Performance qualification (PQ) of a new isolator for reconstitution of cytotoxics

J.Gotzamanis[1], G.Bouguéon[1,2], M.Sangnier[1], A.Berroneau[1], S.Crauste-Manciet[1,2]
(1) Pharmaceutical Technology Department, Bordeaux university hospital (CHU de Bordeaux), France
(2) ARNA Laboratory-ChemBioPharm U1212 INSERM - UMR5320, CNRS - University of Bordeaux, France

Introduction

- The PQ checks the effectiveness of the biodecontamination cycles of the isolator and the airlocks in daily active conditions
- Realized in routine activity, 2 months after the supplier's one at the installation

Materials/methods

- Isolator : 15 surface samples and one active air sample using contact plates and an aerobiocollector, then stored into an oven (37°C) for 2 days and at room temperature for 5 days
- Airlocks : *Bacillus atrophaeus* strips inserted into 6 loads of material before a cycle, then inoculated into TSA media and stored into the oven for 7 days
- Particle counting at rest using a particle counter
- Media fill test by 3 pharmacy technicians

Results

nb : Positive and negative controls were proved correct for all these tests

	Surface samples	Active air samples
Right after general cycle	-	-
18 days after	-	-

✓ Effectiveness of the general cycle

	Airlock 1 strips	Airlock 2 strips
1st cycle	-	-
2nd cycle	-	-
3rd cycle	-	-

✓ Effectiveness of the airlocks cycles

	0,5µm particles	5µm particles
Our isolator	1200	**45**
Class A criteria	3520	20

✗ Improper particle counting

	Media fill test
Technician 1	-
Technician 2	-
Technician 3	-

✓ No contamination of the preparations

Discussion/conclusion

- The PQ validated the maintenance of the microbiological class.
- Particular class : particle counter handling error ? New particle counting has been performed and has been proved correct.

Important to carry out a PQ in addition to the supplier's one : reassured us when a potential non-conformity of the flowmeter measuring the amount of disinfectant blend was suspected.