

112766-2025 - Wettbewerb

Deutschland – Dienstleistungen im Bereich Forschung und experimentelle Entwicklung – SMALL MOLECULE CONTRACT MANUFACTURING SERVICES

OJ S 35/2025 19/02/2025

Auftrags- oder Konzessionsbekanntmachung – Standardregelung - Änderungsbekanntmachung
Lieferleistungen - Dienstleistungen

1. Beschaffer

1.1. Beschaffer

Offizielle Bezeichnung: Helmholtz-Zentrum für Infektionsforschung GmbH

E-Mail: einkauf@helmholtz-hzi.de

Rechtsform des Erwerbers: Von einer zentralen Regierungsbehörde kontrollierte Einrichtung des öffentlichen Rechts

Tätigkeit des öffentlichen Auftraggebers: Gesundheit

2. Verfahren

2.1. Verfahren

Titel: SMALL MOLECULE CONTRACT MANUFACTURING SERVICES

Beschreibung: The headline objectives of the present manufacturing project are the use of the deliverables in GLP compliant preclinical toxicology and safety pharmacology studies as well as a phase 1 first-in-human clinical trial. The objective of the project is to manufacture two alternative pharmaceutical dosage forms, sterile liquid and semi-solid, to enable dosing as i.v. infusion and topical administration, respectively. This solely relates to current lack of clinical target validation and the requirement to ready the technology for proof-of-mechanism in systemic versus skin administration. We are targeting a virulence factor of S. aureus that may cause pulmonary or dermal infections. HZI wishes to commission the following activities under Master Service Agreement to a suited contractor. A Go/ NoGo milestone is set after scope 1 while the tendering process and resulting contract shall comprise SCOPE1, SCOPE2, and SCOPE3 activities so as to assure these can be offered in the most economical way in terms of price and quality from one legal entity. SCOPE1: process development and non-GMP manufacture of drug substance and injectable drug product to enable preclinical efficacy, pharmacokinetic and exploratory tox/safety studies in preclinical animal models SCOPE2: process scale up to GMP manufacturing of drug substance and drug product to perform regulatory preclinical tox and safety studies (GLP compliant) as well as a GCP-compliant phase 1 first-in-human clinical trial for the sterile liquid dosage form and infusion administration SCOPE3: development of the semisolid dosage form for preclinical and phase 1 clinical administration via the topical route

Kennung des Verfahrens: e699c4a8-d49d-47af-9fc8-8095a6304873

Verfahrensart: Offenes Verfahren

2.1.1. Zweck

Art des Auftrags: Dienstleistungen

Zusätzliche Art des Auftrags: Lieferleistungen

Haupteinstufung (cpv): 73100000 Dienstleistungen im Bereich Forschung und experimentelle Entwicklung

Zusätzliche Einstufung (cpv): 33600000 Arzneimittel

2.1.2. Erfüllungsort

Land, Gliederung (NUTS): Braunschweig, Kreisfreie Stadt (DE911)

Land: Deutschland

Zusätzliche Informationen: The place of performance refers only to the delivery service. The place of manufacture shall be the bidder's place of business.

2.1.4. Allgemeine Informationen

Zusätzliche Informationen: In order to obtain the confidential document

"A_05_AdditionalConfidentialInformation", the signed CDA "A_01_CDA_small molecule manufacturing .doc" must be submitted. This is a prerequisite for submitting a valid offer.

Subcontractors must also sign and submit the CDA. The main contractor is not allowed to pass on the confidential information. Documents that become part of the contract and must be completed, signed and enclosed with the offer: 1. A_01_CDA_small molecule manufacturing 2. A_03_Price Schedule 3. A_04_Catalogue A_cirtiera 4. A_05_(AFTER CDA) _AdditionalConfidentialInformation 5. B_01_Data protection 6. C_00_Declaration on Exclusion Grounds 7. C_01_Self-declaration 8. C_02_Declaration_EU sanctions 9. C_03_Questions by applicants 10. D_01_Submission of Tender 11. D_02_Terms and Conditions 12. Project Schedule (according to B_02_Submission of a Project Schedule) 13. manufacturing quality concept (according to B_03_Submission of a manufacturing quality concept) Documents that become part of the contract and remain with the bidder: 14. B_00_Cover Letter 15.

A_02_Performance description 16. Additional Contractual Conditions Further documents that must be enclosed with the offer: 17. D_00_Master Service Agreement-Template_20231127 (for information only)

Rechtsgrundlage:

Richtlinie 2014/24/EU

vgv -

2.1.5. Bedingungen für die Auftragsvergabe

Bedingungen für die Einreichung:

Höchstzahl der Lose, für die ein Bieter Angebote einreichen kann: 1

Auftragsbedingungen:

Höchstzahl der Lose, für die Aufträge an einen Bieter vergeben werden können: 1

2.1.6. Ausschlussgründe

Rein innerstaatliche Ausschlussgründe: When submitting the tender, the form "Self-declarations on exclusion grounds" relating to sections 123 and 124 GWB" provided by the awarding authority must be submitted, in which it is declared that there are no grounds for exclusion within the meaning of Sections 123, 124 GWB or that successful self-cleaning measures within the meaning of Section 125 GWB have been carried out. In the case of bidding consortia, the form must be submitted by each member of the consortium.

Schwere Verfehlung im Rahmen der beruflichen Tätigkeit: Along with the offer, applicants should submit the completed form "Self-declaration EU sanctions" provided by the Contracting Authority. In the case of an applicant consortium, each member of the consortium should submit the form.

5. Los

5.1. Los: LOT-0001

Titel: Small Molecule Contract Manufacturing Services

Beschreibung: Small Molecule Contract Manufacturing Services

5.1.1. Zweck

Art des Auftrags: Dienstleistungen

Zusätzliche Art des Auftrags: Lieferleistungen

Haupteinstufung (cpv): 73100000 Dienstleistungen im Bereich Forschung und experimentelle Entwicklung

Zusätzliche Einstufung (cpv): 33600000 Arzneimittel

Optionen:

Beschreibung der Optionen: Minimum contract term: 1 year (with the completion of SCOPE 1) ***Optional contract terms: 2 extensions (1,5 years/1,5 years; max. 4 years in total)***End: With the completion of SCOPE 2 and 3 (expected end: 12/2028) If the contract is not cancelled at least three months before its expiry date, it will be automatically renewed for a further year. The contract ends automatically when the maximum term of 4 years is reached without prior cancellation.

5.1.2. Erfüllungsort

Land, Gliederung (NUTS): Braunschweig, Kreisfreie Stadt (DE911)

Land: Deutschland

Zusätzliche Informationen: The place of performance refers only to the delivery service. The place of manufacture shall be the bidder's place of business.

5.1.3. Geschätzte Dauer

Laufzeit: 4 Jahre

5.1.4. Verlängerung

Maximale Verlängerungen: 2

5.1.6. Allgemeine Informationen

Vorbehaltene Teilnahme:

Teilnahme ist nicht vorbehalten.

Auftragsvergabeprojekt nicht aus EU-Mitteln finanziert

Die Beschaffung fällt unter das Übereinkommen über das öffentliche Beschaffungswesen: ja

Diese Auftragsvergabe ist auch für kleine und mittlere Unternehmen (KMU) geeignet: nein

Zusätzliche Informationen: The following A-criteria (minimum requirements) must be met and explicitly confirmed by the bidder with a 'Yes'. Failure to meet at least one of these A Criteria will result in the exclusion of the tender from further consideration: > Compliant with the

principles of Good Manufacturing Practices? (certificate(s) of GMP compliance for drug substance, injectable products and semi-solids have to be handed in) > Regulatory Release of

IMPs in the European Union? (By certificate) > Qualified to manufacture the following IMPs: sterile liquids (injectable dosage form) and semi-solids (topical dosage form)? (please provide

authorizations as applicable) > Existing business liability insurance policy with minimum coverage of EUR 5m per occurrence and policy year? (please answer yes or no) >

Competence and Experience with formulation development in the research phase available

(one references has to be handed in) *** A valid tender cannot be submitted without a CDA.

To obtain the confidential document ' A_05_(AFTER CDA)_AdditionalConfidentialInformation',

the signed CDA must be submitted by 28 February at the latest. It is possible to submit the

CDA later, but this is the bidder's responsibility. If a bidder submits the CDA after 28 February,

the bidder runs the risk that the remaining time may not be sufficient to prepare a complete

and timely bid. The contracting authority is under no obligation to extend the tender deadline

as a result of a late submission. The CDA can be requested up to five days before the tender

deadline. Subcontractors must also sign and submit the CDA. Disclosure of confidential

information by the main contractor is not permitted. *** In order to verify the information provided in the tender (in particular the concepts), the contracting authority reserves the right to invite the two best bidders to a verification tender presentation. The purpose of the tender submission is the verification of the information provided by the tenderer. No negotiations will take place and no changes can be made to the offer. The offer presentation is expected to take place on 3 April 2025. The exact time and any change of the date will be communicated via the Tender Platform by 1 April 2025. The contracting authority reserves the right to correct the evaluation of the concept in case of non-performance or insufficient performance.

5.1.7. Strategische Auftragsvergabe

Ziel der strategischen Auftragsvergabe: Keine strategische Beschaffung

5.1.9. Eignungskriterien

Kriterium:

Art: Eignung zur Berufsausübung

Bezeichnung: Suitability to practice the profession including conditions relating to entry in a professional or commercial register

Beschreibung des Auswahlkriteriums: Applicants should submit the following documents with the offer if possible (from each member in the case of consortia): #a) Informal company presentation stating the name, registered office, contact details, VAT identification number and entry in the commercial register/professional register. #b) Informal self-declaration stating that - there are no grounds for exclusion within the meaning of §§ 123, 124 GWB respectively that successful self-remediation measures within the meaning of § 125 GWB have been carried out; - that they comply with the provisions of Art. 5k of the Regulation (EU) 833/2014 in the version of Art. 1 point 22 of Council Regulation (EU) 2023/1214 of June 23, 2023 as part of the EU sanctions package related to Russia's war of aggression on Ukraine. #c) Applicant consortia should also submit a declaration stating that there has been no breach of antitrust law and that no unlawful agreements restricting competition have been made. Applicants should use the forms provided by the Contracting Authority. The Contracting Authority reserves the right to request additional documents in accordance with § 56 (2) VgV. There is no legal entitlement to this.

Kriterium:

Art: Wirtschaftliche und finanzielle Leistungsfähigkeit

Bezeichnung: Economic and financial standing

Beschreibung des Auswahlkriteriums: If possible, applicants should submit the following documents with their tender (in the case of applicant consortia with at least one member): #a) Confirmation that the applicant maintains professional indemnity/company liability insurance with cover of at least EUR 5 million per claim, 2 times maximum, or will take out such insurance if the contract is awarded. In the event that a candidate wishes to use individual companies as subcontractors, reference is made to the possibility of suitability lending and the requirements specified in Section 47 VgV. If and insofar as the applicant relies on the suitability of the subcontractor, a declaration of commitment from the subcontractor that it will make its resources and capacities available to the applicant in the event of a contract being awarded must be submitted with the tender. Applicants should use the forms provided by the contracting authority. The contracting authority reserves the right to request additional documents in accordance with Section 56 (2) VgV; there is no legal entitlement to this.

Kriterium:

Art: Technische und berufliche Leistungsfähigkeit

Bezeichnung: Technical and professional ability

Beschreibung des Auswahlkriteriums: Applicants should submit the following documents with the offer if possible (in the case of applicant consortia of at least one member): Informal self-declaration in which the applicant states whether and how it intends to cooperate with other companies in the event of a contract. Applicant consortia are considered as a whole when assessing the suitability. In the event that an applicant / a consortium of applicants wishes to use individual companies as subcontractors, reference is made to the possibility of suitability lending and the requirements specified in § 47 VgV. If and insofar as the applicant / consortium of applicants relies on the suitability of the subcontractor, a declaration of commitment by the subcontractor that it will make its resources and capacities available to the applicant / consortium of applicants in the event of a contract must be submitted with the application. Applicants should use the forms provided by the Contracting Authority. The Contracting Authority reserves the right to request additional documents in accordance with § 56 (2) VgV. There is no legal entitlement to this.

Kriterium:

Art: Sonstiges

Bezeichnung: Minimum requirements

Beschreibung des Auswahlkriteriums: In addition, proof of suitability is required by written statement for the following project specific matters: referee for proving his competence and experience with formulation development in the research phase.

5.1.10. Zuschlagskriterien

Kriterium:

Art: Preis

Bezeichnung: Weighting (exact percentage): 30

Beschreibung: Evaluation of price The criterion "price" is evaluated on the basis of the following points. The most favourable offer (lowest price) receives a score of 30. The prices of the other offers receive the score depending on the most favourable offer of the A_03_Price Schedule.xlsx. Formula (price) = $30 * (\text{most favourable offer} / \text{offer under consideration})$

Kategorie des Gewicht-Zuschlagskriteriums: Gewichtung (Prozentanteil, genau)

Zuschlagskriterium — Zahl: 30

Kriterium:

Art: Qualität

Bezeichnung: Weighting (exact percentage): 35

Beschreibung: Submission of a Project Schedule Concept Requirement and Evaluation

Bidders are requested to submit a detailed Project Schedule covering the following aspects: • time planning • work packages/tasks; major deliverables • regulatory support • client communication The concept will be evaluated according to the following criteria: • completeness and depth of detail • quality of the proposed measures • conformity with quality requirements and relevant regulations Formal requirements: minimum 5, maximum 30 pages (excluding table of contents and cover page) Time planning (30 points) 25 - 30 points Very good Conclusive, realistic and flexible planning with sensible milestones and buffer times. 17 - 24 points Satisfactory Basic scheduling with minor ambiguities or insufficient adaptability. 0 - 16 points Poor Unclear, unrealistic planning without buffer times and dependencies. Project structure & tasks (30 points) 25 - 30 points Very good Clear, logical distribution of tasks with sensibly linked deliverables. 17 - 24 points Satisfactory Basic structure in place, but with ambiguities in tasks or dependencies. 0 - 16 points Poor Illogical, incomplete task structure with missing deliverables. Regulatory support (20 points) 16-20 points Very good Support with IMPD writing (DS&DP sections) 8-15 points Satisfactory Support in answering regulatory

questions (e.g. analytical methods) 0-7 points Poor Little to no support Client communication (20 points) 16 - 20 points Very good Clear reporting channels and communication structures with systematic documentation. 8 - 15 points Satisfactory Communication available, but not always clear or consistent. 0 - 7 points Poor Missing or inadequate communication structures and reporting channels. Overall rating (100 points) - Coherent and comprehensive concept that meets high standards. - Solid planning with optimization potential in individual areas. - Incomplete or impracticable concept with unfulfilled requirements. Quality evaluation The criterion "quality" is evaluated based on the following documents: B_02_Submission of a Project Schedule B_03_Submission of a manufacturing quality concept A maximum of 100 points can be achieved for the Project Schedule, representing a maximum of 35% of the quality score. Formula (quality per concept) = $35 * (\text{bidder's concept} / 100)$
 Kategorie des Gewicht-Zuschlagskriteriums: Gewichtung (Prozentanteil, genau)
 Zuschlagskriterium — Zahl: 35

Kriterium:

Art: Qualität

Bezeichnung: Weighting (exact percentage): 35

Beschreibung: Submission of a manufacturing quality concept Bidders are requested to submit a manufacturing quality concept covering the following aspects: • manufacturing track record (previous projects can be used as examples) • manufacturing sites, technical equipment and manufacturing processes • staff qualification and training • quality management measures The concept is evaluated according to the following criteria: • completeness and depth of detail • quality of the proposed measures • conformity with quality requirements and relevant regulations Formal requirements: minimum 4, maximum 10 pages (excluding table of contents and cover page) Evaluation scheme: manufacturing track record (25 points) 20 - 25 points Very good Coherent, detailed and methodical approach; successful production implementation proven through quality assured implementation. (Refer to projects already completed) 12 - 19 points Satisfactory Solid approach, but not consistently convincing; track record in manufacturing partly recognizable, but not specific enough. 0 - 11 points Poor Inadequate approach, vague description, no realistic implementation, no visible track record in manufacturing. manufacturing sites, technical equipment and manufacturing processes (25 points) 20 - 25 points Very good State-of-the-art technology, regularly maintained and innovative systems 12 - 19 points Satisfactory Solid equipment, functional and typical industry standard 0 - 11 points Poor Outdated or limited equipment, occasional failures Staff qualification and training (25 points) 20 - 25 points Very good Highly qualified and specialized staff with many years of experience 12 - 19 points Satisfactory Expert staff with solid training and relevant experience 0 - 11 points Poor Limited specialist knowledge or lack of experience in specific areas Quality management measures (25 points) 20 - 25 points Very good Convincing, consistent, modern quality management concept 12 - 19 points Satisfactory Quality concept available but incomplete 0 - 11 points Poor Not available. Overall rating (100 points) - Coherent and comprehensive concept that meets high standards. - Solid planning with optimization potential in individual areas. - Incomplete or impracticable concept with unfulfilled requirements. A maximum of 100 points can be achieved for the manufacturing quality concept, representing a maximum of 35% of the quality score. Formula (quality per concept) = $35 * (\text{bidder's concept} / 100)$ *** Overall result The overall result is calculated from the composition of all points achieved for the individual award criteria. The contract will be awarded to the highest score bid.

Kategorie des Gewicht-Zuschlagskriteriums: Gewichtung (Prozentanteil, genau)

Zuschlagskriterium — Zahl: 35

5.1.11. Auftragsunterlagen

Zugang zu bestimmten Auftragsunterlagen ist beschränkt

Begründung für die Beschränkung des Zugangs zu bestimmten Auftragsunterlagen: Schutz besonders sensibler Informationen

Sprachen, in denen die Auftragsunterlagen (oder Teile davon) offiziell verfügbar sind: Englisch

Frist für die Anforderung zusätzlicher Informationen: 05/03/2025 10:00:00 (UTC+01:00)

Mitteuropäische Zeit, Westeuropäische Sommerzeit

Informationen über zugangsbeschränkte Dokumente einsehbar unter: <https://www.subreport.de/E63191771>

5.1.12. Bedingungen für die Auftragsvergabe

Bedingungen für die Einreichung:

Elektronische Einreichung: Erforderlich

Adresse für die Einreichung: <https://www.subreport.de/E63191771>

Sprachen, in denen Angebote oder Teilnahmeanträge eingereicht werden können: Englisch, Deutsch

Elektronischer Katalog: Nicht zulässig

Varianten: Nicht zulässig

Die Bieter können mehrere Angebote einreichen: Nicht zulässig

Frist für den Eingang der Angebote: 18/03/2025 10:00:00 (UTC+01:00) Mitteleuropäische Zeit, Westeuropäische Sommerzeit

Dauer, während der das Angebot gültig bleiben muss: 3 Monate

Informationen, die nach Ablauf der Einreichungsfrist ergänzt werden können:

Nach Ermessen des Käufers können alle fehlenden Bieterunterlagen nach Fristablauf nachgereicht werden.

Zusätzliche Informationen: The contracting authority reserves the right to request missing documents. The contracting authority also reserves the right not to request missing documents in accordance with § 56(2) VgV.

Informationen über die öffentliche Angebotsöffnung:

Eröffnungstermin: 18/03/2025 10:00:00 (UTC+01:00) Mitteleuropäische Zeit, Westeuropäische Sommerzeit

Auftragsbedingungen:

Die Auftragsausführung muss im Rahmen von Programmen für geschützte Beschäftigungsverhältnisse erfolgen: Nein

Es ist eine Geheimhaltungsvereinbarung erforderlich: ja

Zusätzliche Angaben zur Geheimhaltungsvereinbarung: In order to obtain the confidential document "A_05_AdditionalConfidentialInformation", the signed CDA "A_01_CDA_small molecule manufacturing .doc" must be signed and submitted by 28 February at the latest. This is a prerequisite for submitting a valid offer. Subcontractors must also sign and submit the CDA. The main contractor is not allowed to pass on the confidential information.

Elektronische Rechnungsstellung: Erforderlich

Aufträge werden elektronisch erteilt: ja

Zahlungen werden elektronisch geleistet: ja

5.1.15. Techniken

Rahmenvereinbarung:

Keine Rahmenvereinbarung

Informationen über das dynamische Beschaffungssystem:

Kein dynamisches Beschaffungssystem

5.1.16. Weitere Informationen, Schlichtung und Nachprüfung

Überprüfungsstelle: Vergabekammer des Bundes

Informationen über die Überprüfungsfristen: 1) A review procedure before the Public Procurement Tribunal is inadmissible pursuant to Section 160 (3) Sentence 1 No. 4 ARC if more than 15 calendar days have elapsed since receipt of the contracting authority's notification that it does not intend to remedy a complaint. 2) In particular, Section 160 (3) Sentence 1 Nos. 1, 2 and 3 of the ARC and Section 134 (2) of the ARC shall be observed. 3) The period for asserting the invalidity of the contract pursuant to Section 135 of the ARC ends no later than 30 calendar days after publication of the notice of award procedures in the Official Journal of the European Union; see Section 135(2), second sentence, of the ARC.

Organisation, die zusätzliche Informationen über das Vergabeverfahren bereitstellt: Helmholtz-Zentrum für Infektionsforschung GmbH

Organisation, die einen Offline-Zugang zu den Vergabeunterlagen bereitstellt: Helmholtz-Zentrum für Infektionsforschung GmbH

Organisation, die Teilnahmeanträge entgegennimmt: Helmholtz-Zentrum für Infektionsforschung GmbH

Organisation, die Angebote bearbeitet: Helmholtz-Zentrum für Infektionsforschung GmbH

TED eSender: Datenservice Öffentlicher Einkauf (in Verantwortung des Beschaffungsamts des BMI)

8. Organisationen

8.1. ORG-0001

Offizielle Bezeichnung: Helmholtz-Zentrum für Infektionsforschung GmbH

Registrierungsnummer: Leitweg-ID 992-80177-07

Postanschrift: Inhoffenstr. 7

Stadt: Braunschweig

Postleitzahl: 38124

Land, Gliederung (NUTS): Braunschweig, Kreisfreie Stadt (DE911)

Land: Deutschland

E-Mail: einkauf@helmholtz-hzi.de

Telefon: 000

Internetadresse: <https://www.helmholtz-hzi.de>

Rollen dieser Organisation:

Beschaffer

Organisation, die zusätzliche Informationen über das Vergabeverfahren bereitstellt

Organisation, die einen Offline-Zugang zu den Vergabeunterlagen bereitstellt

Organisation, die Teilnahmeanträge entgegennimmt

Organisation, die Angebote bearbeitet

8.1. ORG-0002

Offizielle Bezeichnung: Vergabekammer des Bundes

Registrierungsnummer: t:022894990

Postanschrift: Villemombler Straße 76

Stadt: Bonn

Postleitzahl: 53123

Land, Gliederung (NUTS): Bonn, Kreisfreie Stadt (DEA22)

Land: Deutschland

E-Mail: vk@bundeskartellamt.bund.de

Telefon: 022894990

Rollen dieser Organisation:

Überprüfungsstelle

8.1. ORG-0003

Offizielle Bezeichnung: Datenservice Öffentlicher Einkauf (in Verantwortung des Beschaffungsamts des BMI)

Registrierungsnummer: 0204:994-DOEVD-83

Stadt: Bonn

Postleitzahl: 53119

Land, Gliederung (NUTS): Bonn, Kreisfreie Stadt (DEA22)

Land: Deutschland

E-Mail: noreply.esender_hub@bescha.bund.de

Telefon: +49228996100

Rollen dieser Organisation:

TED eSender

10. Änderung

Fassung der zu ändernden vorigen Bekanntmachung

:

1d4f9bdc-c05c-46b2-9f03-4a8306430b9b-01

Informationen zur Bekanntmachung

Kennung/Fassung der Bekanntmachung: 93b61551-90f7-4e54-91b0-4ea8888cb8ad - 01

Formulartyp: Wettbewerb

Art der Bekanntmachung: Auftrags- oder Konzessionsbekanntmachung – Standardregelung

Unterart der Bekanntmachung: 16

Datum der Übermittlung der Bekanntmachung: 17/02/2025 09:00:24 (UTC+01:00)

Mitteuropäische Zeit, Westeuropäische Sommerzeit

Sprachen, in denen diese Bekanntmachung offiziell verfügbar ist: Deutsch

Veröffentlichungsnummer der Bekanntmachung: 112766-2025

ABl. S – Nummer der Ausgabe: 35/2025

Datum der Veröffentlichung: 19/02/2025