



100/2026/M/RNA

Att. 2

General Information

The objective of the project is the manufacture and characterization of one Master Cell Bank (MCB) corresponding to a specified plasmid construct introduced into a selected *E. coli* host strain. The MCB will be intended for use in the manufacturing process of plasmid DNA (pDNA). The pDNA will serve as a critical starting material for the manufacture of mRNA therapeutic product.

Scope of the Order

The scope of the order includes:

- qualified transfer of the starting materials (host strain and plasmid DNA) to the Contactor's facility;
- manufacture of one Master Cell Bank (MCB);
- performance of appropriate quality control, characterization, and validation testing applicable to cell banks used for the manufacture of critical starting materials;
- preparation of complete manufacturing and testing documentation including the applicable Certificate of Analysis (CoA) and/or Certificate of Testing.

Strain and Plasmid

The Client will provide the Contractor with all relevant information regarding the *E. coli* host strain and the plasmid to be used for the manufacture of MCB. Where required, the Client will also provide the Research Cell Bank (RCB) used during development activities.

Regulatory Requirements

Manufacture of the MCB may be performed under non-GMP conditions. However, all manufacturing and testing activities shall be conducted within an established Quality Management System (QMS), in accordance with approved and controlled internal procedures.

The Contractor should ensure appropriate traceability of materials, manufacturing activities, testing, and associated documentation throughout the process.

Upon completion of manufacture and testing, the Contractor shall provide the required batch documentation and a Certificate of Testing (CoT) for the MCB.

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Organ rejestrowy: Sąd Rejonowy dla m. st. Warszawy, XIV Wydział Gospodarczy Krajowego Rejestru Sądowego

Prezes Zarządu: Maciej Wieczorek, **Wysokość kapitału zakładowego:** 5.391.150 PLN

KRS: 0000437778, **NIP :** 118 16 42 061

**DESCRIPTION OF THE SUBJECT OF ORDER No.**

Minimum required parameters	Parameters of the offered item (Completed by the Bidder)
Preparation of Material	
The Client will provide the Contractor with all relevant information regarding the <i>E. coli</i> host strain and the plasmid to be used for the manufacture of the MCB. Where required, the Client will also provide the Research Cell Bank (RCB) used during development activities. The Client will provide information regarding the characteristics of the host strain, including its applicable biosafety level. The information shall serve as the basis for defining the culture conditions, handling requirements, and appropriate quality control strategy for the MCB.	
Host strain license fee	
If the use of the host strain or competent cells proposed by the Contractor requires a license, the Contractor shall provide, as a part of its Proposal, the applicable licensing terms and the associated license fees. The license shall, at a minimum, grant the right to use the competent cells for transformation with the plasmid construct specified by the Customer, to establish and store the Master Cell Bank (MCB), and to use the MCB and any cell banks derived therefrom for the manufacture of plasmid DNA (pDNA) intended for use as a starting material in the manufacture of mRNA-based therapeutic products. The Contractor shall provide the following information in its Proposal (as an optional position): • the license fee, quoted as a separate line item; • the licensing model and applicable fee structure, including any one-time fees, recurring fees, milestone payments, or other fees associated with the use of the host strain; • the scope of the rights granted under the license, in particular with respect to clinical and commercial use; • the term of the license and any applicable territorial restrictions	
MCB Production and Filling	
Target production yield: 300-400 vials	
Bank vial volume: 1 mL per vial	
Cell concentration/density at the time of banking shall be defined and documented. The target viable cell concentration (CFU/mL) shall be agreed with the Client before manufacture	
Cryogenic vials: sterile, γ-irradiated, certified non-pyrogenic, nominal capacity 2.0 mL, Corning® or equivalent subject to Client approval	

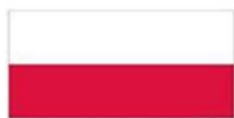
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The filling process shall ensure appropriate homogeneity of the cell suspension and consistency between MCB vials	
The Contractor shall define appropriate in-process controls to demonstrate consistency of filling and bank homogeneity	
Cryopreservation	
The MCB shall be cryopreserved using a defined, documented, and qualified freezing procedure suitable for the <i>E. coli</i> production strain	
Glycerol or another appropriately justified cryoprotectant shall be used	
The concentration of the cryoprotectant shall be defined and justified by the Contractor (e.g. approximately 10-20% glycerol concentration)	
Requirement for cryoprotectant characterization (identity, grade/quality, manufacturer, batch/lot number)	
The composition and preparation of the cryopreservation medium shall be documented	
Controlled-rate freezing, direct freezing at ultra-low temperature, rapid freezing, or another appropriately qualified procedure may be used, provided that the selected procedure ensures reproducible post-thaw recovery and maintenance of relevant MCB characteristics	
Culture Conditions	
Culture medium composition and preparation, inoculation conditions, culture temperature, incubation time, and other relevant parameters shall be based on the Client's documentation and/or agreed between the Client and Contractor before manufacture	
All critical culture parameters shall be defined in an approved Master Cell Banking Protocol before initiation of MCB manufacture	
The Contractor shall: - document relevant culture parameters, including time, temperature, and, where applicable, pH, dissolved oxygen (DO), agitation and other relevant process parameters; - perform culture and handling operations under appropriately controlled conditions designed to prevent contamination and cross-contamination; - maintain complete and traceable manufacturing records; - have appropriate procedures for handling process deviations and equipment failures; - document and investigate deviations in accordance with the Contractor's Quality Management System. Deviations with a potential impact on MCB quality shall be communicated to the Client.	
Quality Control and Characterization	
The Contractor shall propose a scientifically justified quality control and characterization panel for the MCB, taking into consideration the intended use of the MCB for manufacture of plasmid DNA used as a starting material for mRNA production	
The testing program shall include, as applicable: Host strain identity – confirmation of the identity of the <i>E. coli</i> production strain using an appropriate molecular method	

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• Plasmid identity – confirmation of plasmid identity using appropriate methods, which include sequencing and restriction analysis • Plasmid sequence – confirmation of relevant plasmid sequence against the approved reference sequence, as agreed with the Client • Microbiological purity – demonstration of absence of detectable contamination with adventitious microorganisms using appropriately qualified methods • Bacteriophage testing – demonstration of absence of detectable Lytic/lysogenic bacteriophage contamination using an appropriate method, where applicable • Viable cell count – determination of viable cell concentration (CFU/mL) following thawing • Post-thaw recovery – demonstration of satisfactory recovery of the MCB following the defined thawing procedure • Assessment of plasmid genetic stability and maintenance during culture, including plasmid retention and, where scientifically justified, plasmid copy number (PCN) determination. Testing shall include comparison of cells representative of the MCB with cells collected at the end of a defined culture period or number of generations representative of the intended manufacturing process	
The Contractor shall define test methods and proposed acceptance criteria in the Master Cell Banking Protocol and/or MCB specification. The acceptance criteria shall be agreed with the Client prior to initiation of testing	
Release of the MCB shall be performed by appropriately authorized Contractor Quality personnel following satisfactory review of the manufacturing records, test results, deviations, and other relevant documentation	
Documentation	
Approved Master Cell Banking Protocol	
Complete executed manufacturing/batch record	
Final MCB manufacturing and characterization report	
Complete results of release and characterization testing	
Documentation describing the cryopreservation, storage, and recommended thawing procedure	
Records of relevant deviations and investigations	
Certificate of Analysis (CoA) and/or Certificate of Testing (CoT)	
Traceability documentation for Client-supplied biological starting materials from receipt through MCB manufacture and release	
MCB Storage	
Following manufacture, the MCB shall be stored under defined and controlled conditions appropriate for long-term preservation of the <i>E. coli</i> cell bank	
Storage at $\leq -80^{\circ}\text{C}$, or at an alternative qualified temperature demonstrated to be appropriate for the MCB	
Continuous temperature monitoring using a qualified monitoring system	
Appropriate alarm systems and procedures for responding to temperature changes	
Documented procedures for equipment failure and emergency transfer of the MCB	

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Where required, continued storage of the MCBs following completion of the project shall be subject to a separate agreement between the Client and Contractor	
Project Timeline	
The manufacture, testing, characterization, and preparation of release documentation for the MCB shall be completed within a maximum of 10 weeks from the agreed project start date	
The project start date shall be defined as the date on which all materials, information, documentation, and approvals required to initiate MCB manufacture have been received and accepted by the Contractor	
If circumstances outside the planned project activities arise that may affect the agreed timeline, including unexpected technical events, deviations, investigations, test repetitions, or other justified circumstances, the Contractor shall notify the Client without undue delay	
The notification shall include the reason for the delay, an assessment of its impact on the project timeline, and a proposed revised completion date. Any extension beyond the agreed 10-week timeline shall be justified and agreed with the Client	

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(signature of the Contractor or an authorized representative on behalf of the Contractor)

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