

Request for Information (RFI)

Isolator for aseptic inoculation of ATMP samples for sterility testing

Document purpose

The Department of Cancer Treatment at Oslo University Hospital (OUS) is planning a procurement of an isolator intended for aseptic preparation and inoculation of Advanced Therapy Medicinal Product samples into culture bottles for sterility testing according to European Pharmacopoeia principles (Ph. Eur. 2.6.1 and/or Ph. Eur. 2.6.27). The isolator will be installed in a non-classified room and shall provide a controlled Grade A/ISO 5 aseptic working environment for the critical inoculation step.

The purpose of this request is to obtain an overview of available solutions in the market and gather technical information and price estimates. This request does not constitute a competition and implies no obligation to purchase. Information received will be used solely for procurement planning purposes.

1. Intended use and process scope

The isolator shall be used for aseptic handling and inoculation of ATMP samples, controls, and associated materials into culture bottles prior to incubation and automated microbial detection. The isolator is not intended for ATMP manufacturing, product filling, or long-term incubation. The system shall support sterility testing, QC, and ATMP applications, consistent with the selected configuration and the manufacturer's stated application area.

The system shall enable safe introduction of samples, bottles, syringes, needles, tubing, disinfectants, and other consumables through an airlock and shall maintain aseptic conditions during all open manipulations.

2. Regulatory and quality requirements

The isolator shall be suitable for aseptic sterility-test sample preparation in accordance with current European Pharmacopoeia expectations for aseptic test conditions and regular environmental monitoring of the working area. The supplier shall provide evidence that the working chamber achieves GMP Grade A / ISO 5 conditions with unidirectional airflow during operation.

The isolator and supporting qualification package shall support compliance with applicable GMP principles, including data integrity, contamination control, environmental monitoring, cleaning/decontamination validation, change control, deviation handling, and traceability. The supplier shall provide IQ/OQ documentation and the system shall be suitable for inclusion in the site contamination control strategy.

Because the isolator will be located in a non-classified room, the supplier shall document the required room conditions, operational limitations, and risk controls needed to ensure that the non-classified background does not compromise Grade A conditions inside the isolator. The user shall approve the installation based on risk assessment, qualification data, and routine monitoring results.

3. Required isolator configuration

The isolator shall be supplied with the following minimum configuration:

<i>Requirement</i>	<i>User requirement</i>
<i>Working chamber</i>	2-glove working chamber
<i>Pressure mode</i>	Positive pressure, +60 Pa
<i>Transfer system</i>	One airlock for material transfer
<i>Power socket</i>	Right-side power socket; standard plug and power supply
<i>Application</i>	Sterility testing, QC, ATMP
<i>Gloves</i>	Two glove ports compatible with glove integrity testing
<i>Decontamination</i>	Integrated automated H ₂ O ₂ decontamination system
<i>Filtration</i>	Double HEPA H14 filtration; intake and exhaust HEPA filtration
<i>Airflow</i>	Unidirectional downflow suitable for Grade A / ISO 5 operation
<i>Installation</i>	Plug-and-play design suitable for non-classified laboratory installation after qualification

The selected configuration includes a 2-glove positive-pressure isolator for sterility testing/QC/ATMP use, with right-side power socket and standard power supply.

4. Environmental monitoring and process control

The isolator shall include or support integration of environmental monitoring for routine verification of aseptic conditions during sterility-test inoculation. The selected configuration shall include air velocity sensors, particle monitoring capability, HMI integration of a compatible remote particle counter, a particle probe, and provision for viable monitoring through a tri-clamp for viable counter head.

The system shall allow monitoring and documentation of at least the following parameters:

<i>Parameter</i>	<i>Requirement</i>
<i>Differential pressure</i>	Continuous or routine monitoring of isolator pressure status
<i>Air velocity</i>	Monitoring of downflow air velocity
<i>Particles</i>	Non-viable particle monitoring suitable for Grade A verification
<i>Viabiles</i>	Interface for viable air monitoring during qualification and/or routine use
<i>H₂O₂</i>	H ₂ O ₂ TLV transmitter and leakage/concentration sensor for operator safety
<i>Alarms</i>	Visual and/or audible alarms for critical deviations
<i>Records</i>	Batch logs, alarms, trends, and decontamination cycle records

5. Cleaning, decontamination, and material transfer

The isolator shall include an automated H₂O₂ decontamination system with reproducible, validated cycles. The decontamination process shall be suitable for the working chamber and airlock and shall include defined cycle parameters, aeration, residual H₂O₂ acceptance criteria, and validated hold time after decontamination. All product-contact or critical internal surfaces shall be compatible with routine cleaning and sporicidal decontamination. The

working area shall be stainless steel AISI 316L with surface finish suitable for GMP cleaning, as described in the technical specification.

The airlock shall allow transfer of culture bottles and consumables without compromising the working chamber. A shelf for the transfer door/left airlock is included in the selected configuration.

6. Ergonomics, safety, and utilities

The isolator shall allow ergonomic two-glove operation for inoculation, bottle handling, labelling, and transfer of materials. The system shall provide adequate illumination, front access for operation and maintenance, and safe glove-port operation. The supplier shall specify all required utilities, including electrical supply, compressed air quality, H₂O₂ supply, exhaust requirements, heat load, room clearance, and maintenance access. The isolator shall not require connection to building exhaust if operated with the integrated catalytic converter, provided this is confirmed by supplier risk assessment and installation qualification.

7. Qualification, validation, and documentation

The supplier shall provide a complete documentation package sufficient for GMP qualification and release for routine use, including:

<i>Documentation / testing</i>	<i>Requirement</i>
<i>Design documentation</i>	Technical drawings, P&ID if applicable, component list, materials of construction
<i>Certificates</i>	HEPA filter certificates, material certificates where applicable, CE/safety documentation
<i>FAT/SAT</i>	FAT optional; SAT or installation verification required on site
<i>IQ/OQ</i>	IQ/OQ qualification plan and executed protocols required
<i>Airflow qualification</i>	Air velocity, airflow visualisation if applicable, ISO 5 / Grade A verification
<i>Leak/integrity testing</i>	Isolator and glove integrity test strategy
<i>H₂O₂ cycle</i>	Cycle development or documented standard cycle; validation by user/site
<i>EM qualification</i>	Particle and viable monitoring locations and acceptance criteria
<i>Data integrity</i>	User access control, audit trail or equivalent controls, backup/export of records
<i>Maintenance</i>	Preventive maintenance plan, calibration requirements, spare parts list

The selected configuration includes the supplier IQ/OQ qualification plan for the isolator and selected monitoring options.

8. Acceptance criteria

The isolator shall be accepted for routine use when installation and operational qualification demonstrate that the system:

1. Achieves and maintains Grade A / ISO 5 conditions in the working chamber during representative operation.
2. Maintains positive pressure and unidirectional airflow within defined limits.
3. Provides validated and reproducible H₂O₂ decontamination with acceptable residual H₂O₂ levels before use.
4. Allows aseptic inoculation of culture bottles without compromising sample integrity or sterility-test validity.
5. Supports routine environmental monitoring and alarm review.
6. Provides complete GMP-relevant documentation, calibration, maintenance, and training records.
7. Is justified by documented risk assessment for operation in the specified non-classified room.

Requested information and response instructions

Interested suppliers and vendors are requested to respond with via the communication module in Mercell by **03.06.2026 at 12:00**. Oslo University Hospital reserves the right to invite selected respondents to clarifying meetings where this is considered relevant for the purpose of the market survey.

Please include the following information:

- Description of available solutions that meet the needs described above.
- Technical specifications (dimensions, weight, pressure, filtration, airflow, power requirements, and site requirements/installation guide).
- Scope of any proprietary consumables (gloves, filters, H₂O₂ cartridges, etc.) and their availability in the Norwegian market.
- Available qualification documentation (IQ/OQ) and references from equivalent GMP installations.
- Estimated price of the solution, including any modules for environmental monitoring and the qualification package.
- Suppliers are also welcome to include any other information they consider relevant.

Med vennlig hilsen

Frank Sætre

Prosjektleder

Teknologi- og innovasjonsklinikken | Medisinsk teknologi | Seksjon for plan og anskaffelse

Oslo universitetssykehus HF