Feedback from the temporary relocation of a sterile production activity

Maïté SANGNIER[1], Guillaume BOUGUEON[1,2], Aude BERRONEAU[1], Sylvie CRAUSTE-MANCIET[1,2]
[1] *Pharmaceutical Technology Department, Bordeaux University Hospital, Avenue de Magellan, 33604 Pessac, France*
[2] *ARNA Laboratoire ChemBioPharm U1212 INSERM - UMR 5320 CNRS, Université de Bordeaux, France*

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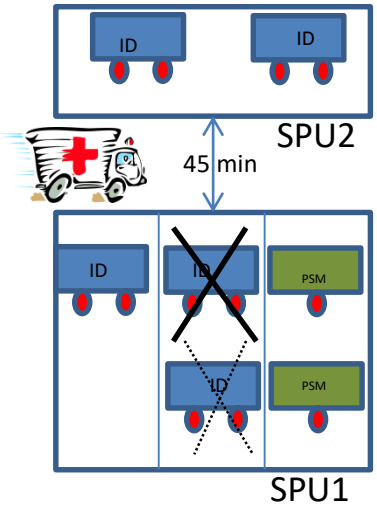
Context

Our university hospital has 3 sterile production units (SPU) on 3 different sites.

- renewal of a double isolator (ID) on SPU1 (our site): choice to close one of our 3 rooms.
- relocation of part of the production to SPU2, 45 minutes from our site (2 out of 6 shifts for 12 days) and to another room on our site with laminar flow hood (2 out of 6 shifts for 3 days).
- unfavourable context: growing activity (+6% in 2021), undersizing of SPU1, reduced workforce.

Need for an organisation to ensure continuity of care, and safety of preparation and staff



Multidisciplinary brainstorming meetings

- Pharmacists, technicians, managers, quality referents, hygiene, technical, biomedical and logistics departments of both sites
- Evaluation of several scenarios for each stage of the circuit

Quality of the preparation

- Waiting for the room to be re-qualified before resuming production
- No degradation of the usual controls (environmental, analytical and release)

Needs assessment

- Human resources reallocated daily
- Training needs (for the new isolator, for handling under hoods)
- Double stock of preparation material and products
- Regular and secure transport between the 2 SPU
- Important anticipation of prescriptions

Post-assessment

- Relocation during 12 working days
- 688 preparations (30%) were made in SPU2, only anticipated preparations (of which 450 were controlled by analytical assay)
- No increase in the number of non-conformities
- **Managing the unexpected**
- **High workload for pharmacists**
- **Overall satisfaction of the team**

Conclusion

This requires a very good knowledge of the two structures, close coordination and increased vigilance on the part of all staff.
In addition, a strong anticipation of prescriptions is required