

Flexibility Enables Managing Large Leaflet on Automatic Packaging Line

patheon





A large multinational pharmaceutical company asked the Thermo Fisher Scientific Ferentino site to fix an issue that resulted from a change request to increase the size of the product information leaflets. These leaflets were important and required for regulatory and marketing reasons.

Problem to solve

Due to regulatory and marketing reasons, Thermo Fisher's client voiced a need for larger product information leaflets. Initially, due to the new, larger size, there were several problems with managing the leaflet format (300 x 600 mm) which caused downtime of the machine, breakage of rollers,

and leaflets not being folded well. Because of these issues, the product was temporarily packaged on a slower, semiautomatic line used for some of the smaller volume stock keeping units (SKU). Several SKUs (about 220 SKUs) were impacted by the leaflet size change. Due to the high batch size volumes being packaged, the Client asked for an urgent solution to improve the packaging of these SKUs with a fully automated solution to better ensure meeting timelines.

As further background, the supplier sent to the Ferentino site unfolded leaflet formats which were either folded automatically on the automatic line or manually for the semi-automatic line, causing further delays. A solution was urgently needed.

Solution

Due to the criticality of the situation, a team was created to complete an urgent internal and external assessment on how to solve the problem.

A multi-functional project team was created with representatives from the following departments: Packaging Development, Engineering, Documentation, Production and Engineering & Equipment Validation. The team meticulously discuss various scenarios to decide which solution would be best. They outlined and discussed several considerations and then met and discussed with the client to ensure client buy-in before agreeing on the solution to implement pre-folded leaflets for both lines.

Based on the chosen solution of implementing pre-folded leaflets for both lines, a feasibility study was carried out with leaflet suppliers to avoid any impact on artworks changes. The study was conducted on all leaflet formats managed by both the packaging lines including a total of about 1000 SKUs. In particular, suppliers were requested to check the feasibility for providing the pre-folded leaflets while maintaining the unchanged position of laetus code for automatic feeding.



Ferentino is located in central Italy near Rome and specializes in sterile manufacturing and packaging. A development center is currently being constructed to supplement the existing commercial facility.

Mechanical adjustments were necessary for the automated line to implement the automation of the packaging process and to eliminate the stand alone equipment used to fold the leaflets for the semiautomatic line.

During implementation, various activities were carried out in a very short time including conducting machinability trials (including Factory Acceptance Testing (FAT), Site Acceptance Test (SAT), Installation Qualification/ Operation Qualification (IQ/OQ), updating about leaflet technical specifications to include the fold setup, and updating packaging line working instructions for all the impacted SKUs for both lines.

The team met the project timeline and in six months all activities (including the feasibility study with suppliers) were completed, and the first batch was successfully packaged on the automatic line with the larger leaflet.

Solution advantages and cost saving

In spite of the increased leaflets costs due to additional folding step performed by the supplier, the implementation of pre-folded leaflets on the packaging lines enabled a reduction in time and costs for each batch due to the following:

- The overall packaging timing was reduced since a process step (leaflet folding) was no longer executed;
- Material yields were increased 2% by the elimination of the separate processing step
- Equipment wear part costs were reduced by the simplification of the automated folding process
- Elimination of a maintenance contract for the off-line folding equipment

Other benefits related to the implementation project were:

- · Additional free capacity on both the semiautomatic and automatic line
- Increased Overall Equipment Effectiveness on the automatic line

Customer satisfaction

The client was very satisfied with the diligence of the project management team and the team's ability to meet the timeline of implementation. The client highly appreciated the feasibility study carried out with supplier and the solution found regarding the leaflet folding that allowed no changes to the artworks, with no impact on marketing / regulatory side.



Thermofisher has sterile packaging capabilities at several facilities including Ferentino and Monza in Italy, Greenville in NC, Allentown in PA, and Horsham in the UK.