

GENIUS SYSTEM

T R I O . B A S I C

PRESS RELEASE

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ORUM INTERNATIONAL introduces the GENIUS SYSTEM: Multiple Microbial Satellites for Continuous Environmental Monitoring

In response to the last updated GMP ANNEX 1 which requires continuous microbial monitoring in grade A and B areas, ORUM INTERNATIONAL introduces the GENIUS SYSTEM, the new generation of Multiple Microbial Sampling Satellite designed to ensure full regulatory compliance and operational efficiency in controlled environments.

The GENIUS SYSTEM consists of a flexible, intelligent, and integrated solution for microbiological air sampling, enabling seamless management of multiple sampling points with enhanced safety and simplified operations. It facilitates operator activity, minimizes risks, streamlines audits and calibrations, and allows consistent data comparison across different areas.



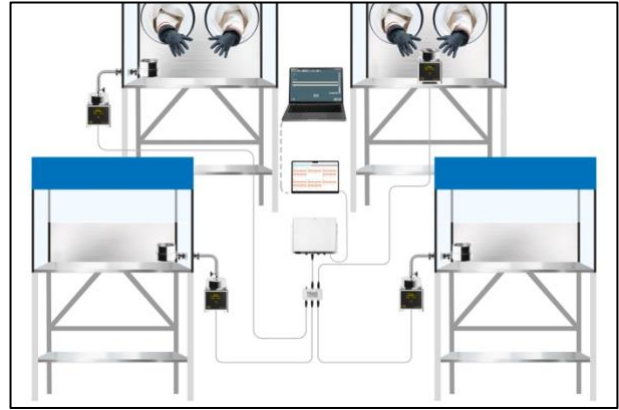
INTELLIGENT AND INTEGRATED DESIGN

The single GENIUS Satellite is a smart electronic system with a LCD display, providing real-time information on every sampling phase. Each satellite operates autonomously, while also being managed via a central console command unit equipped with GENIUS software.

The system can control from 1 up to 24 satellites, allowing flexible configurations for complex production environments such as sterile drug manufacturing lines.



Example of GENIUS SYSTEM in 2 RABS isolators. The system is made by 2 GENIUS satellites and 4 GENIUS satellites with remote heads



Example of GENIUS SYSTEM in 2 RABS isolators and 2 BSC, consisting of 1 GENIUS satellite and 3 GENIUS satellites with remote heads

The satellites can also integrate with other control instruments (particle counters, temperature and humidity sensors, differential pressure, airflow velocity sensors, etc.) and interface with SCADA systems.

CONTINUOUS SAMPLING FOR UP TO 4 HOURS

The GENIUS SYSTEM is available in two versions, both designed to provide reliable continuous air sampling using standard 90 mm Petri dishes:

Rotating Plate Version:

- Performs continuous air sampling for up to 4 hours, with the air impacting the agar surface through a rotating slit plate at a flow rate of 15 l/m
- This configuration ensures:
 - No dehydration of the agar media
 - The ability to identify the exact moment contamination occurs
 - Reduced contamination risk, as operator intervention is limited to setup only
 - Lower operating costs thanks to the use of a single Petri dish for 4-hour session



Fixed Plate Version:

- Allows continuous air sampling for up to 3 hours at a flow rate of 25 l/m on a fixed Petri dish, maintaining stable and consistent airflow for short-to-mid duration monitoring cycles.
- This version is ideal for processes requiring simplified operation and shorter sampling intervals.



OPERATIONAL AND REGULATORY ADVANTAGES

The GENIUS SYSTEM is designed to make microbiological air monitoring easier, safer, and more compliant:

- Management of up to 24 sampling satellites from a single software/console
- Continuous sampling for up to 4 hours (rotating plate) or 3 hours (fixed plate)
- User-friendly guided operation through each sampling phase
- Each satellite is independent from the other ones
- Compliance with 21 CFR Part 11 and Data Integrity principles

ADVANCED CONNECTIVITY AND DATA MANAGEMENT

GENIUS satellites are interconnected via RS485 Modbus RTU protocol and can transfer data to the BAS Software, ORUM's platform for data management, reporting, and traceability.

The GENIUS SW (installed on a mobile console running on Linux OS) and BAS SW (for Windows PC environments) work to manage:

- Sampling processes and results
- User permissions and audit trails
- Instrument configuration and environmental parameters

This architecture ensures complete control, data security, and real-time synchronization between production and Quality Control departments.

WHO SHOULD ADOPT GENIUS SYSTEM?

- **RABS and Isolator Manufacturers because it** simplifies the designs and delivers customers a cutting-edge monitoring solution that saves space and reduces installation complexity
- **Pharmaceutical and Medical Device Manufacturers:** enhance the monitoring capabilities with continuous, real-time data—without the need for extensive engineering modifications.
- **Healthcare Facilities and Pharmacies:** especially those with limited engineering resources can benefit from GENIUS's easy installation and user-friendly operation.

A NEW STANDARD IN MICROBIAL AIR MONITORING

Thanks to the GENIUS SYSTEM, ORUM sets a new benchmark in environmental monitoring technology, delivering precision, flexibility, and compliance for pharmaceutical and biotech industries seeking to meet the highest standards of sterile manufacturing.

For more information:

ORUM INTERNATIONAL

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