# Benefit of operational quality in hospital preparation production performance within a new technical platform

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Avec le soutien de l'Association des Internes et des Anciens Internes

## Introduction:

In a context of sterile hospital preparations activity resumption, various manufacturing processes were re-analysed, taking into account the organization of the new facility and equipments.

In addition to a complete restructuring of the quality system with a view to ISO 9001 certification, operational quality management has been applied with the aim of controlling manufacturing processes by eliminating the causes of malfunctions (errors or non-conformities).

## Objectives:

The objective of this work is to report a concrete example of the application of a manufacturing process optimization of a sterile hospital preparation initially packaged in 1-litre vials.

## Materials and methods:

In order to ensure a rapid recovery, the use of tools giving a rapid outcome was favoured:

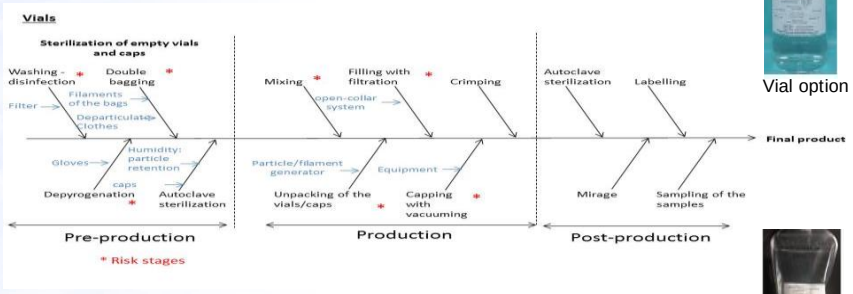
(i) Brainstorming using the **QQOQCCP** method for the analysis of the manufacturing process, of problems encountered and problem solving method with the presence of particles and/or filaments at candling as a performance indicator.

(ii) AMDEC methods: ratings of the 2 manufacturing processes, taking into account the risks associated with the different stages of the process.

(iii) An action plan in the form of an **ISHIKAWA** diagram and a comparative study of the 2 processes by implementing corrective and preventive actions to address the problems observed.

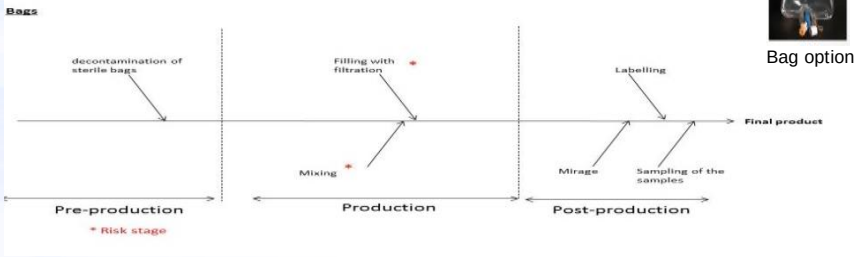
## Results:

| | 1L Glass vials | 1L EVA bags |
|---|---|---|
| **Particulate contamination** | Important : refusal of several batch (open-collar system) | Almost non-existent (closed system) |
| **Yield after candling** | 43% | 100% |
| **Terminal sterilization** | Autoclave | Sterilizing filtration |
| **Staff** | 3 PPH | 2 PPH |
| **Overall preparation time** | 18 H | 3 H |
| **Cost per unit** | 6,23 € | 3,44 € |
| **Use-by date** | 2 years | 6 months (stability study in progress) |
| **Manufacturing process** | Complex, cumbersome and long. | Simple, fast and perfectly controlled. |






Vial option




Bag option

## Discussion / Conclusion :

Quality, production lead-times, costs and, more generally, production performance depend on the level of operational quality. A stability study is underway to determine the use-by-date (compliant after 6 months) in order to optimize production management.

In addition, a new range of autoclavable polypropylene bags (pending CE mark) will soon be used.