89/2025/Z/FAIND2.0

Att. No. 2

General information
The aim of the project is to establish and fully qualify a Master Cell Bank (MCB) and Working Cell Bank (WCB) in accordance with GMP standards, which will serve as a source for the preparation of a Working Cell Bank (WCB) used in the manufacturing process of the active substance (Drug Substance) of a recombinant protein intended for phase I clinical trials.

The scope of the contract includes: qualified transfer of starting material (RCB) to a GMP facility; preparation of a Master Cell Bank (MCB); optional preparation of a Working Cell Bank (WCB) from the MCB produced; performance of control and validation tests required for cell banks in accordance with ICH Q5D; development of complete documentation in accordance with GMP requirements.

Strain and plasmid
The client shall provide the contractor with data on the E. coli strain and plasmids comprising the expression system, together with the RCB (Research Cell Bank) used for development work.

Regulatory requirements
MCB must comply with GMP (Good Manufacturing Practice) standards.

DESCRIPTION OF THE SUBJECT OF THE ORDER

Minimum required specifications	Specifications of the Offered Item (To Be Completed by the Bidder)
Prepared material	
Production capacity: 300 vials of MCB bank	
Production capacity: 300 vials of WCB bank	
Bank portion size in vial; 1 ml	
Optical density OD 600 of the bank in a vial; 1	
Cryoprotection methods: glycerol	
Physicochemical quality criteria (e.g. pH, osmolality) of the medium used for banking	
Breeding Conditions (According to the Client's Documentation)	
Culture medium Temperature and incubation time of bacterial culture Induction of expression	
Requirement to document and approve culture parameters (time, temperature, pH, DO).	
Indication of controlled sterility conditions and parameter monitoring.	
Backup/emergency procedures in the event of deviations from the specified parameters	
Quality control	
Plasmid analysis, sequencing and restriction analysis	
Strain identity testing using molecular methods (sequencing)	

Confirmation that the correct strain of E. coli was used	
Microbiological purity tests, confirmation of the absence of contamination by other microorganisms	
Stabilność plazmidów i ekspresji białka w dłuższym czasie (dodatkowe punkty kontrolne)	
Determination of microbiological viability, determination of the percentage of cells surviving freezing and thawing of the cell bank (CFU/ml count)	
Stability tests, number of plasmid copies, determination of the number of plasmids per host cell PCN. And the range of stability of plasmid maintenance in cells.	
Ekspresja białka rekombinowanego, weryfikacja czy klon po rozmrożeniu nadal efektywnie produkuje białko rekombinowane. Za pomocą SDS-PAGE, Western blot	
Recombinant protein expression, verification that the clone still effectively produces recombinant protein after thawing. Using SDS-PAGE, Western blot	
Virological and bacteriological tests in accordance with GMP	
Traceability statement – documentation of the origin of biological material	
Documentation	
Compliant with GMP requirements	
Detailed production protocol	
Reports from quality control tests	
Certificate of Analysis (CoA)	
Certificate of Compliance (CoC)	
copy of the contractor's GMP certificate	
List of equipment and materials with serial numbers	
Final report on all studies (including stability, viability and expression results)	
Documentation concerning cryoprotection and thawing procedures	
Maintenance of MCB and WCB banks	
For 1 year	
Compliant with GMP requirements	
Certificate of Analysis (CoA)	
Storage under controlled conditions	
Re-certification in the field of regulatory requirements	
Continuous temperature monitoring system with alarms	
Disaster recovery plan in the event of cryostat failure	
Requirement for redundant storage in two locations or in two independent cryogenic tanks.	
Delivery time	
Order fulfilment time: 3 months	

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(signature of the Bidder or a person authorised on behalf of the Bidder)