MEP National Network™

COMPLETE THIS FORM TO INITIATE SUPPLIER SCOUTING

MEPNN Supplier Scouting Opportunity Synopsis

☒ *The submitting organization (ex. MEP Center, requesting company, federal/state agency) agrees to notify NIST MEP of the status of actions taken as a result of this scouting instance within 30 days after receiving a results report. Notification should be via email to scouting@nist.gov, indicating the following:

- Contact with matches identified in report complete and supply contract awarded, process complete
- Contact with matches identified in report complete and no supply contract awarded, process complete
- Contact with matches identified in report complete and supply negotiations underway, process in progress
- Contact with matches identified in report underway; supply negotiations not yet begun; process in progress
- Contact with matches identified in report not yet begun, process in progress
- Contact with matches identified in report will not occur within the next 6-months, process complete

Vitrocell Cloud Alpha12

Item to be Scouted

15 **days**

Opportunities will be posted for 30 days unless specified

Please describe the item application/ the end use of item.* Provide the item number if applicable: (N95 Mask vs Protective Mask).
Inhalation toxicology exposure system: used exposure of cell cultures to liquid aerosols at the Air/Liquid Interface. The Cloud system is suitable of solutions and suspensions. Fields of application are virus research, screening of inhaled drugs and toxicity testing of inhaled substances such as chemicals or nanoparticles.

Supplier Scouting Number (NIST MEP use)

334516

Scouting customer/product NAICS Code, if known

TECHNICAL INFORMATION:

1. Supplier Information

a. Type of supplier being sought*

☒ **Manufacturer** ☐ **Contract Manufacturer** ☐ **Distributor**

☐ **Other** _____

b. Reason for scouting submission*

☐ **2nd Supplier** ☐ **Price** ☐ **Re-shore** ☐ **Past supplier no longer available**

☐ **New Product Startup**

☒ **Other** Explore potential establishment of a US (domestic) source per Executive Order 14005.

2. Summary of Technical Specifications and Performance Requirements:

a. Describe the manufacturing processes (elaborate to provide as much detail as possible).*

Item is made of stainless steel which may be cast or forged, cut, welded, formed, machined and fabricated. Please see attached product depiction and descriptions.

b. Provide dimensions / size / tolerances / performance specifications for the item.*

Please see attached product depiction and description.

c. List required materials needed to make the product, including materials of product components.*

Product is a complex electronic scientific device consisting of a stainless steel casing, a heating system, nebulizers, touch screen display, and various control mechanisms and electronic components (e.g. circuit boards, LED light). Please see attached product leaflet.

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	2. Summary of Technical Specifications and PerformanceRequirements cont:	**d. Are there applicable certification requirements?*** ☒ **Yes** ☐ **No** **Please explain**
		Although the FDA does not require UL listing, a Nationally Recognized Testing Laboratories (NRTLs) product labeling or marking with the registered certification mark may be needed to ensure that the equipment was tested and certified for the safe use in the workplace.
		e. Are there applicable regulations?* ☐ **Yes** ☐ **No** **Please explain**
		The FDA regulates manufacturers and devices under the Federal Food, Drug, and Cosmetic Act (FFDCA) to ensure that devices, including those intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, are reasonable safe and effective. FDA regulations detained in Title 21 US Code of Federal Regulations (CRF) Part 800 applies.
		f. Are there any other standards, requirements, etc.?* ☐ **Yes** ☐ **No** **Please explain**
		Laboratory Equipment and Devices Applicable Standards: International Commission (IEC) Standards, International Organization for Standardization (ISO) Standards, and ANSI/AAMI Standards.
		g. Additional Comments: Is there other information that would impact the item's performance or usefulness? Please explain.
		N/A
BUSINESS INFORMATION:	**3. Volume and Pricing**	**3a. Estimated potential business volume (i.e., # Units Per Day, Month, Year) *:**
		According to USASpending data reports for FYs 2019 through FY 2022 (to date) Total Federal Dollars Obligated FY 2019 thru FY 2022 to Vitrocell prime contract - $1,146,670.32; Sub-Contract - $741,859.74. Other purchasers/users of the item include universities, medical and other research entities, medical facilities (e.g., clinics, hospitals).
		b. Estimated target price / unit cost information (if unavailable explain) ***:**
		$64.5K complete set as described in leaflet.
	4. Delivery Requirements:	**a. When is it needed by? (Immediate, 30 Days, 6 months, etc.)***
		Immediate and for long term future needs.
		b. Describe packaging requirements (i.e., individually/group packaging)*
		Laboratory Equipment and Devices Applicable Standards: International Electrotechnical Commission (EIC) Standards, International Organization for Standardization (ISO) Standards, and ANSI/AAMI Standards applicable packaging.
		c. Where will this item be shipped? *
		Research Triangle Park, North Carolina
	5. Additional Comments:	**Is there other information you would like to include?**
		The following US Companies are also engaged in research and manufacture of inhalation toxicology exposure system devices: 1) DSI, a Division of Harvard Bioscience, New Brighton, MN (DSI Inhalation & Exposure Systems) 2) In-Tox Products, LLC, Clinton, MS

Photos or diagrams of the item (helpful but not required).

Advanced in vitro exposure systems

VITROCELL® Cloud α 12



VITROCELL® SYSTEMS

VITROCELL® Exposure Systems for Inhalation Toxicology

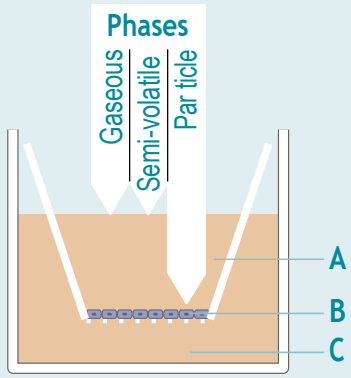
Direct Exposure Technology at Air/Liquid Interface

In response to the scientific need to expose in physiologically relevant conditions, VITROCELL® Cloud exposure modules have been specifically designed and engineered to enable direct exposure of mammalian cells or tissue at the air/liquid interface where the cell systems are not covered with culture media. Researchers can thus use all cell types cultivated on microporous membranes. This approach allows for more credible and authentic results than by submerged exposure due to a closer replication of the human physiology.

The exposure of mammalian cells or tissues to airborne substances is frequently performed under submerged conditions. Here, the test substances are dosed into the culture media. This procedure results in an undesired interaction of the formerly airborne substances with the media causing limitations for authentic analysis.

The advantages:

- No losses
- No dissolution
- No reaction of constituents with culture media
- High sensitivity

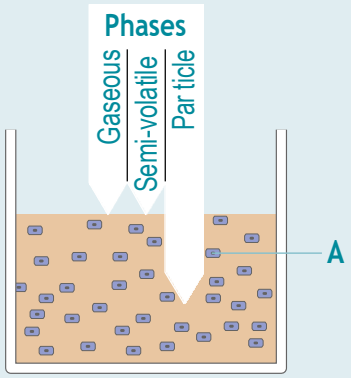


Submerged Cultivation and Exposure in Incubator

A Media above cells
B Cells on membrane
C Media below cells

Interaction of test components with culture media

Low sensitivity

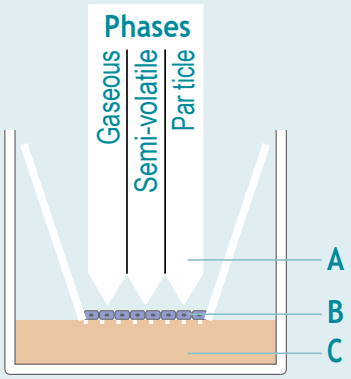


Suspension Cultivation and Exposure in Incubator

A Cells in media

Interaction of test components with culture media

Low sensitivity



Air / Liquid Cultivation and Exposure in Exposure Module

A Direct and controlled exposure of test atmosphere to cells
B Cells on membrane
C Media below cells

No losses
No reaction of principle components with culture media

High sensitivity of system

VITROCELL® SYSTEMS

VITROCELL® Cloud α 12

For exposure of cell cultures to liquid aerosols at the Air/Liquid Interface

The VITROCELL® Cloud Alpha 12 is our new innovation in the Cloud family and presents a great leap forward in automated exposure of cell cultures. It combines high deposition efficiency with ease of use. The development is based on the well-known and frequently published VITROCELL® Cloud formats (6-, 12- and 24-well) of the first generation.
It's functionality enables fully automated processes with an all-in-one control unit. Everyday experiments at the Air/Liquid Interface have never been easier.

The new Cloud Alpha 12 was developed as a result of numerous customer requests and is capable to expose mammalian cell cultures in 12- or 24-well sized cell culture inserts. All commercial brands are supported.

The Cloud system is suitable for nebulization of solutions and suspensions. Fields of application are virus research, screening of inhaled drugs and toxicity testing of inhaled substances such as chemicals or nanoparticles.

The system has an integrated controller for the aerosol generator, adjustable via touchscreen.

Insert holder system

Insert holders for 12- and 24-well sized inserts are part of the delivery.
All commercial brands are supported.

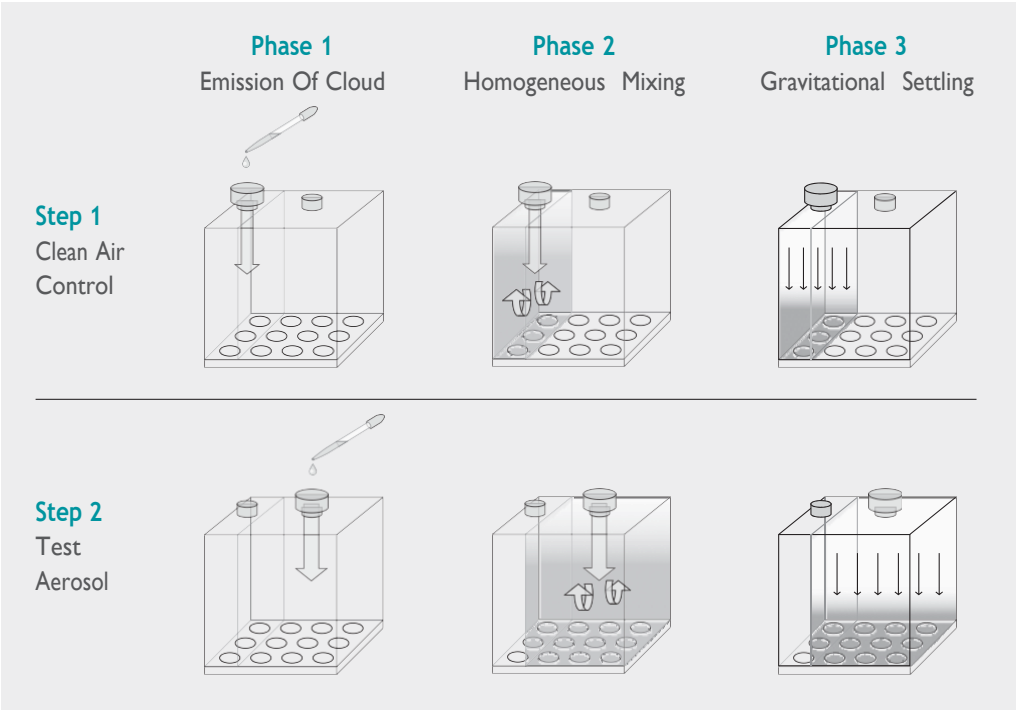
Dosimetry using Quartz Crystal Microbalance (QCM)

The QCM sensor is integrated in the Cloud Alpha 12 exposure module.
It is capable of measuring the deposited mass at a resolution of 10 nanogram/cm^2 per second.

Results are reported online by the VITROCELL® Monitor software. Data is presented in graphs and stored in MS Excel®.

How the Vitrocell® Cloud works

After pipetting the suspension, exposure to the cell cultures takes place in two steps, each with three phases:



Different choices of nebulizers

The system comes with a choice of 3 types of vibrating mesh nebulizers having droplet MMAD ranges of
2.5 – 6.0 µm,
2.5 – 4.0 µm and
4.0 – 6.0 µm.

Recommended nebulisation volumes are 200 µl.
So the device is particularly suitable for testing whenever small quantitities of testing materials are available.

Features

- Integrated controller for aerosol generator
- Optional integrated microbalance controller
- Defined experiment recipes
- Automatisation of the experiment by nebulization time or by user-defined volume
- Output rate database for nebulizers
- Heating system
- Optional PowerVent function: evacuation of potentially residual aerosols via vacuum pump
- Designed for virus research, screening of inhaled drugs and toxicity testing of inhaled substances such as chemicals or nanoparticles

VITROCELL® SYSTEMS

VITROCELL® Cloud Alpha - Touch Screen Display

for easy definition of the experimental parameters

Home Screen

After defining the sequence of an experiment, there is only a single tap on the “Start”-Button required to perform a completely automated exposure. This ensures higher reproducibility and gives a perfect ease of use. The deposited particle mass is monitored by the integrated microbalance dosimetry tool (option).

Recipies

Recipies may be set according to the experimental design. The integrated nebulizer and linked output rate data base allows to use the nebulizer as a reservoir and generate an aerosol out of a defined volume. Alternatively a time-based nebulization may be chosen. Additionally, settling and evacuation times (for the optional PowerVent version) may be defined according to individual needs.

Manual Mode

While offering fully automated, recipe-controlled experiments, the VITROCELL® Cloud Alpha control unit has the option to control each of its functions manually. There is only a touch of your finger required to switch individual nebulizers on or off, evacuate the exposure chamber after an experiment or toggle a LED light for better visibility.

About VITROCELL®

VITROCELL® exclusively concentrates on the developing, producing, installing, training and servicing of advanced *in vitro* exposure systems.

The VITROCELL® Systems' team is driven by their vision for new in-vitro standards through state-of-the-art technology, highly qualified workmanship and absolute client dedication. VITROCELL® has successfully collaborated with clients from leading research institutes, contract research organizations, regulatory authorities or industrial laboratories across the world. Working with our team experts, all modules have been tailored to create durable and complete turnkey-systems for *in vitro* inhalation toxicology. Gases, environmental atmospheres, nano particles and complex mixtures are analyzed on lung cells at the air/liquid interface using these systems. VITROCELL® technologies are also applicable to solutions for skin research.

Over a decade of devotion to research in this specific field has given our team of design & precision manufacturing specialists the opportunity to mentor highly diversified and complex projects from conception to completion. We strive to become a constructive member of each research team, providing support when it is needed, advice when it is required and modules of the highest quality, which are even polished by hand before leaving here to be integrated into your workspace. Every piece of our German engineered equipment is manufactured to the highest of standards – yours.

For more information
please scan the QR-Code:

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