



Issue: 122/2022/M/RNA

Appendix no 2

In connection with the implementation of the project No. 2021 / ABM / 05/00005 under the name "**Development of Innovative Therapeutic Solutions using RNA technology (TransformRNA - mRNA Therapeutics generation platform)**" co-financed by the Medical Research Agency, Celon Pharma S.A. invites you to submit offers:

The subject matter of the procedure: *Fermentation unit with Mobile CIP*

The device in question must be brand new, manufactured not earlier than in 2022, not used in any laboratory, not exhibited at conferences or trade fairs. The device must meet the technical and functional requirements specified in the description of the subject-matter of the contract, including delivery and installation. Description of the subject-matter of the contract presents the minimal requirements of the device being the subject-matter of the contract. The Contractors entering the procurement should offer a device with parameters equal to or greater than those indicated below.

Description of the subject-matter

	General description of required Fermentation unit Mobile CIP intended production in GMP	Parameters of subject-matter (to be filled by the supplier)
1.	The Fermentation unit must include the following primary components: <ol style="list-style-type: none">10 L inoculum stainless steel bioreactor;100 L production stainless steel bioreactor;100 L stainless steel product transfer vessel;Mobile CIP system;SCADA system.	
	All system parts (bioreactors, Mobile CIP) must be integrated into one unitary SCADA. The communication between devices (bioreactors, Mobile CIP) must be realized through Profinet network. Through Profinet is ensured also data exchange between this bioreactor system and central monitoring station. The communication between SCADA of each device with corresponding PLC is realized through Ethernet TCP/IP network. Field instruments and valves are connected to the PLCs with hardware. Each bioreactor must be equipped with a process skid to ensure automated fermentation, cleaning, sterilization, heating and cooling processes. Thus, the local control of each particular bioreactor is ensured separately from other bioreactors. The SCADA ensures the interaction between different bioreactors and the Mobile CIP system. Actually, the SCADA controls certain groups of valves, depending on the selected recipe and the status of the respective sensors in the bioreactors, as well as in the Mobile CIP system and pipelines (medium	

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	presence sensors must be built in in the valve groups). In such way are directly controlled the following processes in the selected bioreactors or pipelines: CIP cleaning of selected bioreactors and pipelines, SIP sterilization of pipelines, biomass transfer from one bioreactor to another, and bioreactor discharge.	
2.	Be compliant with GMP requirements	

1. 10 and 100 liter stainless steel bioreactors, 100 liter product transfer vessel.

2.1 Proposed dimensions

Vessel	10 liter bioreactor	100 liter bioreactor	100 liter product transfer vessel
Total Volume, L	14	105	105
Ratio H/D	2	2	2
Inside diameter, mm (D)	213	400	400
Straight Inside Length, mm (H)	430	800	800

2.2 Technical design of the vessels

Design pressure, barg	<i>Inside the vessel</i>	3.5
	<i>Inside the jacket</i>	4.0
Operating pressure, barg	<i>Inside the vessel</i>	3.0
	<i>Inside the jacket</i>	3.5
Design temperature range, °C	<i>Inside the vessel</i>	0...145
	<i>Inside the jacket</i>	0...150
Operating temperature range, °C	<i>Inside the vessel</i>	5...135
	<i>Inside the jacket</i>	5...145
Material	<i>Process contact surface</i>	Stainless steel (AISI316 or AISI316L)
	<i>Other parts</i>	Stainless steel AISI304
Surface roughness	<i>Inside</i>	Ra ≤ 0.63 μm
	<i>Outside</i>	Ra ≤ 0.8 μm
Insulation	Vessel insulated with chlorine free mineral wool, covered with grinded, passivated stainless steel	

2.3 Table of main features

Vessel	10 liter bioreactor	100 liter bioreactor	100 liter product transfer vessel
Total Volume, L	14	105	105
Working Volume, L	10	75	75
H/D Ratio	2	2	2
Top	Flat	Flat	Flat

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Bottom	Torispherical	Torispherical	Torispherical
Jacketed	Yes	Yes	Yes
Insulation, mm	50	50	50
Baffles	3	4	4
Agitator	Top mounted	Bottom mounted	Bottom mounted
Type	Magnetic	Magnetic	Magnetic
Turbines	2xRushton	2xRushton	1xRushton
Agitator RPM	40-750	40-600	40-200
Gas	Air	Air	Air
Filters	Inlet and Outlet 0.2 µm	Inlet and Outlet 0.2 µm	Inlet and Outlet 0.2 µm
Sparger	Ring	Ring	Ring
Gas flow control	MFC	MFC	Manual
Gas flow range	2 vvm	2 vvm	1vvm
Pumps (fixed speed)	3 (acid, base, antifoam)	3 (acid, base, antifoam)	No
Cooling	Water	Water	Water
Heating	Electric Heater	Electric Heater	No
SIP	External via Saturated steam	External via Saturated steam	External via Saturated steam
pH sensor	Yes	Yes	No
DO sensor	Yes	Yes	No
Temperature	Yes	Yes	Yes
Foam level	Yes	Yes	No
Alarm level	Yes	Yes	Yes
CIP spray ball	Yes	Yes	Yes
Pressure sensor	Yes	Yes	Yes
Pressure Gauge	Yes	Yes	Yes
Safety valve	Yes	Yes	Yes
Lighting with sight glass	Yes	Yes	Yes
Sampling device	Yes	Yes	No
Dip tubes (for base, acid, anti-foam)	3	3	No
Glass bottles (for base, acid, anti-foam)	3x250 ml	3x500 ml	No
Ports	4 inclined Ingold connections in lower cylindrical part, straight Ingold connector for sampling device		4 inclined Ingold connections in lower cylindrical part
Peristaltic pump	3	3	1
SIP automation	Reactor (empty and full) and filters automatic sterilization, automatic blow of filters		
Control/Automation	Siemens Simatic S7 - 1500 series PLC.Touch screen display panel at least 12"		
Controlled parameters	Temperature, pH, pO ₂ (according cascade control), foam indication, alarm level indication,		Temperature, pressure

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	inlet air flow, overpressure; Substrate feeding according to the adjusted profiles.	
Communication with other devices	PLC can be connected to network of Profinet and Ethernet for communication with other devices (bioreactors, CIP/SIP, SCADA etc.). Profibus connection to LAN or WAN. MODBUS protocol via TCI/IP.	
All pilot bioreactor units have to be connected between each other in a closed loop with the help of isolated stainless steel pipes for execution product transfer and CIP procedures. All processes have to be automated providing routes for transfer and cleaning.		

2. Mobile CIP system

This system must be an equipment unit, placed on a movable platform.. Maximum speed of detergent circulation – 1500 l/h .

The CIP platform contains self-priming pump (for CIP supply and return), two dosing pumps with two plastic vessels, pipes and fittings for detergent concentrate, a control cabinet with a touchscreen operator panel, manual and automatic valves, couplings and armature to provide cleaning operation. Buffer vessel functions presents vessel to be cleaned. In the vessel cleaning solution preparation process is executed (heating solution to desired temperature).

The mobile CIP unit must allow implementing of both manual and completely automatic modes of cleaning process. CIP cleaning mode consists of stages, but each stage – of steps. In fact, a stage of the cleaning process is considered as realization of definite type of cleaning process with selected parameters (temperature, time of CIP cleaning, time of discharge output, detergent conductivity, speed of concentrate supply, fast speed of mixer rotation, slow speed of mixer rotation, speed of CIP supply pump, duration of dosing impulse and a pump interval at impulse working mode etc.).

In automatic mode it is possible to perform the following operations of CIP:

- Pre-rinse,
- Cleaning with the base solution,
- Intermediate rinse,
- Cleaning with the acid solution,
- Final rinse.

The automatic process of CIP is carried out according to a selected recipe. The recipe includes the defined stages and steps with corresponding parameters.

3. SCADA

SCADA for monitoring, reporting, archiving and full process control of each bioreactor, CIP and each operation between bioreactors and CIP, must be developed according to the requirements of 21 CFR Part 11 (code of federal regulations from US Food and Drugs Administration) adapted to particular project with extension

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possibilities. The program is installed on PC, and communicates with all bioreactor, CIP. SCADA must provide following main functions:

1. Process selection,
2. Recipe composition and storage selection,
3. Process and device condition control visualization,
4. Graphical process and parameter display,
5. Control system data archiving,
6. Event log,
7. Alarm signal log,
8. Audit trail,
9. Ensured several access levels to SCADA SW,
10. Remote access to the system via Internet.

4. FAT

5. Training

6. SAT

7. Installation on customer side

Additional requirements		
Warranty	Minimum warranty period: 12 months	
Post-warranty service	The supplier will provide access to spare parts and post-warranty service for at least 5 years following the date of contract performance	
User manual	Printed user manual in Polish or in English with a translation into Polish	
Training	The supplier will conduct training covering the principles of use and basic service activities for the Contracting Party's personnel (unlimited number of participants)	

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(Signature by Tender's authorized person)

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