







Université Lille 2 Droit et Santé

Financial assessment of aseptic preparation facilities in European hospital pharmacies

B. Dekyndt1, D. Meyer2, C. Barthélémy1, P. Odou1, 3. 1 - Department of Biopharmacy, Galenic and Hospital Pharmacy (EA GRIIOT 4481), Université Lille Nord de France, F-59000 Lille, France 2 - GETINGE LIFE SCIENCES, 31170 Tournefeuille France 3 - Department of Pharmacy, Regional University Hospital of Lille, CHU Lille, F-59000 Lille, France

OBJECTIVES

The drug manufacturing conditions in hospitals have become increasingly demanding and the use of Controlled Atmosphere Area (CAA) in compounding unit has been imposed. This study allowed to:

- make an inventory of fixtures of European aseptic manufacturing unit's practices;





- to compare, with real costs, CAA provided with isolators to CAA with Biological Safety Cabinets (BSC) in order to determine the most economical scheme in hospital and to develop a cost model estimating the CAA conception and functioning costs.

STUDY DESIGN

The study was conducted in Europe during seven months (From January 2011 to August 2011). Through email, telephone contacts and visits, a total of 43 hospitals have been interviewed (21 from France and 22 from other European hospitals). Hospitals were selected based on their size and activity of aseptic compounding.

The form was programmed in VBA (Visual Basic for Applications) to make filling easier and faster by hospital pharmacists

Hospitals were shared into the following two groups: - group **isolators**: those equipped with isolator

- group **BSC**: those fitted with other equipment for aseptic production (included, Biosafety Cabinet Class I, BSCII or UniDirectionalFlow cabinet).

To realize the comparison between these two groups, the Mann & Whitney's test has been used with the Monte-Carlo model.

RESULTS

Caracteristics	Global	France	Others European Counttries	Ρ	
Groupe ISOLATORS	10	3	7	0,0502	
Groupe BSC	11	8	3		

Cost / Workstation	Isolators	BSC
Construction Cost (straight-line depreciation 10 years)	9 048 €	18 906 €
Room Qualification (IQ+OQ) Cost (straight-line depreciation 10 years)	127€	530€
Room Qualification (PQ+maintenance) Cost	1 506 €	3 126 €
Room Cleaning Cost	2 616 €	439€
Room Microbiological Control Cost	62€	1 186 €
Equipment Cost (straight-line depreciation 7 years)	5 873 €	5 249 €
Equipment Qualification (IQ+OQ) Cost (straight-line depreciation 7 years)	2 606 €	1 089 €
Equipment Qualification (PQ+maintenance) Cost	1 909 €	5 355 €
Equipment Cleaning Cost	6 647 €	4 927 €
Dressing Cost	1 150 €	4 929 €
Material's Preparation Cost	9 589 €	13 578 €
Staff Cost	85 358 €	122 402 €
Staff Training Cost	4 114 €	10 428 €
Preparation Microbiological Control Cost	516€	1 135 €

21 hospitals have answered (11 French and 10 outside France). All European compounding unit organisations are not significantly different except that in France, the isolator use seems more common than in the rest of Europe (73%) vs 30% respectively; p=0.0502).

Each cost item was compared but few are significantly different.

*Significant difference

Simulation	Isolators	BSC
Total Annual Cost / Workstation	131 120€	193 279 €
Total Annual Cost / Workstation (Without Staff Cost)	45 762 €	70 877 €
Total Cost / Preparation	30€	41 €
Total Cost / Preparation (Without Staff Cost)	11€	15€

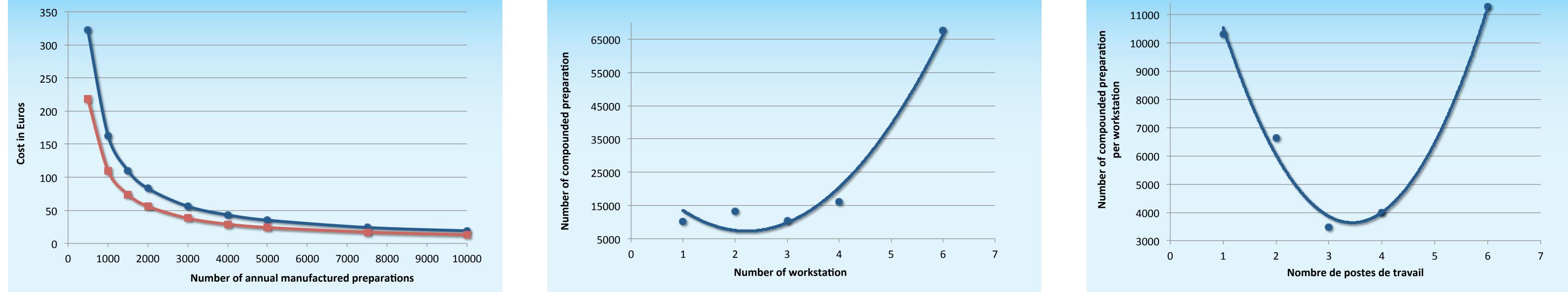
DISCUSSION

Average Costs related to the number of annually manufactured preparations

Isolators

number of compounded preparations related to the number of workstation in the unit

number of compounded preparations per workstation in relation with the number of workstation in the unit



CONCLUSION

This pilot study permits to optimise resources and save money. A further international study would allow to obtain more significant results.

ACKNOWLEDGMENTS

I thank GETINGE life Sciences company that has taken coverage of my travel expenses and Mr Meyer for his help and advices.