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New generation AIR SAMPLER
Quick & reliable air control

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).

Material

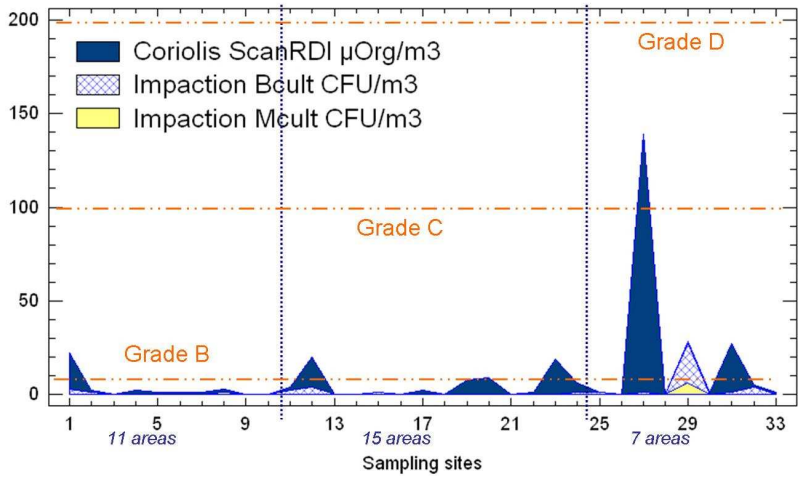
- Coriolis®µ + sterile cones + collection liquid (Bertin Technologies).
- ScanRDI® (AES-Chemunex).
- Traditional air sampler and agar plates (impaction).

Protocol

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

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.



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.

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