

QUALITY AND ECONOMIC EFFICIENCY OF INSPECTION-METHODS

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Introduction

The manufacture of sterile products is subject to special requirements to ensure continuously high quality.

One of these requirements is the visual inspection of each filled container for particulate contamination.

Two methods are used for this process:

1. Manual inspection, which depends subjectively on the inspector
2. Automated inspection with camera systems.

A validation of a manual inspection is not feasible due to the lack of reproducibility.

Generally, the inspection process should be automatized. On the other hand high costs for the machine and validation studies should be taken into consideration. From August 2004 to January 2005 studies were performed at Essex Animal Health Friesoythe, a Division of Essex Pharma Germany, to evaluate the efficiency of manual and automatic inspections methods. Four different inspection methods were available and compared:

1. Black and White Box according to Ph.Eur. 4
2. Control Unit for Particles and Bottles with the aid of a magnifying glass (manual inspection)
3. Semi-automatic inspection machine (manual inspection, but automatic product transportation)
4. Fully automated inspection based on camera system evaluation.

The systems were analyzed systematically in respect to their quality and economic efficiency. The purpose of the study was to find out if a fully automatic inspection machine really shows a higher quality and better economic efficiency than manual systems.

Investigations on quality and economic efficiency

1. Quality

• Knapp-Test

The Knapp-Test is used to determine the

efficiency of an inspection system [1]. It is based on a comparison between the efficiency of an inspection system already existing and a new one.

The Knapp-Test is performed using a test set with 80 injection vials containing particles and 170 non inspected vials of the same product. The statistical rejection probability of each vial is determined first by the manual inspection (4x magnifying lens), whereas 5 inspectors have to inspect each test vial 10 times, and then by the new automatic inspection machine, whereas the machine has to inspect each vial 10 times. The efficiency is calculated with defined formulas. If the ratio is equal or greater to 100% then the new inspection system is equivalent or better than the existing one [2,3].

• Test-set with prepared vials

This test includes the control of particles as well as other defects like deviations on fill level or colour, glass or cap defects. After examining the test with the four systems the results are evaluated to determine their recovery rate of defective containers and their false rejects.

2. Economic efficiency

• Speed of the systems

The productivity depends on the different speed of the visual inspection. The efficiency of the systems and the inspection time per vial depending on the size of the vial are taken into consideration.

• Capacity of the systems

The capacity shows how many vials of the annual production of Essex Animal Health can be inspected by the different systems. The time and the staff needed for inspecting 3,4 mio vials with an inspection method is calculated.

• Comparison of the costs

First the fixed and variable costs are set up. Then a break-even calculation was made with the systems. The annual costs depending on the produced vials are also taken into consideration.

Results and Discussion

1. Quality

Knapp-Test

The calculated efficiency of the automatic inspection versus the manual inspection amounts to 103,83%. Consequently the new fully automated method is considered superior to the existing one. In addition the test supports the higher reproducibility of the fully automated machine.

Test-set with prepared vials

The fully automated inspection machine as well as the manual Control Unit shows recovery rates of nearly 100%. On average the automatic inspection machine has the highest recovery rate of defective vials of about 97,49% with a standard deviation of about only 1,83%.

The amount of false rejects should be as small as possible. Here the Black and White Box gave the best result followed by the automated inspection machine.

2. Economic efficiency

• Speed of the systems

The following figure shows the speed of the systems.

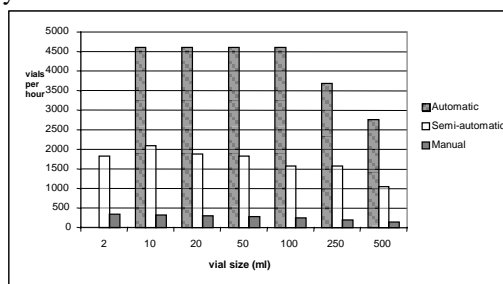


Figure 1: Efficiency of the inspection systems depending on the size of the vial

The efficiency of the automatic inspection machine is more than double that of the semi-automatic inspection machine and about fifteen times more than the manual system.

• Capacity of the systems

The inspection of a production of 3,4 mio. vials shows the following results:

System	Time	Staff
Manual	13.535 h/a	13
Semi-automatic	1.799 h/a	7
Automatic	685 h/a	3

Table 1: Time and staff needed for inspecting 3,4 mio. vials (working a single shift)

Comparison of the costs

The comparison refers to a production of 3,4 mio. vials.

The break-even calculation of the automated and semi-automated inspection machine shows that, after four years, the automated system (in-line) is the one with minimum costs. After already 1,5

years the automatic inspection is more cost efficient than the manual inspection. Right from the start, the costs of the semi-automatic machine are below those of the manual control.

The calculations in the following diagram refer to one year only. For this reason the depreciation of the systems has to be considered.

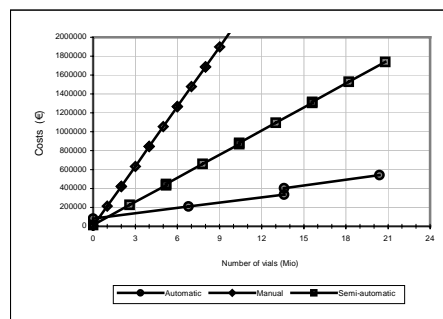


Figure 2: Cost trend depending on the produced vials

Only a low annual production of about 100.000 vials can keep the costs of the manual inspection under those of the semi and full automatic inspection. When inspecting up to 1 mio. vials the semi-automated inspection machine shows a cost advantage compared to the automatic inspection machine. From that point of view the full automatic system is the minimum-cost alternative.

Conclusion

None of the four systems can guarantee a 100% detection of defective vials. According to the results of the tests the fully automated inspection machine represents the best qualitative method. Considering the economic efficiency, especially over a long period of time, the automatic inspection machine is the minimum cost alternative. A higher annual production would show this advantage even more. The initial high costs of the automatic system can be compensated by its higher efficiency and by the staff savings.

In conclusion, with the focus of applications for Essex Animal Health Friesoythe the fully automated inspection machine represents the most effective method.

References

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