PNRR Missione 4, Componente 2, Investimento 1.4 "Potenziamento strutture di ricerca e creazione di "campioni nazionali di R&S" su alcune Key Enabling Technologies"

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National Center for Gene Therapy and Drugs based on RNA Technology

Sviluppo di terapia genica e farmaci con tecnologia a RNA

Codice progetto MUR: CN00000041 – CUP UNINA: E63C22000940007

UNIVERSITÀ DEGLI STUDI DI NAPOLI FEDERICO II

DIPARTIMENTO DI FARMACIA

TECHNICAL SPECIFICATIONS

Open procedure with application of the criterion of the most economically advantageous offer identified on the basis of the best value for money, pursuant to articles. 71 and 108 paragraph 1 of the Legislative Decree. n. 36/2023 as amended having as its object the supply of a" LOT 1: Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System; LOT 2: Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical".

Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System – Lot 1

Requirements and essential technical characteristics

- A fully automated equipment suitable for non-GMP manufacturing of mRNA at a scale for drug discovery and pre-clinical development.
- The equipment must be autonomous except for placing reagents including priming and calibration, disposables, collecting products and samples, and removing waste.

- The automated system for mRNA production should allow increased efficiency, performing mRNA synthesis and processing tasks much faster than manual methods, leading to higher throughput and productivity. This efficiency allows for the rapid production of large quantities of mRNA, which is essential for applications such as vaccine development or high-throughput screening assays.
- The automated system for mRNA production should allow improved accuracy and precision, reducing the risk of human error inherent in manual processes, resulting in more consistent and reproducible mRNA products. The system should allow precise control of reaction conditions, timing, and reagent volumes, minimizing variability and ensuring the quality and integrity of the mRNA molecules.
- The automated system for mRNA production should allow scalability, accommodating varying production demands.
- The automated system for mRNA production should allow streamlined workflow, integrating multiple steps of the mRNA production process into a single platform and reducing the need for manual intervention. This integration should save time and minimize the risk of sample contamination and cross-contamination between samples.
- The automated system for mRNA production should allow resource savings by automating repetitive and labor-intensive tasks, reducing the need for skilled labor and manual labor hours, minimizing the consumption of expensive reagents and materials.
- The equipment must process 19.2 ml of IVT.
- The equipment must ensure a well-defined sequence capture and purification step for each IVT output.
- The overall dimension of the main frame must be minimized, and the system must be easily liftable for installation.
- The automated system for mRNA production should allow flexibility and customization allowing users to tailor the mRNA production process to their specific requirements (e.g., multiple/ preferably 48 DNA templates introduced in parallel for the In vitro transcription of various RNA sequences and producing at least 2 mg mRNA for each DNA template).

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Automated System for GMP mRNA production at scale for clinical stages and commercial production

with Critical - LOT 2

Requirements and essential technical characteristics

- The fully automated equipment suitable for GMP manufacturing of mRNA at a scale for clinical phases and commercial production.
- The process chamber of the fully automated equipment shall meet Grade C requirements at rest and in operation.
- The fully automated equipment must be used in grade D GMP manufacturing areas.
- The equipment must be autonomous except for placing reagents including priming and calibration, disposables, collecting products and samples, and removing waste.
- The automated system for mRNA production should allow increased efficiency, performing mRNA synthesis and processing tasks much faster than manual methods, leading to higher throughput and productivity. This efficiency allows for the rapid production of large quantities of mRNA, which is essential for applications such as vaccine development or high-throughput screening assays.
- The automated system for mRNA production should allow improved accuracy and precision, reducing the risk of human error inherent in manual processes, resulting in more consistent and reproducible mRNA products. The system should allow precise control of reaction conditions, timing, and reagent volumes, minimizing variability and ensuring the quality and integrity of the mRNA molecules.
- The automated system for mRNA production should allow scalability, accommodating varying production demands.
- The automated system for mRNA production should allow streamlined workflow, integrating multiple steps of the mRNA production process into a single platform and reducing the need for manual intervention. This integration should save time and minimize the risk of sample contamination and cross-contamination between samples.
- The automated system for mRNA production should allow quality control, incorporating built-in quality control measures, such as in process sampling, to ensure the quality and purity of the mRNA product. These quality control features should help identify and address any deviations from expected results, guaranteeing control and quality over the final product.
- The automated system for mRNA production should allow resource savings by automating

repetitive and labor-intensive tasks, reducing the need for skilled labor and manual labor hours, minimizing the consumption of expensive reagents and materials.

- The equipment must process 200ml and/or 800 ml of IVT.
- The equipment must ensure a well-defined sequence capture and purification step for each IVT output.
- The overall dimension of the main frame must be minimized, and the system must be easily liftable for installation.
- The automated system must allow GMP manufacturing of mRNA in large scale (one DNA template for the In vitro transcription of the corresponding RNA sequence and producing at least 4 g of purified RNA per day, and more than 800 g of purified RNA per year).