ordering Party will decide on the selection of the most advantageous offer.
- The contracting authority reserves the right not to select the most advantageous offer. At any time during the tender procedure for selecting a supplier, the contracting authority has the right to terminate the process without selecting any bidder. Bidders shall have no claims against the contracting authority in this regard.
- The Ordering Party will immediately notify the bidders about the results of the procedure or about closing the procedure without selecting a Bidder.
- The order/technical agreement to conduct the active substance (API) audit will be submitted no later than 07.05.2025.

IX. Criteria for evaluation of offers:

The offers will be assessed by the Ordering Party based on the following criteria:

1. **Price: 100%.**

To evaluate individual offers in terms of the offer price criterion, a method will be used, which consists in comparing the price under consideration with the cheapest among the prices presented by the Bidders whose offers were admitted to the evaluation and meet the conditions specified in the request for proposals. The offer price is assumed to be the net price given in the Bid Form. The average exchange rate of the National Bank of Poland (NBP) on the day of publication of the request for proposals is used to evaluate offers submitted in foreign currencies (USD, EUR). The Ordering Party will award the contract to the Bidder whose offer obtained the lowest price.

X. Contractual Penalties

The Ordering Party reserves that the order concluded with the selected contractor will provide for contractual penalties for delay in submitting the report on the audit of the production of active pharmaceutical substance (API) in the amount of 0.1% of the gross contract value for each day of delay, but not more than 5% of the order value, to which the Bidder agrees by submitting an offer to this request.

XI. Disclaimers

- Pharmaceutical-Chemical Company SYNTEZA Sp. z o.o. reserves the right to withdraw from executing the order if the amount of the lowest submitted offer exceeds the value of the assumptions made in the project;
- Pharmaceutical-Chemical Company SYNTEZA Sp. z o.o. cannot be held liable for any costs or expenses incurred by bidders in connection with the preparation and submission of their offers;
- Pharmaceutical-Chemical Company SYNTEZA Sp. z o.o. reserves the right to make changes to the entire request for proposals or any part of it at any time.

XII. Attachments:

Appendix No. 1 - Offer form

Appendix No. 2 - Bidder's Declarations