Microbiological monitoring of clean rooms – A New Approach

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National GMP & Validation Forum

Hosted by PharmOut

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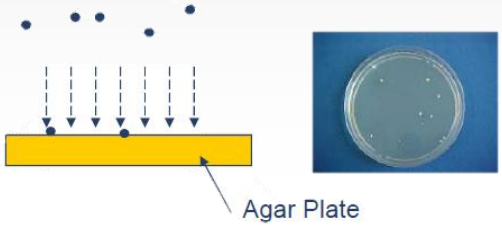
Current Airborne Contamination Control

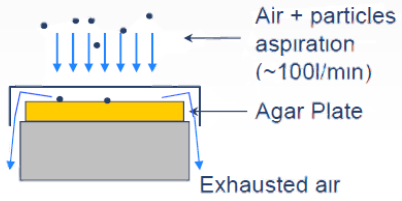
Passive monitoring

- On plate



Active monitoring

- Impactors
- Filtration
- Impingers



Potential sources of contamination:

People
Raw materials
Water
Air

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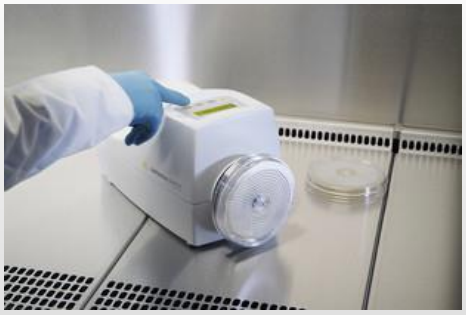
Limitations of Traditional Techniques

- Information only on cultivable flora (what can grow on the nutritive agar)
- Limited volume of air collected ($1m^3$)
- Saturation of collection media
- Result in days or weeks (incubation step for growth) = several days
- Short collection time (10 min)
- Air flow rate limited (to avoid stress to microorganisms) ~100 L/min



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Alternative solution - Patented wet cyclonic technology

- Captures and concentrates all airborne particles into sterile liquid collection media
  - Bio-contamination results beyond the cultivable flora (incl. viruses, pollens, allergens, endotoxins)
  - Access to alternative analysis (PCR, qPCR, Sequencing, ELISA, Mass Spectrometry)
  - Shorter time to results (hours instead of days)
  - Split up your sample for different analysis
- High Air Flow Rate 300l/min
  - Increase sample volume capabilities
  - Concentrating particles from 0.5 to 20µm
  - Long Time Monitoring option - Up to 6 hours sample collection time
- Validated method by third parties - conforms to ISO 14698

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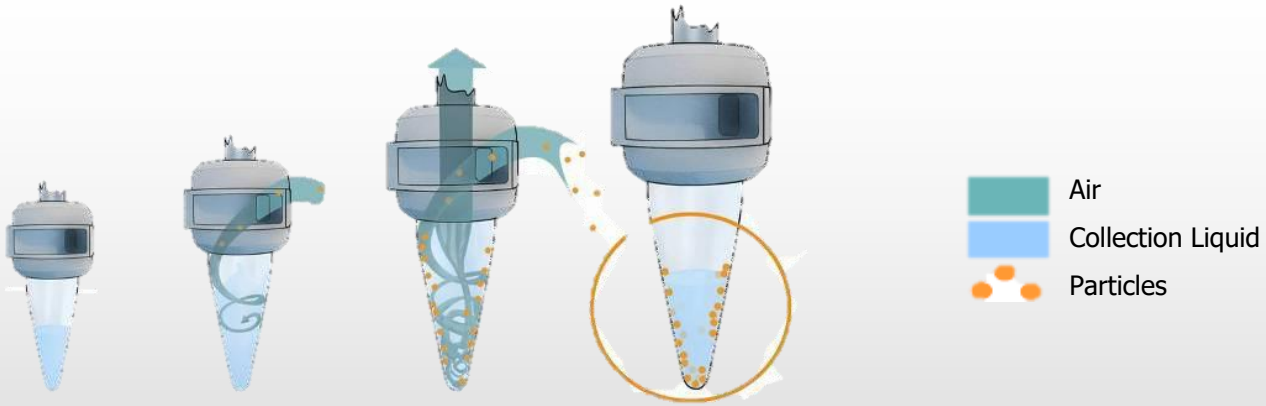
How it works - Patented wet cyclonic technology

Bertin Coriolis Technology

1. Pre-filled sterile cone with adapted collection liquid
2. Air & particles enters in the cone and forms a vortex: Aspirated particles are centrifuged with collection liquid on the wall
3. Particles are concentrated into the collection liquid



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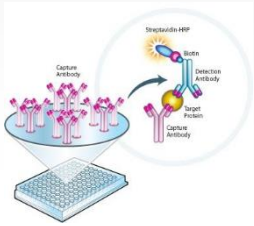
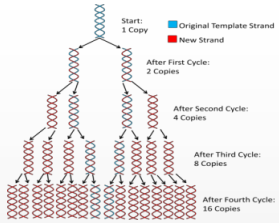
Compatible with Biological Analysis

- Culturing methods:
  - Based on the study of the main phenotypic characteristics of bacteria
- Immunological methods
  - Based on the recognition of a specific antigen of the agent
- Genetic methods
  - Based on the recognition of a specific nucleic acid sequence of the agent
- Spectrometry methods
  - Physical methods based on the recognition of molecular structures by their mass





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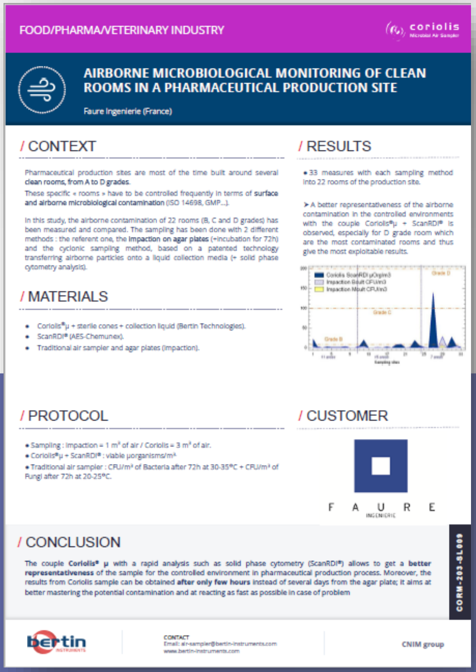
Case Study



FOOD/PHARMA/VETERINARY INDUSTRY

coriolis
Microbial Air Sampler

AIRBORNE MICROBIOLOGICAL MONITORING OF CLEAN ROOMS IN A PHARMACEUTICAL PRODUCTION SITE

Faure Ingenierie (France)

/ CONTEXT

Pharmaceutical production sites are most of the time built around several **clean rooms, from A to D grades.**

These specific « rooms » have to be controlled frequently in terms of **surface and airborne microbiological contamination** (ISO 14698, GMP…).

In this study, the airborne contamination of 22 rooms (B, C and D grades) has been measured and compared. The sampling has been done with 2 different methods : the referent one, the **impaction on agar plates** (+incubation for 72h) and the cyclonic sampling method, based on a patented technology transferring airborne particles onto a liquid collection media (+ solid phase cytometry analysis).

/ MATERIALS

- Coriolis®µ + sterile cones + collection liquid (Bertin Technologies).
- ScanRDI® (AES-Chemunex).
- Traditional air sampler and agar plates (impaction).

/ RESULTS

• 33 measures with each sampling method into 22 rooms of the production site.

➤ A better representativeness of the airborne contamination in the controlled environments with the couple Coriolis®µ + ScanRDI® is observed, especially for D grade room which are the most contaminated rooms and thus give the most exploitable results.

/ PROTOCOL

• Sampling : Impaction = 1 m³ of air / Coriolis = 3 m³ of air.
• Coriolis®µ + ScanRDI® : viable µorganisms/m³
• Traditional air sampler : CFU/m³ of Bacteria after 72h at 30-35°C + CFU/m³ of Fungi after 72h at 20-25°C.

/ CUSTOMER

FAURE INGENIERIE

/ CONCLUSION

The couple **Coriolis® µ** with a rapid analysis such as solid phase cytometry (ScanRDI®) allows to get a **better representativeness** of the sample for the controlled environment in pharmaceutical production process. Moreover, the results from Coriolis sample can be obtained **after only few hours** instead of several days from the agar plate; it aims at better mastering the potential contamination and at reacting as fast as possible in case of problem

CORM-203-SL009

bertin INSTRUMENTS

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CNIM group

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Case Study

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- 2 different sampling methods tested
  - impaction on agar plates (+incubation for 72h)
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Materials & Protocol

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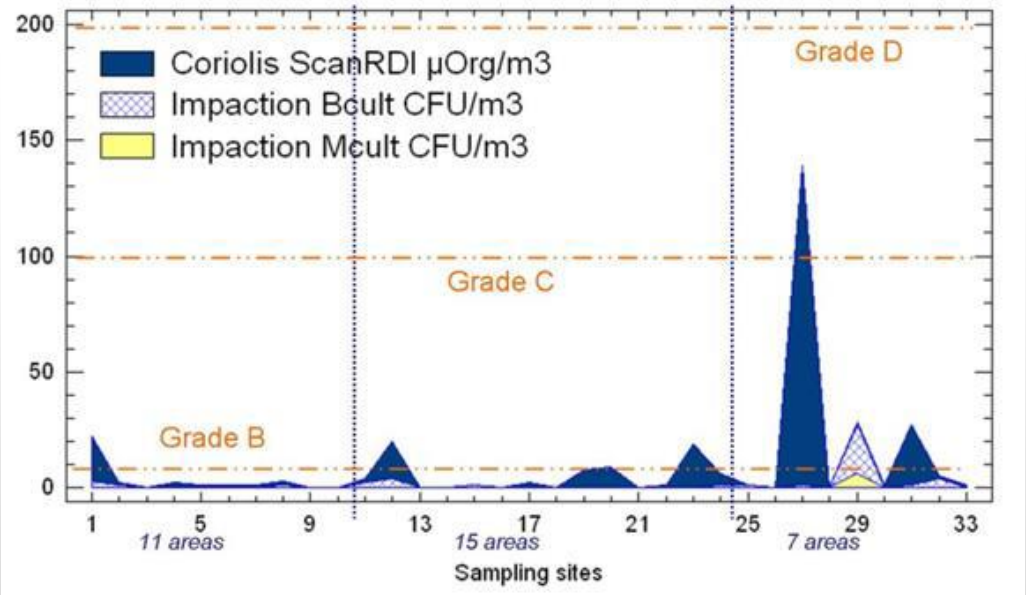
Results & Conclusion

- Using the **Coriolis® µ** with a rapid analysis method (e.g ScanRDI®) provided a **better representation** of the environment sampled
- The results from a Coriolis sample can be obtained **after only few hours** instead of several days from the agar plate
- Allows for a **faster response time** in the event of contamination



33 measurements with each sampling method into 22 rooms of the production site.

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Coriolis µ - Product

Designed for clean rooms, hospital and indoor air control

- High air flow rate: 300 L/min
- From 1 to 10 min
- Up to 6 hours sampling with Long Time Monitoring
- Light: 3 kg
- Easy decontamination
- Battery operated

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ANY QUESTIONS?

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