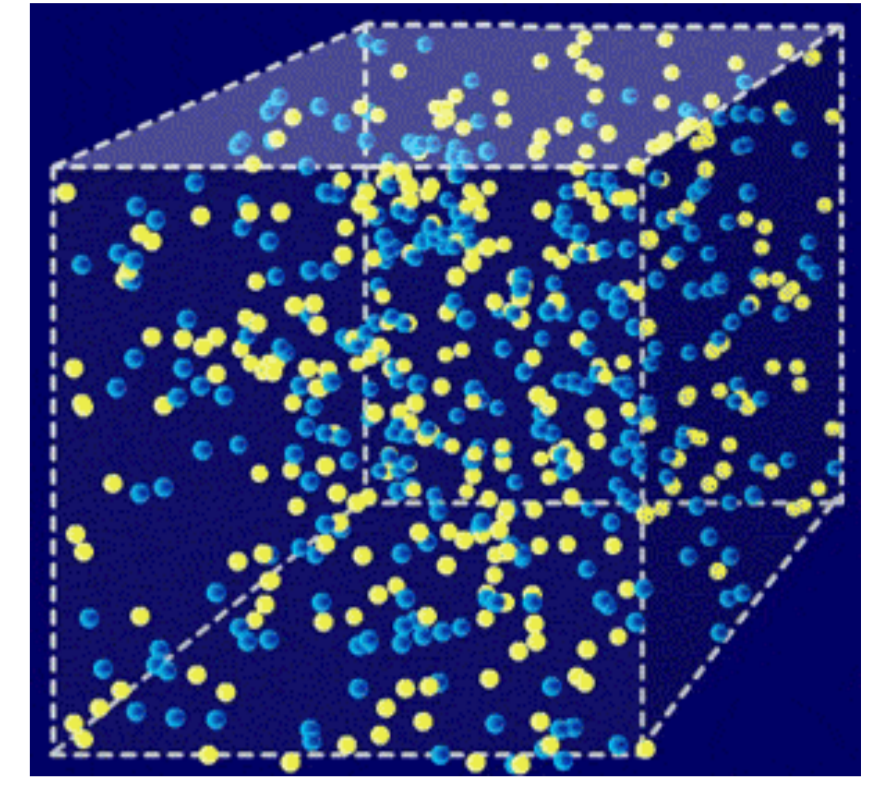


PARTICULATE QUALITY OF A CONTROLLED ATMOSPHERE AREA. COMPLIANCE WITH GOOD MANUFACTURING PRACTICES AT REST AND DURING ACTIVITY, HIGHLIGHTING OF FACTORS IMPACTING CONTAMINATION

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INTRODUCTION



The activity of chemotherapy preparation is constantly evolving :

- ⇒ It is increasing (+17% in our center in 5 years)
- ⇒ Particulate Quality monitoring in operation is recommended but rarely done in hospital pharmacies.

The pharmacist, who is responsible for this activity, must anticipate these changes.

We thus wanted to first demonstrate the compliance of our controlled atmosphere area with :

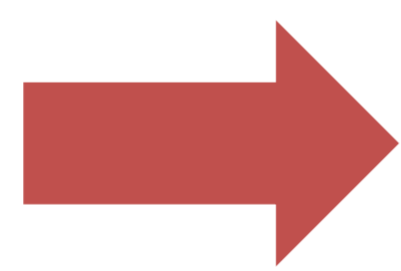
- ⇒ ISO 7 : at rest
- ⇒ ISO 8 : in activity

Then, we determined the factors significantly impacting the particle rate in order to design a mathematical model that predicts the number of particles and thus better control the increase in activity.

MATERIALS & METHODS

The particle count was carried out according to the requirements of the ISO7 and ISO8 standards

- particle size
- sampling plan
- volume
- duration
- height



We have systematically recorded the following factors :

- date,
- time,
- number of people present in the controlled area,
- temperature,
- pressure,
- sampling location,
- sampling conditions (at rest or in activity),
- equipment entering the ZAC mechanically cleaned or not.



For the statistical analysis, a grouping of sampling points by criticality sector (personnel entry and exit area, work area itself, material transfer and basket preparation area) was carried out. Data were analyzed to perform the multivariate models required for predictive mathematical modeling (significant variables at the $p=0.05$ threshold).

RESULTS

All 994 samples (from 16 counting points) in our 80m² depressed area comply with the ISO7 and 8 criteria for particulate contamination.

Predictive mathematical modelling of the number of particles is based on the significant criteria "time of day"; "location of sampling"; "number of people".



DISCUSSION AND CONCLUSION

Particulate quality criteria are met at rest and especially during activity (which is rarely evaluated). These results could be related to the technical quality of the air plant (all new air and 25 air changes /hour), the materials and characteristics of the PPE used (low particle release).

By taking into account the factors integrated in the mathematical models, smoothing the number of people over the day and increasing the cleaning of risk areas, it will be possible to guarantee and better understand the particular quality of our areas.

