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WORLDWIDE SOLUTIONS

# Continuous Microbial Monitoring

## in Aseptic Manufacturing Cleanrooms Following EU GMP Annex1:2020, ISO 14698:2003 & EN17141:2020

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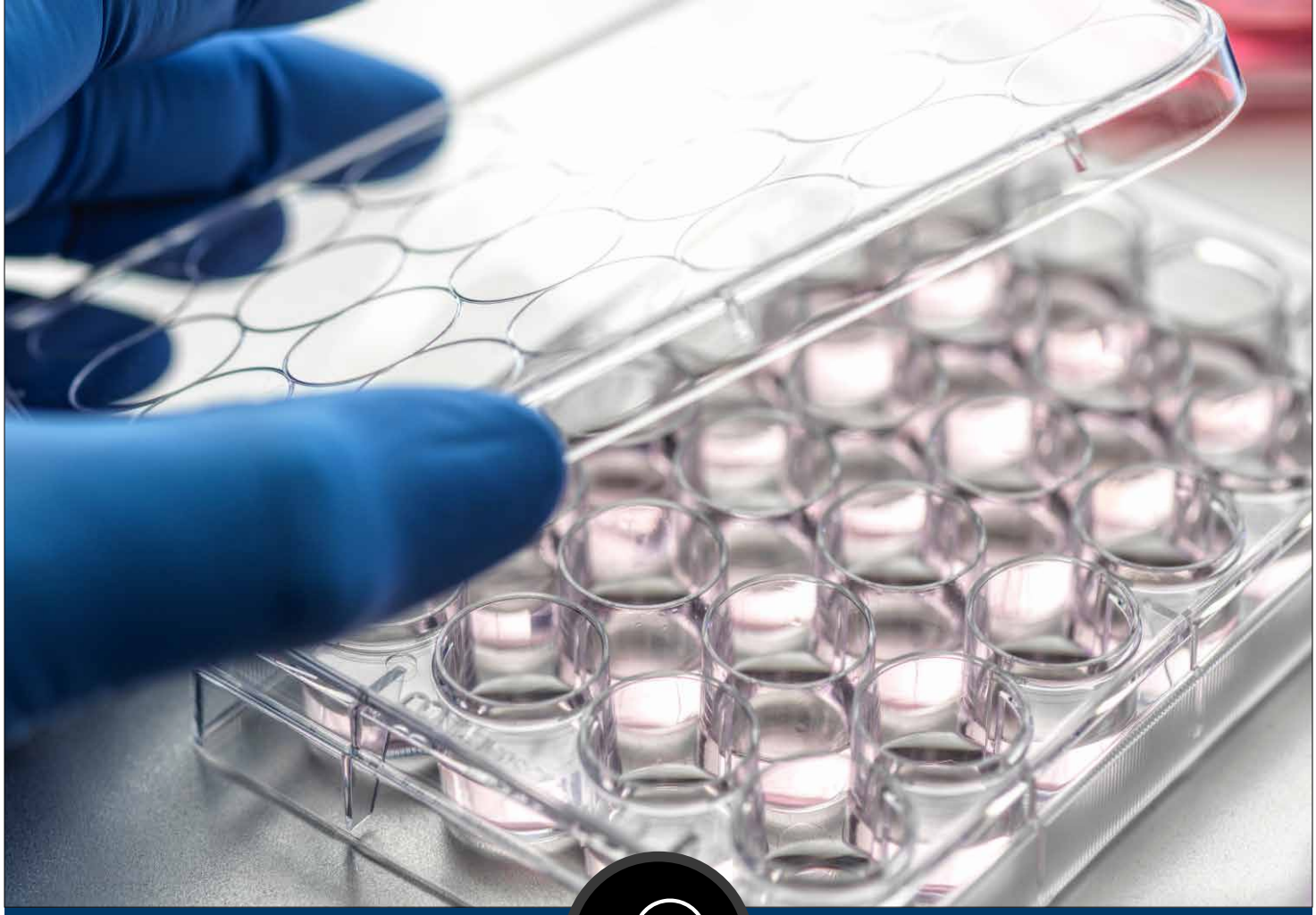


## Overview

Contamination Free Manufacturing (CFM) of Sterile injectable pharmaceutical products has historically involved particle control and removal.

Although yield-destroying and batch destroying defects are often traced to process non-uniformities, a majority of the effort to control contamination in Pharma facilities has focused on particle control.


Remote Active Count (ActiveCountR) Continuous Microbial Monitoring System.

# Continuous Monitoring Made Easy

## What is the Remote Active Count (RAC)?

Designed to meet the industry need for continuous trouble-free operation and flexible running parameters. The RAC ActiveCountR sample head can be operated via the local start/stop button or remotely via a software interface connected to a Real Time Monitoring System (RTMS).

The compact size provides true “plug and play” functionality in an easy-to-use package that quickly integrates into the real-time monitoring systems.

> 9.24 Continuous viable air monitoring in grade A (e.g. air sampling or settle plates) should be undertaken for the full duration of critical processing, including equipment (aseptic set-up) assembly and critical processing. A similar approach should be considered for grade B cleanrooms based on the risk of impact on the aseptic processing. The monitoring should be performed in such a way that all interventions, transient events and any system deterioration would be captured and any risk caused by interventions of the monitoring operations is avoided.

EU GMP Annex1:2022 Section 9.24 Statement on continuous air monitoring during Aseptic Manufacturing Processes.

Whether you are sampling within a cleanroom or inside of a Biosafety Cabinet, Laminar Flow Bench, or Isolator/RABs system the ActiveCountR will meet your cGMP compliant monitoring needs.

The ActiveCountR was built for the new EU GMP Annex1 requirement of continuous monitoring during aseptic operations in Grade A/B environments.

## What Applications Are Air Samplers Used In?

Cleanroom Monitoring is a regular commitment required to continuously (during aseptic manufacturing) monitor the manufacturing environment, record the environmental data and alert users of critical environmental conditions that may impact on product sterility and safety.

The Remote Active Count can also be fully integrated into a RTMS where other environmental monitoring sensors are connected and gathering environmental data. Applications where RTMS and the RAC are used are outlined in the Applications box.


Overview of applications where continuous microbial monitoring can be used.

## Fundamentals of Air Sampling

An air sampler is a device used in cleanroom applications to monitor airborne contaminants such as microorganisms. These devices capture viable particles on agar media, which are then incubated to detect and quantify microbial contamination. Anything that grows on the media dish is known as a colony forming unit (CFU) and there are limits on CFU growth for different Cleanroom grades. The table below indicates the limits of CFU's based on a 1m3 sample of air.

| Grade | Air sample CFU /m³ | Settle plates (diam. 90 mm) CFU /4 hours[a] | Contact plates (diam. 55mm), CFU / plate[b] | Glove print, Including 5 fingers on both hands CFU / glove |
|---|---|---|---|---|
| A | | No growth[c] | | |
| B | 10 | 5 | 5 | 5 |
| C | 100 | 50 | 25 | - |
| D | 200 | 100 | 50 | - |

EU GMP Annex1:2022 Table 6: Maximum action limits for viable particle contamination.

# EU GMP Annex 1 Overview

EU GMP Annex 1 mandates (section 9.24) continuous monitoring of aseptic environments, particularly in Grade A/B cleanrooms. This requirement ensures that environmental conditions are consistently controlled to prevent microbial contamination during critical manufacturing processes. Annex 1 emphasizes the development of a comprehensive Contamination Control Strategy (CCS) to manage and mitigate contamination risks effectively.

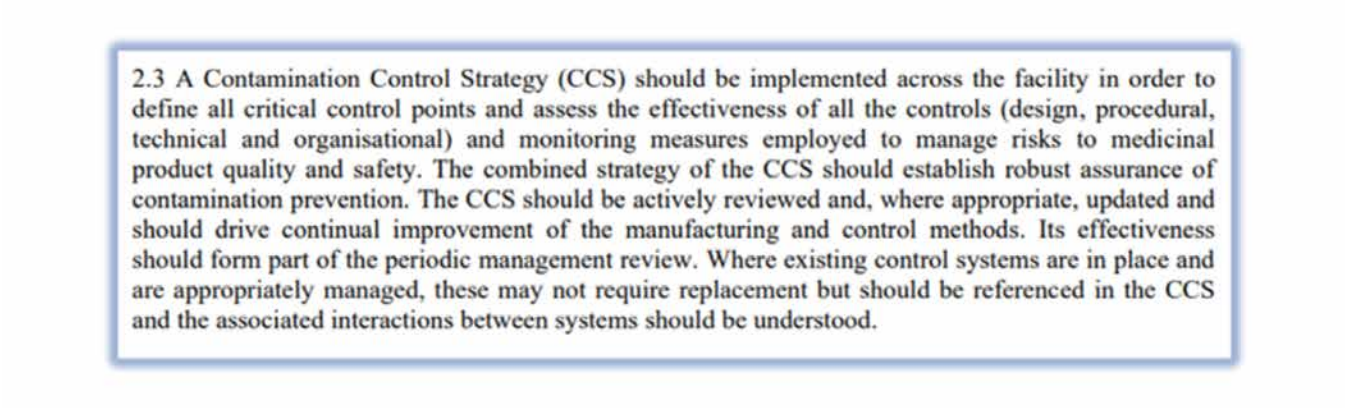
EU GMP Annex1:2022 covers various aspects of sterile manufacturing, including the design and maintenance of cleanrooms, contamination control strategies, environmental monitoring, personnel training, and equipment validation.

Cleanrooms are categorized into different grades based on their cleanliness levels, with specific requirements for each grade to minimize the risk of microbial, particulate, and endotoxin contamination. The guidelines emphasize the importance of a comprehensive contamination control strategy (CCS) that includes regular monitoring and review of all critical control points to ensure the effectiveness of contamination prevention measures.

***The manufacture of sterile products is subject to special requirements in order to minimize risks of microbial, particulate and endotoxin/pyrogen contamination***

Environmental monitoring is a key aspect of the guidelines, detailing the procedures for routine monitoring of air quality, surfaces, and personnel to detect any potential sources of contamination.

Personnel working in cleanrooms must be adequately trained and regularly assessed to maintain aseptic conditions.



2.3 A Contamination Control Strategy (CCS) should be implemented across the facility in order to define all critical control points and assess the effectiveness of all the controls (design, procedural, technical and organisational) and monitoring measures employed to manage risks to medicinal product quality and safety. The combined strategy of the CCS should establish robust assurance of contamination prevention. The CCS should be actively reviewed and, where appropriate, updated and should drive continual improvement of the manufacturing and control methods. Its effectiveness should form part of the periodic management review. Where existing control systems are in place and are appropriately managed, these may not require replacement but should be referenced in the CCS and the associated interactions between systems should be understood.

EU GMP Annex1:2022 Section 2.3 Overview of a Contamination Control Strategy.

The guidelines also provide detailed requirements for the design, qualification, and validation of equipment and processes used in sterile manufacturing. This includes ensuring that all equipment and materials used in cleanrooms are appropriately sterilized and maintained to prevent contamination.

Another update that was interesting in Annex1 is that it mandates the use of isolators and Restricted Access Barriers (RABS) to enhance aseptic conditions in the manufacture of sterile products. Isolators ensure grade A conditions through physical barriers and bio-decontamination processes, while RABS provide a controlled environment using rigid-wall enclosures and integrated gloves. Both technologies aim to minimize human intervention, thus reducing the risk of microbial contamination during critical processes. Continuous Microbial monitoring is used inside these RABs, Isolators and BSC devices.

## Types of Impaction Air Samplers

**Portable Air Samplers**: Designed for flexibility and mobility, these devices are used for spot checks and certification monitoring. They are cost-effective, quick to deploy, and ergonomic, making them suitable for various applications, including pharmaceutical, medical device, and food and beverage industries.

**Continuous Air Samplers**: Fixed solutions integrated into cleanroom environments for ongoing monitoring during production processes. They are crucial for ensuring continuous compliance with regulatory standards by providing real-time data on airborne contaminants.

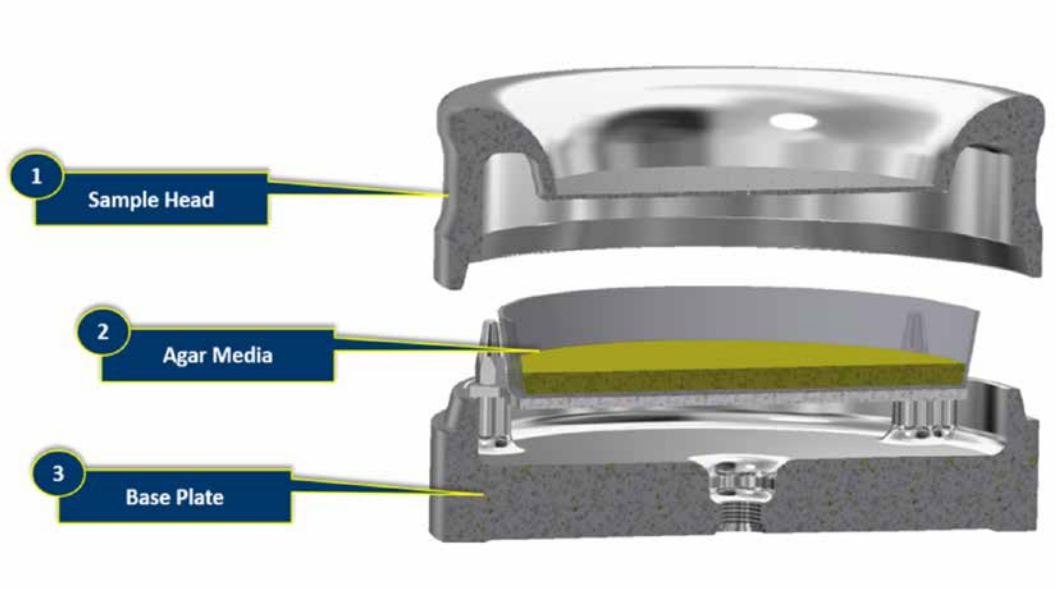

# Remote Active Count (RAC) System

The RAC system is designed for continuous microbial monitoring. The AcriveCountR sample head is designed for optimum performance and impaction velocity. Offering Physical and Biological efficiencies to ensure high recovery rates of microorganisms and viable particles in the cleanroom. The Flow is controlled using a valve system connected to an external vacuum pump through a critical orifice with a flowrate of 1cfm (28.3L/min).


RAC System continuous microbial monitoring system.

# How Air Samplers Work

**Impaction Technology**: Impaction air samplers collect airborne particles by directing an air stream onto a solid collection surface. The critical parameter, d50, represents the particle size at which 50% of particles impact the media, ensuring accurate sampling.




Cross Section of ActiveCountR sample head with agar media and base plate

# Physical and Biological Efficiencies

**Physical Efficiency**: The ability of the sampler to capture and retain airborne particles during sampling across a wide size range, ISO 14698:2003 requires a resolution sensitivity to 1 micron.

The actual design, flowrate, number of holes or slits in the sample head, their size and their distance to the agar media below in the sample dish equate to the physical efficiency of the air sampler and its ability to capture particles of various sizes based on the impaction velocity and the d50.

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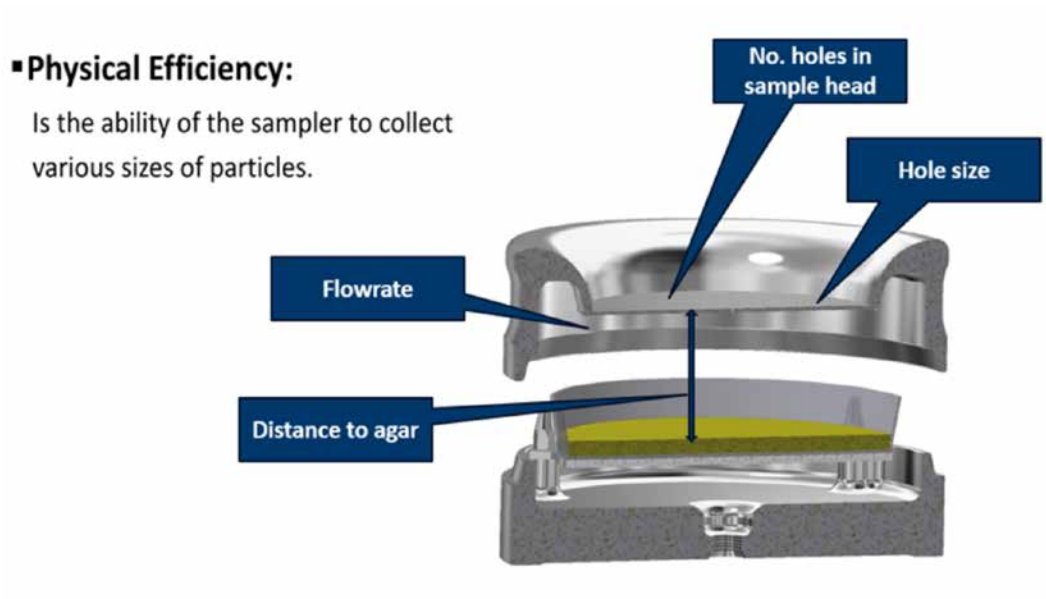



Overview of the design parameters in ActiveCountR sample head that effect Physical Efficiency

**Biological Efficiency**: The ability of the sampler to effectively grow the captured microorganisms on the media without rendering them unculturable.


Impaction velocity is a critical parameter that effects biological efficiency of the air sampler

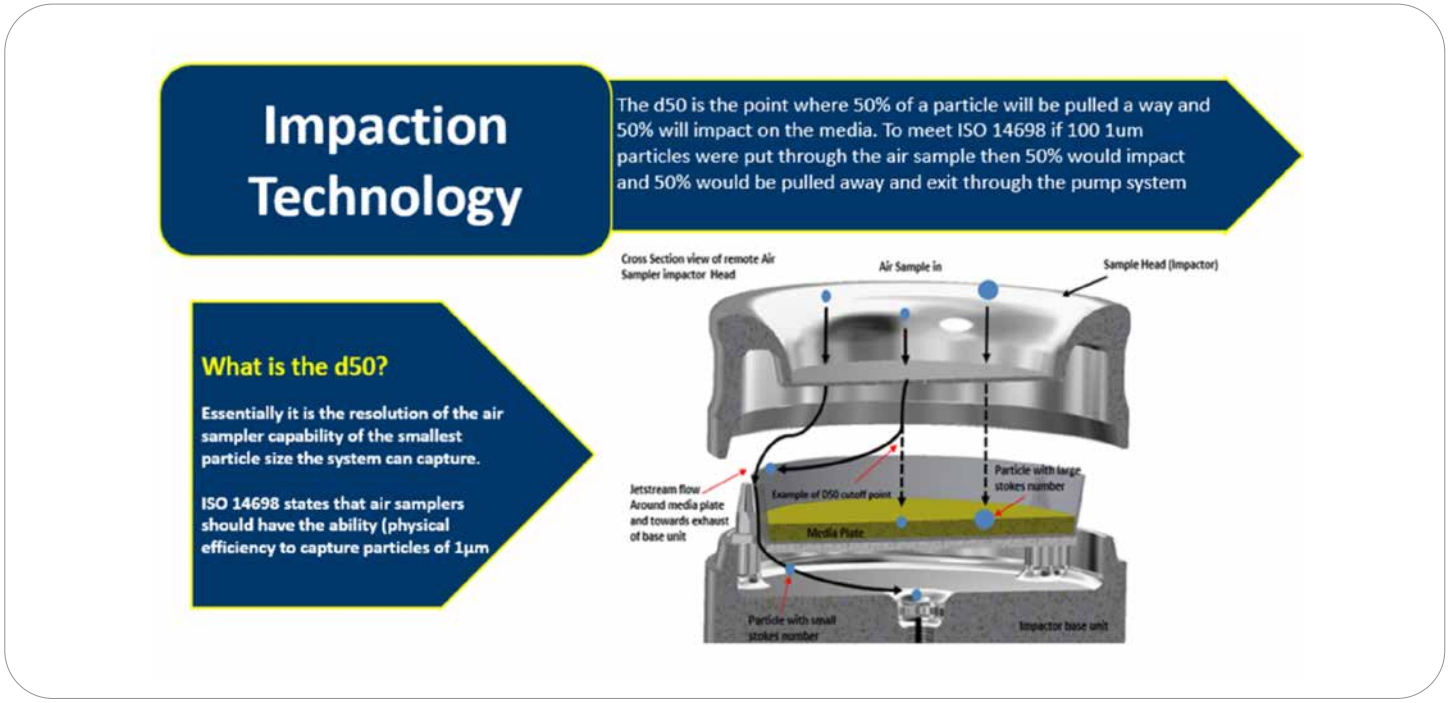



Diagram of how the Air Sampler works in capturing particles down to 1µm size (d50 resolution)

***ISO 14698-1:2003, A.3.4.2(a)(1): "Impact velocity of the air hitting the culture medium must be high enough to allow the entrapment of viable particles down to approximately 1 µm."***

# What is the Optimum Impaction Velocity

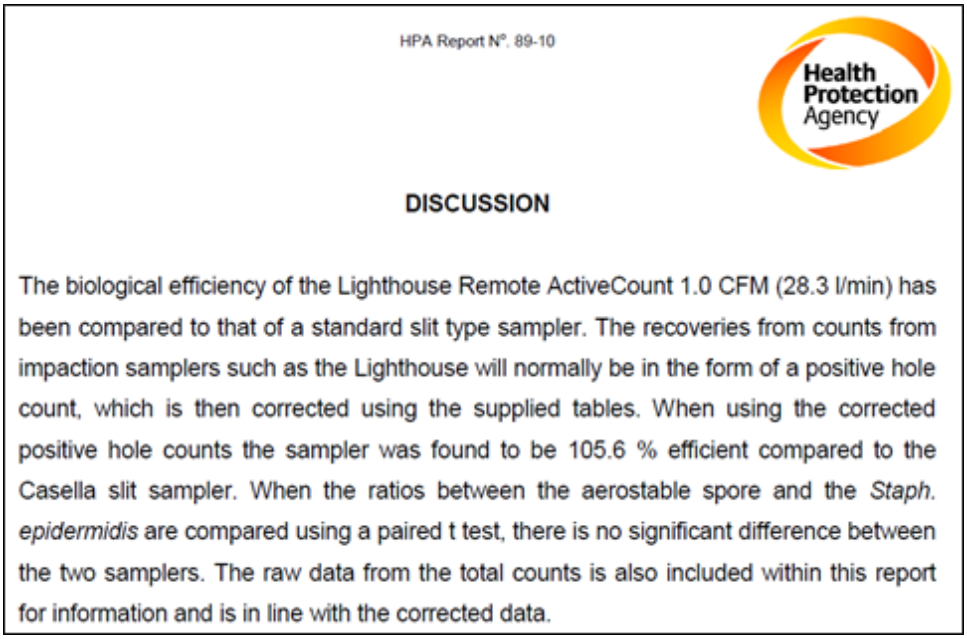
From a biological collection perspective, if the impaction velocity is excessively high, the sampler can kill or mechanically damage microorganisms, making them unviable for culture. Conversely, if the velocity is too low, the microorganisms may not sufficiently embed into the agar, rendering them unculturable. Additionally, at low velocities, there is a higher likelihood that particle-bound microbes will remain in the air stream and fail to impact the agar surface.

If a stream of gas undergoes a sharp change in direction, the particles it transports will tend to continue in their original direction so much the more as the ratio of their mass to their linear dimensions is larger. Particles having different dimensions and densities will thus follow different trajectories and may not be collected due to their inertia.

The impact efficiency can be expressed in terms of a dimensionless parameter called the Stokes number, which takes account of the physical laws that govern the motion of the particles in a fluid moving under laminar-flow conditions.

With the many different models of air samplers on the market all with different designs and flow rates it is important to understand that these air samplers require an external 3rd party evaluation to validate their effectiveness in microbiological recovery efficiencies for Biological and Physical efficiencies.

The required microbiological recovery efficiencies for impaction air samplers are critical to ensure accurate environmental monitoring in cleanrooms. Generally, a good microbial air sampler should have a recovery efficiency of around ≥70% to ≥100% for various particle sizes, ensuring effective capture and culturing of microorganisms. This efficiency ensures that viable microorganisms are adequately collected without causing significant physical damage due to high-velocity impacts, thus maintaining accurate microbial monitoring.



HPA Report N°. 89-10

Health Protection Agency

**DISCUSSION**

The biological efficiency of the Lighthouse Remote ActiveCount 1.0 CFM (28.3 l/min) has been compared to that of a standard slit type sampler. The recoveries from counts from impaction samplers such as the Lighthouse will normally be in the form of a positive hole count, which is then corrected using the supplied tables. When using the corrected positive hole counts the sampler was found to be 105.6 % efficient compared to the Casella slit sampler. When the ratios between the aerostable spore and the *Staph. epidermidis* are compared using a paired t test, there is no significant difference between the two samplers. The raw data from the total counts is also included within this report for information and is in line with the corrected data.

Sample report from HPA based in UK where RAC ActiveCountR was tested for biological efficiency against a reference standard.

# Fundamental Characteristics for Selecting the Right Microbiological Air Sampler

- Reliability Of Data – data Integrity
- Reproducibility & Accuracy
- High Physical Efficiency in Particle Collection range
- Biological Efficiency ability to successfully culture sample particles
- Sterilizability – easy to clean with no crevices or protruding buttons, switches etc.
- Ease Of Operation – lightweight and small footprint
- Compliance with International Regulation d50 down to 1µm (ISO 14698)
- No Stress on Collected Microbes – Biological Efficiency
- HEPA filtered exhaust – captures viable
- particles that have not impacted
- Touchscreen interface – reduces contact and potential particle generation
- Battery operated for better portability on portable units
- Remote sample options – offer more flexibility
- Gas connector options for testing gases to ISO 8573 requirements
- Local or field calibration options from supplier
- Easily autoclaved parts, sample head and base place as well as media holder plate
- Validated for collection efficiency by third party
- Cleanroom friendly material and enclosure

# Agar Media Selection & Validation

**Choosing the Best Collection Media**: Selecting the best collection media for microbiological culture is a common question among microbiologists and often a topic of debate. According to the FDA, the microbiological culture media used in environmental monitoring must be validated and capable of detecting fungi (i.e., yeasts and molds) as well as bacteria. The media must be incubated under appropriate conditions of time and temperature to ensure accurate results.


Example of TSA 90mm agar media widely used in cleanrooms

## Commonly Used Agars

The most widely used agars in environmental monitoring are:

- Tryptone Soya Agar (TSA): Primarily used for aerobic bacteria.
- Sabouraud Dextrose Agar (SDA) / Sabouraud Maltose Agar (SMA): Commonly used for fungi (yeasts and molds).

## Optimal Media for Environmental Monitoring

One study suggests that using TSA with 1% glucose and incubating it at 25°C for 5 days can serve as an all-purpose medium for both bacteria and fungi, including molds and yeasts. The study concluded that while SDA alone is not suitable as a general-purpose environmental medium, TSA with 1% glucose can enhance fungal recovery to the same level as SDA. This makes TSA with glucose a practical choice, especially in busy pharmaceutical applications, as it allows for the use of a single medium for comprehensive environmental monitoring. However, if there is a change in the agar used, validation studies should be conducted to ensure its effectiveness.

## Validation of Culture Media

It is essential that whatever culture media is used, it should be validated to support the growth of the organisms being cultured. This validation ensures that the media can reliably detect and support the growth of the targeted microorganisms, providing accurate and consistent environmental monitoring results. By understanding the strengths and limitations of different culture media and ensuring proper validation, microbiologists can effectively monitor and maintain the cleanliness of cleanroom environments.

# Example of a Validation Protocol

**1. Growth Promotion Testing**:

Inoculate TSA and SDA plates with 10-100 CFU of Bacillus subtilis, Aspergillus brasiliensis, and other relevant organisms.

Incubate TSA at 30-35°C for 3 days and SDA at 20-25°C for 5 days.

Compare the number of CFUs on the test plates to control plates to ensure at least a 70% recovery rate.

**2. Sterility Testing**:

Incubate uninoculated TSA and SDA plates at 30-35°C for 3 days and 20-25°C for 5 days respectively.

Ensure no microbial growth is observed.

**3. Environmental Suitability Testing**:

Place TSA and SDA plates in different areas of the cleanroom.

Sample air using an impaction air sampler.

Incubate the plates under specified conditions and evaluate the number of colonies formed.

By following these steps and adhering to regulatory guidelines, you can ensure the agar media used in your cleanroom's microbiological air sampling is validated, providing reliable and accurate results.

# Contamination Control Strategy (CCS)

**ISO 14698 and EN 17141**:

Both ISO 14698 and EN 17141 emphasize the importance of a comprehensive CCS. This strategy involves identifying potential contamination sources, implementing control measures, and continuously monitoring and assessing the effectiveness of these measures. Key components include risk assessment, regular monitoring, and documentation to ensure ongoing compliance and improvement


Overview of a CCS based on EU GMP Annex1 Guidelines.

A CCS should be implemented across the facility to define critical control points and assess the effectiveness of all controls and monitoring measures to manage risks to product quality and safety. The CCS should be actively reviewed, updated as necessary, and drive continuous improvement in manufacturing and control methods. Its effectiveness should be part of the periodic management review. Existing control systems should be referenced in the CCS, and their interactions should be understood.

A CCS is a documented plan that outlines all the measures and procedures in place to control contamination in a manufacturing facility. It's a critical component of Good Manufacturing Practice (GMP) guidelines, especially for sterile product production.

## Why is a CCS Important?

The primary goal of a CCS is to ensure that the sterile medicinal products are free from contamination, which is crucial for patient safety. By systematically controlling and monitoring all potential sources of contamination, manufacturers can maintain high standards of product quality and comply with regulatory requirements.

**In Practice**:

Imagine a pharmaceutical company manufacturing sterile injectable drugs. Their CCS would include:

- Detailed procedures for gowning and handwashing to ensure personnel do not introduce contaminants.
- Use of isolators or Restricted Access Barrier Systems (RABS) to protect the sterile environment from human intervention.
- Routine air and surface sampling to detect any microbial contamination early.
- Regular training sessions for all staff working in cleanrooms to reinforce good aseptic practices.

In summary, a CCS is like a detailed blueprint for maintaining cleanliness and sterility in the production of sterile medicinal products, ensuring the highest standards of patient safety and product quality.

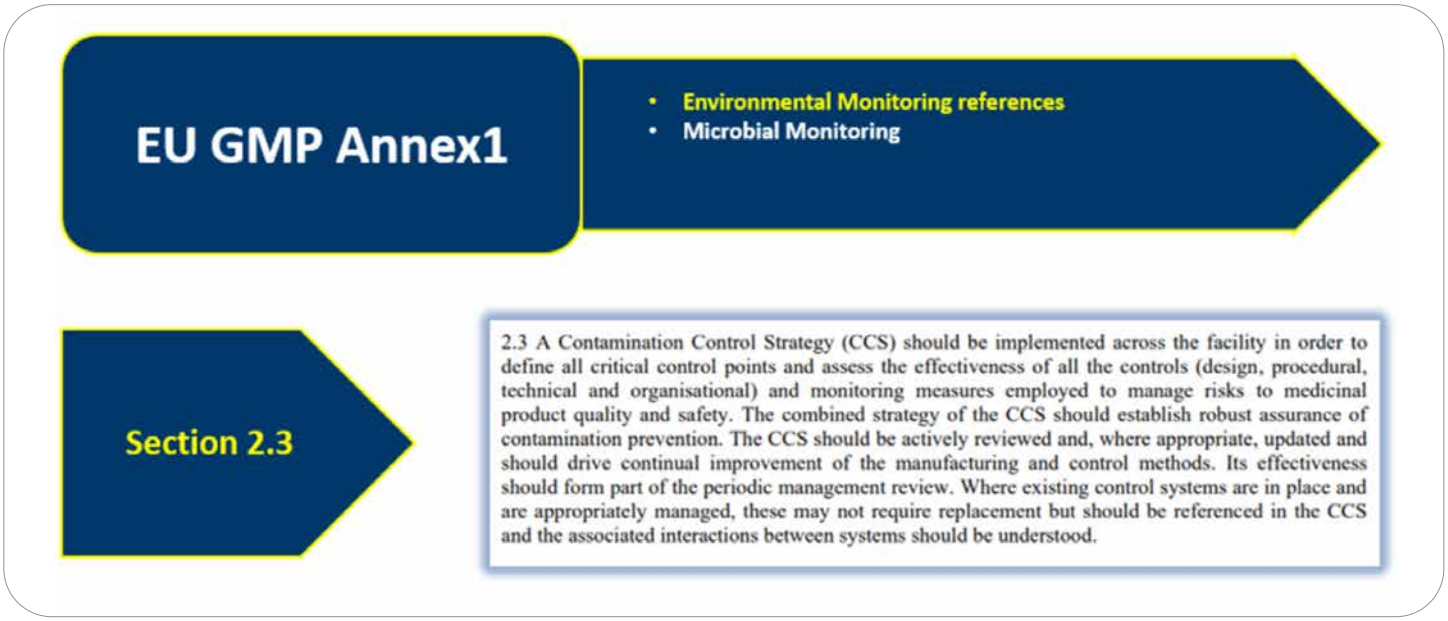
## Contamination Sources and Control Measures

### Common Sources of Contamination

- Airborne Particles: Dust, fibers, and other microscopic particles.
- Personnel-Generated Particles: Skin flakes, hair, and clothing fibers.
- Equipment and Materials: Machinery and materials introduced into the cleanroom.
- HVAC Systems: Inadequate filtration or poorly maintained systems.
- Processes and Cleaning Procedures: Manufacturing processes and ineffective cleaning methods.

### Control Measures

- Air Filtration: Using HEPA filters to remove particles from the air.
- Sterilization: Sterilizing equipment and materials to eliminate microorganisms.
- Restricted Access: Limiting access to cleanrooms to trained and qualified personnel only.
- Monitoring and Testing: Regular environmental monitoring to ensure control measures are effective.




EUGMP Annex1:2022 Statement on a Contamination Control Strategy.

# Case Study: RAC System Implementation

### Setup and Integration

The RAC system was integrated into a pharmaceutical cleanroom environment to provide continuous monitoring of airborne contaminants inside a Biological Safety Cabinet used for the aseptic processing of ATMP's. The system was configured to sample air at 1 CFM, ensuring optimal impaction velocity and accurate data collection.


Overview of Environmental Monitoring of BSC cabinet used in ATMP aseptic Processing.

### Results and Benefits

- Improved Compliance: The system met all regulatory requirements, including EU GMP Annex 1.
- Enhanced Data Integrity: Real-time data collection and logging ensured accurate and reliable monitoring.
- Reduced Contamination Risks: Continuous monitoring allowed for immediate detection and response to contamination events.

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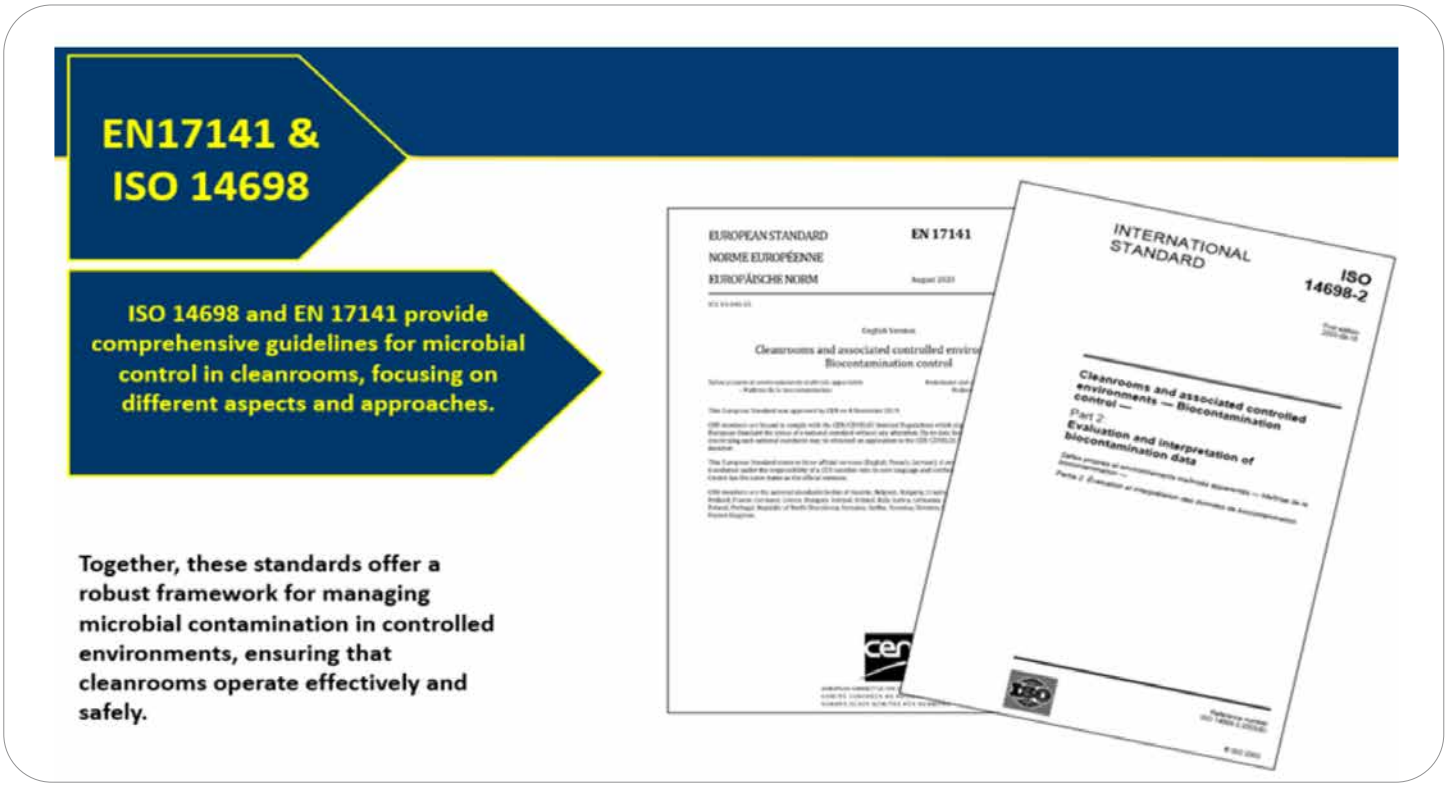
### Conclusion

Continuous microbial monitoring is a fundamental aspect of maintaining sterility in cleanroom environments. The RAC system, with its advanced features and compliance with international standards, provides an effective solution for ongoing environmental monitoring. Implementing a robust CCS as outlined in ISO 14698 and EN 17141 is essential for ensuring product quality and patient safety.

## What Standard should we follow for Microbial Monitoring?

We already have covered EU GMP Annex1:2022 so let's look at ISO 14698:2003 and EN17141:2020.




# ISO 14698:2003 Overview

**Part 1**: ISO 14698-1:2003 outlines the general principles and methods for biocontamination control in cleanrooms and associated controlled environments. This standard establishes a formal system for assessing and controlling biocontamination, ensuring that cleanroom technology effectively monitors and mitigates contamination risks. Here's an overview of the key elements of ISO 14698-1:

### Key Principles of ISO 14698 Part 1

### Hazard Identification and Risk Assessment

- Identify Potential Hazards: Determine sources of biocontamination that could impact the production process or product quality.
- Risk Assessment: Evaluate the likelihood of these hazards occurring and identify preventive or control measures.

### Designation of Risk Zones

- Risk Zone Classification: Classify different areas within the cleanroom based on the level of contamination risk.
- Control Measures: Implement procedures and conditions to eliminate or reduce the chances of biocontamination within these zones.

### Control Limits and Monitoring

- Establish Control Limits: Define acceptable levels of biocontamination for each risk zone.
- Monitoring Schedule: Develop a regular monitoring schedule to observe and measure biocontamination levels consistently.

### Corrective Actions

- Trigger Conditions: Set conditions that, when met, require immediate corrective actions.
- Corrective Procedures: Implement procedures to address and rectify biocontamination incidents.

### Verification and Documentation

- Verification Procedures: Establish tests and supplementary procedures to verify the effectiveness of the biocontamination control system.

### Personnel Training

- Training Programs: Develop and implement training programs for cleanroom personnel to ensure they are knowledgeable about biocontamination control practices and procedures.

### Objectives

- Promote Hygienic Practices: Ensure that all activities within the cleanroom adhere to high standards of cleanliness and hygiene.
- Minimize Contamination Risk: Reduce the risk of biocontamination affecting the production process or product quality.
- Ensure Compliance: Align cleanroom practices with international standards and regulatory requirements.

### Implementation

To implement ISO 14698-1 effectively, facilities need to establish a tailored formal system that addresses their specific needs and conditions. This includes setting up proper monitoring guidelines, training programs for personnel, and comprehensive documentation practices. The ultimate goal is to detect and control biocontamination promptly, ensuring a clean and safe production environment.

For more detailed information, you can refer to the official ISO 14698-1:2003 documentation and related resources on biocontamination control standards.

**Part 2**: ISO 14698-2:2003 provides guidance on the methods for evaluating and interpreting microbiological data collected in cleanrooms and controlled environments. This part of the standard is essential for ensuring that biocontamination control measures are effective and that the collected data accurately reflect the microbial contamination levels.

# Key Principles of ISO 14698 Part 2

### Evaluation of Microbiological Data

- Objective: To provide a standardized approach for evaluating microbiological data from cleanrooms.
- Methods: Describes various methods to estimate and interpret results obtained from viable particle sampling.

### Data Interpretation

- Guidance: Offers detailed guidance on how to interpret microbiological data to assess the level of biocontamination in different risk zones.
- Application: Ensures that the interpretation of data is consistent and aligns with the control measures outlined in ISO 14698-1.

### Corrective Actions and Verification

- Trigger Conditions: Defines conditions that trigger corrective actions when biocontamination levels exceed control limits.
- Verification Procedures: Includes procedures for verifying the effectiveness of biocontamination control measures.

### Objectives

- Standardized Evaluation: To ensure a consistent approach to evaluating microbiological data across different cleanrooms and controlled environments.
- Effective Control: To enhance the effectiveness of biocontamination control measures by providing clear guidelines for data evaluation and interpretation.

### Implementation

ISO 14698-2 should be used in conjunction with ISO 14698-1 to provide a comprehensive framework for biocontamination control. The standard helps cleanroom operators implement effective monitoring strategies, interpret microbiological data accurately, and take appropriate corrective actions to maintain cleanroom standards

By adhering to ISO 14698-2, organizations can ensure that their cleanroom environments are monitored effectively, biocontamination risks are minimized, and regulatory compliance is maintained.

For more detailed information, you can refer to the official ISO 14698-2:2003 documentation and related resources on biocontamination control standards.

Sampling (Section 5.3.2.1)

***"The appropriate sampling method and related procedures shall be selected and performed to reflect the complexity and variety of situations. Sampling shall be carried out using a device and method selected in accordance with the written procedure and in accordance with the instructions provided by the device***

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# Overview of EN 17141 Standard

### Evaluation of Microbiological Data

EN 17141:2020 is the European standard that establishes requirements and best practices for biocontamination control in cleanrooms and controlled environments. This standard supersedes the older EN ISO 14698-1:2003 and EN ISO 14698-2:2003 standards, providing a more comprehensive and updated framework for ensuring microbial control in various cleanroom applications.

### Key Principles and Requirements of EN17141:2020

### Biocontamination Control System

- EN 17141 emphasizes the implementation of a formal system for biocontamination control. This includes the identification and assessment of contamination sources, risk management, and the establishment of monitoring programs to ensure ongoing control of microbial contamination.

### Risk Assessment

- The standard requires a thorough risk assessment to identify potential sources of biocontamination, assess the likelihood and impact of contamination, and determine appropriate control measures. This helps tailor the biocontamination strategy to the needs and risks of the cleanroom environment.

### Environmental Monitoring Plan

EN 17141 outlines the need for a detailed environmental monitoring plan. This plan should include:

- Monitoring locations and frequencies
- Establishment of alert and action limits

- Documentation systems for recording and trending data
- Training and education for personnel involved in monitoring activities

**Microbiological Measurement Methods**

- The standard provides guidance on selecting appropriate microbiological measurement methods, including volumetric air sampling, surface sampling, and culture media selection. It emphasizes the validation of these methods to ensure accurate and reliable data collection.

**Demonstration of Control**

- A critical aspect of EN 17141 is the requirement to demonstrate the effectiveness of the biocontamination control system. This involves regular analysis and trending of microbiological data, investigation of out-of-specification results, and maintaining thorough records to support audits and verification processes.

**Continuous Improvement**

- The standard advocates for continuous review and improvement of the biocontamination control system. This includes regular updates to the risk assessment, monitoring plan, and control measures based on new data, technological advancements, and changes in the cleanroom environment.

**Implementation**

To comply with EN 17141, organizations should conduct a gap analysis to identify discrepancies between current practices and the new standard. This process involves reviewing and updating the Quality Management System (QMS) to incorporate the requirements of EN 17141, ensuring all potential contamination sources are identified and managed effectively.

**Key Benefits**

- Enhanced Biocontamination Control: By following EN 17141, organizations can ensure a high level of microbial control in cleanrooms, reducing the risk of contamination and improving product safety and quality.
- Regulatory Compliance: Adhering to this standard helps organizations meet regulatory requirements, avoiding non-compliance risks and potential penalties.
- Improved Risk Management: The risk-based approach of EN 17141 allows for targeted and effective control measures, optimizing resource use and enhancing overall cleanroom management.

For more detailed information, you can refer to the official EN 17141:2020 documentation and related resources on biocontamination control standards.

*References:*

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*2. Stewart, Grinshpun, Terzieva, Ulevicius and Donnelly. Effect of Impact Stress on Microbial Recovery on an Agar Surface. Applied and Environmental Microbiology, Vol. 61, No. 4, Apr 1995, p. 1232-1239.American Society for Microbiology.*

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*4. USP <1116>, Microbial Control and Monitoring of Aseptic Processing Environments. August 1, 2013.*

*5. EN 17144:2022*

*6. EU GMP, Annex 1:2022*

*7. ISO 14698:2003*

# Expand Your Knowledge

**Lighthouse Worldwide Solutions** offers comprehensive and industry standard-setting options for both possibilities, designed to meet your needs, abide by regulations, and keep your cleanroom clean.

**For more information on monitoring for contamination in cleanroom applications visit our knowledge center for the most comprehensive library of cleanroom monitoring applications, webinars, tech papers and more:**

**www.golighthouse.com/en/knowledge-center/**