CASE STUDY

How to maximize performance and productivity of existing pharmaceutical sterilization lines?

New trends in automation and process control for sterilization systems by integrating robotized loading and unloading technology

Telstar®

ABSTRACT

Increasingly the pharmaceutical industry is challenged to increase the OEE (Overall Equipment Effectiveness) of their manufacturing process. The sterilization lines for parenteral products are no exceptions.

What are the latest trends in automation and process control in pharmaceutical sterilization process? The implementation of new integrated solutions for sterilization process equipment integrating robotic and automated loading and unloading technology is proven to offer significant increase in performance and productivity, in addition to helping reduce operational costs, increasing savings in multiple connected machines covering a whole operational phases.

This article provides the main aspects to respond to the new trends while describing the retrofitting in an IV Bags sterilization line, in order to maximizes its OEE and make it ready for the technological opportunities of industry 4.0.

Customer

Parenteral Product Manufacturer

Challenge

Our client has four large superheated water shower autoclaves for the terminal sterilization of IV bags. Each autoclave has a capacity of more than 50 m3. In other words, up to 32 trolleys can be placed in two rows in each autoclave.

The bags arrive from the filling line through a conveyor system and are manually positioned on the trays. Subsequently, another operator houses the trays in each of the trolleys. These have guides to accommodate up to 10 levels of trays.

After sterilization, bags are unloaded from the trays by operators, also manually, with several operators entering inside the autoclave chamber.

The overall process requires a high amount of labour in loading/unloading stages and placing the product in trays.

Inside the autoclave. Trolleys are loaded and unloaded manually

Many times the sterilization process was suffering downtimes as operators were still placing the bags in the trolleys.

In order to improve the productivity of its process, the client contacted Telstar to automate its sterilization line.

Holistic vision of the process

Different work sessions were held between both companies to evaluate the best technical alternatives of the retrofitting and maximize the OEE of their line.

Overall Equipment Effectiveness	Recommended Six Big Losses	Traditional Six Big Losses
Availability Loss	Unplanned Stops	Equipment Failure
	Planned Stops	Setup and Adjustments
Performance Loss	Small Stops	Idling and Minor Stops
	Slow Cycles	Reduced Speed
Quality Loss	Production Rejects	Process Defects
	Startup Rejects	Reduced Yield
OEE	Fully Productive Time	Valuable Operating Time

Capture the Six Big Losses to gain additional actionable insight to the OEE Factors of Availability, Performance, and Quality.

The following framework was agreed:

- Change the design of product trays
- Install an automatic loading and unloading system
- Incorporate a robotic system in the filling and inspection line
- Upgrade the SCADA system

Product trays design

The trays and trolleys were originally designed for a manual loading/unloading system. The compatibility of the trays with the robotic system was evaluated together with the customer. It was agreed to redesign the trays since it allowed taking greater advantage of the automation of the process. The main advantages offered by the new design were:

- Reduction of accessories

  The new trays were designed to be stackable. Thus, the trolleys no longer needed to be used and the logistics of the process were simplified.

- Integration with loading/uploading system

  The trays have a design that allows a better manoeuvrability of the robot during the stacking and unstacking process. Additionally, they also allow a better movement through the conveyors that communicate the robotic stations with the autoclave's automatic loading and unloading system.

- Autoclave capacity

  The elimination of the trolleys allows the use of larger trays. Since the stacking system allows a reduced distance between trays, this also permitted increasing the set of stackable trays by one more level. Both improvements enabled the autoclave capacity to be increased up to 20%.

Installation of loading/unloading system inside the autoclave

The autoclave had in its interior a system of guides to allow the correct accommodation of the trolleys inside the autoclave. The trolleys weighted around 600 kg and were manually pushed by the operators.

Guides to allow movement of trolleys

Before carrying out the loading or unloading operation, the chamber interior had to be at a maximum temperature of 40°C in order for the operator to enter. This forced the sterilization cooling stage to last quite a while.

The installation of an automatic loading/unloading system involved replacing the inner guides with a set of rollers inside that allowed the free movement of the trays. A mechanism constituted by a shuttle allowed pushing the trolleys in/out.

The incorporation of the automatic loading system had the following advantages:

- Reduction of operating costs

  The system no longer required operators for loading and unloading work.

- Minimization of occupational hazards

  The system no longer required the operators to go inside the autoclave chamber for loading and unloading operations.

- Reduction of the sterilization cycle

  The automatic system allowed the product to be discharged at a higher temperature and consequently the cooling stage was reduced. Additionally, the heating time was also reduced as the process water was at a higher temperature at the beginning of the cycle.

- Energy saving

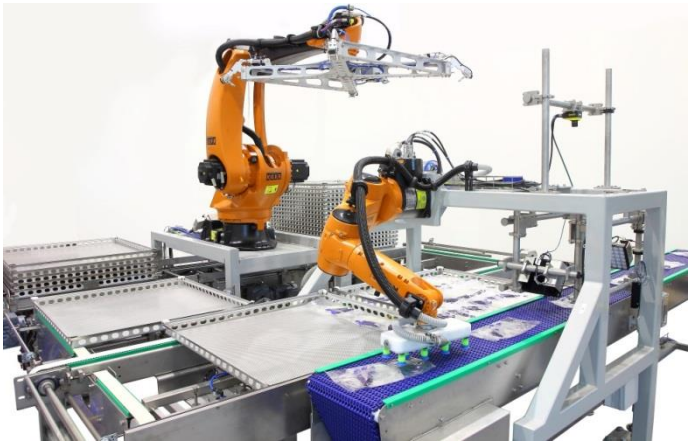
  Since the heating and cooling stages were reduced, this implied a significant reduction in energy consumption. An energy saving study was carried out based on the product's unloading temperature.

Robotic station

The bags arrived at the manual loading station by means of a conveyor belt. The position of the bags in the trays was done manually and then the trays were placed manually in the trolleys.

Bags are placed manually in trays.

This stage required a lot of labour and on many occasions it was a bottleneck since the lot was not ready for the execution of the next sterilization cycle.



Loading station. Courtesy ATP Packaging

The conveyor belt bags continuously fed with filled bags at the robotic station. An artificial vision system detects the orientation of the product.

A robot picks the bags by gripper in the correct position and houses them in the tray. The gripper is constituted by a system of suction cups that allow the picking of the bags.

The gripper is designed for the different bag sizes (from 250ml to 4000ml) as well as for the loading mosaics specifically defined for each type of product.

Once the tray is loaded, it moves to the next stage. An anthropomorphic robot stacks the trays up to a maximum of 10 levels.

The unloading station has the same design although the process begins by unstacking the trays. The robot picks the bags and leaves them in a conveyor belt that directs them to the inspection station. The empty trays are stacked again in the same station and sent by another conveyor to the robotic loading station to start the cycle again.

The advantages of implementing a robotic station in the process were:

- Reduction of operating costs

  The system no longer required operators for loading and unloading the bags into the trays.

- Minimization of occupational hazards

The system no longer required operators for loading and unloading the bags into the trays.

- Increase of productivity

  The robotic stations allow a continuous process between the filling line, the autoclave and the inspection line.

SCADA System

The SCADA system was upgraded in order to integrate the robotic stations, the autoclave and the conveyors system. It allowed customer to have an integral vision of the whole process. The track and trace system permitted users to know the positioning of each trolley. Additionally, thanks the RFID system it was possible to identify the different batches and automatically associate them with the sterilization report.

Conclusions

The implementation of an integrated solution for a sterilization process line using omated loading and unloading technology is proven to offer significant increases in productivity. The deployed solution not only has led to increased performance but it has also met other relevant customer expectations: a significant non-quality cost reduction was achieved, operating cost was reduced and, finally, the installation was set up and prepared to adapt for technological opportunities of industry 4.0.

This project has been developed in the operational field of a specific retrofitting service, designed by the company to improve the productivity of existing pharmaceutical facilities, providing high efficiency and reducing operational cost for a quick return of investment.

Telstar Sterilization Product Manager

Jordi Martinez, Sterilization Product manager at Telstar, holds a Bachelor degree in Industrial Engineering from the Universitat Politècnica de Catalunya.

He has been working at Telstar for more than 8 years in sales and technical positions related to the Pharmaceutical Market. His interests are related to smart manufacturing and digital transformation.

Telstar SteriDelta

50m3 autoclave with automatic loading and unloading system

The sterilization system integrates robotized processing for preparing the product arriving from one or more filling lines to be loaded directly into the sterilizer chamber without any human intervention.

The robotized sterilization system is designed to be highly versatile and can be gradually implemented based on particular needs in both greenfield or existing units. Engineered to sterilize large batches, the equipment includes a Telstar Scada supervisory control and data acquisition system, providing full production line traceability; helping store, retrieve and transfer process knowledge.

The custom configured robotized sterilization system is created to be fully integrated into the installation with a tailored design adapted to each specific plant layout. The automated process integrated to the system reduces the duration of the sterilization cycle on average by 15% and saves up to 20% energy consumption, in addition of offering up to a 40% increase in performance and productivity. The overall automation and process control helps reduce operational costs and significantly increase savings.

About Telstar

Telstar, part of the azbil Group, is a company specialized in the development of engineering & construction projects, integrated process equipment and GMP consultancy solutions, including turnkey projects and critical installations, for companies associated with Life & Health Sciences (pharmaceutical & biotechnology, healthcare, cosmetic, veterinary and food & beverage industries, hospitals, laboratories & research centers). Acknowledged as one of the 10 major suppliers for the pharmaceutical industry, Telstar is one of the few international manufacturers able to offer integrated process solutions for the biopharmaceutical industry with in-house sterilization, freeze drying, containment, process water & waste treatment, clean air and cold storage technologies.

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