# ANNEX 2 – CHECKLIST FOR THE BIDDER (with a list of required attachments)

Instruction: This form must be submitted together with the offer. In addition to marking YES/NO responses, please attach the required annexes. The absence of any annex may result in rejection of the offer at the stage of formal assessment. If a given item is not applicable, please provide a brief justification in the 'Comments' column.

## 0. Basic information of the Bidder

|  |  |
| --- | --- |
| Full company name: |  |
| Registered office address: |  |
| VAT / REGON / KRS: |  |
| Authorized contact person: |  |
| Position of the contact person: |  |
| Phone / e-mail: |  |
| Website (if applicable): |  |

## I. Compliance with legal requirements and guidelines

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder declares that the study will be conducted in compliance with: ICH E6(R3) GCP, Declaration of Helsinki (2013), Directive 2001/83/EC, Directive 2005/28/EC, Regulation (EU) 536/2014 (if applicable), BE Guideline CPMP/EWP/QWP/1401/98 Rev.1/Corr (2010), GLP principles (EMA/INS/GCP/532137/2010), ICH M10 (EMA/CHMP/ICH/172948/2019, 2022). | ☐ YES ☐ NO |  |
| Documentation and the final report will be prepared in accordance with ICH E3 (CPMP/ICH/137/95). | ☐ YES ☐ NO |  |

## II. Study participants and regulatory approvals

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder has the capability to recruit healthy participants of both sexes, in accordance with the protocol criteria. | ☐ YES ☐ NO |  |
| The Bidder has experience in obtaining Ethics Committee opinions and Competent Authority approvals. | ☐ YES ☐ NO |  |

## III. Participant safety

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder has infrastructure and procedures in place to provide immediate treatment to participants (emergency preparedness). | ☐ YES ☐ NO |  |
| The Bidder has AE/SAE reporting procedures compliant with GCP (SAEs reported to the Sponsor within 24h). | ☐ YES ☐ NO |  |

## IV. Certificates, inspections, and audits

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder holds valid GCP/GLP certificates or has a positive inspection history. | ☐ YES ☐ NO |  |
| In the last 4 years, the Bidder has not received critical findings during inspections by European authorities. | ☐ YES ☐ NO |  |
| The Bidder has been audited by sponsors in the last 2 years. | ☐ YES ☐ NO |  |

## V. Experience and personnel

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder has conducted ≥3 bioavailability/bioequivalence studies in the last 3 years, including ≥1 resulting in EU registration. | ☐ YES ☐ NO |  |
| The Bidder employs competent personnel (clinical, bioanalysis, PK/statistics). | ☐ YES ☐ NO |  |
| The Principal Investigator holds valid GCP training (statement; evidence available upon request). | ☐ YES ☐ NO |  |
| The Bidder employs a pharmacokinetics/statistics specialist with relevant experience. | ☐ YES ☐ NO |  |
| The Bidder employs staff competent to prepare integrated clinical study reports (CSR) compliant with ICH E3. | ☐ YES ☐ NO |  |

## VI. Organizational and technical facilities

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder has the infrastructure and technical capability to perform services (clinical, bioanalytical, PK, statistical parts). | ☐ YES ☐ NO |  |

## VII. Bioanalytical methods (ICH M10)

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder has or can validate bioanalytical methods in compliance with ICH M10 before the study initiation. | ☐ YES ☐ NO |  |
| The Bidder has infrastructure, equipment, and experience to conduct analysis of biological samples (determination of analyte concentrations in blood/plasma). | ☐ YES ☐ NO |  |

## VIII. Liability insurance

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder has valid liability insurance covering participants and the entire study period; declares continuity of coverage under the same terms. | ☐ YES ☐ NO |  |
| The insurance policy covers responsibility for payment of compensations (no-fault compensation). | ☐ YES ☐ NO |  |

## IX. Quality system and SOPs

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder has a quality system compliant with GCP and maintains up-to-date SOPs. | ☐ YES ☐ NO |  |
| The Bidder has a quality system compliant with GLP and maintains up-to-date SOPs. | ☐ YES ☐ NO |  |

## X. Audit readiness

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder declares readiness for audit of the site and laboratory by the Sponsor/Contracting Authority. | ☐ YES ☐ NO |  |

## XI. Subcontractors

|  |  |  |
| --- | --- | --- |
| Criterion / Statement | YES/NO | Comments |
| The Bidder may use subcontractors and declares that they comply with the requirements of this RFP and hold GCP/GLP certificates or positive inspection history. | ☐ YES ☐ NO |  |
| The Bidder undertakes to conclude relevant agreements with subcontractors ensuring compliance with GCP/GLP. | ☐ YES ☐ NO |  |
| The Sponsor will be informed of and must approve all subcontractors before the start of the study. | ☐ YES ☐ NO |  |

## A. Required annexes (to be attached to the offer)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| No. | Annex name | Scope/What it must contain | Required | Attached | File name / Comments |
| 1 | GCP/GLP Certificates | Valid certificates; for PI – valid GCP training certificate. | YES | ☐ |  |
| 2 | List of regulatory inspections | Completed table in Section B. | YES | ☐ |  |
| 3 | List of BE/BA studies (last 3 years) | Completed table in Section C. | YES | ☐ |  |
| 4 | List of SOPs | Summary of current SOPs (Section E) – title, code, version, date. | YES | ☐ |  |
| 6 | Subcontractors | List of subcontractors + their GCP/GLP certificates/inspection history (if applicable). | If applicable | ☐ |  |
| 8 | Participant safety | Description of infrastructure and procedures (emergency, AE/SAE, referral hospital). | YES | ☐ |  |
| 9 | Bioanalysis – list of methods | Section D: scope of validation (LLOQ–ULOQ, stability, ISR), laboratory, date. | YES | ☐ |  |

## B. Table of regulatory inspections (last 4 years)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Authority/Agency | Country | Type (GCP/GLP) | Date | Scope (clinical/bioanalytical) | Result/Status | Remarks (Critical/Major/Minor) | Related to BE/BA? |
|  |  |  |  |  |  |  |  |

## C. List of BE/BA studies in the last 3 years

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Product/API | N | Analyte(s) | Bioanalytical lab | CSR date | Submitted in EU? | Registration status | Key remarks |
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## D. Bioanalysis – list of methods and validation status (ICH M10)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method ID | Analyte | Matrix | Range (LLOQ–ULOQ) | Calibration model | ISR – plan/status | Stability | Validation date | Laboratory | Report/Reference |
|  |  |  |  |  |  |  |  |  |  |
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## E. List of current SOPs (Quality System)

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| --- | --- | --- | --- | --- | --- |
| Code/ID | SOP title | Version | Effective date | Area (clinical/bioanalytical/QA) | Status |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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## F. Key personnel

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Role | Name | Experience in BE/BA (years) | GCP – training date | Remarks |
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## G. Final declaration

I declare that all information provided in this form and the attached annexes is true and complete. I undertake to provide source documents confirming the above data at the Sponsor’s request.

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Place, date

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Signature and stamp of the Bidder